

**Dossier zur Nutzenbewertung
gemäß § 35a SGB V**

Dapagliflozin (Forxiga® 5 mg/10 mg Filmtabletten)

AstraZeneca GmbH

Separater Anhang 4-G

*Behandlung des Diabetes mellitus Typ 2
bei Kindern und Jugendlichen*

Medizinischer Nutzen und
medizinischer Zusatznutzen,
Patientengruppen mit therapeutisch
bedeutsamem Zusatznutzen

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Statistische Nachberechnung für die Studie D1690C00017

AstraZeneca, 2021

Demographics and baseline characteristics	
PFAS population	
T2DM1_FOB0	Demographic and other baseline characteristics - Age
T2DM2_FOB0	Demographic and other baseline characteristics - Sex
T2DM3_FOB0	Demographic and other baseline characteristics - Race
T2DM4_FOB0	Demographic and other baseline characteristics - Ethnic group
T2DM5_FOB0	Demographic and other baseline characteristics - Geographic region
T2DM6_FOB0	Demographic and other baseline characteristics - Country
T2DM7_FOB0	Demographic and other baseline characteristics - Height
T2DM8_FOB0	Demographic and other baseline characteristics - Body weight
T2DM9_FOB0	Demographic and other baseline characteristics - BMI
T2DZ1_FOB0	Disease-specific baseline characteristics - Duration of T2DM
T2DZ2_FOB0	Disease-specific baseline characteristics - Screening HbA1c
T2DZ3_FOB0	Disease-specific baseline characteristics - Baseline HbA1c
T2DZ4_FOB0	Disease-specific baseline characteristics - Screening Baseline FPG
T2DZ5_FOB0	Disease-specific baseline characteristics - Baseline FPG
T2DBM1_FOB0	Diabetes background medication
T2DBM2_FOB0	Diabetes background medication - Metformin daily dose
T2DBM3_FOB0	Diabetes background medication - Insulin daily dose
T2DR1_FOB0	Renal Baseline Characteristics - Screening eGFR
T2DR2_FOB0	Renal Baseline Characteristics - Baseline eGFR
T2DCM_FOB0	Current medication for the 24 - week period
T2DCA_FOB0	Concomitant antihypertensive, antipsychotic, and antihyperlipidemic medications during the 24 - week period
T2DCI_FOB0	Concomitant insulin anti-diabetic medications
T2DCN_FOB0	Concomitant non-insulin anti-diabetic medications
T2DD1_EOB0	Patients disposition - Screening period
T2DD2_EOB0	Patients disposition - Lead-in period
T2DD3_EOB0	Patients disposition - 52-week period
T2DP_EOB0	Patients disposition - Analysis sets
T2RM_FOB0	Patients with rescue medication until week 24
T2DT1_FOB0	Time in study
T2DT2_FOB0	Duration of exposure
T2DST_FOB0	Duration of ST-Period
PPPS population (sensitivity analysis II)	
T2DM1_POB0	Demographic and other baseline characteristics - Age
T2DM2_POB0	Demographic and other baseline characteristics - Sex
T2DM3_POB0	Demographic and other baseline characteristics - Race
T2DM4_POB0	Demographic and other baseline characteristics - Ethnic group
T2DM5_POB0	Demographic and other baseline characteristics - Geographic region
T2DM6_POB0	Demographic and other baseline characteristics - Country
T2DM7_POB0	Demographic and other baseline characteristics - Height
T2DM8_POB0	Demographic and other baseline characteristics - Body weight
T2DM9_POB0	Demographic and other baseline characteristics - BMI

T2DZ1_POB0	Disease-specific baseline characteristics - Duration of T2DM
T2DZ2_POB0	Disease-specific baseline characteristics - Screening HbA1c
T2DZ3_POB0	Disease-specific baseline characteristics - Baseline HbA1c
T2DZ4_POB0	Disease-specific baseline characteristics - Screening Baseline FPG
T2DZ5_POB0	Disease-specific baseline characteristics - Baseline FPG
T2DBM1_POB0	Diabetes background medication
T2DBM2_POB0	Diabetes background medication - Metformin daily dose
T2DBM3_POB0	Diabetes background medication - Insulin daily dose
T2DR1_POB0	Renal Baseline Characteristics - Screening eGFR
T2DR2_POB0	Renal Baseline Characteristics - Baseline eGFR
T2DCM_POB0	Current medication for the 24 - week period
T2DCA_POB0	Concomitant antihypertensive, antipsychotic, and antihyperlipidemic medications during the 24 - week period
T2DCI_POB0	Concomitant insulin anti-diabetic medications
T2DCN_POB0	Concomitant non-insulin anti-diabetic medications
T2RM_POB0	Patients with rescue medication until week 24
T2DT1_POB0	Time in study
T2DT2_POB0	Duration of exposure
T2DST_POB0	Duration of ST-Period

Main analysis	
PFAS population	
T2HA_FAF0	Course of HbA1c up to Week 24
T2HAC_FAC0	Change in HbA1c up to Week 24
F2HAC_FAG0	Change in HbA1c up to Week 24
T2HAC_FAH0	Hedges G for Change in HbA1c up to Week 24
T2HAR_F7AP0	Patients with HbA1c < 7% at Week 24
T2FG_FAF0	Course of FPG up to Week 24
T2FGC_FAC0	Change in FPG up to Week 24
F2FGC_FAG0	Change in FPG up to Week 24
T2FGC_FAH0	Hedges G for Change in FPG up to Week 24
T2GR_FAP0	Patients with need of glycemic rescue/discont. due to lack of glycemic control during ST
T2A_SAI0	Incidence of AEs
T2AN_SAI0	Incidence of non-severe AEs
T2AS_SAI0	Incidence of serious AEs
T2AC_SAI0	Incidence of severe AEs
T2AT_SAI0	Incidence of AEs leading to study drug discontinuation
T2SHA_SAI0	Incidence of hypoglycaemic events (ADA)
T2SHAN_SAI0	Incidence of non-severe hypoglycaemic events (ADA)
T2SHAN2_SAI0	Incidence of documented symptomatic hypoglycaemic events (ADA)
T2SHAC_SAI0	Incidence of severe hypoglycaemic events (ADA)
T2ASL_SAI0	Incidence of hepatic AEs
T2AA_SAI0	Incidence of non-disease related AEs
T2AAC_SAI0	Incidence of non-disease related severe AEs
T2A_SAS0	AEs by SOC and PT
T2AC_SAS0	Severe AEs by SOC and PT

T2AT_SAS0	AEs leading to study drug discontinuation by SOC and PT
PFAS population excluding values after rescue medication initiation or discontinuation from study drug (sensitivity analysis I)	
T2HAM_FAF0	Course of HbA1c up to Week 24 (censored)
T2HAMC_FAC0	Change in censored HbA1c up to Week 24
F2HAMC_FAG0	Change in censored HbA1c up to Week 24
T2HAMC_FAH0	Hedges G for Change in censored HbA1c up to Week 24
T2HAMR_F7AP0	Patients with HbA1c < 7% at Week 24 (censored)
T2FGM_FAF0	Course of censored FPG up to Week 24
T2FGMC_FAC0	Change in censored FPG up to Week 24
F2FGMC_FAG0	Change in censored FPG up to Week 24
T2FGMC_FAH0	Hedges G for Change in censored FPG up to Week 24
PPPS population (sensitivity analysis II)	
T2HA_PAF0	Course of HbA1c up to Week 24
T2HAC_PAC0	Change in HbA1c up to Week 24
F2HAC_PAG0	Change in HbA1c up to Week 24
T2HAR_P7AP0	Patients with HbA1c < 7% at Week 24
T2HAC_PAH0	Hedges G for Change in HbA1c up to Week 24

Subgroup analysis	
PFAS population	
T2HAC_FSCS	Change in HbA1c at Week 24 by subgroup
T2HAC_FSHS	Hedges G for Change in HbA1c up to week 24 by subgroup
T2HA_FSFS	Course of HbA1c up to Week 24 by subgroup
T2FGC_FSCS	Change in FPG at Week 24 by subgroup
T2FGC_FSHS	Hedges G for Change in FPG up to Week 24 by subgroup
T2FG_FSFS	Course of FPG up to Week 24 by subgroup
T2A_SGIS	Incidence of AEs by subgroup
T2AN_SGIS	Incidence of non-severe AEs by subgroup
T2AA_SGIS	Incidence of non-disease related AEs by subgroup
PFAS population excluding values after rescue medication initiation or discontinuation from study drug (sensitivity analysis I)	
T2HAMC_FSCS	Change in censored HbA1c at Week 24 by subgroup
T2HAM_FSFS	Course of censored HbA1c up to Week 24 by subgroup
T2HAMC_FSHS	Hedges G for Change in censored HbA1c at Week 24 by subgroup
T2FGMC_FSCS	Change in censored FPG at Week 24 by subgroup
T2FGM_FSFS	Course of censored FPG up to Week 24 by subgroup
T2FGMC_FSHS	Hedges G for Change in censored FPG at Week 24 by subgroup
PPPS population (sensitivity analysis II)	
T2HAC_PSCS	Change in HbA1c at week 24 by subgroup
T2HA_PSFS	Course of HbA1c up to Week 24 by subgroup

Table T2DBM1_FOB0: Diabetes background medication
 PFAS

Parameter		Dapa 10mg	Placebo	Total
N		29	24	53
Background diabetic medication n(%)	Metformin	11 (37.9)	14 (58.3)	25 (47.2)
	Insulin	6 (20.7)	3 (12.5)	9 (17.0)
	Insulin + metformin	12 (41.4)	7 (29.2)	19 (35.8)
Background diabetic medication - aggregated n(%)	Metformin	11 (37.9)	14 (58.3)	25 (47.2)
	Insulin or insulin + metformin	18 (62.1)	10 (41.7)	28 (52.8)

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group,
 n = Frequency count.

Source Data: asl, created on: 17SEP2021:19:41:02

Table T2DBM2_FOB0: Diabetes background medication - Metformin daily dose
 PFAS

Parameter		Dapa 10mg	Placebo	Total
N		29	24	53
Metformin diabetic background medication - Total	n	23	21	44
daily dose (mg)	Mean	1604.3	1540.5	1573.9
	Std Dev	455.5	498.8	472.2
	Minimum	1000	1000	1000
	1st quartile	1000.0	1000.0	1000.0
	Median	1700.0	1500.0	1700.0
	3rd quartile	1700.0	2000.0	1850.0
	Maximum	2550	2500	2550

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group,
 n = Number of valid observations, Std Dev = Standard deviation.
 Source Data: asl, created on: 17SEP2021:19:41:02

Table T2DBM3_FOB0: Diabetes background medication - Insulin daily dose
 PFAS

Parameter		Dapa 10mg	Placebo	Total
N		29	24	53
Insulin diabetic background medication - Total daily dose (Insulin unit)	n	18	10	28
	Mean	56.6	62.8	58.8
	Std Dev	40.5	54.0	44.9
	Minimum	5	3	3
	1st quartile	30.0	35.0	32.5
	Median	44.5	39.5	40.5
	3rd quartile	77.0	90.0	83.5
	Maximum	170	170	170

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group,
 n = Number of valid observations, Std Dev = Standard deviation.
 Source Data: asl, created on: 17SEP2021:19:41:02

Table T2DCA_FOB0: Concomitant antihypertensive, antipsychotic, and antihyperlipidemic medications during the 24 - week period
 PFAS

Parameter	ATC classification	Generic term	Dapa 10mg	Placebo	Total
N			29	24	53
Number of subjects with concomitant antihypertensive, antipsychotic, and antihyperlipidemic medication n(%)	All	All	4 (13.8)	6 (25.0)	10 (18.9)
Subjects with concomitant antihypertensive, antipsychotic, and antihyperlipidemic medication n(%)	ACE INHIBITORS, PLAIN	All	3 (10.3)	3 (12.5)	6 (11.3)
		ENALAPRIL	1 (3.4)	1 (4.2)	2 (3.8)
		ENALAPRIL MALEATE	1 (3.4)	0 (0.0)	1 (1.9)
		LISINOPRIL	0 (0.0)	2 (8.3)	2 (3.8)
		TRITACE	1 (3.4)	0 (0.0)	1 (1.9)
	BETA BLOCKING AGENTS, SELECTIVE	All	0 (0.0)	1 (4.2)	1 (1.9)
		METOPROLOL	0 (0.0)	1 (4.2)	1 (1.9)
	CENTRALLY ACTING SYMPATHOMIMETICS	All	1 (3.4)	0 (0.0)	1 (1.9)
		DEXMETHYLPHENIDATE HYDROCHLORIDE	1 (3.4)	0 (0.0)	1 (1.9)
	FIBRATES	All	1 (3.4)	1 (4.2)	2 (3.8)
		BEZAFIBRATE	0 (0.0)	1 (4.2)	1 (1.9)
		GEMFIBROZIL	1 (3.4)	0 (0.0)	1 (1.9)
	HMG COA REDUCTASE INHIBITORS	All	0 (0.0)	1 (4.2)	1 (1.9)
		LIPITOR	0 (0.0)	1 (4.2)	1 (1.9)
	OTHER ANTIEPILEPTICS	All	1 (3.4)	0 (0.0)	1 (1.9)
		LAMOTRIGINE	1 (3.4)	0 (0.0)	1 (1.9)
	OTHER ANXIOLYTICS	All	2 (6.9)	1 (4.2)	3 (5.7)
		ESCITALOPRAM	1 (3.4)	1 (4.2)	2 (3.8)
		PROZAC	0 (0.0)	1 (4.2)	1 (1.9)
		ZOLOFT	1 (3.4)	0 (0.0)	1 (1.9)
	SELECTIVE SEROTONIN (5HT1) AGONISTS	All	1 (3.4)	0 (0.0)	1 (1.9)

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group, n = Frequency count, ATC = Anatomical Therapeutic Chemical.
 Source Data: acm, created on: 17SEP2021:19:42:56

Table T2DCA_FOB0: Concomitant antihypertensive, antipsychotic, and antihyperlipidemic medications during the 24 - week period
PFAS

Parameter	ATC classification	Generic term	Dapa 10mg	Placebo	Total
		RIZATRIPTAN	1 (3.4)	0 (0.0)	1 (1.9)

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group,
n = Frequency count, ATC = Anatomical Therapeutic Chemical.
Source Data: acm, created on: 17SEP2021:19:42:56

Table T2DCI_FOB0: Concomitant insulin anti-diabetic medications
 PFAS

Parameter	ATC classification	Generic term	Dapa 10mg	Placebo	Total
N			29	24	53
Number of subjects with concomitant insulin anti-diabetic medication n(%)	All	All	18 (62.1)	10 (41.7)	28 (52.8)
Subjects with concomitant insulin anti-diabetic medication n(%)	INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING	All	13 (44.8)	5 (20.8)	18 (34.0)
		ACTRAPID [INSULIN HUMAN]	1 (3.4)	0 (0.0)	1 (1.9)
		ADMELOG	1 (3.4)	1 (4.2)	2 (3.8)
		HUMALOG	6 (20.7)	3 (12.5)	9 (17.0)
		INSULIN ASPART	1 (3.4)	0 (0.0)	1 (1.9)
		LISPRO INSULIN	1 (3.4)	0 (0.0)	1 (1.9)
		NOVOLIN 30R [INSULIN]	2 (6.9)	1 (4.2)	3 (5.7)
		NOVOLOG	1 (3.4)	1 (4.2)	2 (3.8)
	INSULINS AND ANALOGUES FOR INJECTION, INTERMEDIATE- OR LONG-ACTING COMBINED WITH FAST-ACTING	All	2 (6.9)	2 (8.3)	4 (7.5)
		HUMALOG MIX	1 (3.4)	2 (8.3)	3 (5.7)
		NOVOMIX	1 (3.4)	0 (0.0)	1 (1.9)
	INSULINS AND ANALOGUES FOR INJECTION, INTERMEDIATE-ACTING	All	4 (13.8)	1 (4.2)	5 (9.4)
		HUMULINE	1 (3.4)	0 (0.0)	1 (1.9)
		INSULATARD HUMAN	1 (3.4)	0 (0.0)	1 (1.9)
		INSUMAN BASAL	1 (3.4)	0 (0.0)	1 (1.9)
		NPH INSULIN	1 (3.4)	1 (4.2)	2 (3.8)
	INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING	All	10 (34.5)	8 (33.3)	18 (34.0)
		BASAGLAR	1 (3.4)	3 (12.5)	4 (7.5)
		INSULIN GLARGINE	2 (6.9)	0 (0.0)	2 (3.8)
		LANTUS	6 (20.7)	4 (16.7)	10 (18.9)
		LEVEMIR	1 (3.4)	0 (0.0)	1 (1.9)
		TRESIBA	0 (0.0)	2 (8.3)	2 (3.8)

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Table T2DCM_FOB0: Current medication for the 24 - week period
 PFAS

Parameter	ATC classification	Generic term	Dapa 10mg	Placebo	Total
N			29	24	53
Number of subjects with current medication n(%)	All	All	29 (100.0)	24 (100.0)	53 (100.0)
Subjects with current medication n(%)	ACE INHIBITORS, PLAIN	All	3 (10.3)	3 (12.5)	6 (11.3)
		ENALAPRIL	1 (3.4)	1 (4.2)	2 (3.8)
		ENALAPRIL MALEATE	1 (3.4)	0 (0.0)	1 (1.9)
		LISINOPRIL	0 (0.0)	2 (8.3)	2 (3.8)
		TRITACE	1 (3.4)	0 (0.0)	1 (1.9)
	ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES	All	1 (3.4)	0 (0.0)	1 (1.9)
		KETOROLAC	1 (3.4)	0 (0.0)	1 (1.9)
	ANALGESICS	All	1 (3.4)	0 (0.0)	1 (1.9)
		ANALGESICS	1 (3.4)	0 (0.0)	1 (1.9)
	ANILIDES	All	6 (20.7)	3 (12.5)	9 (17.0)
		ACETAMINOPHEN	2 (6.9)	2 (8.3)	4 (7.5)
		DAYQUIL	2 (6.9)	0 (0.0)	2 (3.8)
		DEXTROMETHORPHAN;PARACETAMOL; PHENYLEPHRINE	1 (3.4)	0 (0.0)	1 (1.9)
		MIDOL COMPLETE	0 (0.0)	1 (4.2)	1 (1.9)
		NYQUIL	1 (3.4)	0 (0.0)	1 (1.9)
		PARACETAMOL	1 (3.4)	0 (0.0)	1 (1.9)
		TYLENOL	0 (0.0)	1 (4.2)	1 (1.9)
	ANTIBIOTICS	All	0 (0.0)	1 (4.2)	1 (1.9)
		NYSTATIN;TRIAMCINOLONE ACETONIDE	0 (0.0)	1 (4.2)	1 (1.9)
	ANTIINFECTIVES AND ANTISEPTICS FOR LOCAL ORAL TREATMENT	All	1 (3.4)	1 (4.2)	2 (3.8)
		CLOTRIMAZOLE	1 (3.4)	1 (4.2)	2 (3.8)
	ANTIINFECTIVES FOR TREATMENT OF ACNE	All	3 (10.3)	0 (0.0)	3 (5.7)
		AZITHROMYCIN	2 (6.9)	0 (0.0)	2 (3.8)
		CLINDAMYCIN PHOSPHATE	1 (3.4)	0 (0.0)	1 (1.9)

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Table T2DCM_FOB0: Current medication for the 24 - week period
 PFAS

Parameter	ATC classification	Generic term	Dapa 10mg	Placebo	Total
	ANTIINFLAMMATORY PRODUCTS FOR VAGINAL ADMINISTRATION	All	0 (0.0)	1 (4.2)	1 (1.9)
		MENSTRIDOL	0 (0.0)	1 (4.2)	1 (1.9)
	ASCORBIC ACID (VITAMIN C), PLAIN	All	0 (0.0)	1 (4.2)	1 (1.9)
		VIT C ROSEHIP	0 (0.0)	1 (4.2)	1 (1.9)
	BETA BLOCKING AGENTS, SELECTIVE	All	0 (0.0)	1 (4.2)	1 (1.9)
		METOPROLOL	0 (0.0)	1 (4.2)	1 (1.9)
	BETA-LACTAM ANTIBACTERIALS, PENICILLINS	All	0 (0.0)	1 (4.2)	1 (1.9)
		PENICILLIN NOS	0 (0.0)	1 (4.2)	1 (1.9)
	BIGUANIDES	All	23 (79.3)	21 (87.5)	44 (83.0)
		METFORMIN	23 (79.3)	21 (87.5)	44 (83.0)
	CENTRALLY ACTING SYMPATHOMIMETICS	All	1 (3.4)	0 (0.0)	1 (1.9)
		DEXMETHYLPHENIDATE HYDROCHLORIDE	1 (3.4)	0 (0.0)	1 (1.9)
	COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS	All	0 (0.0)	1 (4.2)	1 (1.9)
		AMOXICILLIN;CLAVULANIC ACID	0 (0.0)	1 (4.2)	1 (1.9)
	COMBINATIONS OF SULFONAMIDES AND TRIMETHOPRIM, INCL. DERIVATIVES	All	0 (0.0)	1 (4.2)	1 (1.9)
		TRIMETHOPRIM SULFAMETHOXAZOLE	0 (0.0)	1 (4.2)	1 (1.9)
	CORTICOSTEROIDS	All	0 (0.0)	1 (4.2)	1 (1.9)
		SYNALAR	0 (0.0)	1 (4.2)	1 (1.9)
	CORTICOSTEROIDS ACTING LOCALLY	All	1 (3.4)	1 (4.2)	2 (3.8)
		PREDNISONE	1 (3.4)	1 (4.2)	2 (3.8)
		QVAR	1 (3.4)	0 (0.0)	1 (1.9)
	CORTICOSTEROIDS, MODERATELY POTENT, COMBINATIONS WITH ANTIBIOTICS	All	1 (3.4)	0 (0.0)	1 (1.9)
		TEVACUTAN	1 (3.4)	0 (0.0)	1 (1.9)
	CORTICOSTEROIDS, POTENT (GROUP III)	All	0 (0.0)	4 (16.7)	4 (7.5)
		FLONASE [FLUTICASONE PROPIONATE]	0 (0.0)	1 (4.2)	1 (1.9)

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Table T2DCM_FOB0: Current medication for the 24 - week period
 PFAS

Parameter	ATC classification	Generic term	Dapa 10mg	Placebo	Total
		FLOVENT	0 (0.0)	1 (4.2)	1 (1.9)
		FLUTICASONE	0 (0.0)	2 (8.3)	2 (3.8)
		MOMETASONE FUROATE	0 (0.0)	1 (4.2)	1 (1.9)
	FIBRATES	All	1 (3.4)	1 (4.2)	2 (3.8)
		BEZAFIBRATE	0 (0.0)	1 (4.2)	1 (1.9)
		GEMFIBROZIL	1 (3.4)	0 (0.0)	1 (1.9)
	FIRST-GENERATION CEPHALOSPORINS	All	3 (10.3)	1 (4.2)	4 (7.5)
		CEFALEXIN	3 (10.3)	1 (4.2)	4 (7.5)
	GLYCOGENOLYTIC HORMONES	All	1 (3.4)	0 (0.0)	1 (1.9)
		GLUCAGON	1 (3.4)	0 (0.0)	1 (1.9)
	H2-RECEPTOR ANTAGONISTS	All	0 (0.0)	1 (4.2)	1 (1.9)
		RANITIDINE	0 (0.0)	1 (4.2)	1 (1.9)
	HERBAL STOMATOLOGICAL REMEDIES CONTAINING MUCILAGE	All	1 (3.4)	0 (0.0)	1 (1.9)
		MUCALTINUM	1 (3.4)	0 (0.0)	1 (1.9)
	HMG COA REDUCTASE INHIBITORS	All	0 (0.0)	1 (4.2)	1 (1.9)
		LIPITOR	0 (0.0)	1 (4.2)	1 (1.9)
	IMIDAZOLE AND TRIAZOLE DERIVATIVES	All	1 (3.4)	0 (0.0)	1 (1.9)
		DIFLUCAN	1 (3.4)	0 (0.0)	1 (1.9)
	INFLUENZA VACCINES	All	0 (0.0)	1 (4.2)	1 (1.9)
		INFLUENZA VACCINE	0 (0.0)	1 (4.2)	1 (1.9)
	INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING	All	13 (44.8)	5 (20.8)	18 (34.0)
		ACTRAPID [INSULIN HUMAN]	1 (3.4)	0 (0.0)	1 (1.9)
		ADMELOG	1 (3.4)	1 (4.2)	2 (3.8)
		HUMALOG	6 (20.7)	3 (12.5)	9 (17.0)
		INSULIN ASPART	1 (3.4)	0 (0.0)	1 (1.9)
		LISPRO INSULIN	1 (3.4)	0 (0.0)	1 (1.9)
		NOVOLIN 30R [INSULIN]	2 (6.9)	1 (4.2)	3 (5.7)
		NOVOLOG	1 (3.4)	1 (4.2)	2 (3.8)

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group,
 n = Frequency count, ATC = Anatomical Therapeutic Chemical.
 Source Data: acm, created on: 17SEP2021:19:42:56

Table T2DCM_FOB0: Current medication for the 24 - week period
 PFAS

Parameter	ATC classification	Generic term	Dapa 10mg	Placebo	Total
	INSULINS AND ANALOGUES FOR INJECTION, INTERMEDIATE- OR LONG-ACTING COMBINED WITH FAST-ACTING	All	2 (6.9)	2 (8.3)	4 (7.5)
		HUMALOG MIX	1 (3.4)	2 (8.3)	3 (5.7)
		NOVOMIX	1 (3.4)	0 (0.0)	1 (1.9)
	INSULINS AND ANALOGUES FOR INJECTION, INTERMEDIATE-ACTING	All	4 (13.8)	1 (4.2)	5 (9.4)
		HUMULINE	1 (3.4)	0 (0.0)	1 (1.9)
		INSULATARD HUMAN	1 (3.4)	0 (0.0)	1 (1.9)
		INSUMAN BASAL	1 (3.4)	0 (0.0)	1 (1.9)
		NPH INSULIN	1 (3.4)	1 (4.2)	2 (3.8)
	INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING	All	10 (34.5)	8 (33.3)	18 (34.0)
		BASAGLAR	1 (3.4)	3 (12.5)	4 (7.5)
		INSULIN GLARGINE	2 (6.9)	0 (0.0)	2 (3.8)
		LANTUS	6 (20.7)	4 (16.7)	10 (18.9)
		LEVEMIR	1 (3.4)	0 (0.0)	1 (1.9)
		TRESIBA	0 (0.0)	2 (8.3)	2 (3.8)
	IRON BIVALENT, ORAL PREPARATIONS	All	0 (0.0)	1 (4.2)	1 (1.9)
		FERROUS SULFATE	0 (0.0)	1 (4.2)	1 (1.9)
	LEUKOTRIENE RECEPTOR ANTAGONISTS	All	0 (0.0)	2 (8.3)	2 (3.8)
		MONTELUKAST	0 (0.0)	1 (4.2)	1 (1.9)
		SINGULAIR	0 (0.0)	1 (4.2)	1 (1.9)
	MELATONIN RECEPTOR AGONISTS	All	1 (3.4)	0 (0.0)	1 (1.9)
		MELATONIN	1 (3.4)	0 (0.0)	1 (1.9)
	NATURAL OPIUM ALKALOIDS	All	0 (0.0)	1 (4.2)	1 (1.9)
		OXYCODONE	0 (0.0)	1 (4.2)	1 (1.9)
	NEURAMINIDASE INHIBITORS	All	0 (0.0)	1 (4.2)	1 (1.9)
		TAMIFLU	0 (0.0)	1 (4.2)	1 (1.9)
	OPIUM ALKALOIDS AND DERIVATIVES	All	1 (3.4)	0 (0.0)	1 (1.9)
		DELSYM	1 (3.4)	0 (0.0)	1 (1.9)

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group,
 n = Frequency count, ATC = Anatomical Therapeutic Chemical.

Source Data: acm, created on: 17SEP2021:19:42:56

Table T2DCM_FOB0: Current medication for the 24 - week period
 PFAS

Parameter	ATC classification	Generic term	Dapa 10mg	Placebo	Total
	OPIUM DERIVATIVES AND EXPECTORANTS	All	0 (0.0)	1 (4.2)	1 (1.9)
		GUAIFENESIN AND DEXTROMETHORPHAN	0 (0.0)	1 (4.2)	1 (1.9)
	OSMOTICALLY ACTING LAXATIVES	All	1 (3.4)	0 (0.0)	1 (1.9)
		MIRALAX	1 (3.4)	0 (0.0)	1 (1.9)
	OTHER AGENTS FOR LOCAL ORAL TREATMENT	All	0 (0.0)	1 (4.2)	1 (1.9)
		DICLOFENAC	0 (0.0)	1 (4.2)	1 (1.9)
	OTHER ANALGESICS AND ANTIPYRETICS	All	1 (3.4)	0 (0.0)	1 (1.9)
		OXCARBAZEPINE	1 (3.4)	0 (0.0)	1 (1.9)
	OTHER ANTI-ACNE PREPARATIONS FOR SYSTEMIC USE	All	0 (0.0)	1 (4.2)	1 (1.9)
		ORTHO-CYCLEN-28	0 (0.0)	1 (4.2)	1 (1.9)
	OTHER ANTIBIOTICS FOR TOPICAL USE	All	1 (3.4)	0 (0.0)	1 (1.9)
		CIPROFLOXACIN	1 (3.4)	0 (0.0)	1 (1.9)
	OTHER ANTIEMETICS	All	3 (10.3)	2 (8.3)	5 (9.4)
		DIPHENHYDRAMINE	1 (3.4)	2 (8.3)	3 (5.7)
		HYDROXYZINE	1 (3.4)	0 (0.0)	1 (1.9)
		PROMETHAZINE	1 (3.4)	0 (0.0)	1 (1.9)
	OTHER ANTIEPILEPTICS	All	1 (3.4)	0 (0.0)	1 (1.9)
		LAMOTRIGINE	1 (3.4)	0 (0.0)	1 (1.9)
	OTHER ANTIMIGRAINE PREPARATIONS	All	1 (3.4)	0 (0.0)	1 (1.9)
		AMITRIPTYLINE HCL	1 (3.4)	0 (0.0)	1 (1.9)
	OTHER ANXIOLYTICS	All	2 (6.9)	1 (4.2)	3 (5.7)
		ESCITALOPRAM	1 (3.4)	1 (4.2)	2 (3.8)
		PROZAC	0 (0.0)	1 (4.2)	1 (1.9)
		ZOLOFT	1 (3.4)	0 (0.0)	1 (1.9)
	OTHER CARDIAC PREPARATIONS	All	4 (13.8)	2 (8.3)	6 (11.3)
		IBUPROFEN	4 (13.8)	2 (8.3)	6 (11.3)
		MOTRIN [IBUPROFEN]	0 (0.0)	1 (4.2)	1 (1.9)
	OTHER DERMATOLOGICALS	All	0 (0.0)	1 (4.2)	1 (1.9)

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group,
 n = Frequency count, ATC = Anatomical Therapeutic Chemical.
 Source Data: acm, created on: 17SEP2021:19:42:56

Table T2DCM_FOB0: Current medication for the 24 - week period
PFAS

Parameter	ATC classification	Generic term	Dapa 10mg	Placebo	Total
		IVERMECTIN	0 (0.0)	1 (4.2)	1 (1.9)
	OTHER DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)	All	2 (6.9)	0 (0.0)	2 (3.8)
		BISMUTH SUBSALICYLATE	1 (3.4)	0 (0.0)	1 (1.9)
		BISMUTH SUBSALICYLATE;MAGNESIUM CARBONATE	1 (3.4)	0 (0.0)	1 (1.9)
	OTHER LIPID MODIFYING AGENTS	All	1 (3.4)	0 (0.0)	1 (1.9)
		FISH OIL	1 (3.4)	0 (0.0)	1 (1.9)
	OTHER NASAL PREPARATIONS	All	2 (6.9)	0 (0.0)	2 (3.8)
		HALLS	2 (6.9)	0 (0.0)	2 (3.8)
	OTHER OPIOIDS	All	1 (3.4)	0 (0.0)	1 (1.9)
		TRAMADOL	1 (3.4)	0 (0.0)	1 (1.9)
	OTHER PLAIN VITAMIN PREPARATIONS	All	2 (6.9)	1 (4.2)	3 (5.7)
		VITAMIN E NOS	2 (6.9)	1 (4.2)	3 (5.7)
	OTHER UROLOGICALS	All	1 (3.4)	0 (0.0)	1 (1.9)
		PYRIDIUM	1 (3.4)	0 (0.0)	1 (1.9)
	PAPAVERINE AND DERIVATIVES	All	1 (3.4)	0 (0.0)	1 (1.9)
		PAPAVERINE	1 (3.4)	0 (0.0)	1 (1.9)
	PENICILLINS WITH EXTENDED SPECTRUM	All	2 (6.9)	0 (0.0)	2 (3.8)
		AMOXICILLIN	2 (6.9)	0 (0.0)	2 (3.8)
	PIPERAZINE DERIVATIVES	All	0 (0.0)	2 (8.3)	2 (3.8)
		CETIRIZINE	0 (0.0)	1 (4.2)	1 (1.9)
		ZYRTEC [CETIRIZINE HYDROCHLORIDE]	0 (0.0)	1 (4.2)	1 (1.9)
	PREGNADIEN DERIVATIVES	All	1 (3.4)	0 (0.0)	1 (1.9)
		DUPHASTON	1 (3.4)	0 (0.0)	1 (1.9)
	PROGESTOGENS	All	1 (3.4)	0 (0.0)	1 (1.9)
		NEXPLANON	1 (3.4)	0 (0.0)	1 (1.9)

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group, n = Frequency count, ATC = Anatomical Therapeutic Chemical.
Source Data: acm, created on: 17SEP2021:19:42:56

Table T2DCM_FOB0: Current medication for the 24 - week period
 PFAS

Parameter	ATC classification	Generic term	Dapa 10mg	Placebo	Total
	PROTON PUMP INHIBITORS	All	1 (3.4)	0 (0.0)	1 (1.9)
		OMEPRAZOLE	1 (3.4)	0 (0.0)	1 (1.9)
	PYRAZOLONES	All	2 (6.9)	0 (0.0)	2 (3.8)
		DIPYRONE	1 (3.4)	0 (0.0)	1 (1.9)
		METAMIZOLE SODIUM	1 (3.4)	0 (0.0)	1 (1.9)
	SALICYLIC ACID AND DERIVATIVES	All	2 (6.9)	0 (0.0)	2 (3.8)
		ACETYLSALICYLIC ACID;CAFFEINE	1 (3.4)	0 (0.0)	1 (1.9)
		SALICYLATE SODIUM	1 (3.4)	0 (0.0)	1 (1.9)
		SALICYLIC ACID AND DERIVATIVES	1 (3.4)	0 (0.0)	1 (1.9)
	SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS	All	2 (6.9)	4 (16.7)	6 (11.3)
		SALBUTAMOL	1 (3.4)	3 (12.5)	4 (7.5)
		VENTOLIN HFA	0 (0.0)	1 (4.2)	1 (1.9)
		VENTOLIN [SALBUTAMOL]	1 (3.4)	0 (0.0)	1 (1.9)
	SELECTIVE SEROTONIN (5HT1) AGONISTS	All	1 (3.4)	0 (0.0)	1 (1.9)
		RIZATRIPTAN	1 (3.4)	0 (0.0)	1 (1.9)
	SOLUTIONS FOR PARENTERAL NUTRITION	All	1 (3.4)	0 (0.0)	1 (1.9)
		GLUCOSE	1 (3.4)	0 (0.0)	1 (1.9)
	THYROID HORMONES	All	0 (0.0)	2 (8.3)	2 (3.8)
		LEVOTHYROXIN	0 (0.0)	1 (4.2)	1 (1.9)
		LEVOTHYROXINE	0 (0.0)	2 (8.3)	2 (3.8)
	VITAMIN D AND ANALOGUES	All	7 (24.1)	6 (25.0)	13 (24.5)
		CHOLECALCIFEROL	0 (0.0)	2 (8.3)	2 (3.8)
		ERGOCALCIFEROL	0 (0.0)	1 (4.2)	1 (1.9)
		VITAMIN D NOS	4 (13.8)	3 (12.5)	7 (13.2)
		VITAMIN D [ERGOCALCIFEROL]	1 (3.4)	0 (0.0)	1 (1.9)
		VITAMIN D3	2 (6.9)	0 (0.0)	2 (3.8)
	VITAMINS WITH MINERALS	All	1 (3.4)	0 (0.0)	1 (1.9)
		EMERGEN C	1 (3.4)	0 (0.0)	1 (1.9)

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group,
 n = Frequency count, ATC = Anatomical Therapeutic Chemical.

Source Data: acm, created on: 17SEP2021:19:42:56

Table T2DCN_FOB0: Concomitant non-insulin anti-diabetic medications
 PFAS

Parameter	ATC classification	Generic term	Dapa 10mg	Placebo	Total
N			29	24	53
Number of subjects with concomitant non-insulin anti-diabetic medication n(%)	All	All	23 (79.3)	21 (87.5)	44 (83.0)
Subject with concomitant non-insulin anti-diabetic medication n(%)	BIGUANIDES	All	23 (79.3)	21 (87.5)	44 (83.0)
		METFORMIN	23 (79.3)	21 (87.5)	44 (83.0)

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group, n = Frequency count, ATC = Anatomical Therapeutic Chemical.

Source Data: acm, created on: 17SEP2021:19:42:56

Table T2DD1_EOB0: Patients disposition - Screening period
 Enrolled pediatric subjects

Subject disposition status	Reason for discontinuation of treatment	Number of subjects n(%)
Subjects enrolled		126
Subjects who completed screening period		60 (47.6)
Subjects discontinued from the screening period		66 (52.4)
Reason for the discontinuation from the screening period	Withdrawal by subject	1 (0.8)
	Withdrawal by parent/guardian	0 (0.0)
	Failure to meet randomization criteria	64 (50.8)
	Death	0 (0.0)
	Adverse event	0 (0.0)
	Other	1 (0.8)

Table T2DD2_EOB0: Patients disposition - Lead-in period
Enrolled pediatric subjects

<u>Subject disposition status</u>	<u>Reason for discontinuation of treatment</u>	<u>Number of subjects n(%)</u>
Subjects entered lead in period		60
Subjects randomized		53 (88.3)
Subjects who were not randomized		7 (11.7)
Reason for not being randomized	Withdrawal by subject	2 (3.3)
	Withdrawal by parent/guardian	1 (1.7)
	Failure to meet randomization criteria	3 (5.0)
	Death	0 (0.0)
	Adverse event	0 (0.0)
	Other	1 (1.7)

Note: n = Number of subjects.

Source Data: asl, created on: 17SEP2021:19:41:02

Table T2DD3_EOB0: Patients disposition - 52-week period
 Enrolled pediatric subjects

Subject disposition status	Reason for discontinuation of treatment	Dapa 10mg	Placebo	Total
Subjects Randomized		29	24	53
Receipt of IP	Subjects who received treatment	29 (100.0)	24 (100.0)	53 (100.0)
	Subjects who did not receive treatment	0 (0.0)	0 (0.0)	0 (0.0)
Subjects who completed IP treatment during the ST period		23 (79.3)	18 (75.0)	41 (77.4)
Subjects who discontinued IP treatment during the ST period		6 (20.7)	6 (25.0)	12 (22.6)
Subjects who discontinued IP treatment during the ST period - reason	Subject/legal representative decision	4 (13.8)	5 (20.8)	9 (17.0)
	Adverse event	1 (3.4)	1 (4.2)	2 (3.8)
	Severe non-compliance to protocol	1 (3.4)	0 (0.0)	1 (1.9)
	Development of study specific discontinuation criteria	0 (0.0)	0 (0.0)	0 (0.0)
	Subject lost to follow-up	0 (0.0)	0 (0.0)	0 (0.0)
	Other	0 (0.0)	0 (0.0)	0 (0.0)
Subjects who completed ST period		25 (86.2)	19 (79.2)	44 (83.0)
Subjects who discontinued from study during the ST period		4 (13.8)	5 (20.8)	9 (17.0)
Subjects who discontinued from study during the ST period - reason	Withdrawal by subject	4 (13.8)	3 (12.5)	7 (13.2)
	Withdrawal by parent/guardian	0 (0.0)	2 (8.3)	2 (3.8)
	Lost to follow-up	0 (0.0)	0 (0.0)	0 (0.0)
	Death	0 (0.0)	0 (0.0)	0 (0.0)
	Study terminated by sponsor	0 (0.0)	0 (0.0)	0 (0.0)
Subjects who entered long-term period		24 (82.8)	19 (79.2)	43 (81.1)
Subjects who did not enter long-term period		5 (17.2)	5 (20.8)	10 (18.9)
Subjects who completed IP treatment during the LT period		22 (75.9)	16 (66.7)	38 (71.7)
Subjects who discontinued IP treatment during the LT period		1 (3.4)	2 (8.3)	3 (5.7)
Subjects who discontinued IP treatment during the LT period - reason	Subject/legal representative decision	0 (0.0)	2 (8.3)	2 (3.8)
	Adverse event	0 (0.0)	0 (0.0)	0 (0.0)
	Severe non-compliance to protocol	0 (0.0)	0 (0.0)	0 (0.0)
	Development of study specific discontinuation criteria	1 (3.4)	0 (0.0)	1 (1.9)
	Subject lost to follow-up	0 (0.0)	0 (0.0)	0 (0.0)

Note: Dapa = Dapagliflozin, ST = 24-week short-term period, LT = 28-week long-term period, IP = Investigational product, 1 patient discontinued IP treatment during LT period due to study specific discontinuation period Lack of glycemic control
 Source Data: asl, created on: 17SEP2021:19:41:02

Table T2DD3_EOB0: Patients disposition - 52-week period
 Enrolled pediatric subjects

Subject disposition status	Reason for discontinuation of treatment	Dapa 10mg	Placebo	Total
	Other	0 (0.0)	0 (0.0)	0 (0.0)
Subjects who completed the LT period		24 (82.8)	17 (70.8)	41 (77.4)
Subjects who discontinued from the study during the LT period		0 (0.0)	2 (8.3)	2 (3.8)
Subjects who discontinued from the study during the LT period - reason	Withdrawal by subject	0 (0.0)	2 (8.3)	2 (3.8)
	Withdrawal by parent/guardian	0 (0.0)	0 (0.0)	0 (0.0)
	Lost to follow-up	0 (0.0)	0 (0.0)	0 (0.0)
	Death	0 (0.0)	0 (0.0)	0 (0.0)
	Study terminated by sponsor	0 (0.0)	0 (0.0)	0 (0.0)

Note: Dapa = Dapagliflozin, ST = 24-week short-term period, LT = 28-week long-term period, IP = Investigational product,
 1 patient discontinued IP treatment during LT period due to study specific discontinuation period Lack of glycemic control
 Source Data: asl, created on: 17SEP2021:19:41:02

Table T2DM1_FOB0: Demographic and other baseline characteristics - Age
 PFAS

Demographic characteristic		Dapa 10mg	Placebo	Total
N		29	24	53
Age (years)	n	29	24	53
	Mean	14.6	14.4	14.5
	Std Dev	2.0	2.3	2.1
	Minimum	11	11	11
	1st quartile	13.0	12.5	13.0
	Median	14.0	14.5	14.0
	3rd quartile	16.0	17.0	16.0
	Maximum	17	17	17
Age (cat.) n(%)	<= 15 years	16 (55.2)	14 (58.3)	30 (56.6)
	> 15 and < 18 years	13 (44.8)	10 (41.7)	23 (43.4)
	>= 18 years	0 (0.0)	0 (0.0)	0 (0.0)

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group,
 n = Number of valid observations, Std Dev = Standard deviation.
 Source Data: asl, created on: 17SEP2021:19:41:02

Table T2DM2_FOB0: Demographic and other baseline characteristics - Sex
PFAS

Demographic characteristic		Dapa 10mg	Placebo	Total
N		29	24	53
Sex n(%)	Male	12 (41.4)	9 (37.5)	21 (39.6)
	Female	17 (58.6)	15 (62.5)	32 (60.4)

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group,
n = Frequency count.

Source Data: asl, created on: 17SEP2021:19:41:02

Table T2DM3_FOB0: Demographic and other baseline characteristics - Race
 PFAS

Demographic characteristic		Dapa 10mg	Placebo	Total
N		29	24	53
Race n(%)	American Indian or Alaska Native	1 (3.4)	2 (8.3)	3 (5.7)
	Asian	0 (0.0)	1 (4.2)	1 (1.9)
	Black or African American	4 (13.8)	9 (37.5)	13 (24.5)
	Native Hawaiian or other Pacific Islander	1 (3.4)	0 (0.0)	1 (1.9)
	White	23 (79.3)	9 (37.5)	32 (60.4)
	Other	0 (0.0)	3 (12.5)	3 (5.7)
Race (aggreg.) n(%)	White	23 (79.3)	9 (37.5)	32 (60.4)
	non-White	6 (20.7)	15 (62.5)	21 (39.6)

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group, n = Frequency count.

Source Data: asl, created on: 17SEP2021:19:41:02

Table T2DM4_FOB0: Demographic and other baseline characteristics - Ethnic group
PFAS

Demographic characteristic		Dapa 10mg	Placebo	Total
N		29	24	53
Ethnic group n(%)	Hispanic or Latino	11 (37.9)	9 (37.5)	20 (37.7)
	Not Hispanic or Latino	17 (58.6)	15 (62.5)	32 (60.4)

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group,
n = Frequency count.

Source Data: asl, created on: 17SEP2021:19:41:02

Table T2DM5_FOB0: Demographic and other baseline characteristics - Geographic region
 PFAS

Demographic characteristic		Dapa 10mg	Placebo	Total
N		29	24	53
Geographic region n(%)	North America	11 (37.9)	14 (58.3)	25 (47.2)
	Latin America	6 (20.7)	7 (29.2)	13 (24.5)
	Europe	12 (41.4)	3 (12.5)	15 (28.3)
	Asia/Pacific	0 (0.0)	0 (0.0)	0 (0.0)
Geographic region (aggreg.) n(%)	Europe	12 (41.4)	3 (12.5)	15 (28.3)
	Non-Europe	17 (58.6)	21 (87.5)	38 (71.7)

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group,
 n = Frequency count, Europe = Hungary, Israel, Russian Federation.
 Source Data: asl, created on: 17SEP2021:19:41:02

Table T2DM6_FOB0: Demographic and other baseline characteristics - Country
 PFAS

Demographic characteristic		Dapa 10mg	Placebo	Total
N		29	24	53
Country n(%)	Hungary	2 (6.9)	0 (0.0)	2 (3.8)
	Israel	7 (24.1)	2 (8.3)	9 (17.0)
	Mexico	6 (20.7)	7 (29.2)	13 (24.5)
	Russian Federation	3 (10.3)	1 (4.2)	4 (7.5)
	United States	11 (37.9)	14 (58.3)	25 (47.2)

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group,
 n = Frequency count.

Source Data: asl, created on: 17SEP2021:19:41:02

Table T2DM7_FOB0: Demographic and other baseline characteristics - Height
 PFAS

Demographic characteristic		Dapa 10mg	Placebo	Total
N		29	24	53
Baseline height (cm)	n	29	24	53
	Mean	166.68	162.05	164.58
	Std Dev	9.44	11.39	10.53
	Minimum	137.0	141.0	137.0
	1st quartile	160.00	155.25	158.70
	Median	167.70	164.20	166.00
	3rd quartile	173.70	168.80	173.00
	Maximum	182.0	182.0	182.0

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group,
 n = Number of valid observations, Std Dev = Standard deviation.
 Source Data: asl, created on: 17SEP2021:19:41:02

Table T2DM8_FOB0: Demographic and other baseline characteristics - Body weight
 PFAS

Demographic characteristic		Dapa 10mg	Placebo	Total
N		29	24	53
Baseline weight (kg)	n	29	24	53
	Mean	83.10	94.57	88.29
	Std Dev	22.78	36.26	29.90
	Minimum	41.6	31.2	31.2
	1st quartile	71.80	64.80	66.00
	Median	78.80	90.85	85.70
	3rd quartile	93.80	126.70	101.90
	Maximum	145.0	165.2	165.2

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group,
 n = Number of valid observations, Std Dev = Standard deviation.

Source Data: asl, created on: 17SEP2021:19:41:02

Table T2DM9_FOB0: Demographic and other baseline characteristics - BMI
 PFAS

Demographic characteristic		Dapa 10mg	Placebo	Total
N		29	24	53
D: Baseline BMI (kg/m**2)	n	29	24	53
	Mean	29.7	34.9	32.1
	Std Dev	7.0	9.9	8.7
	Minimum	17	14	14
	1st quartile	26.0	29.3	26.4
	Median	29.7	32.7	31.4
	3rd quartile	33.4	44.4	36.1
D: Baseline BMI (aggreg) n(%)	< 30 kg/m**2	15 (51.7)	7 (29.2)	22 (41.5)
	>= 30 kg/m**2	14 (48.3)	17 (70.8)	31 (58.5)

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group,
 n = Number of valid observations, Std Dev = Standard deviation, BMI = Body mass index
 Source Data: asl, created on: 17SEP2021:19:41:02

Table T2DP_EOB0: Patients disposition - Analysis sets
Enrolled pediatric subjects set

<u>Parameter</u>		Dapa 10mg	Placebo
Pediatric full analysis set	Subjects excluded	0	0
Pediatric full analysis set	Subjects included	29	24
Pediatric per protocol set	Subjects excluded	4	7
Pediatric per protocol set	Subjects included	25	17
Pediatric treated subjects set	Subjects excluded	0	0
Pediatric treated subjects set	Subjects included	29	24

Table T2DR1_FOB0: Renal Baseline Characteristics - Screening eGFR
 PFAS

Demographic characteristic		Dapa 10mg	Placebo	Total
N		29	24	53
Screening eGFR (mL/min/1.73 m**2)	n	28	24	52
	Mean	120.0	116.5	118.4
	Std Dev	24.8	25.4	24.9
	Minimum	84	82	82
	1st quartile	96.0	97.5	97.0
	Median	115.5	114.0	114.5
	3rd quartile	138.5	126.0	131.5
	Maximum	171	175	175

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group,
 n = Number of valid observations, Std Dev = Standard deviation, eGFR = Estimated glomerular filtration rate.
 Source Data: asl, created on: 17SEP2021:19:41:02

Table T2DR2_FOB0: Renal Baseline Characteristics - Baseline eGFR
 PFAS

Demographic characteristic		Dapa 10mg	Placebo	Total
N		29	24	53
Baseline eGFR (mL/min/1.73 m**2)				
	n	29	24	53
	Mean	119.3	116.6	118.1
	Std Dev	23.0	22.3	22.5
	Minimum	81	88	81
	1st quartile	106.0	100.5	102.0
	Median	116.0	110.5	116.0
	3rd quartile	134.0	134.0	134.0
	Maximum	166	175	175
Baseline eGFR(cat.) n(%)				
	< 60 mL/min/1.73 m**2	0 (0.0)	0 (0.0)	0 (0.0)
	>= 60 and < 90 mL/min/1.73 m**2	3 (10.3)	2 (8.3)	5 (9.4)
	>= 90 and < 120 mL/min/1.73 m**2	14 (48.3)	13 (54.2)	27 (50.9)
	>= 120 mL/min/1.73 m**2	12 (41.4)	9 (37.5)	21 (39.6)

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group,
 n = Number of valid observations, Std Dev = Standard deviation, eGFR = Estimated glomerular filtration rate.
 Source Data: asl, created on: 17SEP2021:19:41:02

Table T2DST_FOB0: Duration of ST-Period
 PFAS

Parameter		Dapa 10mg	Placebo	Total
N		29	24	53
Duration of ST-Period (months)	n	29	24	53
	Mean	5.78	4.90	5.38
	Std Dev	1.64	1.82	1.76
	Minimum	3.2	0.5	0.5
	1st quartile	5.60	5.40	5.57
	Median	5.63	5.63	5.63
	3rd quartile	5.70	5.78	5.73
	Maximum	13.8	6.7	13.8

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group,
 n = Number of valid observations, Std Dev = Standard deviation, ST period = 24 week short-term period.
 Source Data: asl, created on: 17SEP2021:19:41:02

Table T2DT1_FOB0: Time in study
 PFAS

Parameter		Dapa 10mg	Placebo	Total
N		29	24	53
Time in study (months)	n	29	24	53
	Mean	11.97	10.63	11.37
	Std Dev	3.06	4.75	3.94
	Minimum	3.2	0.5	0.5
	1st quartile	12.87	11.57	12.87
	Median	13.07	13.08	13.07
	3rd quartile	13.17	13.13	13.17
	Maximum	14.5	13.7	14.5

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group,
 n = Number of valid observations, Std Dev = Standard deviation.
 Source Data: asl, created on: 17SEP2021:19:41:02

Table T2DT2_FOB0: Duration of exposure
 PFAS

Parameter		Dapa 10mg	Placebo	Total
N		29	24	53
Duration of exposure (days)	n	29	24	53
	Mean	152.69	135.79	145.04
	Std Dev	42.27	62.24	52.42
	Minimum	9	7	7
	1st quartile	167.00	114.50	161.00
	Median	167.00	168.00	168.00
	3rd quartile	170.00	172.00	170.00
	Maximum	176	202	202
Duration of exposure (days) n(%)	1 - 7	0 (0.0)	1 (4.2)	1 (1.9)
	8 - 14	2 (6.9)	0 (0.0)	2 (3.8)
	15 - 28	0 (0.0)	3 (12.5)	3 (5.7)
	29 - 42	0 (0.0)	0 (0.0)	0 (0.0)
	43 - 84	0 (0.0)	0 (0.0)	0 (0.0)
	85 - 98	0 (0.0)	1 (4.2)	1 (1.9)
	99 - 140	3 (10.3)	0 (0.0)	3 (5.7)
	141 - 182	24 (82.8)	17 (70.8)	41 (77.4)
	> 182	0 (0.0)	1 (4.2)	1 (1.9)

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group,
 n = Number of valid observations, Std Dev = Standard deviation.
 Source Data: asl, created on: 17SEP2021:19:41:02

Table T2DZ1_FOB0: Disease-specific baseline characteristics - Duration of T2DM
 PFAS

Parameter		Dapa 10mg	Placebo	Total
N		29	24	53
Duration of type 2 diabetes (years)	n	29	24	53
	Mean	2.68	2.52	2.61
	Std Dev	2.31	2.59	2.41
	Minimum	0.2	0.2	0.2
	1st quartile	1.06	0.63	0.68
	Median	2.04	1.78	1.93
	3rd quartile	3.79	3.69	3.79
	Maximum	10.6	11.1	11.1
Duration of type 2 diabetes (cat.) n(%)	< 3 years	18 (62.1)	17 (70.8)	35 (66.0)
	>= 3 and <= 10 years	10 (34.5)	6 (25.0)	16 (30.2)
	> 10 years	1 (3.4)	1 (4.2)	2 (3.8)

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group,
 n = Number of valid observations, Std Dev = Standard deviation.
 Source Data: asl, created on: 17SEP2021:19:41:02

Table T2DZ2_FOB0: Disease-specific baseline characteristics - Screening HbA1c
 PFAS

Parameter		Dapa 10mg	Placebo	Total
N		29	24	53
Screening HbA1c (%)	n	29	24	53
	Mean	7.99	8.10	8.04
	Std Dev	1.37	1.11	1.25
	Minimum	6.6	6.5	6.5
	1st quartile	6.90	7.35	7.10
	Median	7.50	7.70	7.70
	3rd quartile	8.50	8.95	8.80
	Maximum	11.0	10.5	11.0

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group,
 n = Number of valid observations, Std Dev = Standard deviation, HbA1c = Glycated haemoglobin.
 Source Data: asl, created on: 17SEP2021:19:41:02

Table T2DZ3_FOB0: Disease-specific baseline characteristics - Baseline HbA1c
 PFAS

Parameter		Dapa 10mg	Placebo	Total
N		29	24	53
Baseline HbA1c (%)	n	29	24	53
	Mean	7.80	8.05	7.91
	Std Dev	1.65	1.11	1.42
	Minimum	5.4	6.5	5.4
	1st quartile	6.80	7.20	6.90
	Median	7.30	7.85	7.60
	3rd quartile	8.50	8.70	8.50
Baseline HbA1c (cat.) n(%)	Maximum	12.4	10.5	12.4
	< 6.5%	5 (17.2)	0 (0.0)	5 (9.4)
	>= 6.5% and < 9%	19 (65.5)	19 (79.2)	38 (71.7)
	>= 9% and <= 11%	3 (10.3)	5 (20.8)	8 (15.1)
	> 11%	2 (6.9)	0 (0.0)	2 (3.8)

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group,
 n = Number of valid observations, Std Dev = Standard deviation, HbA1c = Glycated haemoglobin.
 Source Data: asl, created on: 17SEP2021:19:41:02

Table T2DZ4_FOB0: Disease-specific baseline characteristics - Screening Baseline FPG
 PFAS

Parameter		Dapa 10mg	Placebo	Total
N		29	24	53
Screening FPG (mmol/L)	n	29	24	53
	Mean	7.69	8.51	8.06
	Std Dev	1.94	2.95	2.46
	Minimum	4.8	4.7	4.7
	1st quartile	6.33	6.19	6.33
	Median	7.38	7.77	7.50
	3rd quartile	8.70	10.68	9.44
	Maximum	12.2	14.1	14.1

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group,
 n = Number of valid observations, Std Dev = Standard deviation, FPG = Fasting plasma glucose.
 Source Data: asl, created on: 17SEP2021:19:41:02

Table T2DZ5_FOB0: Disease-specific baseline characteristics - Baseline FPG
 PFAS

Parameter		Dapa 10mg	Placebo	Total
N		29	24	53
Baseline FPG (mmol/L)	n	29	24	53
	Mean	8.88	8.99	8.93
	Std Dev	3.32	2.68	3.02
	Minimum	5.3	4.7	4.7
	1st quartile	6.50	7.38	6.70
	Median	7.33	8.66	7.99
	3rd quartile	11.16	10.82	11.16
Baseline FPG (cat.) n(%)	Maximum	16.4	14.5	16.4
	<= 14.2 mmol/L	26 (89.7)	23 (95.8)	49 (92.5)
	> 14.2 mmol/L	3 (10.3)	1 (4.2)	4 (7.5)

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group,
 n = Number of valid observations, Std Dev = Standard deviation, FPG = Fasting plasma glucose.
 Source Data: asl, created on: 17SEP2021:19:41:02

Table T2RM_FOB0: Patients with rescue medication until week 24
PFAS

<u>Parameter</u>	<u>Dapa 10mg</u>	<u>Placebo</u>
N	29	24
Patients with rescue medication until week 24 n(%)	2 (6.9)	2 (8.3)

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group,
n = Frequency count.

Source Data: asl, created on: 17SEP2021:19:41:02

Table T2DBM1_POB0: Diabetes background medication
 PPPS

Parameter		Dapa 10mg	Placebo	Total
N		25	17	42
Background diabetic medication n(%)	Metformin	10 (40.0)	11 (64.7)	21 (50.0)
	Insulin	5 (20.0)	3 (17.6)	8 (19.0)
	Insulin + metformin	10 (40.0)	3 (17.6)	13 (31.0)
Background diabetic medication - aggregated n(%)	Metformin	10 (40.0)	11 (64.7)	21 (50.0)
	Insulin or insulin + metformin	15 (60.0)	6 (35.3)	21 (50.0)

Note: Dapa = Dapagliflozin, PPPS = Pediatric per protocol set, N = Number of subjects in treatment group,
 n = Frequency count.

Source Data: asl, created on: 17SEP2021:19:41:02

Table T2DBM2_POB0: Diabetes background medication - Metformin daily dose
 PPPS

Parameter		Dapa 10mg	Placebo	Total
N		25	17	42
Metformin diabetic background medication - Total	n	20	14	34
daily dose (mg)	Mean	1590.0	1496.4	1551.5
	Std Dev	488.4	494.7	485.7
	Minimum	1000	1000	1000
	1st quartile	1000.0	1000.0	1000.0
	Median	1700.0	1387.5	1600.0
	3rd quartile	1850.0	2000.0	2000.0
	Maximum	2550	2500	2550

Note: Dapa = Dapagliflozin, PPPS = Pediatric per protocol set, N = Number of subjects in treatment group,
 n = Number of valid observations, Std Dev = Standard deviation.

Source Data: asl, created on: 17SEP2021:19:41:02

Table T2DBM3_POB0: Diabetes background medication - Insulin daily dose
 PPPS

Parameter		Dapa 10mg	Placebo	Total
N		25	17	42
Insulin diabetic background medication - Total daily dose (Insulin unit)	n	15	6	21
	Mean	53.9	84.8	62.7
	Std Dev	43.4	57.3	48.4
	Minimum	5	35	5
	1st quartile	27.0	38.0	35.0
	Median	36.0	65.5	40.0
	3rd quartile	77.0	135.0	90.0
	Maximum	170	170	170

Note: Dapa = Dapagliflozin, PPPS = Pediatric per protocol set, N = Number of subjects in treatment group,
 n = Number of valid observations, Std Dev = Standard deviation.
 Source Data: asl, created on: 17SEP2021:19:41:02

Table T2DCA_POB0: Concomitant antihypertensive, antipsychotic, and antihyperlipidemic medications during the 24 - week period
 PPPS

Parameter	ATC classification	Generic term	Dapa 10mg	Placebo	Total
N			25	17	42
Number of subjects with concomitant antihypertensive, antipsychotic, and antihyperlipidemic medication n(%)	All	All	4 (16.0)	5 (29.4)	9 (21.4)
Subjects with concomitant antihypertensive, antipsychotic, and antihyperlipidemic medication n(%)	ACE INHIBITORS, PLAIN	All	3 (12.0)	3 (17.6)	6 (14.3)
		ENALAPRIL	1 (4.0)	1 (5.9)	2 (4.8)
		ENALAPRIL MALEATE	1 (4.0)	0 (0.0)	1 (2.4)
		LISINOPRIL	0 (0.0)	2 (11.8)	2 (4.8)
		TRITACE	1 (4.0)	0 (0.0)	1 (2.4)
	BETA BLOCKING AGENTS, SELECTIVE	All	0 (0.0)	1 (5.9)	1 (2.4)
		METOPROLOL	0 (0.0)	1 (5.9)	1 (2.4)
	CENTRALLY ACTING SYMPATHOMIMETICS	All	1 (4.0)	0 (0.0)	1 (2.4)
		DEXMETHYLPHENIDATE HYDROCHLORIDE	1 (4.0)	0 (0.0)	1 (2.4)
	FIBRATES	All	1 (4.0)	1 (5.9)	2 (4.8)
		BEZAFIBRATE	0 (0.0)	1 (5.9)	1 (2.4)
		GEMFIBROZIL	1 (4.0)	0 (0.0)	1 (2.4)
	OTHER ANTIEPILEPTICS	All	1 (4.0)	0 (0.0)	1 (2.4)
		LAMOTRIGINE	1 (4.0)	0 (0.0)	1 (2.4)
	OTHER ANXIOLYTICS	All	2 (8.0)	1 (5.9)	3 (7.1)
		ESCITALOPRAM	1 (4.0)	1 (5.9)	2 (4.8)
		PROZAC	0 (0.0)	1 (5.9)	1 (2.4)
		ZOLOFT	1 (4.0)	0 (0.0)	1 (2.4)
	SELECTIVE SEROTONIN (5HT1) AGONISTS	All	1 (4.0)	0 (0.0)	1 (2.4)
		RIZATRIPTAN	1 (4.0)	0 (0.0)	1 (2.4)

Note: Dapa = Dapagliflozin, PPPS = Pediatric per protocol set, N = Number of subjects in treatment group, n = Frequency count, ATC = Anatomical Therapeutic Chemical.

Source Data: acm, created on: 17SEP2021:19:42:56

Table T2DCI_POB0: Concomitant insulin anti-diabetic medications
 PPPS

Parameter	ATC classification	Generic term	Dapa 10mg	Placebo	Total
N			25	17	42
Number of subjects with concomitant insulin anti-diabetic medication n(%)	All	All	15 (60.0)	6 (35.3)	21 (50.0)
Subjects with concomitant insulin anti-diabetic medication n(%)	INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING	All	11 (44.0)	4 (23.5)	15 (35.7)
		ACTRAPID [INSULIN HUMAN]	1 (4.0)	0 (0.0)	1 (2.4)
		ADMELOG	1 (4.0)	1 (5.9)	2 (4.8)
		HUMALOG	5 (20.0)	2 (11.8)	7 (16.7)
		INSULIN ASPART	1 (4.0)	0 (0.0)	1 (2.4)
		LISPRO INSULIN	1 (4.0)	0 (0.0)	1 (2.4)
		NOVOLIN 30R [INSULIN]	1 (4.0)	1 (5.9)	2 (4.8)
		NOVOLOG	1 (4.0)	1 (5.9)	2 (4.8)
	INSULINS AND ANALOGUES FOR INJECTION, INTERMEDIATE- OR LONG-ACTING COMBINED WITH FAST-ACTING	All	2 (8.0)	2 (11.8)	4 (9.5)
		HUMALOG MIX	1 (4.0)	2 (11.8)	3 (7.1)
		NOVOMIX	1 (4.0)	0 (0.0)	1 (2.4)
	INSULINS AND ANALOGUES FOR INJECTION, INTERMEDIATE-ACTING	All	4 (16.0)	1 (5.9)	5 (11.9)
		HUMULINE	1 (4.0)	0 (0.0)	1 (2.4)
		INSULATARD HUMAN	1 (4.0)	0 (0.0)	1 (2.4)
		INSUMAN BASAL	1 (4.0)	0 (0.0)	1 (2.4)
		NPH INSULIN	1 (4.0)	1 (5.9)	2 (4.8)
	INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING	All	9 (36.0)	4 (23.5)	13 (31.0)
		BASAGLAR	1 (4.0)	2 (11.8)	3 (7.1)
		INSULIN GLARGINE	2 (8.0)	0 (0.0)	2 (4.8)
		LANTUS	5 (20.0)	1 (5.9)	6 (14.3)
		LEVEMIR	1 (4.0)	0 (0.0)	1 (2.4)
		TRESIBA	0 (0.0)	2 (11.8)	2 (4.8)

Note: Dapa = Dapagliflozin, PPPS = Pediatric per protocol set, N = Number of subjects in treatment group, n = Frequency count, ATC = Anatomical Therapeutic Chemical.
 Source Data: acm, created on: 17SEP2021:19:42:56

Table T2DCM_POB0: Current medication for the 24 - week period
 PPPS

Parameter	ATC classification	Generic term	Dapa 10mg	Placebo	Total
N			25	17	42
Number of subjects with current medication n(%)	All	All	25 (100.0)	17 (100.0)	42 (100.0)
Subjects with current medication n(%)	ACE INHIBITORS, PLAIN	All	3 (12.0)	3 (17.6)	6 (14.3)
		ENALAPRIL	1 (4.0)	1 (5.9)	2 (4.8)
		ENALAPRIL MALEATE	1 (4.0)	0 (0.0)	1 (2.4)
		LISINOPRIL	0 (0.0)	2 (11.8)	2 (4.8)
		TRITACE	1 (4.0)	0 (0.0)	1 (2.4)
	ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES	All	1 (4.0)	0 (0.0)	1 (2.4)
		KETOROLAC	1 (4.0)	0 (0.0)	1 (2.4)
	ANALGESICS	All	1 (4.0)	0 (0.0)	1 (2.4)
		ANALGESICS	1 (4.0)	0 (0.0)	1 (2.4)
	ANILIDES	All	5 (20.0)	3 (17.6)	8 (19.0)
		ACETAMINOPHEN	2 (8.0)	2 (11.8)	4 (9.5)
		DAYQUIL	1 (4.0)	0 (0.0)	1 (2.4)
		DEXTROMETHORPHAN;PARACETAMOL; PHENYLEPHRINE	1 (4.0)	0 (0.0)	1 (2.4)
		MIDOL COMPLETE	0 (0.0)	1 (5.9)	1 (2.4)
		NYQUIL	1 (4.0)	0 (0.0)	1 (2.4)
		PARACETAMOL	1 (4.0)	0 (0.0)	1 (2.4)
		TYLENOL	0 (0.0)	1 (5.9)	1 (2.4)
	ANTIINFECTIVES AND ANTISEPTICS FOR LOCAL ORAL TREATMENT	All	1 (4.0)	0 (0.0)	1 (2.4)
		CLOTRIMAZOLE	1 (4.0)	0 (0.0)	1 (2.4)
	ANTIINFECTIVES FOR TREATMENT OF ACNE	All	3 (12.0)	0 (0.0)	3 (7.1)
		AZITHROMYCIN	2 (8.0)	0 (0.0)	2 (4.8)
		CLINDAMYCIN PHOSPHATE	1 (4.0)	0 (0.0)	1 (2.4)
	ANTIINFLAMMATORY PRODUCTS FOR VAGINAL ADMINISTRATION	All	0 (0.0)	1 (5.9)	1 (2.4)
		MENSTRIDOL	0 (0.0)	1 (5.9)	1 (2.4)

Note: Dapa = Dapagliflozin, PPPS = Pediatric per protocol set, N = Number of subjects in treatment group, n = Frequency count, ATC = Anatomical Therapeutic Chemical.
 Source Data: acm, created on: 17SEP2021:19:42:56

Table T2DCM_POB0: Current medication for the 24 - week period
 PPPS

Parameter	ATC classification	Generic term	Dapa 10mg	Placebo	Total
	ASCORBIC ACID (VITAMIN C), PLAIN	All	0 (0.0)	1 (5.9)	1 (2.4)
		VIT C ROSEHIP	0 (0.0)	1 (5.9)	1 (2.4)
	BETA BLOCKING AGENTS, SELECTIVE	All	0 (0.0)	1 (5.9)	1 (2.4)
		METOPROLOL	0 (0.0)	1 (5.9)	1 (2.4)
	BETA-LACTAM ANTIBACTERIALS, PENICILLINS	All	0 (0.0)	1 (5.9)	1 (2.4)
		PENICILLIN NOS	0 (0.0)	1 (5.9)	1 (2.4)
	BIGUANIDES	All	20 (80.0)	14 (82.4)	34 (81.0)
		METFORMIN	20 (80.0)	14 (82.4)	34 (81.0)
	CENTRALLY ACTING SYMPATHOMIMETICS	All	1 (4.0)	0 (0.0)	1 (2.4)
		DEXMETHYLPHENIDATE HYDROCHLORIDE	1 (4.0)	0 (0.0)	1 (2.4)
	COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS	All	0 (0.0)	1 (5.9)	1 (2.4)
		AMOXICILLIN;CLAVULANIC ACID	0 (0.0)	1 (5.9)	1 (2.4)
	COMBINATIONS OF SULFONAMIDES AND TRIMETHOPRIM, INCL. DERIVATIVES	All	0 (0.0)	1 (5.9)	1 (2.4)
		TRIMETHOPRIM SULFAMETHOXAZOLE	0 (0.0)	1 (5.9)	1 (2.4)
	CORTICOSTEROIDS	All	0 (0.0)	1 (5.9)	1 (2.4)
		SYNALAR	0 (0.0)	1 (5.9)	1 (2.4)
	CORTICOSTEROIDS ACTING LOCALLY	All	1 (4.0)	1 (5.9)	2 (4.8)
		PREDNISONE	1 (4.0)	1 (5.9)	2 (4.8)
		QVAR	1 (4.0)	0 (0.0)	1 (2.4)
	CORTICOSTEROIDS, MODERATELY POTENT, COMBINATIONS WITH ANTIBIOTICS	All	1 (4.0)	0 (0.0)	1 (2.4)
		TEVACUTAN	1 (4.0)	0 (0.0)	1 (2.4)
	CORTICOSTEROIDS, POTENT (GROUP III)	All	0 (0.0)	3 (17.6)	3 (7.1)
		FLONASE [FLUTICASONE PROPIONATE]	0 (0.0)	1 (5.9)	1 (2.4)
		FLUTICASONE	0 (0.0)	2 (11.8)	2 (4.8)
		MOMETASONE FUROATE	0 (0.0)	1 (5.9)	1 (2.4)

Note: Dapa = Dapagliflozin, PPPS = Pediatric per protocol set, N = Number of subjects in treatment group,
 n = Frequency count, ATC = Anatomical Therapeutic Chemical.

Source Data: acm, created on: 17SEP2021:19:42:56

Table T2DCM_POB0: Current medication for the 24 - week period
PPPS

Parameter	ATC classification	Generic term	Dapa 10mg	Placebo	Total	
FIBRATES		All	1 (4.0)	1 (5.9)	2 (4.8)	
		BEZAFIBRATE	0 (0.0)	1 (5.9)	1 (2.4)	
		GEMFIBROZIL	1 (4.0)	0 (0.0)	1 (2.4)	
FIRST-GENERATION CEPHALOSPORINS		All	2 (8.0)	1 (5.9)	3 (7.1)	
		CEFALEXIN	2 (8.0)	1 (5.9)	3 (7.1)	
GLYCOGENOLYTIC HORMONES		All	1 (4.0)	0 (0.0)	1 (2.4)	
		GLUCAGON	1 (4.0)	0 (0.0)	1 (2.4)	
H2-RECEPTOR ANTAGONISTS		All	0 (0.0)	1 (5.9)	1 (2.4)	
		RANITIDINE	0 (0.0)	1 (5.9)	1 (2.4)	
HERBAL STOMATOLOGICAL REMEDIES CONTAINING MUCILAGE		All	1 (4.0)	0 (0.0)	1 (2.4)	
		MUCALTINUM	1 (4.0)	0 (0.0)	1 (2.4)	
IMIDAZOLE AND TRIAZOLE DERIVATIVES		All	1 (4.0)	0 (0.0)	1 (2.4)	
		DIFLUCAN	1 (4.0)	0 (0.0)	1 (2.4)	
INFLUENZA VACCINES		All	0 (0.0)	1 (5.9)	1 (2.4)	
		INFLUENZA VACCINE	0 (0.0)	1 (5.9)	1 (2.4)	
INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING		All	11 (44.0)	4 (23.5)	15 (35.7)	
		ACTRAPID [INSULIN HUMAN]	1 (4.0)	0 (0.0)	1 (2.4)	
		ADMELOG	1 (4.0)	1 (5.9)	2 (4.8)	
		HUMALOG	5 (20.0)	2 (11.8)	7 (16.7)	
		INSULIN ASPART	1 (4.0)	0 (0.0)	1 (2.4)	
		LISPRO INSULIN	1 (4.0)	0 (0.0)	1 (2.4)	
		NOVOLIN 30R [INSULIN]	1 (4.0)	1 (5.9)	2 (4.8)	
		NOVOLOG	1 (4.0)	1 (5.9)	2 (4.8)	
		INSULINS AND ANALOGUES FOR INJECTION, INTERMEDIATE- OR LONG-ACTING COMBINED WITH FAST-ACTING	All	2 (8.0)	2 (11.8)	4 (9.5)
		HUMALOG MIX	1 (4.0)	2 (11.8)	3 (7.1)	
NOVOMIX	1 (4.0)	0 (0.0)	1 (2.4)			

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Source Data: acm, created on: 17SEP2021:19:42:56

Table T2DCM_POB0: Current medication for the 24 - week period
 PPPS

Parameter	ATC classification	Generic term	Dapa 10mg	Placebo	Total
	INSULINS AND ANALOGUES FOR INJECTION, INTERMEDIATE-ACTING	All	4 (16.0)	1 (5.9)	5 (11.9)
		HUMULINE	1 (4.0)	0 (0.0)	1 (2.4)
		INSULATARD HUMAN	1 (4.0)	0 (0.0)	1 (2.4)
		INSUMAN BASAL	1 (4.0)	0 (0.0)	1 (2.4)
		NPH INSULIN	1 (4.0)	1 (5.9)	2 (4.8)
	INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING	All	9 (36.0)	4 (23.5)	13 (31.0)
		BASAGLAR	1 (4.0)	2 (11.8)	3 (7.1)
		INSULIN GLARGINE	2 (8.0)	0 (0.0)	2 (4.8)
		LANTUS	5 (20.0)	1 (5.9)	6 (14.3)
		LEVEMIR	1 (4.0)	0 (0.0)	1 (2.4)
		TRESIBA	0 (0.0)	2 (11.8)	2 (4.8)
	IRON BIVALENT, ORAL PREPARATIONS	All	0 (0.0)	1 (5.9)	1 (2.4)
		FERROUS SULFATE	0 (0.0)	1 (5.9)	1 (2.4)
	LEUKOTRIENE RECEPTOR ANTAGONISTS	All	0 (0.0)	1 (5.9)	1 (2.4)
		MONTELUKAST	0 (0.0)	1 (5.9)	1 (2.4)
	MELATONIN RECEPTOR AGONISTS	All	1 (4.0)	0 (0.0)	1 (2.4)
		MELATONIN	1 (4.0)	0 (0.0)	1 (2.4)
	NATURAL OPIUM ALKALOIDS	All	0 (0.0)	1 (5.9)	1 (2.4)
		OXYCODONE	0 (0.0)	1 (5.9)	1 (2.4)
	NEURAMINIDASE INHIBITORS	All	0 (0.0)	1 (5.9)	1 (2.4)
		TAMIFLU	0 (0.0)	1 (5.9)	1 (2.4)
	OPIUM DERIVATIVES AND EXPECTORANTS	All	0 (0.0)	1 (5.9)	1 (2.4)
		GUAIFENESIN AND DEXTROMETHORPHAN	0 (0.0)	1 (5.9)	1 (2.4)
	OSMOTICALLY ACTING LAXATIVES	All	1 (4.0)	0 (0.0)	1 (2.4)
		MIRALAX	1 (4.0)	0 (0.0)	1 (2.4)
	OTHER AGENTS FOR LOCAL ORAL TREATMENT	All	0 (0.0)	1 (5.9)	1 (2.4)
		DICLOFENAC	0 (0.0)	1 (5.9)	1 (2.4)
	OTHER ANALGESICS AND ANTIPYRETICS	All	1 (4.0)	0 (0.0)	1 (2.4)

Note: Dapa = Dapagliflozin, PPPS = Pediatric per protocol set, N = Number of subjects in treatment group,
 n = Frequency count, ATC = Anatomical Therapeutic Chemical.

Source Data: acm, created on: 17SEP2021:19:42:56

Table T2DCM_POB0: Current medication for the 24 - week period
PPPS

Parameter	ATC classification	Generic term	Dapa 10mg	Placebo	Total
		OXCARBAZEPINE	1 (4.0)	0 (0.0)	1 (2.4)
	OTHER ANTI-ACNE PREPARATIONS FOR SYSTEMIC USE	All	0 (0.0)	1 (5.9)	1 (2.4)
		ORTHO-CYCLEN-28	0 (0.0)	1 (5.9)	1 (2.4)
	OTHER ANTIBIOTICS FOR TOPICAL USE	All	1 (4.0)	0 (0.0)	1 (2.4)
		CIPROFLOXACIN	1 (4.0)	0 (0.0)	1 (2.4)
	OTHER ANTIEMETICS	All	2 (8.0)	1 (5.9)	3 (7.1)
		DIPHENHYDRAMINE	0 (0.0)	1 (5.9)	1 (2.4)
		HYDROXYZINE	1 (4.0)	0 (0.0)	1 (2.4)
		PROMETHAZINE	1 (4.0)	0 (0.0)	1 (2.4)
	OTHER ANTIEPILEPTICS	All	1 (4.0)	0 (0.0)	1 (2.4)
		LAMOTRIGINE	1 (4.0)	0 (0.0)	1 (2.4)
	OTHER ANTIMIGRAINE PREPARATIONS	All	1 (4.0)	0 (0.0)	1 (2.4)
		AMITRIPTYLINE HCL	1 (4.0)	0 (0.0)	1 (2.4)
	OTHER ANXIOLYTICS	All	2 (8.0)	1 (5.9)	3 (7.1)
		ESCITALOPRAM	1 (4.0)	1 (5.9)	2 (4.8)
		PROZAC	0 (0.0)	1 (5.9)	1 (2.4)
		ZOLOFT	1 (4.0)	0 (0.0)	1 (2.4)
	OTHER CARDIAC PREPARATIONS	All	2 (8.0)	2 (11.8)	4 (9.5)
		IBUPROFEN	2 (8.0)	2 (11.8)	4 (9.5)
		MOTRIN [IBUPROFEN]	0 (0.0)	1 (5.9)	1 (2.4)
	OTHER DERMATOLOGICALS	All	0 (0.0)	1 (5.9)	1 (2.4)
		IVERMECTIN	0 (0.0)	1 (5.9)	1 (2.4)
	OTHER DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)	All	1 (4.0)	0 (0.0)	1 (2.4)
		BISMUTH SUBSALICYLATE;MAGNESIUM CARBONATE	1 (4.0)	0 (0.0)	1 (2.4)
	OTHER LIPID MODIFYING AGENTS	All	1 (4.0)	0 (0.0)	1 (2.4)
		FISH OIL	1 (4.0)	0 (0.0)	1 (2.4)

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Source Data: acm, created on: 17SEP2021:19:42:56

Table T2DCM_POB0: Current medication for the 24 - week period
 PPPS

Parameter	ATC classification	Generic term	Dapa 10mg	Placebo	Total
OTHER NASAL PREPARATIONS		All	2 (8.0)	0 (0.0)	2 (4.8)
		HALLS	2 (8.0)	0 (0.0)	2 (4.8)
OTHER OPIOIDS		All	1 (4.0)	0 (0.0)	1 (2.4)
		TRAMADOL	1 (4.0)	0 (0.0)	1 (2.4)
OTHER PLAIN VITAMIN PREPARATIONS		All	2 (8.0)	1 (5.9)	3 (7.1)
		VITAMIN E NOS	2 (8.0)	1 (5.9)	3 (7.1)
OTHER UROLOGICALS		All	1 (4.0)	0 (0.0)	1 (2.4)
		PYRIDIUM	1 (4.0)	0 (0.0)	1 (2.4)
PAPAVERINE AND DERIVATIVES		All	1 (4.0)	0 (0.0)	1 (2.4)
		PAPAVERINE	1 (4.0)	0 (0.0)	1 (2.4)
PENICILLINS WITH EXTENDED SPECTRUM		All	2 (8.0)	0 (0.0)	2 (4.8)
		AMOXICILLIN	2 (8.0)	0 (0.0)	2 (4.8)
PIPERAZINE DERIVATIVES		All	0 (0.0)	2 (11.8)	2 (4.8)
		CETIRIZINE	0 (0.0)	1 (5.9)	1 (2.4)
		ZYRTEC [CETIRIZINE HYDROCHLORIDE]	0 (0.0)	1 (5.9)	1 (2.4)
PREGNADIEN DERIVATIVES		All	1 (4.0)	0 (0.0)	1 (2.4)
		DUPHASTON	1 (4.0)	0 (0.0)	1 (2.4)
PROGESTOGENS		All	1 (4.0)	0 (0.0)	1 (2.4)
		NEXPLANON	1 (4.0)	0 (0.0)	1 (2.4)
PROTON PUMP INHIBITORS		All	1 (4.0)	0 (0.0)	1 (2.4)
		OMEPRAZOLE	1 (4.0)	0 (0.0)	1 (2.4)
PYRAZOLONES		All	1 (4.0)	0 (0.0)	1 (2.4)
		METAMIZOLE SODIUM	1 (4.0)	0 (0.0)	1 (2.4)
SALICYLIC ACID AND DERIVATIVES		All	2 (8.0)	0 (0.0)	2 (4.8)
		ACETYLSALICYLIC ACID;CAFFEINE	1 (4.0)	0 (0.0)	1 (2.4)
		SALICYLATE SODIUM	1 (4.0)	0 (0.0)	1 (2.4)
		SALICYLIC ACID AND DERIVATIVES	1 (4.0)	0 (0.0)	1 (2.4)

Note: Dapa = Dapagliflozin, PPPS = Pediatric per protocol set, N = Number of subjects in treatment group,
 n = Frequency count, ATC = Anatomical Therapeutic Chemical.

Source Data: acm, created on: 17SEP2021:19:42:56

Table T2DCM_POB0: Current medication for the 24 - week period
 PPPS

Parameter	ATC classification	Generic term	Dapa 10mg	Placebo	Total
	SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS	All	1 (4.0)	3 (17.6)	4 (9.5)
		SALBUTAMOL	0 (0.0)	2 (11.8)	2 (4.8)
		VENTOLIN HFA	0 (0.0)	1 (5.9)	1 (2.4)
		VENTOLIN [SALBUTAMOL]	1 (4.0)	0 (0.0)	1 (2.4)
	SELECTIVE SEROTONIN (5HT1) AGONISTS	All	1 (4.0)	0 (0.0)	1 (2.4)
		RIZATRIPTAN	1 (4.0)	0 (0.0)	1 (2.4)
	SOLUTIONS FOR PARENTERAL NUTRITION	All	1 (4.0)	0 (0.0)	1 (2.4)
		GLUCOSE	1 (4.0)	0 (0.0)	1 (2.4)
	THYROID HORMONES	All	0 (0.0)	1 (5.9)	1 (2.4)
		LEVOTHYROXIN	0 (0.0)	1 (5.9)	1 (2.4)
		LEVOTHYROXINE	0 (0.0)	1 (5.9)	1 (2.4)
	VITAMIN D AND ANALOGUES	All	6 (24.0)	4 (23.5)	10 (23.8)
		CHOLECALCIFEROL	0 (0.0)	2 (11.8)	2 (4.8)
		VITAMIN D NOS	3 (12.0)	2 (11.8)	5 (11.9)
		VITAMIN D [ERGOCALCIFEROL]	1 (4.0)	0 (0.0)	1 (2.4)
		VITAMIN D3	2 (8.0)	0 (0.0)	2 (4.8)
	VITAMINS WITH MINERALS	All	1 (4.0)	0 (0.0)	1 (2.4)
		EMERGEN C	1 (4.0)	0 (0.0)	1 (2.4)

Note: Dapa = Dapagliflozin, PPPS = Pediatric per protocol set, N = Number of subjects in treatment group,
 n = Frequency count, ATC = Anatomical Therapeutic Chemical.

Source Data: acm, created on: 17SEP2021:19:42:56

Table T2DCN_POB0: Concomitant non-insulin anti-diabetic medications
 PPPS

Parameter	ATC classification	Generic term	Dapa 10mg	Placebo	Total
N			25	17	42
Number of subjects with concomitant non-insulin anti-diabetic medication n(%)	All	All	20 (80.0)	14 (82.4)	34 (81.0)
Subject with concomitant non-insulin anti-diabetic medication n(%)	BIGUANIDES	All	20 (80.0)	14 (82.4)	34 (81.0)
		METFORMIN	20 (80.0)	14 (82.4)	34 (81.0)

Note: Dapa = Dapagliflozin, PPPS = Pediatric per protocol set, N = Number of subjects in treatment group, n = Frequency count, ATC = Anatomical Therapeutic Chemical.

Source Data: acm, created on: 17SEP2021:19:42:56

Table T2DM1_POB0: Demographic and other baseline characteristics - Age
 PPPS

Demographic characteristic		Dapa 10mg	Placebo	Total
N		25	17	42
Age (years)	n	25	17	42
	Mean	14.4	14.6	14.5
	Std Dev	2.0	2.3	2.1
	Minimum	11	11	11
	1st quartile	13.0	13.0	13.0
	Median	14.0	15.0	14.5
	3rd quartile	16.0	17.0	17.0
	Maximum	17	17	17
Age (cat.) n(%)	<= 15 years	14 (56.0)	10 (58.8)	24 (57.1)
	> 15 and < 18 years	11 (44.0)	7 (41.2)	18 (42.9)
	>= 18 years	0 (0.0)	0 (0.0)	0 (0.0)

Note: Dapa = Dapagliflozin, PPPS = Pediatric per protocol set, N = Number of subjects in treatment group,
 n = Number of valid observations, Std Dev = Standard deviation.
 Source Data: asl, created on: 17SEP2021:19:41:02

Table T2DM2_POB0: Demographic and other baseline characteristics - Sex
PPPS

Demographic characteristic		Dapa 10mg	Placebo	Total
N		25	17	42
Sex n(%)	Male	11 (44.0)	5 (29.4)	16 (38.1)
	Female	14 (56.0)	12 (70.6)	26 (61.9)

Note: Dapa = Dapagliflozin, PPPS = Pediatric per protocol set, N = Number of subjects in treatment group,
n = Frequency count.

Source Data: asl, created on: 17SEP2021:19:41:02

Table T2DM3_POB0: Demographic and other baseline characteristics - Race
 PPPS

Demographic characteristic		Dapa 10mg	Placebo	Total
N		25	17	42
Race n(%)	American Indian or Alaska Native	1 (4.0)	2 (11.8)	3 (7.1)
	Asian	0 (0.0)	1 (5.9)	1 (2.4)
	Black or African American	4 (16.0)	6 (35.3)	10 (23.8)
	Native Hawaiian or other Pacific Islander	1 (4.0)	0 (0.0)	1 (2.4)
	White	19 (76.0)	6 (35.3)	25 (59.5)
	Other	0 (0.0)	2 (11.8)	2 (4.8)
Race (aggreg.) n(%)	White	19 (76.0)	6 (35.3)	25 (59.5)
	non-White	6 (24.0)	11 (64.7)	17 (40.5)

Note: Dapa = Dapagliflozin, PPPS = Pediatric per protocol set, N = Number of subjects in treatment group,
 n = Frequency count.

Source Data: asl, created on: 17SEP2021:19:41:02

Table T2DM4_POB0: Demographic and other baseline characteristics - Ethnic group
PPPS

Demographic characteristic	Dapa 10mg	Placebo	Total
N	25	17	42
Ethnic group n(%)			
Hispanic or Latino	11 (44.0)	8 (47.1)	19 (45.2)
Not Hispanic or Latino	13 (52.0)	9 (52.9)	22 (52.4)

Note: Dapa = Dapagliflozin, PPPS = Pediatric per protocol set, N = Number of subjects in treatment group,
n = Frequency count.

Source Data: asl, created on: 17SEP2021:19:41:02

Table T2DM5_POB0: Demographic and other baseline characteristics - Geographic region
 PPPS

Demographic characteristic		Dapa 10mg	Placebo	Total
N		25	17	42
Geographic region n(%)	North America	10 (40.0)	9 (52.9)	19 (45.2)
	Latin America	6 (24.0)	6 (35.3)	12 (28.6)
	Europe	9 (36.0)	2 (11.8)	11 (26.2)
	Asia/Pacific	0 (0.0)	0 (0.0)	0 (0.0)
Geographic region (aggreg.) n(%)	Europe	9 (36.0)	2 (11.8)	11 (26.2)
	Non-Europe	16 (64.0)	15 (88.2)	31 (73.8)

Note: Dapa = Dapagliflozin, PPPS = Pediatric per protocol set, N = Number of subjects in treatment group,
 n = Frequency count, Europe = Hungary, Israel, Russian Federation.
 Source Data: asl, created on: 17SEP2021:19:41:02

Table T2DM6_POB0: Demographic and other baseline characteristics - Country
 PPPS

Demographic characteristic		Dapa 10mg	Placebo	Total
N		25	17	42
Country n(%)	Hungary	2 (8.0)	0 (0.0)	2 (4.8)
	Israel	4 (16.0)	1 (5.9)	5 (11.9)
	Mexico	6 (24.0)	6 (35.3)	12 (28.6)
	Russian Federation	3 (12.0)	1 (5.9)	4 (9.5)
	United States	10 (40.0)	9 (52.9)	19 (45.2)

Note: Dapa = Dapagliflozin, PPPS = Pediatric per protocol set, N = Number of subjects in treatment group,
 n = Frequency count.

Source Data: asl, created on: 17SEP2021:19:41:02

Table T2DM7_POB0: Demographic and other baseline characteristics - Height
 PPPS

Demographic characteristic		Dapa 10mg	Placebo	Total
N		25	17	42
Baseline height (cm)	n	25	17	42
	Mean	166.66	162.54	164.99
	Std Dev	9.39	10.96	10.14
	Minimum	137.0	141.0	137.0
	1st quartile	160.00	158.00	159.40
	Median	167.70	165.40	166.50
	3rd quartile	173.00	167.60	172.50
	Maximum	182.0	182.0	182.0

Note: Dapa = Dapagliflozin, PPPS = Pediatric per protocol set, N = Number of subjects in treatment group,
 n = Number of valid observations, Std Dev = Standard deviation.

Source Data: asl, created on: 17SEP2021:19:41:02

Table T2DM8_POB0: Demographic and other baseline characteristics - Body weight
 PPPS

Demographic characteristic		Dapa 10mg	Placebo	Total
N		25	17	42
Baseline weight (kg)	n	25	17	42
	Mean	83.07	93.50	87.29
	Std Dev	23.81	37.57	30.16
	Minimum	41.6	31.2	31.2
	1st quartile	71.80	67.40	67.40
	Median	77.00	90.00	85.05
	3rd quartile	93.80	122.70	100.80
Maximum		145.0	165.2	165.2

Note: Dapa = Dapagliflozin, PPPS = Pediatric per protocol set, N = Number of subjects in treatment group,
 n = Number of valid observations, Std Dev = Standard deviation.
 Source Data: asl, created on: 17SEP2021:19:41:02

Table T2DM9_POB0: Demographic and other baseline characteristics - BMI
 PPPS

Demographic characteristic		Dapa 10mg	Placebo	Total
N		25	17	42
D: Baseline BMI (kg/m**2)	n	25	17	42
	Mean	29.7	34.3	31.6
	Std Dev	7.4	10.6	9.0
	Minimum	17	14	14
	1st quartile	26.0	30.3	26.1
	Median	29.7	32.6	31.5
	3rd quartile	33.4	43.8	35.1
D: Baseline BMI (aggreg) n(%)	< 30 kg/m**2	13 (52.0)	4 (23.5)	17 (40.5)
	>= 30 kg/m**2	12 (48.0)	13 (76.5)	25 (59.5)

Note: Dapa = Dapagliflozin, PPPS = Pediatric per protocol set, N = Number of subjects in treatment group,
 n = Number of valid observations, Std Dev = Standard deviation, BMI = Body mass index
 Source Data: asl, created on: 17SEP2021:19:41:02

Table T2DR1_POB0: Renal Baseline Characteristics - Screening eGFR
 PPPS

Demographic characteristic		Dapa 10mg	Placebo	Total
N		25	17	42
Screening eGFR (mL/min/1.73 m**2)	n	24	17	41
	Mean	117.8	118.2	118.0
	Std Dev	24.1	26.6	24.9
	Minimum	84	82	82
	1st quartile	96.0	98.0	97.0
	Median	113.0	115.0	114.0
	3rd quartile	134.5	127.0	130.0
	Maximum	171	175	175

Note: Dapa = Dapagliflozin, PPPS = Pediatric per protocol set, N = Number of subjects in treatment group,
 n = Number of valid observations, Std Dev = Standard deviation, eGFR = Estimated glomerular filtration rate.
 Source Data: asl, created on: 17SEP2021:19:41:02

Table T2DR2_POB0: Renal Baseline Characteristics - Baseline eGFR
 PPPS

Demographic characteristic		Dapa 10mg	Placebo	Total
N		25	17	42
Baseline eGFR (mL/min/1.73 m**2)				
	n	25	17	42
	Mean	116.8	118.0	117.3
	Std Dev	21.7	20.9	21.1
	Minimum	81	88	81
	1st quartile	106.0	104.0	104.0
	Median	116.0	116.0	116.0
	3rd quartile	127.0	133.0	133.0
	Maximum	166	175	175
Baseline eGFR(cat.) n(%)				
	< 60 mL/min/1.73 m**2	0 (0.0)	0 (0.0)	0 (0.0)
	>= 60 and < 90 mL/min/1.73 m**2	3 (12.0)	1 (5.9)	4 (9.5)
	>= 90 and < 120 mL/min/1.73 m**2	13 (52.0)	9 (52.9)	22 (52.4)
	>= 120 mL/min/1.73 m**2	9 (36.0)	7 (41.2)	16 (38.1)

Note: Dapa = Dapagliflozin, PPPS = Pediatric per protocol set, N = Number of subjects in treatment group,
 n = Number of valid observations, Std Dev = Standard deviation, eGFR = Estimated glomerular filtration rate.
 Source Data: asl, created on: 17SEP2021:19:41:02

Table T2DST_POB0: Duration of ST-Period
 PPPS

Parameter		Dapa 10mg	Placebo	Total
N		25	17	42
Duration of ST-Period (months)	n	25	17	42
	Mean	5.51	5.45	5.49
	Std Dev	0.53	1.31	0.91
	Minimum	3.2	0.5	0.5
	1st quartile	5.60	5.63	5.60
	Median	5.63	5.67	5.63
	3rd quartile	5.70	5.83	5.73
	Maximum	5.9	6.7	6.7

Note: Dapa = Dapagliflozin, PPPS = Pediatric per protocol set, N = Number of subjects in treatment group,
 n = Number of valid observations, Std Dev = Standard deviation, ST period = 24 week short-term period.
 Source Data: asl, created on: 17SEP2021:19:41:02

Table T2DT1_POB0: Time in study
 PPPS

Parameter		Dapa 10mg	Placebo	Total
N		25	17	42
Time in study (months)	n	25	17	42
	Mean	12.41	12.24	12.34
	Std Dev	2.57	3.08	2.75
	Minimum	3.2	0.5	0.5
	1st quartile	13.03	12.87	12.93
	Median	13.10	13.10	13.10
	3rd quartile	13.17	13.23	13.20
	Maximum	14.5	13.7	14.5

Note: Dapa = Dapagliflozin, PPPS = Pediatric per protocol set, N = Number of subjects in treatment group,
 n = Number of valid observations, Std Dev = Standard deviation.

Source Data: asl, created on: 17SEP2021:19:41:02

Table T2DT2_POB0: Duration of exposure
 PPPS

Parameter		Dapa 10mg	Placebo	Total
N		25	17	42
Duration of exposure (days)	n	25	17	42
	Mean	158.24	160.59	159.19
	Std Dev	33.41	41.30	36.34
	Minimum	13	7	7
	1st quartile	167.00	168.00	167.00
	Median	168.00	168.00	168.00
	3rd quartile	170.00	174.00	171.00
	Maximum	175	202	202
Duration of exposure (days) n(%)	1 - 7	0 (0.0)	1 (5.9)	1 (2.4)
	8 - 14	1 (4.0)	0 (0.0)	1 (2.4)
	15 - 28	0 (0.0)	0 (0.0)	0 (0.0)
	29 - 42	0 (0.0)	0 (0.0)	0 (0.0)
	43 - 84	0 (0.0)	0 (0.0)	0 (0.0)
	85 - 98	0 (0.0)	0 (0.0)	0 (0.0)
	99 - 140	2 (8.0)	0 (0.0)	2 (4.8)
	141 - 182	22 (88.0)	15 (88.2)	37 (88.1)
	> 182	0 (0.0)	1 (5.9)	1 (2.4)

Note: Dapa = Dapagliflozin, PPPS = Pediatric per protocol set, N = Number of subjects in treatment group,
 n = Number of valid observations, Std Dev = Standard deviation.

Source Data: asl, created on: 17SEP2021:19:41:02

Table T2DZ1_POB0: Disease-specific baseline characteristics - Duration of T2DM
 PPPS

Parameter		Dapa 10mg	Placebo	Total
N		25	17	42
Duration of type 2 diabetes (years)	n	25	17	42
	Mean	2.33	2.90	2.56
	Std Dev	1.67	2.86	2.22
	Minimum	0.2	0.2	0.2
	1st quartile	0.68	0.97	0.68
	Median	2.04	1.93	1.98
	3rd quartile	3.75	3.87	3.79
	Maximum	5.6	11.1	11.1
Duration of type 2 diabetes (cat.) n(%)	< 3 years	16 (64.0)	11 (64.7)	27 (64.3)
	>= 3 and <= 10 years	9 (36.0)	5 (29.4)	14 (33.3)
	> 10 years	0 (0.0)	1 (5.9)	1 (2.4)

Note: Dapa = Dapagliflozin, PPPS = Pediatric per protocol set, N = Number of subjects in treatment group,
 n = Number of valid observations, Std Dev = Standard deviation.
 Source Data: asl, created on: 17SEP2021:19:41:02

Table T2DZ2_POB0: Disease-specific baseline characteristics - Screening HbA1c
 PPPS

Parameter		Dapa 10mg	Placebo	Total
N		25	17	42
Screening HbA1c (%)	n	25	17	42
	Mean	7.67	8.15	7.86
	Std Dev	1.04	1.06	1.06
	Minimum	6.6	6.5	6.5
	1st quartile	6.80	7.60	7.00
	Median	7.30	7.70	7.70
	3rd quartile	8.10	8.90	8.70
	Maximum	10.2	10.5	10.5

Note: Dapa = Dapagliflozin, PPPS = Pediatric per protocol set, N = Number of subjects in treatment group,
 n = Number of valid observations, Std Dev = Standard deviation, HbA1c = Glycated haemoglobin.
 Source Data: asl, created on: 17SEP2021:19:41:02

Table T2DZ3_POB0: Disease-specific baseline characteristics - Baseline HbA1c
 PPPS

Parameter		Dapa 10mg	Placebo	Total
N		25	17	42
Baseline HbA1c (%)	n	25	17	42
	Mean	7.38	8.10	7.67
	Std Dev	1.16	1.17	1.21
	Minimum	5.4	6.5	5.4
	1st quartile	6.70	7.30	6.80
	Median	7.10	8.00	7.50
	3rd quartile	8.10	8.80	8.50
	Maximum	10.4	10.5	10.5
Baseline HbA1c (cat.) n(%)	< 6.5%	5 (20.0)	0 (0.0)	5 (11.9)
	>= 6.5% and < 9%	18 (72.0)	13 (76.5)	31 (73.8)
	>= 9% and <= 11%	2 (8.0)	4 (23.5)	6 (14.3)
	> 11%	0 (0.0)	0 (0.0)	0 (0.0)

Note: Dapa = Dapagliflozin, PPPS = Pediatric per protocol set, N = Number of subjects in treatment group,
 n = Number of valid observations, Std Dev = Standard deviation, HbA1c = Glycated haemoglobin.
 Source Data: asl, created on: 17SEP2021:19:41:02

Table T2DZ4_POB0: Disease-specific baseline characteristics - Screening Baseline FPG
 PPPS

Parameter		Dapa 10mg	Placebo	Total
N		25	17	42
Screening FPG (mmol/L)	n	25	17	42
	Mean	7.39	8.89	8.00
	Std Dev	1.71	3.32	2.56
	Minimum	4.8	4.7	4.7
	1st quartile	6.33	5.88	5.99
	Median	7.30	8.16	7.39
	3rd quartile	8.55	11.54	9.44
	Maximum	11.7	14.1	14.1

Note: Dapa = Dapagliflozin, PPPS = Pediatric per protocol set, N = Number of subjects in treatment group,
 n = Number of valid observations, Std Dev = Standard deviation, FPG = Fasting plasma glucose.
 Source Data: asl, created on: 17SEP2021:19:41:02

Table T2DZ5_POB0: Disease-specific baseline characteristics - Baseline FPG
 PPPS

Parameter		Dapa 10mg	Placebo	Total
N		25	17	42
Baseline FPG (mmol/L)	n	25	17	42
	Mean	8.72	9.03	8.85
	Std Dev	3.33	2.91	3.13
	Minimum	5.3	4.7	4.7
	1st quartile	6.38	7.60	6.38
	Median	6.90	8.82	8.02
	3rd quartile	11.16	9.93	11.16
Baseline FPG (cat.) n(%)	Maximum	16.4	14.5	16.4
	<= 14.2 mmol/L	23 (92.0)	16 (94.1)	39 (92.9)
	> 14.2 mmol/L	2 (8.0)	1 (5.9)	3 (7.1)

Note: Dapa = Dapagliflozin, PPPS = Pediatric per protocol set, N = Number of subjects in treatment group,
 n = Number of valid observations, Std Dev = Standard deviation, FPG = Fasting plasma glucose.
 Source Data: asl, created on: 17SEP2021:19:41:02

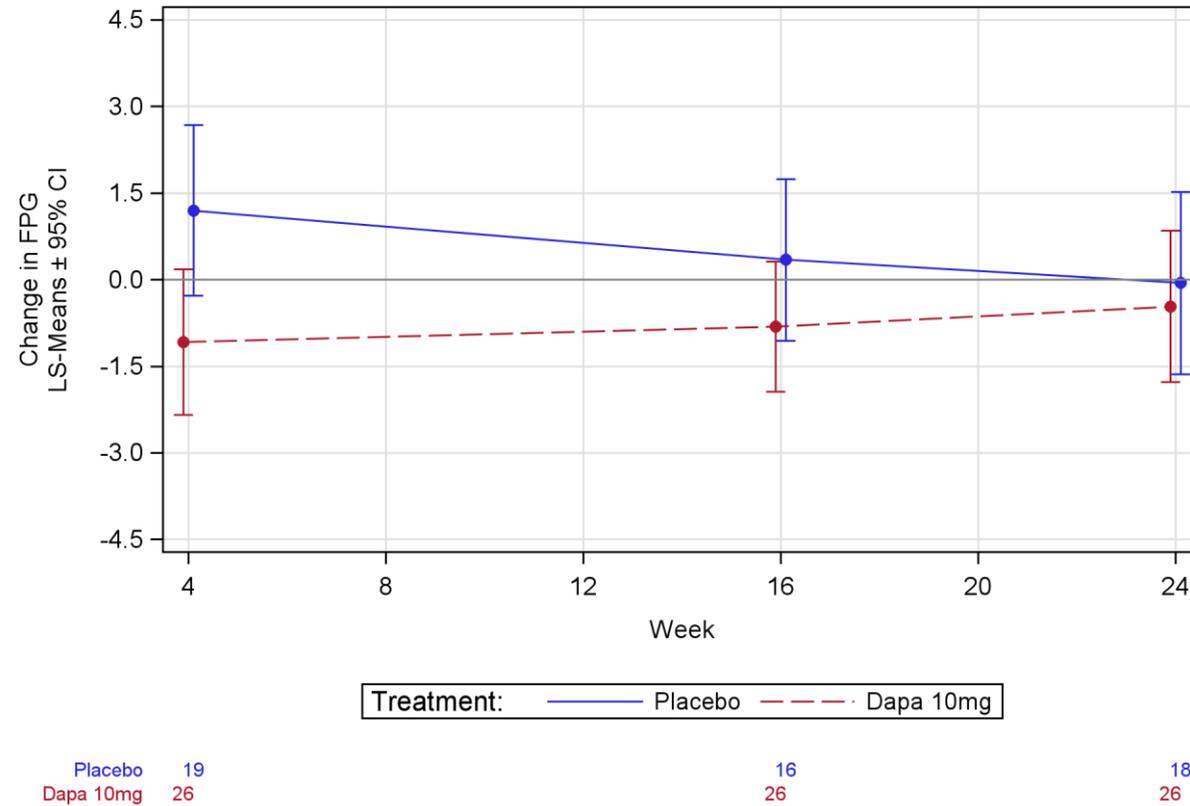
Table T2RM_POB0: Patients with rescue medication until week 24
PPPS

Parameter	Dapa 10mg	Placebo
N	25	17
Patients with rescue medication until week 24 n(%)	2 (8.0)	2 (11.8)

Note: Dapa = Dapagliflozin, PPPS = Pediatric per protocol set, N = Number of subjects in treatment group,
n = Frequency count.

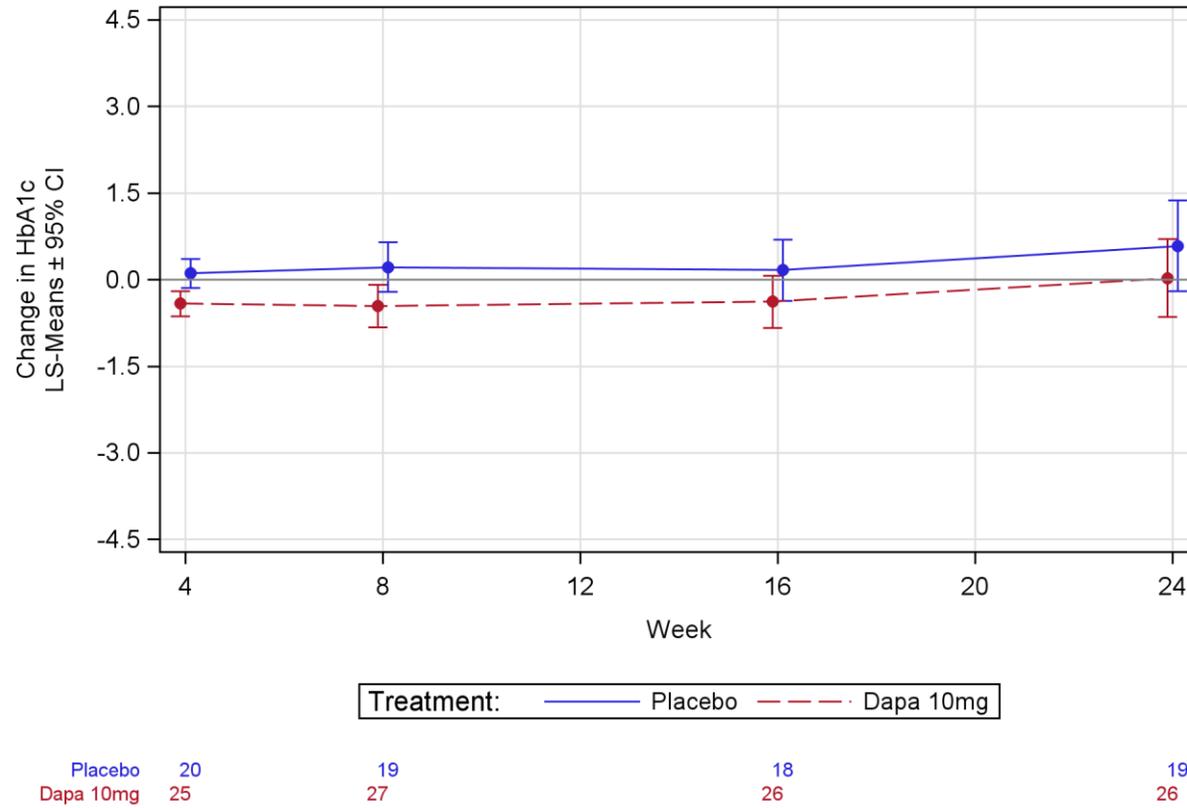
Source Data: asl, created on: 17SEP2021:19:41:02

Figure F2FGC_FAG0: Change in FPG up to Week 24
PFAS



Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, FPG = Fasting plasma glucose, symbols present least square mean (LS-Mean), bars present 95% confidence intervals (CI).
Source Table: T2FGC_FAC0
Source Data: alb, created on: 30SEP2021

Figure F2HAC_FAG0: Change in HbA1c up to Week 24
PFAS



Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, HbA1c = Glycated haemoglobin, symbols present least square mean (LS-Mean), bars present 95% confidence intervals (CI).
Source Table: T2HAC_FAC0
Source Data: alb, created on: 30SEP2021

Table T2A_SAI0: Incidence of AEs
 PFAS

Variable	Dapa 10 mg		Placebo		RR [95 % CI]	OR [95 % CI]	ARR [95 % CI]	p-value
	N	n (%) [95 % CI]	N	n (%) [95 % CI]				
Patients with AEs	29	22 (75.9) [60.3, 91.4]	24	15 (62.5) [43.1, 81.9]	1.214 [0.837, 1.760]	1.886 [0.576, 6.173]	13.4 [-12.7, 38.4]	0.372

Note: PFAS = Pediatric full analysis set, N = total number of patients (denominator), n = number of patients with events,
 OR = odds ratio, RR = relative risk, ARR = absolute risk reduction, CI = confidence interval.
 p-value: Fisher's exact test, CIs: OR, RR: 2-sided (Wald), ARR: 2-sided exact (Chan-Zhang).
 + Adding of 0.5 to each cell.
 Source Data: aae, created on: 17SEP2021

Table T2A_SAS0: AEs by SOC and PT
PFAS

AEs by SOC and PT	Dapa 10 mg		Placebo		RR [95 % CI]	OR [95 % CI]	ARR [95 % CI]	p-value
	N	n (%) [95 % CI]	N	n (%) [95 % CI]				
SOC: Gastrointestinal disorders	29	6 (20.7) [5.9, 35.4]	24	4 (16.7) [1.8, 31.6]	1.241 [0.396, 3.896]	1.304 [0.322, 5.289]	4.0 [-19.6, 26.0]	1.000
Nausea	29	3 (10.3) [0.0, 21.4]	24	0 (0.0) [0.0, 0.0]	5.833 + [0.316, 107.647]	6.472 + [0.318, 131.777]	10.3 [-5.8, 27.9]	0.242
SOC: Infections and infestations	29	9 (31.0) [14.2, 47.9]	24	5 (20.8) [4.6, 37.1]	1.490 [0.576, 3.852]	1.710 [0.485, 6.033]	10.2 [-14.9, 34.0]	0.535
Nasopharyngitis	29	3 (10.3) [0.0, 21.4]	24	0 (0.0) [0.0, 0.0]	5.833 + [0.316, 107.647]	6.472 + [0.318, 131.777]	10.3 [-5.8, 27.9]	0.242
SOC: Investigations	29	5 (17.2) [3.5, 31.0]	24	0 (0.0) [0.0, 0.0]	9.167 + [0.532, 157.837]	11.000 + [0.576, 209.897]	17.2 [1.8, 35.8]	0.056
SOC: Metabolism and nutrition disorders	29	5 (17.2) [3.5, 31.0]	24	5 (20.8) [4.6, 37.1]	0.828 [0.271, 2.525]	0.792 [0.200, 3.140]	-3.6 [-27.9, 18.4]	1.000
Hyperglycaemia	29	0 (0.0) [0.0, 0.0]	24	3 (12.5) [0.0, 25.7]	0.119 + [0.006, 2.197]	0.104 + [0.005, 2.123]	-12.5 [-32.4, 1.4]	0.086
Vitamin D deficiency	29	3 (10.3) [0.0, 21.4]	24	0 (0.0) [0.0, 0.0]	5.833 + [0.316, 107.647]	6.472 + [0.318, 131.777]	10.3 [-5.8, 27.9]	0.242
SOC: Nervous system disorders	29	4 (13.8) [1.2, 26.3]	24	3 (12.5) [0.0, 25.7]	1.103 [0.273, 4.456]	1.120 [0.225, 5.578]	1.3 [-20.7, 21.1]	1.000
Headache	29	4 (13.8) [1.2, 26.3]	24	2 (8.3) [0.0, 19.4]	1.655 [0.331, 8.271]	1.760 [0.293, 10.557]	5.5 [-14.8, 24.3]	0.678
SOC: Respiratory, thoracic and mediastinal disorders	29	5 (17.2) [3.5, 31.0]	24	3 (12.5) [0.0, 25.7]	1.379 [0.367, 5.190]	1.458 [0.311, 6.847]	4.7 [-17.0, 25.3]	0.715
Oropharyngeal pain	29	3 (10.3) [0.0, 21.4]	24	1 (4.2) [0.0, 12.2]	2.483 [0.276, 22.353]	2.654 [0.258, 27.322]	6.2 [-12.1, 24.3]	0.617

Note: PFAS = Pediatric full analysis set, N = total number of patients (denominator), n = number of patients with events, OR = odds ratio, RR = relative risk, ARR = absolute risk reduction, CI = confidence interval.
p-value: Fisher's exact test, CIs: OR, RR: 2-sided (Wald), ARR: 2-sided exact (Chan-Zhang).
+ = Adding of 0.5 to each cell, * significant treatment effect.
Only events are presented which were reported by at least 10% of patients in one study arm.
Source Data: adae, created on: 17SEP2021

Table T2AA_SAI0: Incidence of non-disease related AEs
 PFAS

Variable	Dapa 10 mg		Placebo		RR [95 % CI]	OR [95 % CI]	ARR [95 % CI]	p-value
	N	n (%) [95 % CI]	N	n (%) [95 % CI]				
Patients with non-disease related AEs	29	22 (75.9) [60.3, 91.4]	24	14 (58.3) [38.6, 78.1]	1.300 [0.876, 1.932]	2.245 [0.693, 7.273]	17.5 [-9.6, 42.5]	0.240

Note: PFAS = Pediatric full analysis set, N = total number of patients (denominator), n = number of patients with events, OR = odds ratio, RR = relative risk, ARR = absolute risk reduction, CI = confidence interval.
 p-value: Fisher's exact test, CIs: OR, RR: 2-sided (Wald), ARR: 2-sided exact (Chan-Zhang).
 + Adding of 0.5 to each cell.
 Source Data: aae, created on: 17SEP2021

Table T2AAC_SAI0: Incidence of non-disease related severe AEs
 PFAS

Variable	Dapa 10 mg		Placebo		RR [95 % CI]	OR [95 % CI]	ARR [95 % CI]	p-value
	N	n (%) [95 % CI]	N	n (%) [95 % CI]				
Patients with non-disease related severe AEs	29	0 (0.0) [0.0, 0.0]	24	1 (4.2) [0.0, 12.2]	0.278 + [0.012, 6.523]	0.266 + [0.010, 6.822]	-4.2 [-21.1, 9.0]	0.453

Note: PFAS = Pediatric full analysis set, N = total number of patients (denominator), n = number of patients with events, OR = odds ratio, RR = relative risk, ARR = absolute risk reduction, CI = confidence interval.
 p-value: Fisher's exact test, CIs: OR, RR: 2-sided (Wald), ARR: 2-sided exact (Chan-Zhang).
 + Adding of 0.5 to each cell.
 Source Data: aae, created on: 17SEP2021

Table T2AC_SAI0: Incidence of severe AEs
 PFAS

Variable	Dapa 10 mg		Placebo		RR [95 % CI]	OR [95 % CI]	ARR [95 % CI]	p-value
	N	n (%) [95 % CI]	N	n (%) [95 % CI]				
Patients with severe AEs	29	0 (0.0) [0.0, 0.0]	24	2 (8.3) [0.0, 19.4]	0.167 + [0.008, 3.313]	0.153 + [0.007, 3.337]	-8.3 [-27.9, 4.7]	0.200

Note: PFAS = Pediatric full analysis set, N = total number of patients (denominator), n = number of patients with events,
 OR = odds ratio, RR = relative risk, ARR = absolute risk reduction, CI = confidence interval.

p-value: Fisher's exact test, CIs: OR, RR: 2-sided (Wald), ARR: 2-sided exact (Chan-Zhang).

+ Adding of 0.5 to each cell.

Source Data: aae, created on: 17SEP2021

Table T2AC_SAS0: Severe AEs by SOC and PT
 PFAS

Severe AEs by SOC and PT	Dapa 10 mg		Placebo		RR [95 % CI]	OR [95 % CI]	ARR [95 % CI]	p-value
	N	n (%) [95 % CI]	N	n (%) [95 % CI]				
SOC: Metabolism and nutrition disorders	29	0 (0.0) [0.0, 0.0]	24	2 (8.3) [0.0, 19.4]	0.167 + [0.008, 3.313]	0.153 + [0.007, 3.337]	-8.3 [-27.9, 4.7]	0.200
Hyperglycaemia	29	0 (0.0) [0.0, 0.0]	24	2 (8.3) [0.0, 19.4]	0.167 + [0.008, 3.313]	0.153 + [0.007, 3.337]	-8.3 [-27.9, 4.7]	0.200

Note: PFAS = Pediatric full analysis set, N = total number of patients (denominator), n = number of patients with events,
 OR = odds ratio, RR = relative risk, ARR = absolute risk reduction, CI = confidence interval.
 p-value: Fisher's exact test, CIs: OR, RR: 2-sided (Wald), ARR: 2-sided exact (Chan-Zhang).
 + = Adding of 0.5 to each cell, * significant treatment effect.
 Only events are presented which were reported by at least 5% of patients in one study arm.
 Source Data: adae, created on: 17SEP2021

Table T2AN_SAI0: Incidence of non-severe AEs
 PFAS

Variable	Dapa 10 mg		Placebo		RR [95 % CI]	OR [95 % CI]	ARR [95 % CI]	p-value
	N	n (%) [95 % CI]	N	n (%) [95 % CI]				
Patients with non-severe AEs	29	22 (75.9) [60.3, 91.4]	24	14 (58.3) [38.6, 78.1]	1.300 [0.876, 1.932]	2.245 [0.693, 7.273]	17.5 [-9.6, 42.5]	0.240

Note: PFAS = Pediatric full analysis set, N = total number of patients (denominator), n = number of patients with events,
 OR = odds ratio, RR = relative risk, ARR = absolute risk reduction, CI = confidence interval.
 p-value: Fisher's exact test, CIs: OR, RR: 2-sided (Wald), ARR: 2-sided exact (Chan-Zhang).
 + Adding of 0.5 to each cell.
 Source Data: aae, created on: 17SEP2021

Table T2AS_SAI0: Incidence of serious AEs
 PFAS

Variable	Dapa 10 mg		Placebo		RR [95 % CI]	OR [95 % CI]	ARR [95 % CI]	p-value
	N	n (%) [95 % CI]	N	n (%) [95 % CI]				
Patients with serious AEs	29	0 (0.0) [0.0, 0.0]	24	1 (4.2) [0.0, 12.2]	0.278 + [0.012, 6.523]	0.266 + [0.010, 6.822]	-4.2 [-21.1, 9.0]	0.453

Note: PFAS = Pediatric full analysis set, N = total number of patients (denominator), n = number of patients with events, OR = odds ratio, RR = relative risk, ARR = absolute risk reduction, CI = confidence interval.

p-value: Fisher's exact test, CIs: OR, RR: 2-sided (Wald), ARR: 2-sided exact (Chan-Zhang).

+ Adding of 0.5 to each cell.

Source Data: aae, created on: 17SEP2021

Table T2ASL_SAI0: Incidence of hepatic AEs
 PFAS

Variable	Dapa 10 mg		Placebo		RR [95 % CI]	OR [95 % CI]	ARR [95 % CI]	p-value
	N	n (%) [95 % CI]	N	n (%) [95 % CI]				
Patients with hepatic AEs	29	1 (3.4) [0.0, 10.1]	24	0 (0.0) [0.0, 0.0]	2.500 + [0.106, 58.708]	2.579 + [0.100, 66.236]	3.4 [-11.3, 17.8]	1.000

Note: PFAS = Pediatric full analysis set, N = total number of patients (denominator), n = number of patients with events,
 OR = odds ratio, RR = relative risk, ARR = absolute risk reduction, CI = confidence interval.
 p-value: Fisher's exact test, CIs: OR, RR: 2-sided (Wald), ARR: 2-sided exact (Chan-Zhang).
 + = Adding of 0.5 to each cell, * = significant treatment effect.
 The patient's event had the following classification: moderate (= non-severe) and not serious.
 Source Data: aae, created on: 17SEP2021

Table T2AT_SAI0: Incidence of AEs leading to study drug discontinuation
 PFAS

Variable	Dapa 10 mg		Placebo		RR [95 % CI]	OR [95 % CI]	ARR [95 % CI]	p-value
	N	n (%) [95 % CI]	N	n (%) [95 % CI]				
Patients with AEs leading to study drug discontinuation	29	1 (3.4) [0.0, 10.1]	24	0 (0.0) [0.0, 0.0]	2.500 + [0.106, 58.708]	2.579 + [0.100, 66.236]	3.4 [-11.3, 17.8]	1.000

Note: PFAS = Pediatric full analysis set, N = total number of patients (denominator), n = number of patients with events, OR = odds ratio, RR = relative risk, ARR = absolute risk reduction, CI = confidence interval.
 p-value: Fisher's exact test, CIs: OR, RR: 2-sided (Wald), ARR: 2-sided exact (Chan-Zhang).
 + Adding of 0.5 to each cell.
 Source Data: aae, created on: 17SEP2021

Table T2AT_SAS0: AEs leading to study drug discontinuation by SOC and PT
 PFAS

AEs leading to study drug discontinuation by SOC and PT	Dapa 10 mg		Placebo		RR [95 % CI]	OR [95 % CI]	ARR [95 % CI]	p-value
	N	n (%) [95 % CI]	N	n (%) [95 % CI]				
SOC: Infections and infestations	29	1 (3.4) [0.0, 10.1]	24	0 (0.0) [0.0, 0.0]	2.500 + [0.106, 58.708]	2.579 + [0.100, 66.236]	3.4 [-11.3, 17.8]	1.000
Fungal infection	29	1 (3.4) [0.0, 10.1]	24	0 (0.0) [0.0, 0.0]	2.500 + [0.106, 58.708]	2.579 + [0.100, 66.236]	3.4 [-11.3, 17.8]	1.000

Note: PFAS = Pediatric full analysis set, N = total number of patients (denominator), n = number of patients with events,
 OR = odds ratio, RR = relative risk, ARR = absolute risk reduction, CI = confidence interval.
 p-value: Fisher's exact test, CIs: OR, RR: 2-sided (Wald), ARR: 2-sided exact (Chan-Zhang).
 + = Adding of 0.5 to each cell, * significant treatment effect.
 Source Data: adae, created on: 17SEP2021

Table T2FG_FAF0: Course of FPG up to Week 24
 PFAS

Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max
Dapa 10mg	Day 1	29	29	8.88 (3.32)	5.3	7.33	16.4
	Week 4	29	26	7.78 (3.10)	4.4	6.30	16.0
	Week 16	29	26	7.73 (2.50)	4.1	7.24	14.6
	Week 24	29	26	8.33 (3.73)	4.8	7.03	20.4
Placebo	Day 1	24	24	8.99 (2.68)	4.7	8.66	14.5
	Week 4	24	19	10.08 (4.01)	4.7	9.05	22.3
	Week 16	24	16	9.12 (3.03)	5.0	8.58	16.5
	Week 24	24	18	8.78 (3.25)	5.3	8.10	18.1

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group, n = Number of valid observations, SD = Standard deviation, Q50 = median, FPG = Fasting plasma glucose.
 Source Data: alb, created on: 29SEP2021

Table T2FGC_FAC0: Change in FPG up to Week 24
 PFAS

Treatment	Time point	N	n (%)	Repeated measures analysis				
				Change from Baseline		Treatment Difference		
				LS-Mean (SE)	95% CI	LS-Mean (SE)	95% CI	p-value
Dapa 10mg	Week 4	29	26 (89.7)	-1.08 (0.63)	(-2.34, 0.18)	-2.28 (0.96)	(-4.22, -0.33)	0.023
	Week 16	29	26 (89.7)	-0.81 (0.55)	(-1.94, 0.31)	-1.16 (0.88)	(-2.95, 0.64)	0.198
	Week 24	29	26 (89.7)	-0.46 (0.65)	(-1.77, 0.85)	-0.40 (1.02)	(-2.45, 1.65)	0.694
Placebo	Week 4	24	19 (79.2)	1.20 (0.73)	(-0.28, 2.68)			
	Week 16	24	16 (66.7)	0.35 (0.69)	(-1.05, 1.74)			
	Week 24	24	18 (75.0)	-0.06 (0.78)	(-1.64, 1.52)			

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group,
 n = Number of valid observations, Q50 = Median, SD = Standard deviation, SE = Standard error, CI = Confidence interval,
 FPG = Fasting plasma glucose, LS-Mean = Least square mean.
 A mixed repeated measures model was applied with fixed factors for treatment, week, interactions treatment-by-week,
 baseline-by-week and baseline as covariate.
 Source Data: alb, created on: 30SEP2021

Table T2FGC_FAH0: Hedges G for Change in FPG up to Week 24
 PFAS

Change in FPG up to Week 24	Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max	Hedges G	
									Effect size (SD)	95% CI
Overall	Dapa 10mg	Week 4	29	26	-1.13 (2.53)	-9.0	-1.03	5.6	-0.60 (0.31)	[-1.21, 0.00]
		Week 16	29	26	-0.96 (3.57)	-11.2	-0.84	9.0	-0.39 (0.32)	[-1.02, 0.24]
		Week 24	29	26	-0.44 (3.53)	-10.3	-0.15	5.7	-0.12 (0.31)	[-0.72, 0.48]
	Placebo	Week 4	24	19	1.04 (4.73)	-4.8	0.06	17.1		
		Week 16	24	16	0.30 (2.58)	-3.2	0.19	6.5		
		Week 24	24	18	0.00 (4.05)	-5.7	-0.08	9.6		

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group, n = Number of valid observations, Q50 = Median, SD = Standard deviation, CI = Confidence interval, FPG = Fasting plasma glucose.
 Source Data: alb, created on: 30SEP2021

Table T2GR_FAP0: Patients with need of glyceemic rescue/discont. due to lack of glyceemic control during ST
 PFAS

Variable	Dapa 10 mg		Placebo		RR [95 % CI]	OR [95 % CI]	ARR [95 % CI]	p-value
	N	n (%) [95 % CI]	N	n (%) [95 % CI]				
Patients with need of glyceemic rescue/discont. due to lack of glyceemic control during ST	29	2 (6.9) [0.0, 16.1]	24	2 (8.3) [0.0, 19.4]	0.828 [0.126, 5.445]	0.815 [0.106, 6.261]	-1.4 [-20.7, 16.1]	1.000

Note: PFAS = Pediatric full analysis set, N = total number of patients (denominator), n = number of patients with events,
 OR = odds ratio, RR = relative risk, ARR = absolute risk reduction, CI = confidence interval.
 p-value: Fisher's exact test, CIs: OR, RR: 2-sided (Wald), ARR: 2-sided exact (Chan-Zhang).
 + = Adding of 0.5 to each cell, * = significant treatment effect.
 ST = 24 week short-term period.
 Source Data: alb, created on: 30SEP2021

Table T2HA_FAF0: Course of HbA1c up to Week 24
PFAS

Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max
Dapa 10mg	Day 1	29	29	7.80 (1.65)	5.4	7.30	12.4
	Week 4	29	25	7.35 (1.77)	5.0	7.00	11.9
	Week 8	29	27	7.30 (1.77)	5.2	6.90	12.2
	Week 16	29	26	7.24 (1.71)	5.0	6.95	12.7
	Week 24	29	26	7.49 (2.02)	4.9	7.05	12.6
Placebo	Day 1	24	24	8.05 (1.11)	6.5	7.85	10.5
	Week 4	24	20	8.01 (1.06)	6.5	7.70	10.2
	Week 8	24	19	8.35 (1.60)	6.3	8.10	13.1
	Week 16	24	18	7.98 (1.29)	6.2	7.95	11.4
	Week 24	24	19	8.49 (2.30)	5.9	7.90	15.3

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group,
n = Number of valid observations, SD = Standard deviation, Q50 = median, HbA1c = Glycated haemoglobin.
Source Data: alb, created on: 29SEP2021

Table T2HAC_FAC0: Change in HbA1c up to Week 24
 PFAS

Treatment	Time point	N	n (%)	Repeated measures analysis				
				Change from Baseline		Treatment Difference		
				LS-Mean (SE)	95% CI	LS-Mean (SE)	95% CI	p-value
Dapa 10mg	Week 4	29	25 (86.2)	-0.42 (0.11)	(-0.63, -0.20)	-0.53 (0.16)	(-0.86, -0.20)	0.003
	Week 8	29	27 (93.1)	-0.46 (0.18)	(-0.83, -0.09)	-0.67 (0.28)	(-1.24, -0.11)	0.020
	Week 16	29	26 (89.7)	-0.38 (0.22)	(-0.83, 0.07)	-0.55 (0.34)	(-1.24, 0.15)	0.120
	Week 24	29	26 (89.7)	0.03 (0.33)	(-0.65, 0.70)	-0.56 (0.52)	(-1.60, 0.48)	0.284
Placebo	Week 4	24	20 (83.3)	0.11 (0.12)	(-0.14, 0.36)			
	Week 8	24	19 (79.2)	0.22 (0.21)	(-0.21, 0.64)			
	Week 16	24	18 (75.0)	0.17 (0.26)	(-0.36, 0.69)			
	Week 24	24	19 (79.2)	0.59 (0.39)	(-0.20, 1.38)			

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group,
 n = Number of valid observations, Q50 = Median, SD = Standard deviation, SE = Standard error, CI = Confidence interval,
 HbA1c = Glycated haemoglobin, LS-Mean = Least square mean.
 A mixed repeated measures model was applied with fixed factors for treatment, week, interactions treatment-by-week,
 baseline-by-week and baseline as covariate.
 Source Data: alb, created on: 30SEP2021

Table T2HAC_FAH0: Hedges G for Change in HbA1c up to Week 24
 PFAS

Change in HbA1c up to Week 24	Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max	Hedges G	
									Effect size (SD)	95% CI
Overall	Dapa 10mg	Week 4	29	25	-0.42 (0.60)	-1.7	-0.50	1.6	-0.88 (0.31)	[-1.50, -0.27]
		Week 8	29	27	-0.47 (0.90)	-3.0	-0.60	1.8	-0.74 (0.31)	[-1.35, -0.13]
		Week 16	29	26	-0.43 (1.10)	-3.0	-0.40	1.9	-0.42 (0.31)	[-1.03, 0.19]
		Week 24	29	26	-0.10 (1.39)	-2.6	-0.30	2.6	-0.36 (0.30)	[-0.96, 0.23]
	Placebo	Week 4	24	20	0.01 (0.29)	-0.4	0.00	0.7		
		Week 8	24	19	0.25 (1.06)	-0.7	-0.10	3.9		
		Week 16	24	18	0.01 (0.96)	-2.0	-0.20	1.8		
		Week 24	24	19	0.53 (2.08)	-1.8	-0.20	6.1		

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group, n = Number of valid observations, Q50 = Median, SD = Standard deviation, CI = Confidence interval, HbA1c = Glycated haemoglobin.

Source Data: alb, created on: 30SEP2021

Table T2HAR_F7AP0: Patients with HbA1c < 7% at Week 24
 Patients in PFAS with HbA1c >= 7%

Variable	Dapa 10 mg		Placebo		RR [95 % CI]	OR [95 % CI]	ARR [95 % CI]	p-value
	N	n (%) [95 % CI]	N	n (%) [95 % CI]				
Patients with HbA1c < 7% at Week 24	19	3 (15.8) [0.0, 32.2]	19	1 (5.3) [0.0, 15.3]	3.000 [0.342, 26.327]	3.375 [0.318, 35.789]	10.5 [-13.2, 34.5]	0.604

Note: PFAS = Pediatric full analysis set, N = total number of patients (denominator), n = number of patients with events, OR = odds ratio, RR = relative risk, ARR = absolute risk reduction, CI = confidence interval.
 p-value: Fisher's exact test, CIs: OR, RR: 2-sided (Wald), ARR: 2-sided exact (Chan-Zhang).
 + = Adding of 0.5 to each cell, * = significant treatment effect.
 Source Data: alb, created on: 30SEP2021

Table T2SHA_SAI0: Incidence of hypoglycaemic events (ADA)
 PFAS

Variable	Dapa 10 mg		Placebo		RR [95 % CI]	OR [95 % CI]	ARR [95 % CI]	p-value
	N	n (%) [95 % CI]	N	n (%) [95 % CI]				
Patients with hypoglycaemic events (ADA)	29	8 (27.6) [11.3, 43.9]	24	2 (8.3) [0.0, 19.4]	3.310 [0.775, 14.141]	4.190 [0.796, 22.058]	19.3 [-2.6, 40.2]	0.091

Note: PFAS = Pediatric full analysis set, N = total number of patients (denominator), n = number of patients with events, OR = odds ratio, RR = relative risk, ARR = absolute risk reduction, CI = confidence interval.
 p-value: Fisher's exact test, CIs: OR, RR: 2-sided (Wald), ARR: 2-sided exact (Chan-Zhang).
 + Adding of 0.5 to each cell.
 Source Data: ahypo, created on: 17SEP2021

Table T2SHAC_SAI0: Incidence of severe hypoglycaemic events (ADA)
 PFAS

Variable	Dapa 10 mg		Placebo		RR [95 % CI]	OR [95 % CI]	ARR [95 % CI]	p-value
	N	n (%) [95 % CI]	N	n (%) [95 % CI]				
Patients with severe hypoglycaemic events (ADA)	29	2 (6.9) [0.0, 16.1]	24	0 (0.0) [0.0, 0.0]	4.167 + [0.210, 82.825]	4.455 + [0.204, 97.390]	6.9 [-8.1, 22.8]	0.495

Note: PFAS = Pediatric full analysis set, N = total number of patients (denominator), n = number of patients with events, OR = odds ratio, RR = relative risk, ARR = absolute risk reduction, CI = confidence interval.
 p-value: Fisher's exact test, CIs: OR, RR: 2-sided (Wald), ARR: 2-sided exact (Chan-Zhang).
 + Adding of 0.5 to each cell.
 Source Data: ahypo, created on: 17SEP2021

Table T2SHAN_SAI0: Incidence of non-severe hypoglycaemic events (ADA)
 PFAS

Variable	Dapa 10 mg		Placebo		RR [95 % CI]	OR [95 % CI]	ARR [95 % CI]	p-value
	N	n (%) [95 % CI]	N	n (%) [95 % CI]				
Patients with non-severe hypoglycaemic events (ADA)	29	8 (27.6) [11.3, 43.9]	24	2 (8.3) [0.0, 19.4]	3.310 [0.775, 14.141]	4.190 [0.796, 22.058]	19.3 [-2.6, 40.2]	0.091

Note: PFAS = Pediatric full analysis set, N = total number of patients (denominator), n = number of patients with events,
 OR = odds ratio, RR = relative risk, ARR = absolute risk reduction, CI = confidence interval.
 p-value: Fisher's exact test, CIs: OR, RR: 2-sided (Wald), ARR: 2-sided exact (Chan-Zhang).
 + = Adding of 0.5 to each cell, * = significant treatment effect.

Included ADA classifications: Documented symptomatic hypoglycaemia, asymptomatic hypoglycaemia, probable symptomatic hypoglycaemia, relative hypoglycaemia.

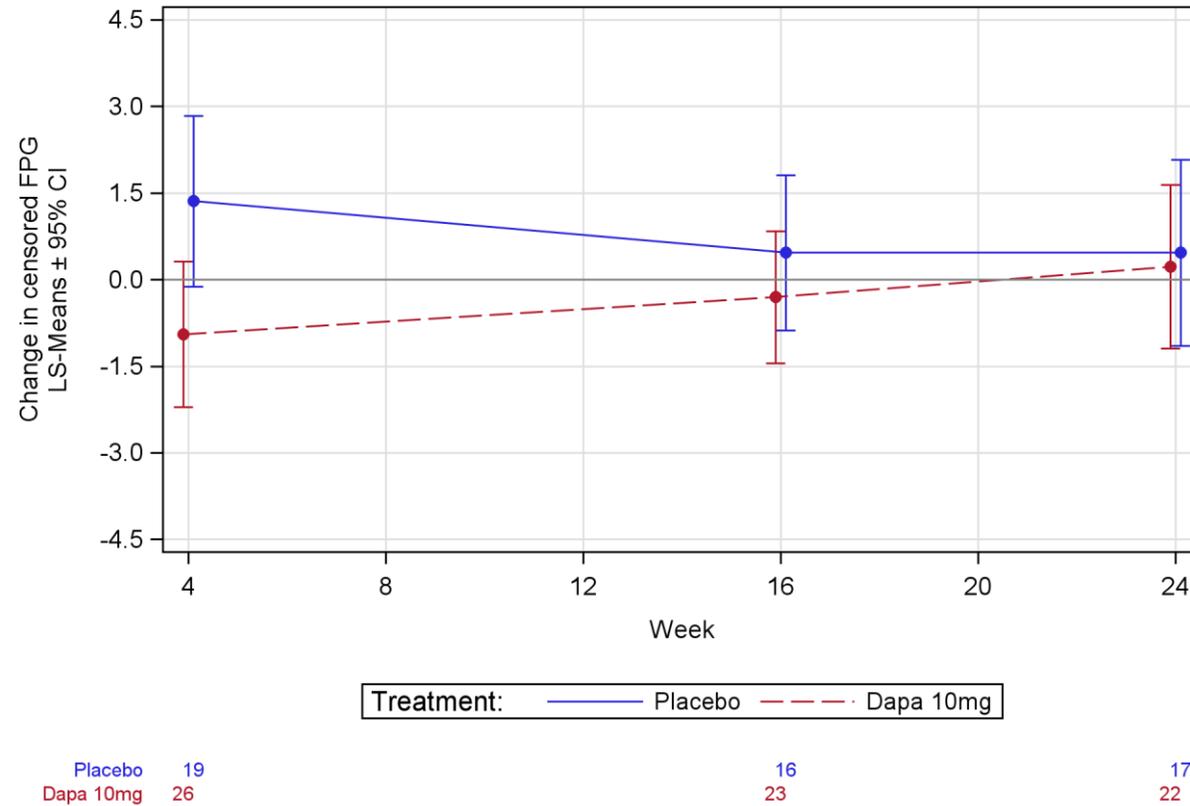
Source Data: ahyppo, created on: 17SEP2021

Table T2SHAN2_SAI0: Incidence of documented symptomatic hypoglycaemic events (ADA)
 PFAS

Variable	Dapa 10 mg		Placebo		RR [95 % CI]	OR [95 % CI]	ARR [95 % CI]	p-value
	N	n (%) [95 % CI]	N	n (%) [95 % CI]				
Patients with documented symptomatic hypoglycaemic events (ADA)	29	2 (6.9) [0.0, 16.1]	24	0 (0.0) [0.0, 0.0]	4.167 + [0.210, 82.825]	4.455 + [0.204, 97.390]	6.9 [-8.1, 22.8]	0.495

Note: PFAS = Pediatric full analysis set, N = total number of patients (denominator), n = number of patients with events, OR = odds ratio, RR = relative risk, ARR = absolute risk reduction, CI = confidence interval.
 p-value: Fisher's exact test, CIs: OR, RR: 2-sided (Wald), ARR: 2-sided exact (Chan-Zhang).
 + Adding of 0.5 to each cell.
 Source Data: ahypo, created on: 17SEP2021

Figure F2FGMC_FAG0: Change in censored FPG up to Week 24
PFAS

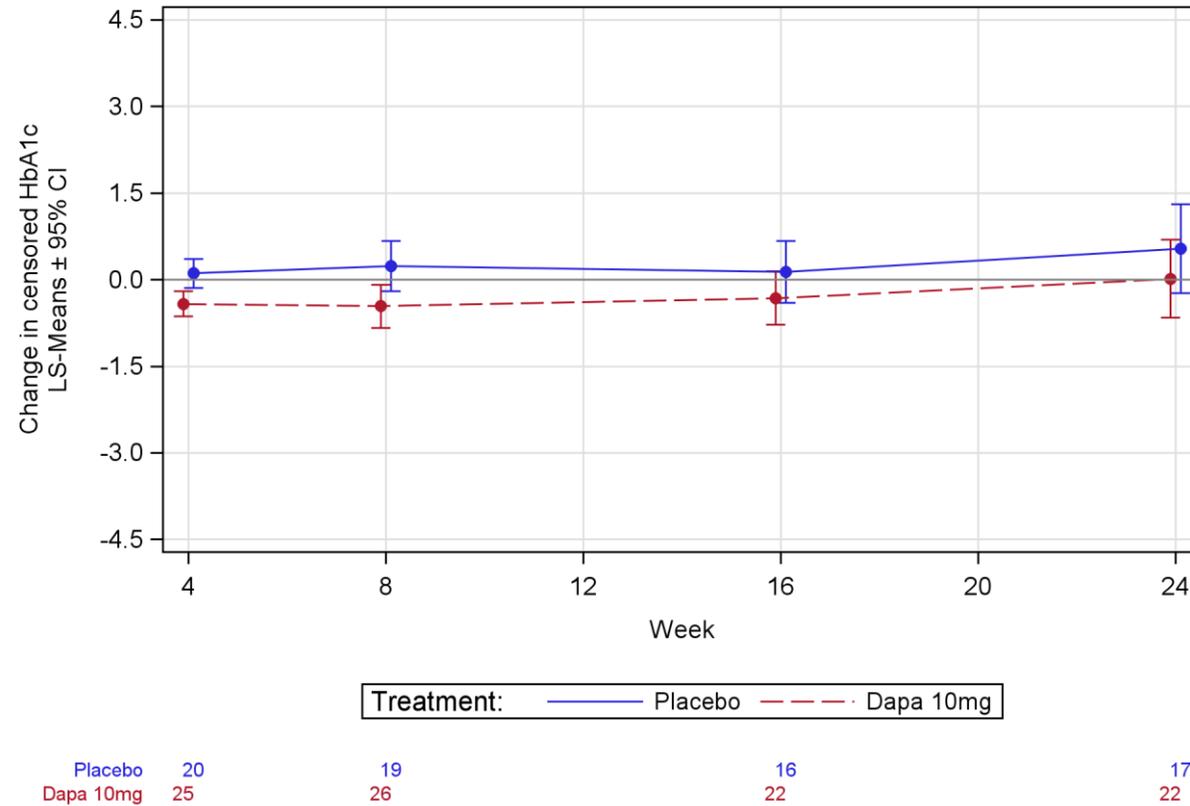


Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, FPG = Fasting plasma glucose, symbols present least square mean (LS-Mean), bars present 95% confidence intervals (CI).

Source Table: T2FGMC_FAC0

Source Data: alb, created on: 30SEP2021

Figure F2HAMC_FAG0: Change in censored HbA1c up to Week 24
PFAS



Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, HbA1c = Glycated haemoglobin, symbols present least square mean (LS-Mean), bars present 95% confidence intervals (CI).
Source Table: T2HAMC_FAC0
Source Data: alb, created on: 30SEP2021

Table T2FGM_FAF0: Course of censored FPG up to Week 24
 PFAS

Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max
Dapa 10mg	Day 1	29	29	8.88 (3.32)	5.3	7.33	16.4
	Week 4	29	26	7.78 (3.10)	4.4	6.30	16.0
	Week 16	29	23	7.59 (2.28)	4.6	7.10	14.6
	Week 24	29	22	8.53 (3.96)	4.8	7.03	20.4
Placebo	Day 1	24	24	8.99 (2.68)	4.7	8.66	14.5
	Week 4	24	19	10.08 (4.01)	4.7	9.05	22.3
	Week 16	24	16	9.12 (3.03)	5.0	8.58	16.5
	Week 24	24	17	8.79 (3.45)	5.3	7.60	18.7

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group, n = Number of valid observations, SD = Standard deviation, Q50 = median, FPG = Fasting plasma glucose.
 Source Data: alb, created on: 30SEP2021

Table T2FGMC_FAC0: Change in censored FPG up to Week 24
 PFAS

Treatment	Time point	N	n (%)	Repeated measures analysis				
				Change from Baseline		Treatment Difference		
				LS-Mean (SE)	95% CI	LS-Mean (SE)	95% CI	p-value
Dapa 10mg	Week 4	29	26 (89.7)	-0.95 (0.63)	(-2.21, 0.32)	-2.31 (0.96)	(-4.25, -0.37)	0.021
	Week 16	29	23 (79.3)	-0.30 (0.56)	(-1.45, 0.84)	-0.77 (0.87)	(-2.54, 1.00)	0.382
	Week 24	29	22 (75.9)	0.22 (0.70)	(-1.19, 1.64)	-0.24 (1.06)	(-2.39, 1.90)	0.821
Placebo	Week 4	24	19 (79.2)	1.36 (0.73)	(-0.12, 2.84)			
	Week 16	24	16 (66.7)	0.47 (0.66)	(-0.88, 1.81)			
	Week 24	24	17 (70.8)	0.47 (0.80)	(-1.15, 2.08)			

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group,
 n = Number of valid observations, Q50 = Median, SD = Standard deviation, SE = Standard error, CI = Confidence interval,
 FPG = Fasting plasma glucose, LS-Mean = Least square mean.
 A mixed repeated measures model was applied with fixed factors for treatment, week, interactions treatment-by-week,
 baseline-by-week and baseline as covariate.
 Source Data: alb, created on: 30SEP2021

Table T2FGMC_FAH0: Hedges G for Change in censored FPG up to Week 24
 PFAS

Change in censored FPG up to Week 24	Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max	Hedges G	
									Effect size (SD)	95% CI
Overall	Dapa 10mg	Week 4	29	26	-1.13 (2.53)	-9.0	-1.03	5.6	-0.60 (0.31)	[-1.21, 0.00]
		Week 16	29	23	-0.42 (3.04)	-5.1	-0.55	9.0	-0.25 (0.33)	[-0.89, 0.39]
		Week 24	29	22	0.27 (2.67)	-4.1	-0.05	5.7	-0.01 (0.32)	[-0.64, 0.63]
	Placebo	Week 4	24	19	1.04 (4.73)	-4.8	0.06	17.1		
		Week 16	24	16	0.30 (2.58)	-3.2	0.19	6.5		
		Week 24	24	17	0.29 (4.11)	-5.7	0.00	10.2		

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group,
 n = Number of valid observations, Q50 = Median, SD = Standard deviation, CI = Confidence interval,
 FPG = Fasting plasma glucose.
 Source Data: alb, created on: 30SEP2021

Table T2HAM_FAF0: Course of censored HbA1c up to Week 24
 PFAS

Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max
Dapa 10mg	Day 1	29	29	7.80 (1.65)	5.4	7.30	12.4
	Week 4	29	25	7.35 (1.77)	5.0	7.00	11.9
	Week 8	29	26	7.26 (1.80)	5.2	6.80	12.2
	Week 16	29	22	6.81 (1.18)	5.0	6.65	9.6
	Week 24	29	22	7.31 (1.91)	4.9	6.90	12.6
Placebo	Day 1	24	24	8.05 (1.11)	6.5	7.85	10.5
	Week 4	24	20	8.01 (1.06)	6.5	7.70	10.2
	Week 8	24	19	8.35 (1.60)	6.3	8.10	13.1
	Week 16	24	16	7.84 (0.99)	6.2	7.95	9.3
	Week 24	24	17	8.53 (2.32)	5.9	7.90	15.3

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group, n = Number of valid observations, SD = Standard deviation, Q50 = median, HbA1c = Glycated haemoglobin.
 Source Data: alb, created on: 30SEP2021

Table T2HAMC_FAC0: Change in censored HbA1c up to Week 24
PFAS

Treatment	Time point	N	n (%)	Repeated measures analysis				
				Change from Baseline		Treatment Difference		
				LS-Mean (SE)	95% CI	LS-Mean (SE)	95% CI	p-value
Dapa 10mg	Week 4	29	25 (86.2)	-0.42 (0.11)	(-0.64, -0.20)	-0.53 (0.16)	(-0.86, -0.20)	0.002
	Week 8	29	26 (89.7)	-0.46 (0.19)	(-0.84, -0.08)	-0.69 (0.29)	(-1.27, -0.12)	0.019
	Week 16	29	22 (75.9)	-0.32 (0.23)	(-0.78, 0.14)	-0.46 (0.35)	(-1.17, 0.25)	0.198
	Week 24	29	22 (75.9)	0.02 (0.33)	(-0.65, 0.69)	-0.52 (0.51)	(-1.55, 0.51)	0.316
Placebo	Week 4	24	20 (83.3)	0.11 (0.12)	(-0.14, 0.36)			
	Week 8	24	19 (79.2)	0.23 (0.22)	(-0.20, 0.67)			
	Week 16	24	16 (66.7)	0.14 (0.26)	(-0.40, 0.67)			
	Week 24	24	17 (70.8)	0.54 (0.38)	(-0.23, 1.30)			

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group,
n = Number of valid observations, Q50 = Median, SD = Standard deviation, SE = Standard error, CI = Confidence interval,
HbA1c = Glycated haemoglobin, LS-Mean = Least square mean.
A mixed repeated measures model was applied with fixed factors for treatment, week, interactions treatment-by-week,
baseline-by-week and baseline as covariate.
Source Data: alb, created on: 30SEP2021

Table T2HAMC_FAH0: Hedges G for Change in censored HbA1c up to Week 24
 PFAS

Change in censored HbA1c up to Week 24	Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max	Hedges G	
									Effect size (SD)	95% CI
Overall	Dapa 10mg	Week 4	29	25	-0.42 (0.60)	-1.7	-0.50	1.6	-0.88 (0.31)	[-1.50, -0.27]
		Week 8	29	26	-0.44 (0.90)	-3.0	-0.50	1.8	-0.70 (0.31)	[-1.31, -0.09]
		Week 16	29	22	-0.39 (1.09)	-3.0	-0.40	1.9	-0.30 (0.33)	[-0.95, 0.34]
		Week 24	29	22	-0.05 (1.35)	-2.6	-0.20	2.6	-0.35 (0.33)	[-0.99, 0.29]
	Placebo	Week 4	24	20	0.01 (0.29)	-0.4	0.00	0.7		
		Week 8	24	19	0.25 (1.06)	-0.7	-0.10	3.9		
		Week 16	24	16	-0.08 (0.92)	-2.0	-0.20	1.8		
		Week 24	24	17	0.55 (2.09)	-1.8	-0.40	6.1		

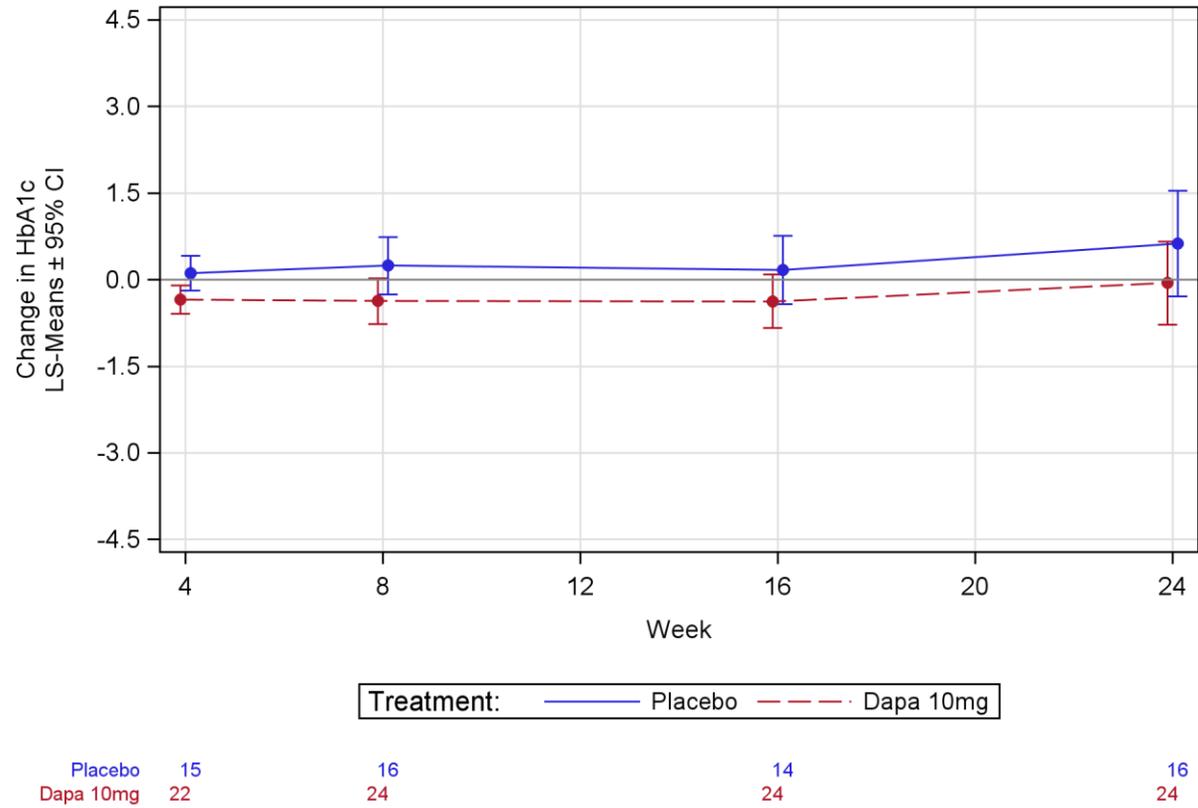
Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group,
 n = Number of valid observations, Q50 = Median, SD = Standard deviation, CI = Confidence interval,
 HbA1c = Glycated haemoglobin.
 Source Data: alb, created on: 30SEP2021

Table T2HAMR_F7AP0: Patients with HbA1c < 7% at Week 24 (censored)
 Patients in PFAS with HbA1c >= 7%

Variable	Dapa 10 mg		Placebo		RR [95 % CI]	OR [95 % CI]	ARR [95 % CI]	p-value
	N	n (%) [95 % CI]	N	n (%) [95 % CI]				
Patients with HbA1c < 7% at Week 24 (censored)	19	3 (15.8) [0.0, 32.2]	19	1 (5.3) [0.0, 15.3]	3.000 [0.342, 26.327]	3.375 [0.318, 35.789]	10.5 [-13.2, 34.5]	0.604

Note: PFAS = Pediatric full analysis set, N = total number of patients (denominator), n = number of patients with events,
 OR = odds ratio, RR = relative risk, ARR = absolute risk reduction, CI = confidence interval.
 p-value: Fisher's exact test, CIs: OR, RR: 2-sided (Wald), ARR: 2-sided exact (Chan-Zhang).
 + = Adding of 0.5 to each cell, * = significant treatment effect.
 Source Data: alb, created on: 30SEP2021

Figure F2HAC_PAG0: Change in HbA1c up to Week 24
PPPS



Note: Dapa = Dapagliflozin, PPPS = Pediatric per protocol set, HbA1c = Glycated haemoglobin, symbols present least square mean (LS-Mean), bars present 95% confidence intervals (CI).
Source Table: T2HAC_PAC0
Source Data: alb, created on: 30SEP2021

Table T2HA_PAF0: Course of HbA1c up to Week 24
 PPPS

Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max
Dapa 10mg	Day 1	25	25	7.38 (1.16)	5.4	7.10	10.4
	Week 4	25	22	6.92 (1.35)	5.0	6.75	10.8
	Week 8	25	24	6.92 (1.36)	5.2	6.60	10.8
	Week 16	25	24	6.98 (1.33)	5.0	6.85	9.9
	Week 24	25	24	7.22 (1.77)	4.9	6.85	12.3
Placebo	Day 1	17	17	8.10 (1.17)	6.5	8.00	10.5
	Week 4	17	15	7.93 (1.08)	6.5	7.60	10.2
	Week 8	17	16	8.26 (1.68)	6.3	8.00	13.1
	Week 16	17	14	7.79 (1.05)	6.2	7.85	9.3
	Week 24	17	16	8.63 (2.45)	5.9	8.00	15.3

Note: Dapa = Dapagliflozin, PPPS = Pediatric per protocol set, N = Number of subjects in treatment group, n = Number of valid observations, SD = Standard deviation, Q50 = median, HbA1c = Glycated haemoglobin.
 Source Data: alb, created on: 30SEP2021

Table T2HAC_PAC0: Change in HbA1c up to Week 24
 PPPS

Treatment	Time point	N	n (%)	Repeated measures analysis				
				Change from Baseline		Treatment Difference		
				LS-Mean (SE)	95% CI	LS-Mean (SE)	95% CI	p-value
Dapa 10mg	Week 4	25	22 (88.0)	-0.34 (0.12)	(-0.58, -0.10)	-0.46 (0.19)	(-0.85, -0.06)	0.025
	Week 8	25	24 (96.0)	-0.37 (0.19)	(-0.76, 0.02)	-0.62 (0.32)	(-1.26, 0.03)	0.059
	Week 16	25	24 (96.0)	-0.37 (0.23)	(-0.84, 0.09)	-0.54 (0.37)	(-1.30, 0.22)	0.155
	Week 24	25	24 (96.0)	-0.06 (0.36)	(-0.78, 0.66)	-0.68 (0.58)	(-1.86, 0.50)	0.250
Placebo	Week 4	17	15 (88.2)	0.11 (0.15)	(-0.19, 0.42)			
	Week 8	17	16 (94.1)	0.25 (0.25)	(-0.25, 0.74)			
	Week 16	17	14 (82.4)	0.17 (0.29)	(-0.42, 0.76)			
	Week 24	17	16 (94.1)	0.62 (0.45)	(-0.29, 1.54)			

Note: Dapa = Dapagliflozin, PPPS = Pediatric per protocol set, N = Number of subjects in treatment group,
 n = Number of valid observations, Q50 = Median, SD = Standard deviation, SE = Standard error, CI = Confidence interval,
 HbA1c = Glycated haemoglobin, LS-Mean = Least square mean.
 A mixed repeated measures model was applied with fixed factors for treatment, week, interactions treatment-by-week,
 baseline-by-week and baseline as covariate.
 Source Data: alb, created on: 30SEP2021

Table T2HAC_PAH0: Hedges G for Change in HbA1c up to Week 24
 PPPS

Change in HbA1c up to Week 24	Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max	Hedges G	
									Effect size (SD)	95% CI
Overall	Dapa 10mg	Week 4	25	22	-0.36 (0.57)	-1.0	-0.50	1.6	-0.77 (0.35)	[-1.45, -0.09]
		Week 8	25	24	-0.40 (0.79)	-1.7	-0.65	1.8	-0.69 (0.33)	[-1.34, -0.04]
		Week 16	25	24	-0.35 (0.99)	-2.5	-0.40	1.9	-0.25 (0.34)	[-0.91, 0.41]
		Week 24	25	24	-0.10 (1.30)	-2.6	-0.30	2.6	-0.42 (0.33)	[-1.06, 0.22]
	Placebo	Week 4	17	15	0.01 (0.29)	-0.4	0.00	0.7		
		Week 8	17	16	0.26 (1.15)	-0.7	-0.10	3.9		
		Week 16	17	14	-0.11 (0.97)	-2.0	-0.20	1.8		
		Week 24	17	16	0.63 (2.25)	-1.8	-0.30	6.1		

Note: Dapa = Dapagliflozin, PPPS = Pediatric per protocol set, N = Number of subjects in treatment group, n = Number of valid observations, Q50 = Median, SD = Standard deviation, CI = Confidence interval, HbA1c = Glycated haemoglobin.

Source Data: alb, created on: 30SEP2021

Table T2HAR_P7AP0: Patients with HbA1c < 7% at Week 24
 Patients in PPPS with HbA1c >= 7%

Variable	Dapa 10 mg		Placebo		RR [95 % CI]	OR [95 % CI]	ARR [95 % CI]	p-value
	N	n (%) [95 % CI]	N	n (%) [95 % CI]				
Patients with HbA1c < 7% at Week 24	15	3 (20.0) [0.0, 40.2]	13	1 (7.7) [0.0, 22.2]	2.600 [0.307, 22.051]	3.000 [0.272, 33.085]	12.3 [-19.5, 41.2]	0.600

Note: PPPS = Pediatric per protocol set, N = total number of patients (denominator), n = number of patients with events,
 OR = odds ratio, RR = relative risk, ARR = absolute risk reduction, CI = confidence interval.
 p-value: Fisher's exact test, CIs: OR, RR: 2-sided (Wald), ARR: 2-sided exact (Chan-Zhang).
 + = Adding of 0.5 to each cell, * = significant treatment effect.
 Source Data: alb, created on: 30SEP2021

Table T2A_SSIS: Incidence of AEs by subgroup
PFAS

Incidence of AEs	Dapa 10 mg		Placebo		RR [95 % CI]	OR [95 % CI]	ARR [95 % CI]	p-value
	N	n (%) [95 % CI]	N	n (%) [95 % CI]				
A: Age (years)								
<= 15	16	13 (81.3) [62.1, 100.0]	14	10 (71.4) [47.8, 95.1]	1.138 [0.758, 1.708]	1.733 [0.314, 9.573]	9.8 [-22.2, 43.9]	0.832 0.675
> 15 and < 18	13	9 (69.2) [44.1, 94.3]	10	5 (50.0) [19.0, 81.0]	1.385 [0.675, 2.839]	2.250 [0.407, 12.439]	19.2 [-23.2, 56.9]	0.417
B: Sex								
Male	12	7 (58.3) [30.4, 86.2]	9	5 (55.6) [23.1, 88.0]	1.050 [0.493, 2.234]	1.120 [0.196, 6.414]	2.8 [-40.0, 45.0]	0.345 1.000
Female	17	15 (88.2) [72.9, 100.0]	15	10 (66.7) [42.8, 90.5]	1.324 [0.889, 1.970]	3.750 [0.605, 23.252]	21.6 [-8.9, 52.3]	0.209
C: Race								
White	23	16 (69.6) [50.8, 88.4]	9	6 (66.7) [35.9, 97.5]	1.043 [0.611, 1.782]	1.143 [0.220, 5.928]	2.9 [-30.5, 41.1]	0.124 1.000
Non-White	6	6 (100.0) [100.0, 100.0]	15	9 (60.0) [35.2, 84.8]	1.667 [1.103, 2.519]	8.895 + [0.424, 186.794]	40.0 [-12.4, 67.7]	0.123
D: Baseline BMI (kg/m**2)								
< 30	15	11 (73.3) [51.0, 95.7]	7	4 (57.1) [20.5, 93.8]	1.283 [0.631, 2.611]	2.063 [0.313, 13.574]	16.2 [-25.9, 59.3]	0.981 0.630
>= 30	14	11 (78.6) [57.1, 100.0]	17	11 (64.7) [42.0, 87.4]	1.214 [0.778, 1.895]	2.000 [0.396, 10.090]	13.9 [-20.7, 45.5]	0.456

Note: PFAS = Pediatric full analysis set, N = total number of patients (denominator), n = number of patients with events,
OR = odds ratio, RR = relative risk, ARR = absolute risk reduction, CI = confidence interval.
p-value: Fisher's exact test, CIs: OR, RR: 2-sided (Wald), ARR: 2-sided exact (Chan-Zhang).
+ = Adding of 0.5 to each cell, i = significant interaction test, * = significant treatment effect.
Source Data: aae, created on: 17SEP2021

Table T2A_SSIS: Incidence of AEs by subgroup
PFAS

Incidence of AEs	Dapa 10 mg		Placebo		RR [95 % CI]	OR [95 % CI]	ARR [95 % CI]	p-value
	N	n (%) [95 % CI]	N	n (%) [95 % CI]				
E: Baseline HbA1c (%)								
< 8	19	13 (68.4) [47.5, 89.3]	12	6 (50.0) [21.7, 78.3]	1.368 [0.719, 2.603]	2.167 [0.489, 9.601]	18.4 [-17.5, 52.4]	0.823 0.452
>= 8	10	9 (90.0) [71.4, 100.0]	12	9 (75.0) [50.5, 99.5]	1.200 [0.815, 1.766]	3.000 [0.260, 34.575]	15.0 [-22.1, 49.0]	0.594
F: Background diabetic medication								
Metformin	11	6 (54.5) [25.1, 84.0]	14	9 (64.3) [39.2, 89.4]	0.848 [0.436, 1.651]	0.667 [0.133, 3.347]	-9.7 [-47.5, 30.3]	0.099 0.697
Insulin or insulin + metformin	18	16 (88.9) [74.4, 100.0]	10	6 (60.0) [29.6, 90.4]	1.481 [0.870, 2.521]	5.333 [0.767, 37.093]	28.9 [-7.0, 63.5]	0.147
G: Geographic region								
Europe	12	7 (58.3) [30.4, 86.2]	3	2 (66.7) [13.3, 100.0]	0.875 [0.344, 2.222]	0.700 [0.049, 10.014]	-8.3 [-57.4, 54.2]	0.229 1.000
Non-Europe	17	15 (88.2) [72.9, 100.0]	21	13 (61.9) [41.1, 82.7]	1.425 [0.977, 2.080]	4.615 [0.828, 25.731]	26.3 [-4.4, 52.6]	0.136

Note: PFAS = Pediatric full analysis set, N = total number of patients (denominator), n = number of patients with events,
OR = odds ratio, RR = relative risk, ARR = absolute risk reduction, CI = confidence interval.
p-value: Fisher's exact test, CIs: OR, RR: 2-sided (Wald), ARR: 2-sided exact (Chan-Zhang).
+ = Adding of 0.5 to each cell, i = significant interaction test, * = significant treatment effect.
Source Data: aae, created on: 17SEP2021

Table T2AA_SSIS: Incidence of non-disease related AEs by subgroup
 PFAS

Incidence of non-disease related AEs	Dapa 10 mg		Placebo		RR [95 % CI]	OR [95 % CI]	ARR [95 % CI]	p-value
	N	n (%) [95 % CI]	N	n (%) [95 % CI]				
A: Age (years)								
<= 15	16	13 (81.3) [62.1, 100.0]	14	9 (64.3) [39.2, 89.4]	1.264 [0.801, 1.994]	2.407 [0.456, 12.720]	17.0 [-16.4, 49.6]	0.956 0.417
> 15 and < 18	13	9 (69.2) [44.1, 94.3]	10	5 (50.0) [19.0, 81.0]	1.385 [0.675, 2.839]	2.250 [0.407, 12.439]	19.2 [-23.2, 56.9]	0.417
B: Sex								
Male	12	7 (58.3) [30.4, 86.2]	9	4 (44.4) [12.0, 76.9]	1.313 [0.548, 3.142]	1.750 [0.306, 10.022]	13.9 [-30.3, 54.3]	0.553 0.670
Female	17	15 (88.2) [72.9, 100.0]	15	10 (66.7) [42.8, 90.5]	1.324 [0.889, 1.970]	3.750 [0.605, 23.252]	21.6 [-8.9, 52.3]	0.209
C: Race								
White	23	16 (69.6) [50.8, 88.4]	9	5 (55.6) [23.1, 88.0]	1.252 [0.658, 2.384]	1.829 [0.374, 8.937]	14.0 [-22.6, 50.8]	0.191 0.681
Non-White	6	6 (100.0) [100.0, 100.0]	15	9 (60.0) [35.2, 84.8]	1.667 [1.103, 2.519]	8.895 + [0.424, 186.794]	40.0 [-12.4, 67.7]	0.123
D: Baseline BMI (kg/m**2)								
< 30	15	11 (73.3) [51.0, 95.7]	7	3 (42.9) [6.2, 79.5]	1.711 [0.690, 4.243]	3.667 [0.557, 24.132]	30.5 [-14.9, 69.0]	0.632 0.343
>= 30	14	11 (78.6) [57.1, 100.0]	17	11 (64.7) [42.0, 87.4]	1.214 [0.778, 1.895]	2.000 [0.396, 10.090]	13.9 [-20.7, 45.5]	0.456

Note: PFAS = Pediatric full analysis set, N = total number of patients (denominator), n = number of patients with events, OR = odds ratio, RR = relative risk, ARR = absolute risk reduction, CI = confidence interval.
 p-value: Fisher's exact test, CIs: OR, RR: 2-sided (Wald), ARR: 2-sided exact (Chan-Zhang).
 + = Adding of 0.5 to each cell, i = significant interaction test, * = significant treatment effect.
 Source Data: aae, created on: 17SEP2021

Table T2AA_SSIS: Incidence of non-disease related AEs by subgroup
PFAS

Incidence of non-disease related AEs	Dapa 10 mg		Placebo		RR [95 % CI]	OR [95 % CI]	ARR [95 % CI]	p-value
	N	n (%) [95 % CI]	N	n (%) [95 % CI]				
E: Baseline HbA1c (%)								
< 8	19	13 (68.4) [47.5, 89.3]	12	6 (50.0) [21.7, 78.3]	1.368 [0.719, 2.603]	2.167 [0.489, 9.601]	18.4 [-17.5, 52.4]	0.608 0.452
>= 8	10	9 (90.0) [71.4, 100.0]	12	8 (66.7) [40.0, 93.3]	1.350 [0.861, 2.118]	4.500 [0.413, 49.077]	23.3 [-16.1, 57.5]	0.323
F: Background diabetic medication								
Metformin	11	6 (54.5) [25.1, 84.0]	14	8 (57.1) [31.2, 83.1]	0.955 [0.472, 1.932]	0.900 [0.183, 4.415]	-2.6 [-41.4, 36.7]	0.158 1.000
Insulin or insulin + metformin	18	16 (88.9) [74.4, 100.0]	10	6 (60.0) [29.6, 90.4]	1.481 [0.870, 2.521]	5.333 [0.767, 37.093]	28.9 [-7.0, 63.5]	0.147
G: Geographic region								
Europe	12	7 (58.3) [30.4, 86.2]	3	1 (33.3) [0.0, 86.7]	1.750 [0.329, 9.298]	2.800 [0.196, 40.057]	25.0 [-39.0, 71.6]	0.756 0.569
Non-Europe	17	15 (88.2) [72.9, 100.0]	21	13 (61.9) [41.1, 82.7]	1.425 [0.977, 2.080]	4.615 [0.828, 25.731]	26.3 [-4.4, 52.6]	0.136

Note: PFAS = Pediatric full analysis set, N = total number of patients (denominator), n = number of patients with events,
OR = odds ratio, RR = relative risk, ARR = absolute risk reduction, CI = confidence interval.
p-value: Fisher's exact test, CIs: OR, RR: 2-sided (Wald), ARR: 2-sided exact (Chan-Zhang).
+ = Adding of 0.5 to each cell, i = significant interaction test, * = significant treatment effect.
Source Data: aae, created on: 17SEP2021

Table T2AN_SSIS: Incidence of non-severe AEs by subgroup
PFAS

Incidence of non-severe AEs	Dapa 10 mg		Placebo		RR [95 % CI]	OR [95 % CI]	ARR [95 % CI]	p-value
	N	n (%) [95 % CI]	N	n (%) [95 % CI]				
A: Age (years)								
<= 15	16	13 (81.3) [62.1, 100.0]	14	9 (64.3) [39.2, 89.4]	1.264 [0.801, 1.994]	2.407 [0.456, 12.720]	17.0 [-16.4, 49.6]	0.956 0.417
> 15 and < 18	13	9 (69.2) [44.1, 94.3]	10	5 (50.0) [19.0, 81.0]	1.385 [0.675, 2.839]	2.250 [0.407, 12.439]	19.2 [-23.2, 56.9]	0.417
B: Sex								
Male	12	7 (58.3) [30.4, 86.2]	9	4 (44.4) [12.0, 76.9]	1.313 [0.548, 3.142]	1.750 [0.306, 10.022]	13.9 [-30.3, 54.3]	0.553 0.670
Female	17	15 (88.2) [72.9, 100.0]	15	10 (66.7) [42.8, 90.5]	1.324 [0.889, 1.970]	3.750 [0.605, 23.252]	21.6 [-8.9, 52.3]	0.209
C: Race								
White	23	16 (69.6) [50.8, 88.4]	9	5 (55.6) [23.1, 88.0]	1.252 [0.658, 2.384]	1.829 [0.374, 8.937]	14.0 [-22.6, 50.8]	0.191 0.681
Non-White	6	6 (100.0) [100.0, 100.0]	15	9 (60.0) [35.2, 84.8]	1.667 [1.103, 2.519]	8.895 + [0.424, 186.794]	40.0 [-12.4, 67.7]	0.123
D: Baseline BMI (kg/m**2)								
< 30	15	11 (73.3) [51.0, 95.7]	7	3 (42.9) [6.2, 79.5]	1.711 [0.690, 4.243]	3.667 [0.557, 24.132]	30.5 [-14.9, 69.0]	0.632 0.343
>= 30	14	11 (78.6) [57.1, 100.0]	17	11 (64.7) [42.0, 87.4]	1.214 [0.778, 1.895]	2.000 [0.396, 10.090]	13.9 [-20.7, 45.5]	0.456

Note: PFAS = Pediatric full analysis set, N = total number of patients (denominator), n = number of patients with events,
OR = odds ratio, RR = relative risk, ARR = absolute risk reduction, CI = confidence interval.
p-value: Fisher's exact test, CIs: OR, RR: 2-sided (Wald), ARR: 2-sided exact (Chan-Zhang).
+ = Adding of 0.5 to each cell, i = significant interaction test, * = significant treatment effect.
Source Data: aae, created on: 17SEP2021

Table T2AN_SSIS: Incidence of non-severe AEs by subgroup
PFAS

Incidence of non-severe AEs	Dapa 10 mg		Placebo		RR [95 % CI]	OR [95 % CI]	ARR [95 % CI]	p-value
	N	n (%) [95 % CI]	N	n (%) [95 % CI]				
E: Baseline HbA1c (%)								
< 8	19	13 (68.4) [47.5, 89.3]	12	6 (50.0) [21.7, 78.3]	1.368 [0.719, 2.603]	2.167 [0.489, 9.601]	18.4 [-17.5, 52.4]	0.608 0.452
>= 8	10	9 (90.0) [71.4, 100.0]	12	8 (66.7) [40.0, 93.3]	1.350 [0.861, 2.118]	4.500 [0.413, 49.077]	23.3 [-16.1, 57.5]	0.323
F: Background diabetic medication								
Metformin	11	6 (54.5) [25.1, 84.0]	14	8 (57.1) [31.2, 83.1]	0.955 [0.472, 1.932]	0.900 [0.183, 4.415]	-2.6 [-41.4, 36.7]	0.158 1.000
Insulin or insulin + metformin	18	16 (88.9) [74.4, 100.0]	10	6 (60.0) [29.6, 90.4]	1.481 [0.870, 2.521]	5.333 [0.767, 37.093]	28.9 [-7.0, 63.5]	0.147
G: Geographic region								
Europe	12	7 (58.3) [30.4, 86.2]	3	1 (33.3) [0.0, 86.7]	1.750 [0.329, 9.298]	2.800 [0.196, 40.057]	25.0 [-39.0, 71.6]	0.756 0.569
Non-Europe	17	15 (88.2) [72.9, 100.0]	21	13 (61.9) [41.1, 82.7]	1.425 [0.977, 2.080]	4.615 [0.828, 25.731]	26.3 [-4.4, 52.6]	0.136

Note: PFAS = Pediatric full analysis set, N = total number of patients (denominator), n = number of patients with events,
OR = odds ratio, RR = relative risk, ARR = absolute risk reduction, CI = confidence interval.
p-value: Fisher's exact test, CIs: OR, RR: 2-sided (Wald), ARR: 2-sided exact (Chan-Zhang).
+ = Adding of 0.5 to each cell, i = significant interaction test, * = significant treatment effect.
Source Data: aae, created on: 17SEP2021

Table T2FG_FSFS: Course of FPG up to Week 24 by subgroup
PFAS

Course of FPG up to Week 24	Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max
A: Age								
<= 15 years	Dapa 10mg	Day 1	16	16	8.95 (3.25)	5.5	7.60	15.3
		Week 4	16	14	7.51 (3.08)	4.4	5.94	14.3
		Week 16	16	15	7.84 (2.99)	4.1	6.66	14.6
		Week 24	16	14	7.46 (2.45)	5.0	6.11	13.1
	Placebo	Day 1	14	14	9.30 (3.05)	4.7	8.74	14.5
		Week 4	14	11	9.44 (3.49)	4.7	8.49	15.3
		Week 16	14	9	9.45 (3.93)	5.0	8.50	16.5
		Week 24	14	10	8.60 (4.02)	5.3	7.27	18.1
> 15 and < 18 years	Dapa 10mg	Day 1	13	13	8.79 (3.53)	5.3	6.90	16.4
		Week 4	13	12	8.09 (3.23)	5.0	7.05	16.0
		Week 16	13	11	7.58 (1.75)	4.9	7.49	11.3
		Week 24	13	12	9.35 (4.74)	4.8	7.55	20.4
	Placebo	Day 1	10	10	8.54 (2.14)	5.2	8.44	13.5
		Week 4	10	8	10.95 (4.73)	7.7	9.21	22.3
		Week 16	10	7	8.69 (1.43)	6.9	8.66	10.3
		Week 24	10	8	9.01 (2.16)	5.9	8.82	11.9

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group, n = Number of valid observations, SD = Standard deviation, Q50 = median, HbA1c = Glycated haemoglobin, FPG = Fasting plasma glucose, BMI = Body mass index, Europe = Hungary, Israel, Russian Federation.
Source Data: alb, created on: 29SEP2021

Table T2FG_FSFS: Course of FPG up to Week 24 by subgroup
 PFAS

Course of FPG up to Week 24	Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max
B: Sex								
Male	Dapa 10mg	Day 1	12	12	8.94 (3.29)	5.3	7.58	15.3
		Week 4	12	10	8.03 (3.17)	5.4	6.23	14.3
		Week 16	12	11	7.12 (1.57)	4.1	7.38	9.4
		Week 24	12	10	7.34 (2.35)	4.8	6.84	12.2
	Placebo	Day 1	9	9	8.96 (2.22)	7.3	8.05	14.5
		Week 4	9	6	9.27 (2.29)	7.1	8.94	13.6
		Week 16	9	5	8.38 (1.18)	7.2	8.05	10.3
		Week 24	9	5	8.19 (2.61)	5.5	8.60	11.9
Female	Dapa 10mg	Day 1	17	17	8.84 (3.43)	5.5	7.33	16.4
		Week 4	17	16	7.62 (3.15)	4.4	6.50	16.0
		Week 16	17	15	8.18 (2.98)	4.6	7.10	14.6
		Week 24	17	16	8.95 (4.34)	5.0	7.80	20.4
	Placebo	Day 1	15	15	9.01 (3.01)	4.7	8.82	13.5
		Week 4	15	13	10.45 (4.63)	4.7	9.60	22.3
		Week 16	15	11	9.45 (3.59)	5.0	8.77	16.5
		Week 24	15	13	9.01 (3.53)	5.3	7.60	18.1

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group, n = Number of valid observations, SD = Standard deviation, Q50 = median, HbA1c = Glycated haemoglobin, FPG = Fasting plasma glucose, BMI = Body mass index, Europe = Hungary, Israel, Russian Federation.
 Source Data: alb, created on: 29SEP2021

Table T2FG_FSFS: Course of FPG up to Week 24 by subgroup
 PFAS

Course of FPG up to Week 24	Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max
C: Race								
White	Dapa 10mg	Day 1	23	23	8.84 (3.41)	5.3	6.90	16.4
		Week 4	23	20	7.31 (3.12)	4.4	6.08	16.0
		Week 16	23	20	7.25 (2.41)	4.1	6.77	14.6
		Week 24	23	20	8.40 (4.04)	4.8	7.03	20.4
	Placebo	Day 1	9	9	10.92 (2.73)	7.7	11.70	14.5
		Week 4	9	7	10.44 (2.82)	7.0	11.16	13.6
		Week 16	9	6	10.14 (3.36)	7.2	9.38	16.5
		Week 24	9	6	8.06 (2.22)	5.5	8.10	11.5
Non-White	Dapa 10mg	Day 1	6	6	9.04 (3.23)	5.5	8.33	13.9
		Week 4	6	6	9.34 (2.68)	5.3	9.38	12.4
		Week 16	6	6	9.34 (2.29)	6.7	8.91	12.8
		Week 24	6	6	8.12 (2.75)	5.5	7.35	13.1
	Placebo	Day 1	15	15	7.83 (1.93)	4.7	7.60	11.7
		Week 4	15	12	9.87 (4.67)	4.7	8.77	22.3
		Week 16	15	10	8.50 (2.82)	5.0	8.19	15.0
		Week 24	15	12	9.14 (3.69)	5.3	8.13	18.1

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group, n = Number of valid observations, SD = Standard deviation, Q50 = median, HbA1c = Glycated haemoglobin, FPG = Fasting plasma glucose, BMI = Body mass index, Europe = Hungary, Israel, Russian Federation.
 Source Data: alb, created on: 29SEP2021

Table T2FG_FSFS: Course of FPG up to Week 24 by subgroup
 PFAS

Course of FPG up to Week 24	Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max
D: Baseline BMI								
< 30 kg/m**2	Dapa 10mg	Day 1	15	15	9.07 (3.03)	5.3	7.90	15.3
		Week 4	15	14	7.73 (2.88)	5.0	6.30	14.3
		Week 16	15	14	7.45 (2.46)	4.1	6.63	12.8
		Week 24	15	13	7.34 (2.53)	4.8	6.33	13.1
	Placebo	Day 1	7	7	9.02 (3.05)	6.0	7.71	14.5
		Week 4	7	3	9.70 (3.46)	7.0	8.49	13.6
		Week 16	7	4	9.38 (0.88)	8.5	9.38	10.3
		Week 24	7	4	8.37 (3.10)	5.5	7.60	12.8
>= 30 kg/m**2	Dapa 10mg	Day 1	14	14	8.68 (3.70)	5.5	6.77	16.4
		Week 4	14	12	7.83 (3.47)	4.4	6.35	16.0
		Week 16	14	12	8.06 (2.62)	4.6	7.38	14.6
		Week 24	14	13	9.33 (4.52)	5.5	7.66	20.4
	Placebo	Day 1	17	17	8.97 (2.62)	4.7	8.82	13.5
		Week 4	17	16	10.15 (4.20)	4.7	9.21	22.3
		Week 16	17	12	9.03 (3.51)	5.0	7.88	16.5
		Week 24	17	14	8.90 (3.39)	5.3	8.63	18.1

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group, n = Number of valid observations, SD = Standard deviation, Q50 = median, HbA1c = Glycated haemoglobin, FPG = Fasting plasma glucose, BMI = Body mass index, Europe = Hungary, Israel, Russian Federation.
 Source Data: alb, created on: 29SEP2021

Table T2FG_FSFS: Course of FPG up to Week 24 by subgroup
 PFAS

Course of FPG up to Week 24	Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max
E: Baseline HbA1c								
< 8 %	Dapa 10mg	Day 1	19	19	7.50 (2.16)	5.3	6.83	13.7
		Week 4	19	18	6.36 (1.64)	4.4	5.74	9.9
		Week 16	19	18	7.43 (2.40)	4.6	6.80	14.6
		Week 24	19	18	7.46 (2.41)	4.8	6.60	13.1
	Placebo	Day 1	12	12	7.60 (1.76)	4.7	7.66	11.7
		Week 4	12	8	8.28 (3.13)	4.7	7.77	15.3
		Week 16	12	9	8.36 (2.92)	5.0	8.05	15.0
		Week 24	12	9	9.14 (3.92)	5.9	7.60	18.1
>= 8 %	Dapa 10mg	Day 1	10	10	11.50 (3.63)	6.4	11.79	16.4
		Week 4	10	8	10.96 (3.34)	6.3	10.96	16.0
		Week 16	10	8	8.41 (2.76)	4.1	7.99	12.8
		Week 24	10	8	10.31 (5.40)	5.0	8.57	20.4
	Placebo	Day 1	12	12	10.38 (2.79)	5.2	9.74	14.5
		Week 4	12	11	11.39 (4.19)	6.9	10.21	22.3
		Week 16	12	7	10.10 (3.11)	7.2	10.05	16.5
		Week 24	12	9	8.42 (2.59)	5.3	8.99	11.9

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group, n = Number of valid observations, SD = Standard deviation, Q50 = median, HbA1c = Glycated haemoglobin, FPG = Fasting plasma glucose, BMI = Body mass index, Europe = Hungary, Israel, Russian Federation.
 Source Data: alb, created on: 29SEP2021

Table T2FG_FSFS: Course of FPG up to Week 24 by subgroup
 PFAS

Course of FPG up to Week 24	Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max
F: Background diabetic medication								
Metformin only	Dapa 10mg	Day 1	11	11	7.20 (1.16)	5.3	6.90	9.3
		Week 4	11	10	5.91 (1.49)	4.4	5.53	9.9
		Week 16	11	10	6.64 (1.34)	4.6	6.30	9.3
		Week 24	11	10	6.94 (2.21)	4.8	5.85	12.2
	Placebo	Day 1	14	14	8.66 (2.84)	4.7	7.85	14.5
		Week 4	14	10	8.13 (1.95)	4.7	8.46	11.8
		Week 16	14	10	7.69 (1.68)	5.0	7.46	10.3
		Week 24	14	11	8.30 (2.67)	5.3	7.60	12.8
Insulin or insulin + metformin	Dapa 10mg	Day 1	18	18	9.91 (3.79)	5.5	9.06	16.4
		Week 4	18	16	8.94 (3.31)	5.0	8.24	16.0
		Week 16	18	16	8.41 (2.84)	4.1	7.55	14.6
		Week 24	18	16	9.20 (4.26)	5.0	7.94	20.4
	Placebo	Day 1	10	10	9.44 (2.53)	5.2	9.02	13.5
		Week 4	10	9	12.24 (4.68)	7.0	11.16	22.3
		Week 16	10	6	11.50 (3.41)	8.5	10.16	16.5
		Week 24	10	7	9.55 (4.11)	5.5	8.99	18.1

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group, n = Number of valid observations, SD = Standard deviation, Q50 = median, HbA1c = Glycated haemoglobin, FPG = Fasting plasma glucose, BMI = Body mass index, Europe = Hungary, Israel, Russian Federation.
 Source Data: alb, created on: 29SEP2021

Table T2FG_FSFS: Course of FPG up to Week 24 by subgroup
 PFAS

Course of FPG up to Week 24	Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max
G: Geographic region								
Europe	Dapa 10mg	Day 1	12	12	8.95 (3.78)	5.3	6.90	16.4
		Week 4	12	11	7.14 (3.29)	4.4	6.30	16.0
		Week 16	12	10	6.79 (2.03)	4.6	6.15	11.3
		Week 24	12	11	8.85 (5.11)	4.8	6.30	20.4
	Placebo	Day 1	3	3	13.23 (1.42)	11.7	13.50	14.5
		Week 4	3	2	9.40 (3.39)	7.0	9.40	11.8
		Week 16	3	2	9.40 (1.27)	8.5	9.40	10.3
		Week 24	3	2	9.55 (2.76)	7.6	9.55	11.5
Non-Europe	Dapa 10mg	Day 1	17	17	8.83 (3.07)	5.5	7.88	15.3
		Week 4	17	15	8.25 (2.98)	5.0	7.60	14.3
		Week 16	17	16	8.32 (2.64)	4.1	7.44	14.6
		Week 24	17	15	7.96 (2.42)	5.0	7.66	13.1
	Placebo	Day 1	21	21	8.38 (2.24)	4.7	8.05	13.5
		Week 4	21	17	10.16 (4.16)	4.7	9.05	22.3
		Week 16	21	14	9.08 (3.24)	5.0	8.35	16.5
		Week 24	21	16	8.69 (3.37)	5.3	8.10	18.1

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group, n = Number of valid observations, SD = Standard deviation, Q50 = median, HbA1c = Glycated haemoglobin, FPG = Fasting plasma glucose, BMI = Body mass index, Europe = Hungary, Israel, Russian Federation.
 Source Data: alb, created on: 29SEP2021

Table T2FGC_FSCS: Change in FPG at Week 24 by subgroup
PFAS

Subgroup	Treatment	Time point	N	n (%)	Repeated measures analysis				
					Change from Baseline		Treatment Difference		p-value
					LS-Mean (SE)	95% CI	LS-Mean (SE)	95% CI	
A: Age	Dapa 10mg	Week 24							0.474
<= 15 years	Dapa 10mg	Week 24	16	14 (87.5)	-1.46 (0.86)	(-3.23, 0.32)	-1.08 (1.32)	(-3.82, 1.66)	0.423
	Placebo	Week 24	14	10 (71.4)	-0.38 (1.01)	(-2.47, 1.72)			
> 15 and < 18 years	Dapa 10mg	Week 24	13	12 (92.3)	0.70 (0.72)	(-0.81, 2.21)	0.40 (1.14)	(-1.99, 2.79)	0.727
	Placebo	Week 24	10	8 (80.0)	0.30 (0.88)	(-1.56, 2.15)			
B: Sex	Dapa 10mg	Week 24							0.741
Male	Dapa 10mg	Week 24	12	10 (83.3)	-1.14 (0.81)	(-2.90, 0.61)	-0.86 (1.40)	(-3.91, 2.19)	0.550
	Placebo	Week 24	9	5 (55.6)	-0.28 (1.14)	(-2.77, 2.21)			
Female	Dapa 10mg	Week 24	17	16 (94.1)	-0.01 (0.90)	(-1.86, 1.84)	-0.06 (1.34)	(-2.82, 2.69)	0.963
	Placebo	Week 24	15	13 (86.7)	0.05 (1.00)	(-1.99, 2.10)			
C: Race	Dapa 10mg	Week 24							0.542
White	Dapa 10mg	Week 24	23	20 (87.0)	-0.44 (0.67)	(-1.82, 0.93)	1.69 (1.43)	(-1.26, 4.64)	0.249
	Placebo	Week 24	9	6 (66.7)	-2.13 (1.25)	(-4.71, 0.45)			
Non-White	Dapa 10mg	Week 24	6	6 (100.0)	-0.11 (1.47)	(-3.24, 3.01)	-0.94 (1.82)	(-4.81, 2.93)	0.613
	Placebo	Week 24	15	12 (80.0)	0.83 (1.03)	(-1.38, 3.03)			
D: Baseline BMI	Dapa 10mg	Week 24							0.509
< 30 kg/m**2	Dapa 10mg	Week 24	15	13 (86.7)	-1.43 (0.74)	(-3.01, 0.16)	-0.94 (1.53)	(-4.21, 2.33)	0.547
	Placebo	Week 24	7	4 (57.1)	-0.49 (1.34)	(-3.35, 2.37)			
>= 30 kg/m**2	Dapa 10mg	Week 24	14	13 (92.9)	0.50 (0.90)	(-1.36, 2.36)	0.49 (1.25)	(-2.08, 3.07)	0.697
	Placebo	Week 24	17	14 (82.4)	0.01 (0.87)	(-1.78, 1.79)			

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group, n = Number of valid observations, SE = Standard error, CI = Confidence interval, FPG = Fasting plasma glucose, LS-Mean = Least square mean. Only results for Week 24 printed. Per subgroup, a mixed repeated measures model was applied with fixed factors for treatment, week, interactions treatment-by-week, baseline-by-week and baseline as covariate. Interaction test utilizes same model with additional interaction effects for subgroup with treatment, subgroup with week and subgroup with week with treatment.
Source Data: alb, created on: 30SEP2021

Table T2FGC_FSCS: Change in FPG at Week 24 by subgroup
PFAS

Subgroup	Treatment	Time point	N	n (%)	Repeated measures analysis				
					Change from Baseline		Treatment Difference		p-value
					LS-Mean (SE)	95% CI	LS-Mean (SE)	95% CI	
E: Baseline HbA1c	Dapa 10mg	Week 24							0.570
< 8 %	Dapa 10mg	Week 24	19	18 (94.7)	-0.12 (0.69)	(-1.55, 1.31)	-1.62 (1.20)	(-4.11, 0.86)	0.189
	Placebo	Week 24	12	9 (75.0)	1.50 (0.98)	(-0.52, 3.53)			
≥ 8 %	Dapa 10mg	Week 24	10	8 (80.0)	-0.76 (1.45)	(-3.86, 2.33)	1.18 (2.04)	(-3.17, 5.54)	0.571
	Placebo	Week 24	12	9 (75.0)	-1.94 (1.38)	(-4.90, 1.01)			
F: Background diabetic medication	Dapa 10mg	Week 24							0.749
Metformin only	Dapa 10mg	Week 24	11	10 (90.9)	-0.73 (0.80)	(-2.41, 0.96)	-1.17 (1.13)	(-3.55, 1.21)	0.317
	Placebo	Week 24	14	11 (78.6)	0.44 (0.77)	(-1.18, 2.06)			
Insulin or insulin + metformin	Dapa 10mg	Week 24	18	16 (88.9)	-0.54 (1.00)	(-2.62, 1.54)	-0.32 (1.83)	(-4.13, 3.49)	0.861
	Placebo	Week 24	10	7 (70.0)	-0.22 (1.53)	(-3.41, 2.97)			
G: Geographic region	Dapa 10mg	Week 24							0.920
Europe	Dapa 10mg	Week 24	12	11 (91.7)	-0.25 (0.80)	(-2.04, 1.53)	3.22 (2.16)	(-1.60, 8.04)	0.167
	Placebo	Week 24	3	2 (66.7)	-3.48 (1.98)	(-7.89, 0.94)			
Non-Europe	Dapa 10mg	Week 24	17	15 (88.2)	-0.56 (0.77)	(-2.14, 1.01)	-0.68 (1.07)	(-2.87, 1.52)	0.534
	Placebo	Week 24	21	16 (76.2)	0.12 (0.75)	(-1.42, 1.65)			

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group, n = Number of valid observations, SE = Standard error, CI = Confidence interval, FPG = Fasting plasma glucose, LS-Mean = Least square mean. Only results for Week 24 printed. Per subgroup, a mixed repeated measures model was applied with fixed factors for treatment, week, interactions treatment-by-week, baseline-by-week and baseline as covariate. Interaction test utilizes same model with additional interaction effects for subgroup with treatment, subgroup with week and subgroup with week with treatment.
Source Data: alb, created on: 30SEP2021

Table T2FGC_FSHS: Hedges G for Change in FPG up to Week 24 by subgroup
 PFAS

Hedges G for Change in FPG up to Week 24	Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max	Hedges G		
									Effect size (SD)	95% CI	
A: Age											
<= 15 years	Dapa 10mg	Week 4	16	14	-1.36 (1.35)	-3.8	-1.18	1.0	-0.63 (0.41)	[-1.44, 0.18]	
		Week 16	16	15	-1.27 (4.34)	-11.2	-1.11	9.0	-0.54 (0.43)	[-1.38, 0.30]	
		Week 24	16	14	-1.41 (4.04)	-10.3	-1.11	5.2	-0.24 (0.42)	[-1.06, 0.57]	
	Placebo	Week 4	14	11	0.22 (3.46)	-4.8	0.06	6.8			
		Week 16	14	9	0.85 (3.00)	-3.2	0.33	6.5			
		Week 24	14	10	-0.30 (5.19)	-5.7	-1.44	9.6			
> 15 and < 18 years	Dapa 10mg	Week 4	13	12	-0.87 (3.49)	-9.0	-0.25	5.6	-0.64 (0.47)	[-1.56, 0.28]	
		Week 16	13	11	-0.54 (2.25)	-5.1	0.20	2.1	-0.06 (0.48)	[-1.00, 0.89]	
		Week 24	13	12	0.68 (2.55)	-3.9	0.17	5.7	0.12 (0.46)	[-0.77, 1.02]	
	Placebo	Week 4	10	8	2.15 (6.16)	-1.7	0.31	17.1			
		Week 16	10	7	-0.42 (1.88)	-3.2	-0.83	2.4			
		Week 24	10	8	0.39 (2.22)	-2.1	-0.08	4.6			

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group,
 n = Number of valid observations, Q50 = Median, SD = Standard deviation, CI = Confidence interval,
 FPG = Fasting plasma glucose.
 Source Data: alb, created on: 30SEP2021

Table T2FGC_FSHS: Hedges G for Change in FPG up to Week 24 by subgroup
 PFAS

Hedges G for Change in FPG up to Week 24	Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max	Hedges G		
									Effect size (SD)	95% CI	
B: Sex											
Male	Dapa 10mg	Week 4	12	10	-0.79 (2.67)	-3.8	-0.89	5.6	-0.62 (0.53)	[-1.66, 0.41]	
		Week 16	12	11	-1.71 (3.80)	-11.2	-0.55	2.1	-0.53 (0.55)	[-1.60, 0.55]	
		Week 24	12	10	-1.12 (4.08)	-10.3	-0.25	3.9	-0.25 (0.55)	[-1.32, 0.83]	
	Placebo	Week 4	9	6	0.78 (2.19)	-1.4	0.31	4.6			
		Week 16	9	5	0.00 (0.90)	-0.9	0.06	1.3			
		Week 24	9	5	-0.19 (3.10)	-3.5	-0.55	4.6			
Female	Dapa 10mg	Week 4	17	16	-1.35 (2.50)	-9.0	-1.18	1.3	-0.60 (0.38)	[-1.35, 0.15]	
		Week 16	17	15	-0.41 (3.41)	-5.1	-1.00	9.0	-0.26 (0.40)	[-1.04, 0.52]	
		Week 24	17	16	-0.02 (3.21)	-7.5	-0.15	5.7	-0.02 (0.37)	[-0.76, 0.71]	
	Placebo	Week 4	15	13	1.16 (5.61)	-4.8	0.06	17.1			
		Week 16	15	11	0.43 (3.09)	-3.2	0.33	6.5			
		Week 24	15	13	0.08 (4.47)	-5.7	0.00	9.6			

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group,
 n = Number of valid observations, Q50 = Median, SD = Standard deviation, CI = Confidence interval,
 FPG = Fasting plasma glucose.
 Source Data: alb, created on: 30SEP2021

Table T2FGC_FSHS: Hedges G for Change in FPG up to Week 24 by subgroup
 PFAS

Hedges G for Change in FPG up to Week 24	Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max	Hedges G		
									Effect size (SD)	95% CI	
C: Race											
White	Dapa 10mg	Week 4	23	20	-1.57 (2.19)	-9.0	-1.14	1.3	-0.48 (0.44)	[-1.35, 0.39]	
		Week 16	23	20	-1.34 (3.77)	-11.2	-0.94	9.0	-0.24 (0.47)	[-1.16, 0.67]	
		Week 24	23	20	-0.30 (3.37)	-10.3	-0.35	5.7	0.73 (0.48)	[-0.21, 1.66]	
	Placebo	Week 4	9	7	-0.43 (2.82)	-4.7	-0.89	4.6			
		Week 16	9	6	-0.48 (2.47)	-3.2	-0.39	3.0			
		Week 24	9	6	-2.57 (1.84)	-4.3	-2.80	0.6			
Non-White	Dapa 10mg	Week 4	6	6	0.31 (3.24)	-4.2	0.42	5.6	-0.32 (0.50)	[-1.31, 0.66]	
		Week 16	6	6	0.31 (2.67)	-4.2	0.86	3.3	-0.17 (0.52)	[-1.19, 0.84]	
		Week 24	6	6	-0.92 (4.35)	-7.5	0.17	5.2	-0.51 (0.51)	[-1.51, 0.48]	
	Placebo	Week 4	15	12	1.89 (5.49)	-4.8	0.19	17.1			
		Week 16	15	10	0.77 (2.65)	-2.8	0.36	6.5			
		Week 24	15	12	1.29 (4.29)	-5.7	1.14	9.6			

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group,
 n = Number of valid observations, Q50 = Median, SD = Standard deviation, CI = Confidence interval,
 FPG = Fasting plasma glucose.
 Source Data: alb, created on: 30SEP2021

Table T2FGC_FSHS: Hedges G for Change in FPG up to Week 24 by subgroup
 PFAS

Hedges G for Change in FPG up to Week 24	Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max	Hedges G		
									Effect size (SD)	95% CI	
D: Baseline BMI											
< 30 kg/m**2	Dapa 10mg	Week 4	15	14	-1.10 (1.53)	-4.2	-1.07	1.1	-0.83 (0.65)	[-2.12, 0.45]	
		Week 16	15	14	-1.54 (3.39)	-11.2	-1.05	3.3	-0.72 (0.58)	[-1.85, 0.42]	
		Week 24	15	13	-1.39 (4.24)	-10.3	-1.00	5.2	-0.27 (0.57)	[-1.39, 0.86]	
	Placebo	Week 4	7	3	0.80 (4.88)	-4.7	2.50	4.6			
		Week 16	7	4	0.81 (2.75)	-3.2	1.83	2.8			
		Week 24	7	4	-0.21 (4.99)	-4.1	-1.75	6.8			
≥ 30 kg/m**2	Dapa 10mg	Week 4	14	12	-1.17 (3.42)	-9.0	-0.97	5.6	-0.52 (0.39)	[-1.28, 0.24]	
		Week 16	14	12	-0.28 (3.79)	-5.1	-0.23	9.0	-0.13 (0.41)	[-0.93, 0.68]	
		Week 24	14	13	0.50 (2.47)	-4.1	0.00	5.7	0.13 (0.39)	[-0.62, 0.89]	
	Placebo	Week 4	17	16	1.08 (4.86)	-4.8	-0.06	17.1			
		Week 16	17	12	0.13 (2.62)	-3.2	-0.11	6.5			
		Week 24	17	14	0.06 (3.96)	-5.7	0.22	9.6			

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group,
 n = Number of valid observations, Q50 = Median, SD = Standard deviation, CI = Confidence interval,
 FPG = Fasting plasma glucose.
 Source Data: alb, created on: 30SEP2021

Table T2FGC_FSHS: Hedges G for Change in FPG up to Week 24 by subgroup
 PFAS

Hedges G for Change in FPG up to Week 24	Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max	Hedges G		
									Effect size (SD)	95% CI	
E: Baseline HbA1c											
< 8 %	Dapa 10mg	Week 4	19	18	-1.18 (1.66)	-4.2	-0.97	1.1	-0.78 (0.44)	[-1.64, 0.08]	
		Week 16	19	18	-0.12 (3.06)	-4.9	-0.23	9.0	-0.25 (0.41)	[-1.06, 0.55]	
		Week 24	19	18	-0.09 (2.59)	-4.1	-0.35	5.2	-0.47 (0.41)	[-1.28, 0.34]	
	Placebo	Week 4	12	8	0.56 (3.24)	-4.7	0.19	6.8			
		Week 16	12	9	0.65 (2.88)	-3.2	0.06	6.5			
		Week 24	12	9	1.43 (4.24)	-4.1	0.61	9.6			
≥ 8 %	Dapa 10mg	Week 4	10	8	-1.03 (4.01)	-9.0	-1.05	5.6	-0.48 (0.47)	[-1.40, 0.45]	
		Week 16	10	8	-2.86 (4.09)	-11.2	-2.30	2.1	-0.80 (0.54)	[-1.86, 0.26]	
		Week 24	10	8	-1.24 (5.22)	-10.3	0.14	5.7	0.04 (0.49)	[-0.91, 0.99]	
	Placebo	Week 4	12	11	1.38 (5.71)	-4.8	-0.17	17.1			
		Week 16	12	7	-0.16 (2.26)	-3.2	0.39	3.0			
		Week 24	12	9	-1.42 (3.50)	-5.7	-2.00	4.6			

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group,
 n = Number of valid observations, Q50 = Median, SD = Standard deviation, CI = Confidence interval,
 FPG = Fasting plasma glucose.

Source Data: alb, created on: 30SEP2021

Table T2FGC_FSHS: Hedges G for Change in FPG up to Week 24 by subgroup
 PFAS

Hedges G for Change in FPG up to Week 24	Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max	Hedges G	
									Effect size (SD)	95% CI
F: Background diabetic medication										
Metformin only	Dapa 10mg	Week 4	11	10	-1.34 (1.44)	-3.8	-1.16	1.1	-0.61 (0.46)	[-1.51, 0.29]
		Week 16	11	10	-0.61 (1.40)	-3.3	-0.68	1.0	-0.18 (0.45)	[-1.06, 0.70]
		Week 24	11	10	-0.31 (1.97)	-3.4	-0.75	3.9	-0.09 (0.44)	[-0.95, 0.77]
	Placebo	Week 4	14	10	-0.27 (2.00)	-4.8	-0.14	2.5		
		Week 16	14	10	-0.30 (1.97)	-3.2	-0.11	2.8		
		Week 24	14	11	-0.04 (3.65)	-5.7	0.00	6.8		
Insulin or insulin + metformin	Dapa 10mg	Week 4	18	16	-1.01 (3.06)	-9.0	-0.94	5.6	-0.77 (0.43)	[-1.62, 0.07]
		Week 16	18	16	-1.18 (4.46)	-11.2	-1.25	9.0	-0.59 (0.49)	[-1.54, 0.37]
		Week 24	18	16	-0.53 (4.30)	-10.3	-0.05	5.7	-0.13 (0.45)	[-1.02, 0.76]
	Placebo	Week 4	10	9	2.49 (6.43)	-4.7	0.06	17.1		
		Week 16	10	6	1.30 (3.31)	-3.2	1.19	6.5		
		Week 24	10	7	0.06 (4.93)	-4.3	-0.55	9.6		

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group,
 n = Number of valid observations, Q50 = Median, SD = Standard deviation, CI = Confidence interval,
 FPG = Fasting plasma glucose.
 Source Data: alb, created on: 30SEP2021

Table T2FGC_FSHS: Hedges G for Change in FPG up to Week 24 by subgroup
 PFAS

Hedges G for Change in FPG up to Week 24	Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max	Hedges G	
									Effect size (SD)	95% CI
G: Geographic region										
Europe	Dapa 10mg	Week 4	12	11	-2.02 (2.81)	-9.0	-1.30	1.3	0.43 (0.77)	[-1.09, 1.95]
		Week 16	12	10	-1.81 (2.10)	-5.1	-1.50	1.0	0.70 (0.79)	[-0.85, 2.25]
		Week 24	12	11	-0.31 (2.66)	-4.1	-0.50	5.7	1.06 (0.80)	[-0.51, 2.64]
	Placebo	Week 4	3	2	-3.20 (2.12)	-4.7	-3.20	-1.7		
		Week 16	3	2	-3.20 (0.00)	-3.2	-3.20	-3.2		
		Week 24	3	2	-3.05 (1.48)	-4.1	-3.05	-2.0		
Non-Europe	Dapa 10mg	Week 4	17	15	-0.48 (2.16)	-4.2	-0.94	5.6	-0.54 (0.36)	[-1.24, 0.17]
		Week 16	17	16	-0.43 (4.21)	-11.2	0.00	9.0	-0.35 (0.37)	[-1.08, 0.37]
		Week 24	17	15	-0.54 (4.15)	-10.3	0.33	5.2	-0.22 (0.36)	[-0.93, 0.48]
	Placebo	Week 4	21	17	1.53 (4.73)	-4.8	0.06	17.1		
		Week 16	21	14	0.80 (2.35)	-2.8	0.36	6.5		
		Week 24	21	16	0.39 (4.13)	-5.7	0.31	9.6		

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group,
 n = Number of valid observations, Q50 = Median, SD = Standard deviation, CI = Confidence interval,
 FPG = Fasting plasma glucose.
 Source Data: alb, created on: 30SEP2021

Table T2HA_FSFS: Course of HbA1c up to Week 24 by subgroup
 PFAS

Course of HbA1c up to Week 24	Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max
A: Age								
<= 15 years	Dapa 10mg	Day 1	16	16	7.72 (1.57)	5.4	7.15	11.1
		Week 4	16	13	7.32 (1.71)	5.0	7.00	10.8
		Week 8	16	14	7.05 (1.56)	5.2	6.70	10.8
		Week 16	16	15	7.18 (1.36)	5.0	7.00	9.9
		Week 24	16	14	7.42 (1.91)	4.9	7.05	12.3
	Placebo	Day 1	14	14	7.83 (1.07)	6.5	7.65	9.7
		Week 4	14	12	7.83 (1.02)	6.5	7.60	10.1
		Week 8	14	11	7.90 (1.09)	6.3	7.90	10.3
		Week 16	14	11	8.02 (1.53)	6.2	8.00	11.4
		Week 24	14	11	8.20 (1.87)	6.1	7.50	12.1
> 15 and < 18 years	Dapa 10mg	Day 1	13	13	7.89 (1.81)	5.7	7.50	12.4
		Week 4	13	12	7.39 (1.91)	5.5	7.00	11.9
		Week 8	13	13	7.56 (2.00)	5.5	7.00	12.2
		Week 16	13	11	7.33 (2.17)	5.2	6.80	12.7
		Week 24	13	12	7.58 (2.23)	5.0	6.95	12.6
	Placebo	Day 1	10	10	8.35 (1.15)	6.7	8.30	10.5
		Week 4	10	8	8.28 (1.14)	7.0	8.05	10.2
		Week 8	10	8	8.96 (2.04)	7.1	8.25	13.1
		Week 16	10	7	7.91 (0.89)	6.5	7.80	9.3
		Week 24	10	8	8.89 (2.87)	5.9	8.40	15.3

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group, n = Number of valid observations, SD = Standard deviation, Q50 = median, HbA1c = Glycated haemoglobin, FPG = Fasting plasma glucose, BMI = Body mass index, Europe = Hungary, Israel, Russian Federation.
 Source Data: alb, created on: 29SEP2021

Table T2HA_FSFS: Course of HbA1c up to Week 24 by subgroup
 PFAS

Course of HbA1c up to Week 24	Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max
B: Sex								
Male	Dapa 10mg	Day 1	12	12	7.72 (1.94)	5.4	7.50	12.4
		Week 4	12	11	7.13 (1.94)	5.0	6.60	11.9
		Week 8	12	11	7.25 (2.03)	5.3	6.40	12.2
		Week 16	12	12	7.37 (2.13)	5.0	6.90	12.7
		Week 24	12	10	6.74 (1.26)	4.9	6.55	9.1
	Placebo	Day 1	9	9	8.27 (1.28)	6.7	8.10	10.5
		Week 4	9	6	8.33 (1.16)	7.0	8.05	10.2
		Week 8	9	5	8.06 (1.13)	7.0	8.10	9.8
		Week 16	9	5	7.64 (0.89)	6.5	8.00	8.5
		Week 24	9	5	8.04 (1.42)	5.9	8.70	9.2
Female	Dapa 10mg	Day 1	17	17	7.85 (1.47)	6.2	7.30	11.1
		Week 4	17	14	7.53 (1.68)	5.4	7.05	10.8
		Week 8	17	16	7.33 (1.64)	5.2	7.05	10.8
		Week 16	17	14	7.14 (1.32)	5.2	6.95	9.9
		Week 24	17	16	7.96 (2.29)	5.0	7.45	12.6
	Placebo	Day 1	15	15	7.91 (1.02)	6.5	7.60	9.7
		Week 4	15	14	7.86 (1.04)	6.5	7.60	10.1
		Week 8	15	14	8.45 (1.77)	6.3	8.05	13.1
		Week 16	15	13	8.11 (1.42)	6.2	7.90	11.4
		Week 24	15	14	8.65 (2.57)	6.1	7.85	15.3

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group, n = Number of valid observations, SD = Standard deviation, Q50 = median, HbA1c = Glycated haemoglobin, FPG = Fasting plasma glucose, BMI = Body mass index, Europe = Hungary, Israel, Russian Federation.
 Source Data: alb, created on: 29SEP2021

Table T2HA_FSFS: Course of HbA1c up to Week 24 by subgroup
 PFAS

Course of HbA1c up to Week 24	Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max
C: Race								
White	Dapa 10mg	Day 1	23	23	7.76 (1.76)	5.4	7.10	12.4
		Week 4	23	19	7.09 (1.81)	5.0	6.40	11.9
		Week 8	23	21	6.98 (1.73)	5.2	6.40	12.2
		Week 16	23	20	6.88 (1.68)	5.0	6.45	12.7
		Week 24	23	20	7.07 (1.89)	4.9	6.45	12.6
	Placebo	Day 1	9	9	8.21 (1.13)	6.7	8.50	9.7
		Week 4	9	7	8.39 (1.03)	7.0	8.50	10.1
		Week 8	9	7	8.14 (1.09)	7.0	8.10	10.3
		Week 16	9	7	8.21 (1.60)	6.5	8.00	11.4
		Week 24	9	6	7.60 (1.10)	5.9	7.60	9.1
Non-White	Dapa 10mg	Day 1	6	6	7.95 (1.26)	7.1	7.40	10.4
		Week 4	6	6	8.18 (1.46)	6.9	7.85	10.8
		Week 8	6	6	8.40 (1.58)	7.0	8.00	10.8
		Week 16	6	6	8.45 (1.24)	6.9	8.50	9.9
		Week 24	6	6	8.90 (1.94)	7.2	8.45	12.3
	Placebo	Day 1	15	15	7.95 (1.13)	6.5	7.60	10.5
		Week 4	15	13	7.80 (1.06)	6.5	7.60	10.2
		Week 8	15	12	8.47 (1.87)	6.3	8.10	13.1
		Week 16	15	11	7.83 (1.10)	6.2	7.90	9.3
		Week 24	15	13	8.90 (2.61)	6.1	8.10	15.3

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group, n = Number of valid observations, SD = Standard deviation, Q50 = median, HbA1c = Glycated haemoglobin, FPG = Fasting plasma glucose, BMI = Body mass index, Europe = Hungary, Israel, Russian Federation.
 Source Data: alb, created on: 29SEP2021

Table T2HA_FSFS: Course of HbA1c up to Week 24 by subgroup
 PFAS

Course of HbA1c up to Week 24	Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max
D: Baseline BMI								
< 30 kg/m**2	Dapa 10mg	Day 1	15	15	8.05 (1.96)	5.7	7.30	12.4
		Week 4	15	14	7.64 (1.99)	5.5	7.00	11.9
		Week 8	15	14	7.53 (1.96)	5.5	6.90	12.2
		Week 16	15	15	7.49 (2.00)	5.2	6.90	12.7
		Week 24	15	13	7.25 (1.99)	5.0	6.70	12.3
	Placebo	Day 1	7	7	7.73 (1.11)	6.7	7.30	9.7
		Week 4	7	5	7.82 (0.75)	7.2	7.60	9.1
		Week 8	7	4	7.95 (0.42)	7.4	8.00	8.4
		Week 16	7	5	7.84 (0.70)	6.8	8.00	8.7
		Week 24	7	5	8.16 (1.92)	6.5	7.10	11.1
>= 30 kg/m**2	Dapa 10mg	Day 1	14	14	7.53 (1.25)	5.4	7.40	10.5
		Week 4	14	11	6.99 (1.46)	5.0	7.00	10.2
		Week 8	14	13	7.05 (1.58)	5.2	6.90	10.6
		Week 16	14	11	6.90 (1.21)	5.0	7.00	9.6
		Week 24	14	13	7.73 (2.11)	4.9	7.60	12.6
	Placebo	Day 1	17	17	8.18 (1.12)	6.5	8.10	10.5
		Week 4	17	15	8.07 (1.17)	6.5	7.80	10.2
		Week 8	17	15	8.45 (1.79)	6.3	8.20	13.1
		Week 16	17	13	8.03 (1.47)	6.2	7.90	11.4
		Week 24	17	14	8.61 (2.47)	5.9	8.00	15.3

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group, n = Number of valid observations, SD = Standard deviation, Q50 = median, HbA1c = Glycated haemoglobin, FPG = Fasting plasma glucose, BMI = Body mass index, Europe = Hungary, Israel, Russian Federation.
 Source Data: alb, created on: 29SEP2021

Table T2HA_FSFS: Course of HbA1c up to Week 24 by subgroup
 PFAS

Course of HbA1c up to Week 24	Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max
E: Baseline HbA1c								
< 8 %	Dapa 10mg	Day 1	19	19	6.85 (0.65)	5.4	6.90	7.9
		Week 4	19	17	6.44 (0.91)	5.0	6.30	8.7
		Week 8	19	18	6.42 (0.87)	5.2	6.25	8.9
		Week 16	19	18	6.55 (1.01)	5.0	6.40	9.0
		Week 24	19	18	6.68 (1.21)	4.9	6.45	9.7
	Placebo	Day 1	12	12	7.14 (0.44)	6.5	7.20	7.7
		Week 4	12	10	7.24 (0.45)	6.5	7.35	7.8
		Week 8	12	9	7.37 (0.73)	6.3	7.40	8.4
		Week 16	12	10	7.36 (1.04)	6.2	7.15	9.2
		Week 24	12	10	7.80 (2.11)	5.9	7.05	12.1
>= 8 %	Dapa 10mg	Day 1	10	10	9.60 (1.45)	8.1	9.15	12.4
		Week 4	10	8	9.29 (1.60)	7.1	9.05	11.9
		Week 8	10	9	9.04 (1.85)	6.4	8.20	12.2
		Week 16	10	8	8.80 (1.98)	6.4	8.50	12.7
		Week 24	10	8	9.33 (2.35)	6.1	9.00	12.6
	Placebo	Day 1	12	12	8.95 (0.77)	8.0	8.70	10.5
		Week 4	12	10	8.77 (0.94)	7.6	8.55	10.2
		Week 8	12	10	9.23 (1.68)	7.8	8.35	13.1
		Week 16	12	8	8.75 (1.18)	7.8	8.40	11.4
		Week 24	12	9	9.26 (2.37)	7.5	8.70	15.3

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group, n = Number of valid observations, SD = Standard deviation, Q50 = median, HbA1c = Glycated haemoglobin, FPG = Fasting plasma glucose, BMI = Body mass index, Europe = Hungary, Israel, Russian Federation.
 Source Data: alb, created on: 29SEP2021

Table T2HA_FSFS: Course of HbA1c up to Week 24 by subgroup
 PFAS

Course of HbA1c up to Week 24	Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max
F: Background diabetic medication								
Metformin only	Dapa 10mg	Day 1	11	11	6.71 (0.62)	5.4	6.90	7.6
		Week 4	11	9	6.00 (0.62)	5.0	6.00	6.9
		Week 8	11	10	6.12 (0.66)	5.2	6.20	7.1
		Week 16	11	10	6.30 (0.91)	5.0	6.25	8.0
		Week 24	11	10	6.32 (0.97)	4.9	6.15	8.4
	Placebo	Day 1	14	14	7.61 (0.93)	6.5	7.55	9.7
		Week 4	14	11	7.48 (0.66)	6.5	7.60	8.6
		Week 8	14	11	7.48 (0.71)	6.3	7.40	8.4
		Week 16	14	10	7.35 (0.87)	6.2	7.50	8.7
		Week 24	14	11	7.65 (1.49)	5.9	7.50	11.1
Insulin or insulin + metformin	Dapa 10mg	Day 1	18	18	8.46 (1.74)	5.7	8.15	12.4
		Week 4	18	16	8.11 (1.76)	5.8	7.75	11.9
		Week 8	18	17	7.99 (1.87)	5.7	7.70	12.2
		Week 16	18	16	7.83 (1.85)	5.2	7.20	12.7
		Week 24	18	16	8.23 (2.18)	5.0	7.70	12.6
	Placebo	Day 1	10	10	8.65 (1.09)	7.1	8.65	10.5
		Week 4	10	9	8.64 (1.15)	7.2	8.50	10.2
		Week 8	10	8	9.54 (1.76)	7.9	9.10	13.1
		Week 16	10	8	8.76 (1.33)	6.8	8.65	11.4
		Week 24	10	8	9.64 (2.79)	7.0	8.90	15.3

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group, n = Number of valid observations, SD = Standard deviation, Q50 = median, HbA1c = Glycated haemoglobin, FPG = Fasting plasma glucose, BMI = Body mass index, Europe = Hungary, Israel, Russian Federation.
 Source Data: alb, created on: 29SEP2021

Table T2HA_FSFS: Course of HbA1c up to Week 24 by subgroup
 PFAS

Course of HbA1c up to Week 24	Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max
G: Geographic region								
Europe	Dapa 10mg	Day 1	12	12	7.69 (1.62)	6.2	7.25	11.1
		Week 4	12	10	6.92 (1.65)	5.4	6.20	10.2
		Week 8	12	11	6.84 (1.54)	5.2	6.30	10.6
		Week 16	12	9	6.29 (0.93)	5.2	6.20	8.1
		Week 24	12	11	7.30 (2.38)	5.0	6.20	12.6
	Placebo	Day 1	3	3	8.60 (1.05)	7.6	8.50	9.7
		Week 4	3	2	8.20 (0.57)	7.8	8.20	8.6
		Week 8	3	2	8.05 (0.21)	7.9	8.05	8.2
		Week 16	3	2	7.95 (0.21)	7.8	7.95	8.1
		Week 24	3	2	7.50 (0.57)	7.1	7.50	7.9
Non-Europe	Dapa 10mg	Day 1	17	17	7.87 (1.71)	5.4	7.30	12.4
		Week 4	17	15	7.64 (1.85)	5.0	7.10	11.9
		Week 8	17	16	7.61 (1.89)	5.3	7.05	12.2
		Week 16	17	17	7.75 (1.83)	5.0	7.30	12.7
		Week 24	17	15	7.63 (1.79)	4.9	7.30	12.3
	Placebo	Day 1	21	21	7.97 (1.12)	6.5	7.70	10.5
		Week 4	21	18	7.98 (1.11)	6.5	7.60	10.2
		Week 8	21	17	8.38 (1.70)	6.3	8.10	13.1
		Week 16	21	16	7.98 (1.37)	6.2	7.95	11.4
		Week 24	21	17	8.61 (2.40)	5.9	8.10	15.3

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group, n = Number of valid observations, SD = Standard deviation, Q50 = median, HbA1c = Glycated haemoglobin, FPG = Fasting plasma glucose, BMI = Body mass index, Europe = Hungary, Israel, Russian Federation.
 Source Data: alb, created on: 29SEP2021

Table T2HAC_FSCS: Change in HbA1c at Week 24 by subgroup
PFAS

Subgroup	Treatment	Time point	N	n (%)	Repeated measures analysis				
					Change from Baseline		Treatment Difference		p-value
					LS-Mean (SE)	95% CI	LS-Mean (SE)	95% CI	
A: Age	Dapa 10mg	Week 24							0.578
<= 15 years	Dapa 10mg	Week 24	16	14 (87.5)	-0.13 (0.46)	(-1.07, 0.82)	-1.01 (0.69)	(-2.43, 0.41)	0.156
	Placebo	Week 24	14	11 (78.6)	0.88 (0.51)	(-0.18, 1.94)			
> 15 and < 18 years	Dapa 10mg	Week 24	13	12 (92.3)	0.24 (0.53)	(-0.86, 1.34)	0.14 (0.85)	(-1.64, 1.91)	0.875
	Placebo	Week 24	10	8 (80.0)	0.10 (0.66)	(-1.27, 1.47)			
B: Sex	Dapa 10mg	Week 24							0.209
Male	Dapa 10mg	Week 24	12	10 (83.3)	-0.23 (0.36)	(-0.99, 0.53)	0.25 (0.65)	(-1.14, 1.65)	0.704
	Placebo	Week 24	9	5 (55.6)	-0.48 (0.53)	(-1.62, 0.66)			
Female	Dapa 10mg	Week 24	17	16 (94.1)	0.08 (0.48)	(-0.90, 1.07)	-0.91 (0.70)	(-2.33, 0.52)	0.203
	Placebo	Week 24	15	14 (93.3)	0.99 (0.50)	(-0.04, 2.02)			
C: Race	Dapa 10mg	Week 24							0.281
White	Dapa 10mg	Week 24	23	20 (87.0)	-0.27 (0.28)	(-0.85, 0.32)	-0.23 (0.58)	(-1.43, 0.97)	0.698
	Placebo	Week 24	9	6 (66.7)	-0.04 (0.51)	(-1.09, 1.01)			
Non-White	Dapa 10mg	Week 24	6	6 (100.0)	0.95 (0.88)	(-0.91, 2.81)	0.08 (1.06)	(-2.16, 2.32)	0.941
	Placebo	Week 24	15	13 (86.7)	0.87 (0.59)	(-0.37, 2.11)			
D: Baseline BMI	Dapa 10mg	Week 24							0.666
< 30 kg/m**2	Dapa 10mg	Week 24	15	13 (86.7)	-0.12 (0.48)	(-1.15, 0.91)	-0.77 (0.95)	(-2.80, 1.27)	0.434
	Placebo	Week 24	7	5 (71.4)	0.65 (0.82)	(-1.10, 2.40)			
>= 30 kg/m**2	Dapa 10mg	Week 24	14	13 (92.9)	0.30 (0.51)	(-0.74, 1.35)	-0.18 (0.71)	(-1.64, 1.28)	0.805
	Placebo	Week 24	17	14 (82.4)	0.48 (0.48)	(-0.50, 1.46)			

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group, n = Number of valid observations, SE = Standard error, CI = Confidence interval, HbA1c = Glycated haemoglobin, LS-Mean = Least square mean. Only results for Week 24 printed.
Per subgroup, a mixed repeated measures model was applied with fixed factors for treatment, week, interactions treatment-by-week, baseline-by-week and baseline as covariate.
Interaction test utilizes same model with additional interaction effects for subgroup with treatment, subgroup with week and subgroup with week with treatment.
Source Data: alb, created on: 30SEP2021

Table T2HAC_FSCS: Change in HbA1c at Week 24 by subgroup
PFAS

Subgroup	Treatment	Time point	N	n (%)	Repeated measures analysis				
					Change from Baseline		Treatment Difference		p-value
					LS-Mean (SE)	95% CI	LS-Mean (SE)	95% CI	
E: Baseline HbA1c	Dapa 10mg	Week 24							0.713
< 8 %	Dapa 10mg	Week 24	19	18 (94.7)	-0.13 (0.36)	(-0.88, 0.61)	-0.81 (0.62)	(-2.08, 0.47)	0.204
	Placebo	Week 24	12	10 (83.3)	0.67 (0.49)	(-0.34, 1.68)			
≥ 8 %	Dapa 10mg	Week 24	10	8 (80.0)	0.18 (0.71)	(-1.31, 1.67)	-0.53 (1.01)	(-2.65, 1.60)	0.609
	Placebo	Week 24	12	9 (75.0)	0.70 (0.69)	(-0.74, 2.15)			
F: Background diabetic medication	Dapa 10mg	Week 24							0.485
Metformin only	Dapa 10mg	Week 24	11	10 (90.9)	-0.36 (0.41)	(-1.21, 0.49)	-0.56 (0.61)	(-1.85, 0.72)	0.368
	Placebo	Week 24	14	11 (78.6)	0.20 (0.39)	(-0.61, 1.02)			
Insulin or insulin + metformin	Dapa 10mg	Week 24	18	16 (88.9)	0.23 (0.51)	(-0.83, 1.29)	-0.92 (0.88)	(-2.73, 0.90)	0.308
	Placebo	Week 24	10	8 (80.0)	1.15 (0.71)	(-0.32, 2.62)			
G: Geographic region	Dapa 10mg	Week 24							0.371
Europe	Dapa 10mg	Week 24	12	11 (91.7)	-0.40 (0.43)	(-1.36, 0.55)	0.19 (1.10)	(-2.25, 2.63)	0.864
	Placebo	Week 24	3	2 (66.7)	-0.60 (1.01)	(-2.85, 1.65)			
Non-Europe	Dapa 10mg	Week 24	17	15 (88.2)	0.26 (0.46)	(-0.68, 1.20)	-0.47 (0.64)	(-1.77, 0.82)	0.465
	Placebo	Week 24	21	17 (81.0)	0.73 (0.44)	(-0.16, 1.62)			

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group, n = Number of valid observations, SE = Standard error, CI = Confidence interval, HbA1c = Glycated haemoglobin, LS-Mean = Least square mean. Only results for Week 24 printed.
Per subgroup, a mixed repeated measures model was applied with fixed factors for treatment, week, interactions treatment-by-week, baseline-by-week and baseline as covariate.
Interaction test utilizes same model with additional interaction effects for subgroup with treatment, subgroup with week and subgroup with week with treatment.
Source Data: alb, created on: 30SEP2021

Table T2HAC_FSHS: Hedges G for Change in HbA1c up to Week 24 by subgroup
 PFAS

Hedges G for Change in HbA1c up to Week 24	Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max	Hedges G	
									Effect size (SD)	95% CI
A: Age										
<= 15 years	Dapa 10mg	Week 4	16	13	-0.39 (0.77)	-1.7	-0.60	1.6	-0.75 (0.42)	[-1.57, 0.06]
		Week 8	16	14	-0.60 (1.05)	-3.0	-0.80	1.8	-0.74 (0.42)	[-1.56, 0.08]
		Week 16	16	15	-0.55 (1.12)	-3.0	-0.50	1.9	-0.79 (0.41)	[-1.60, 0.02]
		Week 24	16	14	-0.23 (1.38)	-2.5	-0.45	2.6	-0.51 (0.41)	[-1.32, 0.29]
	Placebo	Week 4	14	12	0.06 (0.31)	-0.4	0.00	0.7		
		Week 8	14	11	0.07 (0.68)	-0.7	-0.10	1.5		
		Week 16	14	11	0.30 (1.00)	-0.8	-0.10	1.8		
		Week 24	14	11	0.61 (1.90)	-0.5	-0.20	4.6		
> 15 and < 18 years	Dapa 10mg	Week 4	13	12	-0.45 (0.36)	-1.0	-0.50	0.1	-1.22 (0.50)	[-2.19, -0.24]
		Week 8	13	13	-0.33 (0.73)	-1.7	-0.40	1.3	-0.77 (0.47)	[-1.69, 0.14]
		Week 16	13	11	-0.27 (1.09)	-2.4	-0.10	1.4	0.19 (0.48)	[-0.76, 1.14]
		Week 24	13	12	0.06 (1.44)	-2.6	-0.15	2.1	-0.19 (0.46)	[-1.08, 0.71]
	Placebo	Week 4	10	8	-0.06 (0.24)	-0.3	-0.05	0.3		
		Week 8	10	8	0.49 (1.46)	-0.7	0.00	3.9		
		Week 16	10	7	-0.46 (0.74)	-2.0	-0.20	0.3		
		Week 24	10	8	0.41 (2.43)	-1.8	-0.30	6.1		

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group,
 n = Number of valid observations, Q50 = Median, SD = Standard deviation, CI = Confidence interval,
 HbA1c = Glycated haemoglobin.
 Source Data: alb, created on: 30SEP2021

Table T2HAC_FSHS: Hedges G for Change in HbA1c up to Week 24 by subgroup
 PFAS

Hedges G for Change in HbA1c up to Week 24	Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max	Hedges G	
									Effect size (SD)	95% CI
B: Sex										
Male	Dapa 10mg	Week 4	12	11	-0.49 (0.39)	-1.0	-0.50	0.1	-1.18 (0.55)	[-2.26, -0.10]
		Week 8	12	11	-0.37 (0.84)	-1.7	-0.20	1.3	0.04 (0.54)	[-1.02, 1.09]
		Week 16	12	12	-0.35 (1.03)	-2.5	-0.15	1.4	0.49 (0.54)	[-0.57, 1.55]
		Week 24	12	10	-0.40 (1.21)	-2.5	-0.35	1.3	0.02 (0.55)	[-1.06, 1.09]
	Placebo	Week 4	9	6	-0.07 (0.29)	-0.3	-0.20	0.3		
		Week 8	9	5	-0.40 (0.48)	-0.7	-0.70	0.4		
		Week 16	9	5	-0.82 (0.72)	-2.0	-0.80	-0.2		
		Week 24	9	5	-0.42 (0.95)	-1.8	-0.40	0.6		
Female	Dapa 10mg	Week 4	17	14	-0.36 (0.74)	-1.7	-0.50	1.6	-0.73 (0.39)	[-1.50, 0.04]
		Week 8	17	16	-0.54 (0.96)	-3.0	-0.65	1.8	-0.97 (0.39)	[-1.73, -0.21]
		Week 16	17	14	-0.50 (1.19)	-3.0	-0.55	1.9	-0.79 (0.40)	[-1.57, -0.00]
		Week 24	17	16	0.09 (1.50)	-2.6	-0.30	2.6	-0.40 (0.37)	[-1.13, 0.32]
	Placebo	Week 4	15	14	0.04 (0.29)	-0.4	0.05	0.7		
		Week 8	15	14	0.48 (1.13)	-0.5	0.05	3.9		
		Week 16	15	13	0.32 (0.87)	-0.7	-0.10	1.8		
		Week 24	15	14	0.86 (2.29)	-0.8	-0.15	6.1		

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group,
 n = Number of valid observations, Q50 = Median, SD = Standard deviation, CI = Confidence interval,
 HbA1c = Glycated haemoglobin.

Source Data: alb, created on: 30SEP2021

Table T2HAC_FSHS: Hedges G for Change in HbA1c up to Week 24 by subgroup
 PFAS

Hedges G for Change in HbA1c up to Week 24	Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max	Hedges G	
									Effect size (SD)	95% CI
C: Race										
White	Dapa 10mg	Week 4	23	19	-0.63 (0.39)	-1.7	-0.60	0.1	-2.31 (0.55)	[-3.39, -1.22]
		Week 8	23	21	-0.73 (0.72)	-3.0	-0.70	0.5	-0.97 (0.46)	[-1.86, -0.07]
		Week 16	23	20	-0.71 (0.98)	-3.0	-0.50	0.4	-0.74 (0.45)	[-1.62, 0.15]
		Week 24	23	20	-0.41 (1.33)	-2.6	-0.50	2.1	-0.04 (0.47)	[-0.95, 0.88]
	Placebo	Week 4	9	7	0.17 (0.18)	-0.1	0.20	0.4		
		Week 8	9	7	-0.07 (0.53)	-0.7	-0.10	0.6		
		Week 16	9	7	0.00 (0.92)	-0.8	-0.20	1.7		
		Week 24	9	6	-0.37 (0.38)	-0.8	-0.45	0.3		
Non-White	Dapa 10mg	Week 4	6	6	0.23 (0.72)	-0.4	0.00	1.6	0.67 (0.51)	[-0.33, 1.66]
		Week 8	6	6	0.45 (0.91)	-0.4	0.10	1.8	0.01 (0.50)	[-0.97, 0.99]
		Week 16	6	6	0.50 (1.02)	-0.6	0.40	1.9	0.48 (0.51)	[-0.53, 1.49]
		Week 24	6	6	0.95 (1.11)	-0.2	0.75	2.6	0.01 (0.49)	[-0.96, 0.97]
	Placebo	Week 4	15	13	-0.08 (0.30)	-0.4	-0.10	0.7		
		Week 8	15	12	0.43 (1.27)	-0.7	-0.05	3.9		
		Week 16	15	11	0.01 (1.03)	-2.0	-0.20	1.8		
		Week 24	15	13	0.94 (2.42)	-1.8	0.00	6.1		

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group,
 n = Number of valid observations, Q50 = Median, SD = Standard deviation, CI = Confidence interval,
 HbA1c = Glycated haemoglobin.
 Source Data: alb, created on: 30SEP2021

Table T2HAC_FSHS: Hedges G for Change in HbA1c up to Week 24 by subgroup
 PFAS

Hedges G for Change in HbA1c up to Week 24	Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max	Hedges G	
									Effect size (SD)	95% CI
D: Baseline BMI										
< 30 kg/m**2	Dapa 10mg	Week 4	15	14	-0.36 (0.77)	-1.7	-0.50	1.6	-0.93 (0.54)	[-2.00, 0.14]
		Week 8	15	14	-0.46 (1.07)	-3.0	-0.55	1.8	-0.74 (0.58)	[-1.88, 0.40]
		Week 16	15	15	-0.55 (1.29)	-3.0	-0.50	1.9	-0.69 (0.53)	[-1.73, 0.34]
		Week 24	15	13	-0.40 (1.55)	-2.6	-0.20	2.6	-0.61 (0.54)	[-1.66, 0.45]
	Placebo	Week 4	7	5	0.28 (0.25)	0.1	0.20	0.7		
		Week 8	7	4	0.30 (0.91)	-0.7	0.20	1.5		
		Week 16	7	5	0.30 (0.98)	-0.8	0.30	1.8		
		Week 24	7	5	0.62 (2.04)	-0.8	-0.10	4.2		
>= 30 kg/m**2	Dapa 10mg	Week 4	14	11	-0.50 (0.28)	-1.0	-0.50	0.0	-1.63 (0.46)	[-2.54, -0.73]
		Week 8	14	13	-0.48 (0.73)	-1.7	-0.60	1.3	-0.74 (0.39)	[-1.50, 0.03]
		Week 16	14	11	-0.26 (0.78)	-1.7	-0.40	1.4	-0.18 (0.41)	[-0.98, 0.63]
		Week 24	14	13	0.21 (1.20)	-2.0	-0.40	2.1	-0.16 (0.39)	[-0.92, 0.59]
	Placebo	Week 4	17	15	-0.08 (0.24)	-0.4	-0.10	0.4		
		Week 8	17	15	0.23 (1.13)	-0.7	-0.10	3.9		
		Week 16	17	13	-0.11 (0.97)	-2.0	-0.20	1.7		
		Week 24	17	14	0.49 (2.17)	-1.8	-0.30	6.1		

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group,
 n = Number of valid observations, Q50 = Median, SD = Standard deviation, CI = Confidence interval,
 HbA1c = Glycated haemoglobin.
 Source Data: alb, created on: 30SEP2021

Table T2HAC_FSHS: Hedges G for Change in HbA1c up to Week 24 by subgroup
 PFAS

Hedges G for Change in HbA1c up to Week 24	Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max	Hedges G		
									Effect size (SD)	95% CI	
E: Baseline HbA1c											
< 8 %	Dapa 10mg	Week 4	19	17	-0.36 (0.59)	-1.0	-0.50	1.6	-0.92 (0.42)	[-1.74, -0.10]	
		Week 8	19	18	-0.38 (0.69)	-1.0	-0.55	1.8	-0.90 (0.43)	[-1.74, -0.06]	
		Week 16	19	18	-0.26 (0.87)	-2.4	-0.35	1.9	-0.55 (0.40)	[-1.33, 0.24]	
		Week 24	19	18	-0.13 (1.09)	-2.6	-0.30	2.6	-0.53 (0.40)	[-1.32, 0.25]	
	Placebo	Week 4	12	10	0.10 (0.26)	-0.2	0.05	0.7			
		Week 8	12	9	0.22 (0.64)	-0.7	0.10	1.5			
		Week 16	12	10	0.22 (0.88)	-0.8	-0.15	1.8			
		Week 24	12	10	0.66 (2.02)	-0.8	-0.25	4.6			
>= 8 %	Dapa 10mg	Week 4	10	8	-0.55 (0.64)	-1.7	-0.50	0.4	-0.98 (0.51)	[-1.97, 0.01]	
		Week 8	10	9	-0.64 (1.26)	-3.0	-0.60	1.3	-0.69 (0.47)	[-1.62, 0.24]	
		Week 16	10	8	-0.83 (1.49)	-3.0	-0.60	1.4	-0.44 (0.51)	[-1.43, 0.56]	
		Week 24	10	8	-0.02 (2.00)	-2.5	0.25	2.1	-0.19 (0.49)	[-1.14, 0.77]	
	Placebo	Week 4	12	10	-0.08 (0.30)	-0.4	-0.15	0.4			
		Week 8	12	10	0.27 (1.38)	-0.7	-0.20	3.9			
		Week 16	12	8	-0.26 (1.05)	-2.0	-0.25	1.7			
		Week 24	12	9	0.38 (2.25)	-1.8	-0.20	6.1			

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group,
 n = Number of valid observations, Q50 = Median, SD = Standard deviation, CI = Confidence interval,
 HbA1c = Glycated haemoglobin.

Source Data: alb, created on: 30SEP2021

Table T2HAC_FSHS: Hedges G for Change in HbA1c up to Week 24 by subgroup
 PFAS

Hedges G for Change in HbA1c up to Week 24	Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max	Hedges G	
									Effect size (SD)	95% CI
F: Background diabetic medication										
Metformin only	Dapa 10mg	Week 4	11	9	-0.59 (0.30)	-1.0	-0.70	0.0	-1.79 (0.54)	[-2.85, -0.73]
		Week 8	11	10	-0.50 (0.36)	-1.0	-0.55	-0.1	-0.96 (0.46)	[-1.87, -0.05]
		Week 16	11	10	-0.32 (0.49)	-0.9	-0.40	0.7	-0.39 (0.45)	[-1.27, 0.50]
		Week 24	11	10	-0.30 (0.62)	-0.9	-0.45	1.3	-0.39 (0.44)	[-1.26, 0.47]
	Placebo	Week 4	14	11	-0.03 (0.33)	-0.4	-0.10	0.7		
		Week 8	14	11	-0.03 (0.59)	-0.7	-0.10	1.5		
		Week 16	14	10	-0.08 (0.73)	-0.8	-0.25	1.8		
		Week 24	14	11	0.15 (1.44)	-0.8	-0.50	4.2		
Insulin or insulin + metformin	Dapa 10mg	Week 4	18	16	-0.33 (0.71)	-1.7	-0.50	1.6	-0.65 (0.43)	[-1.48, 0.19]
		Week 8	18	17	-0.45 (1.12)	-3.0	-0.60	1.8	-0.87 (0.45)	[-1.75, 0.00]
		Week 16	18	16	-0.50 (1.36)	-3.0	-0.40	1.9	-0.46 (0.44)	[-1.32, 0.40]
		Week 24	18	16	0.03 (1.72)	-2.6	0.20	2.6	-0.48 (0.44)	[-1.34, 0.38]
	Placebo	Week 4	10	9	0.06 (0.24)	-0.3	0.10	0.4		
		Week 8	10	8	0.63 (1.46)	-0.7	0.45	3.9		
		Week 16	10	8	0.11 (1.24)	-2.0	0.05	1.7		
		Week 24	10	8	1.05 (2.76)	-1.8	-0.05	6.1		

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group, n = Number of valid observations, Q50 = Median, SD = Standard deviation, CI = Confidence interval, HbA1c = Glycated haemoglobin.

Source Data: alb, created on: 30SEP2021

Table T2HAC_FSHS: Hedges G for Change in HbA1c up to Week 24 by subgroup
 PFAS

Hedges G for Change in HbA1c up to Week 24	Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max	Hedges G	
									Effect size (SD)	95% CI
G: Geographic region										
Europe	Dapa 10mg	Week 4	12	10	-0.70 (0.45)	-1.7	-0.65	0.0	-1.99 (0.89)	[-3.74, -0.24]
		Week 8	12	11	-0.86 (0.79)	-3.0	-0.70	0.1	-1.13 (0.81)	[-2.71, 0.45]
		Week 16	12	9	-1.01 (1.01)	-3.0	-0.80	-0.1	-0.92 (0.81)	[-2.51, 0.67]
		Week 24	12	11	-0.40 (1.44)	-2.6	-0.50	2.1	0.11 (0.77)	[-1.40, 1.62]
	Placebo	Week 4	3	2	0.15 (0.07)	0.1	0.15	0.2		
		Week 8	3	2	0.00 (0.42)	-0.3	0.00	0.3		
		Week 16	3	2	-0.10 (0.85)	-0.7	-0.10	0.5		
		Week 24	3	2	-0.55 (0.07)	-0.6	-0.55	-0.5		
Non-Europe	Dapa 10mg	Week 4	17	15	-0.23 (0.63)	-1.0	-0.40	1.6	-0.48 (0.35)	[-1.17, 0.22]
		Week 8	17	16	-0.20 (0.90)	-1.7	-0.20	1.8	-0.47 (0.35)	[-1.16, 0.22]
		Week 16	17	17	-0.12 (1.04)	-2.5	0.10	1.9	-0.14 (0.35)	[-0.82, 0.54]
		Week 24	17	15	0.13 (1.36)	-2.5	-0.10	2.6	-0.29 (0.36)	[-0.98, 0.41]
	Placebo	Week 4	21	18	-0.01 (0.30)	-0.4	0.00	0.7		
		Week 8	21	17	0.28 (1.12)	-0.7	-0.10	3.9		
		Week 16	21	16	0.02 (1.00)	-2.0	-0.20	1.8		
		Week 24	21	17	0.65 (2.17)	-1.8	-0.10	6.1		

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group,
 n = Number of valid observations, Q50 = Median, SD = Standard deviation, CI = Confidence interval,
 HbA1c = Glycated haemoglobin.
 Source Data: alb, created on: 30SEP2021

Table T2FGM_FSFS: Course of censored FPG up to Week 24 by subgroup
PFAS

Course of censored FPG up to Week 24	Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max
A: Age								
<= 15 years	Dapa 10mg	Day 1	16	16	8.95 (3.25)	5.5	7.60	15.3
		Week 4	16	14	7.51 (3.08)	4.4	5.94	14.3
		Week 16	16	12	7.60 (2.76)	4.6	6.49	14.6
		Week 24	16	10	7.55 (2.67)	5.5	5.85	13.1
	Placebo	Day 1	14	14	9.30 (3.05)	4.7	8.74	14.5
		Week 4	14	11	9.44 (3.49)	4.7	8.49	15.3
		Week 16	14	9	9.45 (3.93)	5.0	8.50	16.5
		Week 24	14	9	8.60 (4.43)	5.3	6.94	18.7
> 15 and < 18 years	Dapa 10mg	Day 1	13	13	8.79 (3.53)	5.3	6.90	16.4
		Week 4	13	12	8.09 (3.23)	5.0	7.05	16.0
		Week 16	13	11	7.58 (1.75)	4.9	7.49	11.3
		Week 24	13	12	9.35 (4.74)	4.8	7.55	20.4
	Placebo	Day 1	10	10	8.54 (2.14)	5.2	8.44	13.5
		Week 4	10	8	10.95 (4.73)	7.7	9.21	22.3
		Week 16	10	7	8.69 (1.43)	6.9	8.66	10.3
		Week 24	10	8	9.01 (2.16)	5.9	8.82	11.9

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group,
n = Number of valid observations, SD = Standard deviation, Q50 = median, HbA1c = Glycated haemoglobin,
FPG = Fasting plasma glucose, BMI = Body mass index, Europe = Hungary, Israel, Russian Federation.
Source Data: alb, created on: 30SEP2021

Table T2FGM_FSFS: Course of censored FPG up to Week 24 by subgroup
PFAS

Course of censored FPG up to Week 24	Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max
B: Sex								
Male	Dapa 10mg	Day 1	12	12	8.94 (3.29)	5.3	7.58	15.3
		Week 4	12	10	8.03 (3.17)	5.4	6.23	14.3
		Week 16	12	9	7.20 (1.12)	5.5	7.38	8.8
		Week 24	12	9	7.60 (2.34)	4.8	6.90	12.2
	Placebo	Day 1	9	9	8.96 (2.22)	7.3	8.05	14.5
		Week 4	9	6	9.27 (2.29)	7.1	8.94	13.6
		Week 16	9	5	8.38 (1.18)	7.2	8.05	10.3
		Week 24	9	5	8.19 (2.61)	5.5	8.60	11.9
Female	Dapa 10mg	Day 1	17	17	8.84 (3.43)	5.5	7.33	16.4
		Week 4	17	16	7.62 (3.15)	4.4	6.50	16.0
		Week 16	17	14	7.85 (2.80)	4.6	6.88	14.6
		Week 24	17	13	9.17 (4.76)	5.0	7.94	20.4
	Placebo	Day 1	15	15	9.01 (3.01)	4.7	8.82	13.5
		Week 4	15	13	10.45 (4.63)	4.7	9.60	22.3
		Week 16	15	11	9.45 (3.59)	5.0	8.77	16.5
		Week 24	15	12	9.04 (3.83)	5.3	7.60	18.7

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group,
n = Number of valid observations, SD = Standard deviation, Q50 = median, HbA1c = Glycated haemoglobin,
FPG = Fasting plasma glucose, BMI = Body mass index, Europe = Hungary, Israel, Russian Federation.
Source Data: alb, created on: 30SEP2021

Table T2FGM_FSFS: Course of censored FPG up to Week 24 by subgroup
 PFAS

Course of censored FPG up to Week 24	Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max
C: Race								
White	Dapa 10mg	Day 1	23	23	8.84 (3.41)	5.3	6.90	16.4
		Week 4	23	20	7.31 (3.12)	4.4	6.08	16.0
		Week 16	23	18	7.30 (2.37)	4.6	6.77	14.6
		Week 24	23	17	8.55 (4.29)	4.8	6.90	20.4
	Placebo	Day 1	9	9	10.92 (2.73)	7.7	11.70	14.5
		Week 4	9	7	10.44 (2.82)	7.0	11.16	13.6
		Week 16	9	6	10.14 (3.36)	7.2	9.38	16.5
		Week 24	9	5	7.83 (2.41)	5.5	7.60	11.5
Non-White	Dapa 10mg	Day 1	6	6	9.04 (3.23)	5.5	8.33	13.9
		Week 4	6	6	9.34 (2.68)	5.3	9.38	12.4
		Week 16	6	5	8.66 (1.74)	6.7	8.49	11.2
		Week 24	6	5	8.48 (2.91)	5.5	7.94	13.1
	Placebo	Day 1	15	15	7.83 (1.93)	4.7	7.60	11.7
		Week 4	15	12	9.87 (4.67)	4.7	8.77	22.3
		Week 16	15	10	8.50 (2.82)	5.0	8.19	15.0
		Week 24	15	12	9.19 (3.82)	5.3	8.13	18.7

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group,
 n = Number of valid observations, SD = Standard deviation, Q50 = median, HbA1c = Glycated haemoglobin,
 FPG = Fasting plasma glucose, BMI = Body mass index, Europe = Hungary, Israel, Russian Federation.
 Source Data: alb, created on: 30SEP2021

Table T2FGM_FSFS: Course of censored FPG up to Week 24 by subgroup
PFAS

Course of censored FPG up to Week 24	Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max
D: Baseline BMI								
< 30 kg/m**2	Dapa 10mg	Day 1	15	15	9.07 (3.03)	5.3	7.90	15.3
		Week 4	15	14	7.73 (2.88)	5.0	6.30	14.3
		Week 16	15	11	7.09 (1.84)	4.9	6.33	11.2
		Week 24	15	11	7.64 (2.64)	4.8	6.90	13.1
	Placebo	Day 1	7	7	9.02 (3.05)	6.0	7.71	14.5
		Week 4	7	3	9.70 (3.46)	7.0	8.49	13.6
		Week 16	7	4	9.38 (0.88)	8.5	9.38	10.3
		Week 24	7	4	8.37 (3.10)	5.5	7.60	12.8
>= 30 kg/m**2	Dapa 10mg	Day 1	14	14	8.68 (3.70)	5.5	6.77	16.4
		Week 4	14	12	7.83 (3.47)	4.4	6.35	16.0
		Week 16	14	12	8.06 (2.62)	4.6	7.38	14.6
		Week 24	14	11	9.42 (4.92)	5.5	7.16	20.4
	Placebo	Day 1	17	17	8.97 (2.62)	4.7	8.82	13.5
		Week 4	17	16	10.15 (4.20)	4.7	9.21	22.3
		Week 16	17	12	9.03 (3.51)	5.0	7.88	16.5
		Week 24	17	13	8.92 (3.66)	5.3	8.60	18.7

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group,
n = Number of valid observations, SD = Standard deviation, Q50 = median, HbA1c = Glycated haemoglobin,
FPG = Fasting plasma glucose, BMI = Body mass index, Europe = Hungary, Israel, Russian Federation.
Source Data: alb, created on: 30SEP2021

Table T2FGM_FSFS: Course of censored FPG up to Week 24 by subgroup
 PFAS

Course of censored FPG up to Week 24	Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max
E: Baseline HbA1c								
< 8 %	Dapa 10mg	Day 1	19	19	7.50 (2.16)	5.3	6.83	13.7
		Week 4	19	18	6.36 (1.64)	4.4	5.74	9.9
		Week 16	19	18	7.43 (2.40)	4.6	6.80	14.6
		Week 24	19	17	7.45 (2.48)	4.8	6.30	13.1
	Placebo	Day 1	12	12	7.60 (1.76)	4.7	7.66	11.7
		Week 4	12	8	8.28 (3.13)	4.7	7.77	15.3
		Week 16	12	9	8.36 (2.92)	5.0	8.05	15.0
		Week 24	12	9	9.21 (4.10)	5.9	7.60	18.7
>= 8 %	Dapa 10mg	Day 1	10	10	11.50 (3.63)	6.4	11.79	16.4
		Week 4	10	8	10.96 (3.34)	6.3	10.96	16.0
		Week 16	10	5	8.19 (1.90)	6.3	7.49	11.3
		Week 24	10	5	12.23 (5.95)	6.8	10.50	20.4
	Placebo	Day 1	12	12	10.38 (2.79)	5.2	9.74	14.5
		Week 4	12	11	11.39 (4.19)	6.9	10.21	22.3
		Week 16	12	7	10.10 (3.11)	7.2	10.05	16.5
		Week 24	12	8	8.33 (2.75)	5.3	7.96	11.9

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group,
 n = Number of valid observations, SD = Standard deviation, Q50 = median, HbA1c = Glycated haemoglobin,
 FPG = Fasting plasma glucose, BMI = Body mass index, Europe = Hungary, Israel, Russian Federation.
 Source Data: alb, created on: 30SEP2021

Table T2FGM_FSFS: Course of censored FPG up to Week 24 by subgroup
PFAS

Course of censored FPG up to Week 24	Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max
F: Background diabetic medication								
Metformin only	Dapa 10mg	Day 1	11	11	7.20 (1.16)	5.3	6.90	9.3
		Week 4	11	10	5.91 (1.49)	4.4	5.53	9.9
		Week 16	11	10	6.64 (1.34)	4.6	6.30	9.3
		Week 24	11	9	6.86 (2.33)	4.8	5.80	12.2
	Placebo	Day 1	14	14	8.66 (2.84)	4.7	7.85	14.5
		Week 4	14	10	8.13 (1.95)	4.7	8.46	11.8
		Week 16	14	10	7.69 (1.68)	5.0	7.46	10.3
		Week 24	14	11	8.30 (2.67)	5.3	7.60	12.8
Insulin or insulin + metformin	Dapa 10mg	Day 1	18	18	9.91 (3.79)	5.5	9.06	16.4
		Week 4	18	16	8.94 (3.31)	5.0	8.24	16.0
		Week 16	18	13	8.33 (2.62)	4.9	7.49	14.6
		Week 24	18	13	9.69 (4.50)	5.0	7.94	20.4
	Placebo	Day 1	10	10	9.44 (2.53)	5.2	9.02	13.5
		Week 4	10	9	12.24 (4.68)	7.0	11.16	22.3
		Week 16	10	6	11.50 (3.41)	8.5	10.16	16.5
		Week 24	10	6	9.70 (4.73)	5.5	8.30	18.7

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group,
n = Number of valid observations, SD = Standard deviation, Q50 = median, HbA1c = Glycated haemoglobin,
FPG = Fasting plasma glucose, BMI = Body mass index, Europe = Hungary, Israel, Russian Federation.
Source Data: alb, created on: 30SEP2021

Table T2FGM_FSFS: Course of censored FPG up to Week 24 by subgroup
 PFAS

Course of censored FPG up to Week 24	Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max
G: Geographic region								
Europe	Dapa 10mg	Day 1	12	12	8.95 (3.78)	5.3	6.90	16.4
		Week 4	12	11	7.14 (3.29)	4.4	6.30	16.0
		Week 16	12	10	6.79 (2.03)	4.6	6.15	11.3
		Week 24	12	11	8.85 (5.11)	4.8	6.30	20.4
	Placebo	Day 1	3	3	13.23 (1.42)	11.7	13.50	14.5
		Week 4	3	2	9.40 (3.39)	7.0	9.40	11.8
		Week 16	3	2	9.40 (1.27)	8.5	9.40	10.3
		Week 24	3	2	9.55 (2.76)	7.6	9.55	11.5
Non-Europe	Dapa 10mg	Day 1	17	17	8.83 (3.07)	5.5	7.88	15.3
		Week 4	17	15	8.25 (2.98)	5.0	7.60	14.3
		Week 16	17	13	8.21 (2.34)	6.3	7.38	14.6
		Week 24	17	11	8.22 (2.56)	5.5	7.94	13.1
	Placebo	Day 1	21	21	8.38 (2.24)	4.7	8.05	13.5
		Week 4	21	17	10.16 (4.16)	4.7	9.05	22.3
		Week 16	21	14	9.08 (3.24)	5.0	8.35	16.5
		Week 24	21	15	8.69 (3.60)	5.3	7.60	18.7

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group,
 n = Number of valid observations, SD = Standard deviation, Q50 = median, HbA1c = Glycated haemoglobin,
 FPG = Fasting plasma glucose, BMI = Body mass index, Europe = Hungary, Israel, Russian Federation.
 Source Data: alb, created on: 30SEP2021

Table T2FGMC_FSCS: Change in censored FPG at Week 24 by subgroup
PFAS

Subgroup	Treatment	Time point	N	n (%)	Repeated measures analysis				
					Change from Baseline		Treatment Difference		p-value
					LS-Mean (SE)	95% CI	LS-Mean (SE)	95% CI	
A: Age	Dapa 10mg	Week 24							0.867
<= 15 years	Dapa 10mg	Week 24	16	10 (62.5)	-0.41 (1.13)	(-2.77, 1.95)	-0.85 (1.64)	(-4.28, 2.57)	0.607
	Placebo	Week 24	14	9 (64.3)	0.44 (1.19)	(-2.06, 2.95)			
> 15 and < 18 years	Dapa 10mg	Week 24	13	12 (92.3)	0.70 (0.72)	(-0.81, 2.21)	0.40 (1.14)	(-1.99, 2.79)	0.727
	Placebo	Week 24	10	8 (80.0)	0.30 (0.88)	(-1.56, 2.15)			
B: Sex	Dapa 10mg	Week 24							0.881
Male	Dapa 10mg	Week 24	12	9 (75.0)	-0.58 (0.85)	(-2.44, 1.28)	-0.61 (1.41)	(-3.70, 2.48)	0.673
	Placebo	Week 24	9	5 (55.6)	0.03 (1.11)	(-2.41, 2.48)			
Female	Dapa 10mg	Week 24	17	13 (76.5)	0.45 (1.00)	(-1.62, 2.51)	-0.29 (1.45)	(-3.29, 2.70)	0.841
	Placebo	Week 24	15	12 (80.0)	0.74 (1.05)	(-1.43, 2.92)			
C: Race	Dapa 10mg	Week 24							0.653
White	Dapa 10mg	Week 24	23	17 (73.9)	0.30 (0.62)	(-1.00, 1.59)	2.11 (1.31)	(-0.63, 4.85)	0.124
	Placebo	Week 24	9	5 (55.6)	-1.81 (1.14)	(-4.19, 0.56)			
Non-White	Dapa 10mg	Week 24	6	5 (83.3)	0.56 (1.67)	(-3.02, 4.14)	-0.57 (1.99)	(-4.84, 3.69)	0.777
	Placebo	Week 24	15	12 (80.0)	1.14 (1.08)	(-1.18, 3.45)			
D: Baseline BMI	Dapa 10mg	Week 24							0.946
< 30 kg/m**2	Dapa 10mg	Week 24	15	11 (73.3)	-0.43 (0.91)	(-2.41, 1.55)	-0.51 (1.73)	(-4.28, 3.25)	0.771
	Placebo	Week 24	7	4 (57.1)	0.09 (1.44)	(-3.06, 3.23)			
>= 30 kg/m**2	Dapa 10mg	Week 24	14	11 (78.6)	0.37 (1.03)	(-1.77, 2.50)	-0.30 (1.41)	(-3.22, 2.62)	0.833
	Placebo	Week 24	17	13 (76.5)	0.67 (0.96)	(-1.32, 2.66)			

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group, n = Number of valid observations, SE = Standard error, CI = Confidence interval, FPG = Fasting plasma glucose, LS-Mean = Least square mean. Only results for Week 24 printed.
Per subgroup, a mixed repeated measures model was applied with fixed factors for treatment, week, interactions treatment-by-week, baseline-by-week and baseline as covariate.
Interaction test utilizes same model with additional interaction effects for subgroup with treatment, subgroup with week and subgroup with week with treatment.
Source Data: alb, created on: 30SEP2021

Table T2FGMC_FSCS: Change in censored FPG at Week 24 by subgroup
 PFAS

Subgroup	Treatment	Time point	N	n (%)	Repeated measures analysis				
					Change from Baseline		Treatment Difference		
					LS-Mean (SE)	95% CI	LS-Mean (SE)	95% CI	p-value
E: Baseline HbA1c	Dapa 10mg	Week 24							0.271
< 8 %	Dapa 10mg	Week 24	19	17 (89.5)	-0.21 (0.73)	(-1.71, 1.29)	-1.76 (1.25)	(-4.34, 0.81)	0.171
	Placebo	Week 24	12	9 (75.0)	1.56 (1.01)	(-0.54, 3.65)			
≥ 8 %	Dapa 10mg	Week 24	10	5 (50.0)	1.06 (1.65)	(-2.68, 4.80)	1.61 (2.13)	(-3.21, 6.44)	0.469
	Placebo	Week 24	12	8 (66.7)	-0.55 (1.34)	(-3.59, 2.49)			
F: Background diabetic medication	Dapa 10mg	Week 24							0.581
Metformin only	Dapa 10mg	Week 24	11	9 (81.8)	-0.67 (0.85)	(-2.46, 1.13)	-1.09 (1.18)	(-3.58, 1.39)	0.367
	Placebo	Week 24	14	11 (78.6)	0.43 (0.79)	(-1.24, 2.09)			
Insulin or insulin + metformin	Dapa 10mg	Week 24	18	13 (72.2)	0.80 (1.05)	(-1.42, 3.01)	-0.19 (1.85)	(-4.08, 3.70)	0.920
	Placebo	Week 24	10	6 (60.0)	0.98 (1.53)	(-2.23, 4.20)			
G: Geographic region	Dapa 10mg	Week 24							0.625
Europe	Dapa 10mg	Week 24	12	11 (91.7)	-0.25 (0.80)	(-2.04, 1.53)	3.22 (2.16)	(-1.60, 8.04)	0.167
	Placebo	Week 24	3	2 (66.7)	-3.48 (1.98)	(-7.89, 0.94)			
Non-Europe	Dapa 10mg	Week 24	17	11 (64.7)	0.24 (1.04)	(-1.91, 2.39)	-0.59 (1.35)	(-3.38, 2.19)	0.664
	Placebo	Week 24	21	15 (71.4)	0.83 (0.87)	(-0.97, 2.63)			

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group, n = Number of valid observations, SE = Standard error, CI = Confidence interval, FPG = Fasting plasma glucose, LS-Mean = Least square mean. Only results for Week 24 printed. Per subgroup, a mixed repeated measures model was applied with fixed factors for treatment, week, interactions treatment-by-week, baseline-by-week and baseline as covariate. Interaction test utilizes same model with additional interaction effects for subgroup with treatment, subgroup with week and subgroup with week with treatment.
 Source Data: alb, created on: 30SEP2021

Table T2FGMC_FSHS: Hedges G for Change in censored FPG at Week 24 by subgroup
 PFAS

Hedges G for Change in censored FPG at Week 24	Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max	Hedges G	
									Effect size (SD)	95% CI
A: Age										
<= 15 years	Dapa 10mg	Week 4	16	14	-1.36 (1.35)	-3.8	-1.18	1.0	-0.63 (0.41)	[-1.44, 0.18]
		Week 16	16	12	-0.31 (3.72)	-4.9	-0.90	9.0	-0.34 (0.44)	[-1.21, 0.53]
		Week 24	16	10	-0.23 (2.86)	-4.1	-1.05	5.2	-0.10 (0.46)	[-1.00, 0.80]
	Placebo	Week 4	14	11	0.22 (3.46)	-4.8	0.06	6.8		
		Week 16	14	9	0.85 (3.00)	-3.2	0.33	6.5		
		Week 24	14	9	0.21 (5.43)	-5.7	0.61	10.2		
> 15 and < 18 years	Dapa 10mg	Week 4	13	12	-0.87 (3.49)	-9.0	-0.25	5.6	-0.64 (0.47)	[-1.56, 0.28]
		Week 16	13	11	-0.54 (2.25)	-5.1	0.20	2.1	-0.06 (0.48)	[-1.00, 0.89]
		Week 24	13	12	0.68 (2.55)	-3.9	0.17	5.7	0.12 (0.46)	[-0.77, 1.02]
	Placebo	Week 4	10	8	2.15 (6.16)	-1.7	0.31	17.1		
		Week 16	10	7	-0.42 (1.88)	-3.2	-0.83	2.4		
		Week 24	10	8	0.39 (2.22)	-2.1	-0.08	4.6		

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group,
 n = Number of valid observations, Q50 = Median, SD = Standard deviation, CI = Confidence interval,
 FPG = Fasting plasma glucose.
 Source Data: alb, created on: 30SEP2021

Table T2FGMC_FSHS: Hedges G for Change in censored FPG at Week 24 by subgroup
 PFAS

Hedges G for Change in censored FPG at Week 24	Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max	Hedges G	
									Effect size (SD)	95% CI
B: Sex										
Male	Dapa 10mg	Week 4	12	10	-0.79 (2.67)	-3.8	-0.89	5.6	-0.62 (0.53)	[-1.66, 0.41]
		Week 16	12	9	-0.51 (2.25)	-4.9	0.20	2.1	-0.27 (0.56)	[-1.37, 0.83]
		Week 24	12	9	-0.11 (2.67)	-4.1	0.00	3.9	0.03 (0.56)	[-1.06, 1.12]
	Placebo	Week 4	9	6	0.78 (2.19)	-1.4	0.31	4.6		
		Week 16	9	5	0.00 (0.90)	-0.9	0.06	1.3		
		Week 24	9	5	-0.19 (3.10)	-3.5	-0.55	4.6		
Female	Dapa 10mg	Week 4	17	16	-1.35 (2.50)	-9.0	-1.18	1.3	-0.60 (0.38)	[-1.35, 0.15]
		Week 16	17	14	-0.36 (3.53)	-5.1	-0.90	9.0	-0.24 (0.40)	[-1.03, 0.56]
		Week 24	17	13	0.53 (2.74)	-3.9	-0.10	5.7	0.01 (0.40)	[-0.78, 0.79]
	Placebo	Week 4	15	13	1.16 (5.61)	-4.8	0.06	17.1		
		Week 16	15	11	0.43 (3.09)	-3.2	0.33	6.5		
		Week 24	15	12	0.50 (4.58)	-5.7	0.44	10.2		

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group,
 n = Number of valid observations, Q50 = Median, SD = Standard deviation, CI = Confidence interval,
 FPG = Fasting plasma glucose.
 Source Data: alb, created on: 30SEP2021

Table T2FGMC_FSHS: Hedges G for Change in censored FPG at Week 24 by subgroup
 PFAS

Hedges G for Change in censored FPG at Week 24	Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max	Hedges G	
									Effect size (SD)	95% CI
C: Race										
White	Dapa 10mg	Week 4	23	20	-1.57 (2.19)	-9.0	-1.14	1.3	-0.48 (0.44)	[-1.35, 0.39]
		Week 16	23	18	-0.70 (3.10)	-5.1	-0.84	9.0	-0.07 (0.47)	[-1.00, 0.85]
		Week 24	23	17	0.23 (2.59)	-4.1	-0.20	5.7	0.99 (0.53)	[-0.05, 2.04]
	Placebo	Week 4	9	7	-0.43 (2.82)	-4.7	-0.89	4.6		
		Week 16	9	6	-0.48 (2.47)	-3.2	-0.39	3.0		
		Week 24	9	5	-2.22 (1.82)	-4.1	-2.11	0.6		
Non-White	Dapa 10mg	Week 4	6	6	0.31 (3.24)	-4.2	0.42	5.6	-0.32 (0.50)	[-1.31, 0.66]
		Week 16	6	5	0.59 (2.88)	-4.2	1.17	3.3	-0.07 (0.55)	[-1.14, 1.01]
		Week 24	6	5	0.41 (3.23)	-3.9	0.33	5.2	-0.23 (0.53)	[-1.27, 0.82]
	Placebo	Week 4	15	12	1.89 (5.49)	-4.8	0.19	17.1		
		Week 16	15	10	0.77 (2.65)	-2.8	0.36	6.5		
		Week 24	15	12	1.34 (4.40)	-5.7	1.14	10.2		

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group,
 n = Number of valid observations, Q50 = Median, SD = Standard deviation, CI = Confidence interval,
 FPG = Fasting plasma glucose.
 Source Data: alb, created on: 30SEP2021

Table T2FGMC_FSHS: Hedges G for Change in censored FPG at Week 24 by subgroup
 PFAS

Hedges G for Change in censored FPG at Week 24	Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max	Hedges G	
									Effect size (SD)	95% CI
D: Baseline BMI										
< 30 kg/m**2	Dapa 10mg	Week 4	15	14	-1.10 (1.53)	-4.2	-1.07	1.1	-0.83 (0.65)	[-2.12, 0.45]
		Week 16	15	11	-0.57 (2.11)	-4.2	-0.80	3.3	-0.61 (0.60)	[-1.78, 0.56]
		Week 24	15	11	-0.02 (2.80)	-3.9	-0.50	5.2	0.05 (0.58)	[-1.09, 1.20]
	Placebo	Week 4	7	3	0.80 (4.88)	-4.7	2.50	4.6		
		Week 16	7	4	0.81 (2.75)	-3.2	1.83	2.8		
		Week 24	7	4	-0.21 (4.99)	-4.1	-1.75	6.8		
≥ 30 kg/m**2	Dapa 10mg	Week 4	14	12	-1.17 (3.42)	-9.0	-0.97	5.6	-0.52 (0.39)	[-1.28, 0.24]
		Week 16	14	12	-0.28 (3.79)	-5.1	-0.23	9.0	-0.13 (0.41)	[-0.93, 0.68]
		Week 24	14	11	0.56 (2.63)	-4.1	0.00	5.7	0.03 (0.41)	[-0.77, 0.83]
	Placebo	Week 4	17	16	1.08 (4.86)	-4.8	-0.06	17.1		
		Week 16	17	12	0.13 (2.62)	-3.2	-0.11	6.5		
		Week 24	17	13	0.45 (4.03)	-5.7	0.61	10.2		

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group,
 n = Number of valid observations, Q50 = Median, SD = Standard deviation, CI = Confidence interval,
 FPG = Fasting plasma glucose.
 Source Data: alb, created on: 30SEP2021

Table T2FGMC_FSHS: Hedges G for Change in censored FPG at Week 24 by subgroup
 PFAS

Hedges G for Change in censored FPG at Week 24	Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max	Hedges G	
									Effect size (SD)	95% CI
E: Baseline HbA1c										
< 8 %	Dapa 10mg	Week 4	19	18	-1.18 (1.66)	-4.2	-0.97	1.1	-0.78 (0.44)	[-1.64, 0.08]
		Week 16	19	18	-0.12 (3.06)	-4.9	-0.23	9.0	-0.25 (0.41)	[-1.06, 0.55]
		Week 24	19	17	-0.18 (2.63)	-4.1	-0.50	5.2	-0.51 (0.42)	[-1.33, 0.31]
	Placebo	Week 4	12	8	0.56 (3.24)	-4.7	0.19	6.8		
		Week 16	12	9	0.65 (2.88)	-3.2	0.06	6.5		
		Week 24	12	9	1.50 (4.39)	-4.1	0.61	10.2		
>= 8 %	Dapa 10mg	Week 4	10	8	-1.03 (4.01)	-9.0	-1.05	5.6	-0.48 (0.47)	[-1.40, 0.45]
		Week 16	10	5	-1.52 (3.01)	-5.1	-1.60	2.1	-0.53 (0.60)	[-1.70, 0.64]
		Week 24	10	5	1.81 (2.41)	-0.1	0.44	5.7	0.90 (0.60)	[-0.28, 2.08]
	Placebo	Week 4	12	11	1.38 (5.71)	-4.8	-0.17	17.1		
		Week 16	12	7	-0.16 (2.26)	-3.2	0.39	3.0		
		Week 24	12	8	-1.06 (3.56)	-5.7	-1.28	4.6		

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group,
 n = Number of valid observations, Q50 = Median, SD = Standard deviation, CI = Confidence interval,
 FPG = Fasting plasma glucose.
 Source Data: alb, created on: 30SEP2021

Table T2FGMC_FSHS: Hedges G for Change in censored FPG at Week 24 by subgroup
 PFAS

Hedges G for Change in censored FPG at Week 24	Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max	Hedges G	
									Effect size (SD)	95% CI
F: Background diabetic medication										
Metformin only	Dapa 10mg	Week 4	11	10	-1.34 (1.44)	-3.8	-1.16	1.1	-0.61 (0.46)	[-1.51, 0.29]
		Week 16	11	10	-0.61 (1.40)	-3.3	-0.68	1.0	-0.18 (0.45)	[-1.06, 0.70]
		Week 24	11	9	-0.51 (1.97)	-3.4	-1.00	3.9	-0.16 (0.45)	[-1.04, 0.72]
	Placebo	Week 4	14	10	-0.27 (2.00)	-4.8	-0.14	2.5		
		Week 16	14	10	-0.30 (1.97)	-3.2	-0.11	2.8		
		Week 24	14	11	-0.04 (3.65)	-5.7	0.00	6.8		
Insulin or insulin + metformin	Dapa 10mg	Week 4	18	16	-1.01 (3.06)	-9.0	-0.94	5.6	-0.77 (0.43)	[-1.62, 0.07]
		Week 16	18	13	-0.28 (3.92)	-5.1	0.10	9.0	-0.42 (0.50)	[-1.40, 0.56]
		Week 24	18	13	0.81 (3.02)	-4.1	0.39	5.7	-0.02 (0.49)	[-0.99, 0.94]
	Placebo	Week 4	10	9	2.49 (6.43)	-4.7	0.06	17.1		
		Week 16	10	6	1.30 (3.31)	-3.2	1.19	6.5		
		Week 24	10	6	0.90 (5.18)	-4.1	0.50	10.2		

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group,
 n = Number of valid observations, Q50 = Median, SD = Standard deviation, CI = Confidence interval,
 FPG = Fasting plasma glucose.

Source Data: alb, created on: 30SEP2021

Table T2FGMC_FSHS: Hedges G for Change in censored FPG at Week 24 by subgroup
 PFAS

Hedges G for Change in censored FPG at Week 24	Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max	Hedges G	
									Effect size (SD)	95% CI
G: Geographic region										
Europe	Dapa 10mg	Week 4	12	11	-2.02 (2.81)	-9.0	-1.30	1.3	0.43 (0.77)	[-1.09, 1.95]
		Week 16	12	10	-1.81 (2.10)	-5.1	-1.50	1.0	0.70 (0.79)	[-0.85, 2.25]
		Week 24	12	11	-0.31 (2.66)	-4.1	-0.50	5.7	1.06 (0.80)	[-0.51, 2.64]
	Placebo	Week 4	3	2	-3.20 (2.12)	-4.7	-3.20	-1.7		
		Week 16	3	2	-3.20 (0.00)	-3.2	-3.20	-3.2		
		Week 24	3	2	-3.05 (1.48)	-4.1	-3.05	-2.0		
Non-Europe	Dapa 10mg	Week 4	17	15	-0.48 (2.16)	-4.2	-0.94	5.6	-0.54 (0.36)	[-1.24, 0.17]
		Week 16	17	13	0.65 (3.28)	-4.2	0.78	9.0	-0.05 (0.39)	[-0.81, 0.70]
		Week 24	17	11	0.85 (2.67)	-3.9	0.39	5.2	0.03 (0.40)	[-0.75, 0.81]
	Placebo	Week 4	21	17	1.53 (4.73)	-4.8	0.06	17.1		
		Week 16	21	14	0.80 (2.35)	-2.8	0.36	6.5		
		Week 24	21	15	0.74 (4.17)	-5.7	0.61	10.2		

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group,
 n = Number of valid observations, Q50 = Median, SD = Standard deviation, CI = Confidence interval,
 FPG = Fasting plasma glucose.
 Source Data: alb, created on: 30SEP2021

Table T2HAM_FSFS: Course of censored HbA1c up to Week 24 by subgroup
PFAS

Course of censored HbA1c up to Week 24	Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max
A: Age								
<= 15 years	Dapa 10mg	Day 1	16	16	7.72 (1.57)	5.4	7.15	11.1
		Week 4	16	13	7.32 (1.71)	5.0	7.00	10.8
		Week 8	16	13	6.96 (1.59)	5.2	6.50	10.8
		Week 16	16	12	6.83 (1.13)	5.0	6.75	9.0
		Week 24	16	10	7.00 (1.51)	4.9	6.65	9.7
	Placebo	Day 1	14	14	7.83 (1.07)	6.5	7.65	9.7
		Week 4	14	12	7.83 (1.02)	6.5	7.60	10.1
		Week 8	14	11	7.90 (1.09)	6.3	7.90	10.3
		Week 16	14	9	7.78 (1.11)	6.2	8.00	9.2
		Week 24	14	9	8.21 (1.83)	6.1	7.50	11.1
> 15 and < 18 years	Dapa 10mg	Day 1	13	13	7.89 (1.81)	5.7	7.50	12.4
		Week 4	13	12	7.39 (1.91)	5.5	7.00	11.9
		Week 8	13	13	7.56 (2.00)	5.5	7.00	12.2
		Week 16	13	10	6.79 (1.30)	5.2	6.60	9.6
		Week 24	13	12	7.58 (2.23)	5.0	6.95	12.6
	Placebo	Day 1	10	10	8.35 (1.15)	6.7	8.30	10.5
		Week 4	10	8	8.28 (1.14)	7.0	8.05	10.2
		Week 8	10	8	8.96 (2.04)	7.1	8.25	13.1
		Week 16	10	7	7.91 (0.89)	6.5	7.80	9.3
		Week 24	10	8	8.89 (2.87)	5.9	8.40	15.3

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group, n = Number of valid observations, SD = Standard deviation, Q50 = median, HbA1c = Glycated haemoglobin, FPG = Fasting plasma glucose, BMI = Body mass index, Europe = Hungary, Israel, Russian Federation.
Source Data: alb, created on: 30SEP2021

Table T2HAM_FSFS: Course of censored HbA1c up to Week 24 by subgroup
 PFAS

Course of censored HbA1c up to Week 24	Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max
B: Sex								
Male	Dapa 10mg	Day 1	12	12	7.72 (1.94)	5.4	7.50	12.4
		Week 4	12	11	7.13 (1.94)	5.0	6.60	11.9
		Week 8	12	10	7.15 (2.12)	5.3	6.35	12.2
		Week 16	12	9	6.64 (1.34)	5.0	6.40	9.6
		Week 24	12	9	6.71 (1.33)	4.9	6.40	9.1
	Placebo	Day 1	9	9	8.27 (1.28)	6.7	8.10	10.5
		Week 4	9	6	8.33 (1.16)	7.0	8.05	10.2
		Week 8	9	5	8.06 (1.13)	7.0	8.10	9.8
		Week 16	9	5	7.64 (0.89)	6.5	8.00	8.5
		Week 24	9	5	8.04 (1.42)	5.9	8.70	9.2
Female	Dapa 10mg	Day 1	17	17	7.85 (1.47)	6.2	7.30	11.1
		Week 4	17	14	7.53 (1.68)	5.4	7.05	10.8
		Week 8	17	16	7.33 (1.64)	5.2	7.05	10.8
		Week 16	17	13	6.92 (1.09)	5.2	6.90	9.0
		Week 24	17	13	7.73 (2.18)	5.0	7.30	12.6
	Placebo	Day 1	15	15	7.91 (1.02)	6.5	7.60	9.7
		Week 4	15	14	7.86 (1.04)	6.5	7.60	10.1
		Week 8	15	14	8.45 (1.77)	6.3	8.05	13.1
		Week 16	15	11	7.93 (1.06)	6.2	7.90	9.3
		Week 24	15	12	8.73 (2.64)	6.1	7.85	15.3

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group, n = Number of valid observations, SD = Standard deviation, Q50 = median, HbA1c = Glycated haemoglobin, FPG = Fasting plasma glucose, BMI = Body mass index, Europe = Hungary, Israel, Russian Federation.
 Source Data: alb, created on: 30SEP2021

Table T2HAM_FSFS: Course of censored HbA1c up to Week 24 by subgroup
 PFAS

Course of censored HbA1c up to Week 24	Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max
C: Race								
White	Dapa 10mg	Day 1	23	23	7.76 (1.76)	5.4	7.10	12.4
		Week 4	23	19	7.09 (1.81)	5.0	6.40	11.9
		Week 8	23	20	6.92 (1.75)	5.2	6.35	12.2
		Week 16	23	17	6.41 (0.87)	5.0	6.30	8.1
		Week 24	23	17	7.05 (2.04)	4.9	6.20	12.6
	Placebo	Day 1	9	9	8.21 (1.13)	6.7	8.50	9.7
		Week 4	9	7	8.39 (1.03)	7.0	8.50	10.1
		Week 8	9	7	8.14 (1.09)	7.0	8.10	10.3
		Week 16	9	6	7.68 (0.84)	6.5	7.90	8.8
		Week 24	9	5	7.46 (1.17)	5.9	7.30	9.1
Non-White	Dapa 10mg	Day 1	6	6	7.95 (1.26)	7.1	7.40	10.4
		Week 4	6	6	8.18 (1.46)	6.9	7.85	10.8
		Week 8	6	6	8.40 (1.58)	7.0	8.00	10.8
		Week 16	6	5	8.16 (1.13)	6.9	8.00	9.6
		Week 24	6	5	8.22 (1.12)	7.2	7.80	9.7
	Placebo	Day 1	15	15	7.95 (1.13)	6.5	7.60	10.5
		Week 4	15	13	7.80 (1.06)	6.5	7.60	10.2
		Week 8	15	12	8.47 (1.87)	6.3	8.10	13.1
		Week 16	15	10	7.93 (1.10)	6.2	8.10	9.3
		Week 24	15	12	8.98 (2.57)	6.1	8.40	15.3

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group, n = Number of valid observations, SD = Standard deviation, Q50 = median, HbA1c = Glycated haemoglobin, FPG = Fasting plasma glucose, BMI = Body mass index, Europe = Hungary, Israel, Russian Federation.
 Source Data: alb, created on: 30SEP2021

Table T2HAM_FSFS: Course of censored HbA1c up to Week 24 by subgroup
 PFAS

Course of censored HbA1c up to Week 24	Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max
D: Baseline BMI								
< 30 kg/m**2	Dapa 10mg	Day 1	15	15	8.05 (1.96)	5.7	7.30	12.4
		Week 4	15	14	7.64 (1.99)	5.5	7.00	11.9
		Week 8	15	13	7.48 (2.03)	5.5	6.70	12.2
		Week 16	15	11	6.72 (1.20)	5.2	6.30	9.0
		Week 24	15	11	6.82 (1.41)	5.0	6.40	9.7
	Placebo	Day 1	7	7	7.73 (1.11)	6.7	7.30	9.7
		Week 4	7	5	7.82 (0.75)	7.2	7.60	9.1
		Week 8	7	4	7.95 (0.42)	7.4	8.00	8.4
		Week 16	7	4	8.10 (0.45)	7.6	8.05	8.7
		Week 24	7	4	8.45 (2.09)	6.5	8.10	11.1
≥ 30 kg/m**2	Dapa 10mg	Day 1	14	14	7.53 (1.25)	5.4	7.40	10.5
		Week 4	14	11	6.99 (1.46)	5.0	7.00	10.2
		Week 8	14	13	7.05 (1.58)	5.2	6.90	10.6
		Week 16	14	11	6.90 (1.21)	5.0	7.00	9.6
		Week 24	14	11	7.81 (2.27)	4.9	7.60	12.6
	Placebo	Day 1	17	17	8.18 (1.12)	6.5	8.10	10.5
		Week 4	17	15	8.07 (1.17)	6.5	7.80	10.2
		Week 8	17	15	8.45 (1.79)	6.3	8.20	13.1
		Week 16	17	12	7.75 (1.12)	6.2	7.85	9.3
		Week 24	17	13	8.55 (2.47)	5.9	7.90	15.3

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group, n = Number of valid observations, SD = Standard deviation, Q50 = median, HbA1c = Glycated haemoglobin, FPG = Fasting plasma glucose, BMI = Body mass index, Europe = Hungary, Israel, Russian Federation.
 Source Data: alb, created on: 30SEP2021

Table T2HAM_FSFS: Course of censored HbA1c up to Week 24 by subgroup
PFAS

Course of censored HbA1c up to Week 24	Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max
E: Baseline HbA1c								
< 8 %	Dapa 10mg	Day 1	19	19	6.85 (0.65)	5.4	6.90	7.9
		Week 4	19	17	6.44 (0.91)	5.0	6.30	8.7
		Week 8	19	18	6.42 (0.87)	5.2	6.25	8.9
		Week 16	19	18	6.55 (1.01)	5.0	6.40	9.0
		Week 24	19	17	6.69 (1.24)	4.9	6.40	9.7
	Placebo	Day 1	12	12	7.14 (0.44)	6.5	7.20	7.7
		Week 4	12	10	7.24 (0.45)	6.5	7.35	7.8
		Week 8	12	9	7.37 (0.73)	6.3	7.40	8.4
		Week 16	12	9	7.42 (1.08)	6.2	7.40	9.2
		Week 24	12	9	7.78 (1.99)	5.9	7.10	11.1
>= 8 %	Dapa 10mg	Day 1	10	10	9.60 (1.45)	8.1	9.15	12.4
		Week 4	10	8	9.29 (1.60)	7.1	9.05	11.9
		Week 8	10	8	9.15 (1.95)	6.4	8.80	12.2
		Week 16	10	4	7.98 (1.31)	6.4	7.95	9.6
		Week 24	10	5	9.44 (2.38)	6.1	9.10	12.6
	Placebo	Day 1	12	12	8.95 (0.77)	8.0	8.70	10.5
		Week 4	12	10	8.77 (0.94)	7.6	8.55	10.2
		Week 8	12	10	9.23 (1.68)	7.8	8.35	13.1
		Week 16	12	7	8.37 (0.54)	7.8	8.30	9.3
		Week 24	12	8	9.38 (2.50)	7.5	8.90	15.3

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group, n = Number of valid observations, SD = Standard deviation, Q50 = median, HbA1c = Glycated haemoglobin, FPG = Fasting plasma glucose, BMI = Body mass index, Europe = Hungary, Israel, Russian Federation.
Source Data: alb, created on: 30SEP2021

Table T2HAM_FSFS: Course of censored HbA1c up to Week 24 by subgroup
 PFAS

Course of censored HbA1c up to Week 24	Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max
F: Background diabetic medication								
Metformin only	Dapa 10mg	Day 1	11	11	6.71 (0.62)	5.4	6.90	7.6
		Week 4	11	9	6.00 (0.62)	5.0	6.00	6.9
		Week 8	11	10	6.12 (0.66)	5.2	6.20	7.1
		Week 16	11	10	6.30 (0.91)	5.0	6.25	8.0
		Week 24	11	9	6.30 (1.03)	4.9	6.10	8.4
	Placebo	Day 1	14	14	7.61 (0.93)	6.5	7.55	9.7
		Week 4	14	11	7.48 (0.66)	6.5	7.60	8.6
		Week 8	14	11	7.48 (0.71)	6.3	7.40	8.4
		Week 16	14	10	7.35 (0.87)	6.2	7.50	8.7
		Week 24	14	11	7.65 (1.49)	5.9	7.50	11.1
Insulin or insulin + metformin	Dapa 10mg	Day 1	18	18	8.46 (1.74)	5.7	8.15	12.4
		Week 4	18	16	8.11 (1.76)	5.8	7.75	11.9
		Week 8	18	16	7.98 (1.93)	5.7	7.40	12.2
		Week 16	18	12	7.23 (1.24)	5.2	7.05	9.6
		Week 24	18	13	8.02 (2.09)	5.0	7.60	12.6
	Placebo	Day 1	10	10	8.65 (1.09)	7.1	8.65	10.5
		Week 4	10	9	8.64 (1.15)	7.2	8.50	10.2
		Week 8	10	8	9.54 (1.76)	7.9	9.10	13.1
		Week 16	10	6	8.65 (0.55)	8.0	8.65	9.3
		Week 24	10	6	10.13 (2.84)	7.1	9.30	15.3

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group, n = Number of valid observations, SD = Standard deviation, Q50 = median, HbA1c = Glycated haemoglobin, FPG = Fasting plasma glucose, BMI = Body mass index, Europe = Hungary, Israel, Russian Federation.
 Source Data: alb, created on: 30SEP2021

Table T2HAM_FSFS: Course of censored HbA1c up to Week 24 by subgroup
 PFAS

Course of censored HbA1c up to Week 24	Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max
G: Geographic region								
Europe	Dapa 10mg	Day 1	12	12	7.69 (1.62)	6.2	7.25	11.1
		Week 4	12	10	6.92 (1.65)	5.4	6.20	10.2
		Week 8	12	11	6.84 (1.54)	5.2	6.30	10.6
		Week 16	12	9	6.29 (0.93)	5.2	6.20	8.1
		Week 24	12	11	7.30 (2.38)	5.0	6.20	12.6
	Placebo	Day 1	3	3	8.60 (1.05)	7.6	8.50	9.7
		Week 4	3	2	8.20 (0.57)	7.8	8.20	8.6
		Week 8	3	2	8.05 (0.21)	7.9	8.05	8.2
		Week 16	3	2	7.95 (0.21)	7.8	7.95	8.1
		Week 24	3	2	7.50 (0.57)	7.1	7.50	7.9
Non-Europe	Dapa 10mg	Day 1	17	17	7.87 (1.71)	5.4	7.30	12.4
		Week 4	17	15	7.64 (1.85)	5.0	7.10	11.9
		Week 8	17	15	7.57 (1.95)	5.3	7.00	12.2
		Week 16	17	13	7.17 (1.23)	5.0	7.00	9.6
		Week 24	17	11	7.33 (1.41)	4.9	7.30	9.7
	Placebo	Day 1	21	21	7.97 (1.12)	6.5	7.70	10.5
		Week 4	21	18	7.98 (1.11)	6.5	7.60	10.2
		Week 8	21	17	8.38 (1.70)	6.3	8.10	13.1
		Week 16	21	14	7.82 (1.06)	6.2	7.95	9.3
		Week 24	21	15	8.67 (2.45)	5.9	8.10	15.3

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group, n = Number of valid observations, SD = Standard deviation, Q50 = median, HbA1c = Glycated haemoglobin, FPG = Fasting plasma glucose, BMI = Body mass index, Europe = Hungary, Israel, Russian Federation.
 Source Data: alb, created on: 30SEP2021

Table T2HAMC_FSCS: Change in censored HbA1c at Week 24 by subgroup
PFAS

Subgroup	Treatment	Time point	N	n (%)	Repeated measures analysis				
					Change from Baseline		Treatment Difference		
					LS-Mean (SE)	95% CI	LS-Mean (SE)	95% CI	p-value
A: Age	Dapa 10mg	Week 24							0.647
<= 15 years	Dapa 10mg	Week 24	16	10 (62.5)	-0.04 (0.46)	(-1.00, 0.91)	-0.92 (0.67)	(-2.31, 0.48)	0.187
	Placebo	Week 24	14	9 (64.3)	0.87 (0.49)	(-0.15, 1.90)			
> 15 and < 18 years	Dapa 10mg	Week 24	13	12 (92.3)	0.17 (0.53)	(-0.94, 1.28)	0.05 (0.86)	(-1.75, 1.86)	0.950
	Placebo	Week 24	10	8 (80.0)	0.11 (0.66)	(-1.27, 1.50)			
B: Sex	Dapa 10mg	Week 24							0.228
Male	Dapa 10mg	Week 24	12	9 (75.0)	-0.22 (0.37)	(-1.02, 0.59)	0.20 (0.66)	(-1.22, 1.62)	0.767
	Placebo	Week 24	9	5 (55.6)	-0.42 (0.48)	(-1.46, 0.63)			
Female	Dapa 10mg	Week 24	17	13 (76.5)	0.09 (0.48)	(-0.90, 1.07)	-0.83 (0.70)	(-2.26, 0.59)	0.241
	Placebo	Week 24	15	12 (80.0)	0.92 (0.50)	(-0.11, 1.95)			
C: Race	Dapa 10mg	Week 24							0.272
White	Dapa 10mg	Week 24	23	17 (73.9)	-0.13 (0.29)	(-0.74, 0.47)	-0.00 (0.59)	(-1.23, 1.23)	0.995
	Placebo	Week 24	9	5 (55.6)	-0.13 (0.51)	(-1.20, 0.94)			
Non-White	Dapa 10mg	Week 24	6	5 (83.3)	0.53 (0.87)	(-1.31, 2.37)	-0.40 (1.05)	(-2.61, 1.81)	0.709
	Placebo	Week 24	15	12 (80.0)	0.93 (0.58)	(-0.29, 2.15)			
D: Baseline BMI	Dapa 10mg	Week 24							0.621
< 30 kg/m**2	Dapa 10mg	Week 24	15	11 (73.3)	0.04 (0.56)	(-1.21, 1.28)	-0.65 (1.09)	(-3.09, 1.79)	0.565
	Placebo	Week 24	7	4 (57.1)	0.69 (0.94)	(-1.41, 2.78)			
>= 30 kg/m**2	Dapa 10mg	Week 24	14	11 (78.6)	0.28 (0.48)	(-0.71, 1.26)	-0.11 (0.67)	(-1.48, 1.26)	0.870
	Placebo	Week 24	17	13 (76.5)	0.39 (0.45)	(-0.54, 1.31)			

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group, n = Number of valid observations, SE = Standard error, CI = Confidence interval, HbA1c = Glycated haemoglobin, LS-Mean = Least square mean. Only results for Week 24 printed.
Per subgroup, a mixed repeated measures model was applied with fixed factors for treatment, week, interactions treatment-by-week, baseline-by-week and baseline as covariate.
Interaction test utilizes same model with additional interaction effects for subgroup with treatment, subgroup with week and subgroup with week with treatment.
Source Data: alb, created on: 30SEP2021

Table T2HAMC_FSCS: Change in censored HbA1c at Week 24 by subgroup
 PFAS

Subgroup	Treatment	Time point	N	n (%)	Repeated measures analysis				
					Change from Baseline		Treatment Difference		
					LS-Mean (SE)	95% CI	LS-Mean (SE)	95% CI	p-value
E: Baseline HbA1c	Dapa 10mg	Week 24							0.764
< 8 %	Dapa 10mg	Week 24	19	17 (89.5)	-0.13 (0.35)	(-0.85, 0.58)	-0.79 (0.61)	(-2.04, 0.46)	0.205
	Placebo	Week 24	12	9 (75.0)	0.66 (0.49)	(-0.35, 1.66)			
>= 8 %	Dapa 10mg	Week 24	10	5 (50.0)	0.30 (0.78)	(-1.35, 1.95)	-0.28 (1.05)	(-2.50, 1.93)	0.791
	Placebo	Week 24	12	8 (66.7)	0.58 (0.67)	(-0.84, 2.00)			
F: Background diabetic medication	Dapa 10mg	Week 24							0.502
Metformin only	Dapa 10mg	Week 24	11	9 (81.8)	-0.34 (0.42)	(-1.22, 0.54)	-0.54 (0.63)	(-1.86, 0.77)	0.397
	Placebo	Week 24	14	11 (78.6)	0.20 (0.39)	(-0.62, 1.02)			
Insulin or insulin + metformin	Dapa 10mg	Week 24	18	13 (72.2)	0.17 (0.52)	(-0.91, 1.26)	-0.90 (0.91)	(-2.77, 0.96)	0.328
	Placebo	Week 24	10	6 (60.0)	1.08 (0.72)	(-0.41, 2.57)			
G: Geographic region	Dapa 10mg	Week 24							0.348
Europe	Dapa 10mg	Week 24	12	11 (91.7)	-0.40 (0.43)	(-1.36, 0.55)	0.19 (1.10)	(-2.25, 2.63)	0.864
	Placebo	Week 24	3	2 (66.7)	-0.60 (1.01)	(-2.85, 1.65)			
Non-Europe	Dapa 10mg	Week 24	17	11 (64.7)	0.07 (0.49)	(-0.92, 1.06)	-0.66 (0.66)	(-1.99, 0.67)	0.322
	Placebo	Week 24	21	15 (71.4)	0.73 (0.42)	(-0.14, 1.59)			

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group, n = Number of valid observations, SE = Standard error, CI = Confidence interval, HbA1c = Glycated haemoglobin, LS-Mean = Least square mean. Only results for Week 24 printed.
 Per subgroup, a mixed repeated measures model was applied with fixed factors for treatment, week, interactions treatment-by-week, baseline-by-week and baseline as covariate.
 Interaction test utilizes same model with additional interaction effects for subgroup with treatment, subgroup with week and subgroup with week with treatment.
 Source Data: alb, created on: 30SEP2021

Table T2HAMC_FSHS: Hedges G for Change in censored HbA1c at Week 24 by subgroup
 PFAS

Hedges G for Change in censored HbA1c at Week 24	Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max	Hedges G	
									Effect size (SD)	95% CI
A: Age										
<= 15 years	Dapa 10mg	Week 4	16	13	-0.39 (0.77)	-1.7	-0.60	1.6	-0.75 (0.42)	[-1.57, 0.06]
		Week 8	16	13	-0.55 (1.07)	-3.0	-0.80	1.8	-0.68 (0.42)	[-1.50, 0.15]
		Week 16	16	12	-0.44 (1.10)	-3.0	-0.50	1.9	-0.62 (0.45)	[-1.51, 0.27]
		Week 24	16	10	-0.18 (1.29)	-2.2	-0.50	2.6	-0.53 (0.47)	[-1.45, 0.39]
	Placebo	Week 4	14	12	0.06 (0.31)	-0.4	0.00	0.7		
		Week 8	14	11	0.07 (0.68)	-0.7	-0.10	1.5		
		Week 16	14	9	0.21 (0.98)	-0.8	-0.10	1.8		
		Week 24	14	9	0.67 (1.87)	-0.5	-0.40	4.2		
> 15 and < 18 years	Dapa 10mg	Week 4	13	12	-0.45 (0.36)	-1.0	-0.50	0.1	-1.22 (0.50)	[-2.19, -0.24]
		Week 8	13	13	-0.33 (0.73)	-1.7	-0.40	1.3	-0.77 (0.47)	[-1.69, 0.14]
		Week 16	13	10	-0.33 (1.13)	-2.4	-0.20	1.4	0.13 (0.49)	[-0.84, 1.10]
		Week 24	13	12	0.06 (1.44)	-2.6	-0.15	2.1	-0.19 (0.46)	[-1.08, 0.71]
	Placebo	Week 4	10	8	-0.06 (0.24)	-0.3	-0.05	0.3		
		Week 8	10	8	0.49 (1.46)	-0.7	0.00	3.9		
		Week 16	10	7	-0.46 (0.74)	-2.0	-0.20	0.3		
		Week 24	10	8	0.41 (2.43)	-1.8	-0.30	6.1		

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group,
 n = Number of valid observations, Q50 = Median, SD = Standard deviation, CI = Confidence interval,
 HbA1c = Glycated haemoglobin.
 Source Data: alb, created on: 30SEP2021

Table T2HAMC_FSHS: Hedges G for Change in censored HbA1c at Week 24 by subgroup
 PFAS

Hedges G for Change in censored HbA1c at Week 24	Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max	Hedges G	
									Effect size (SD)	95% CI
B: Sex										
Male	Dapa 10mg	Week 4	12	11	-0.49 (0.39)	-1.0	-0.50	0.1	-1.18 (0.55)	[-2.26, -0.10]
		Week 8	12	10	-0.28 (0.82)	-1.7	-0.15	1.3	0.16 (0.55)	[-0.91, 1.24]
		Week 16	12	9	-0.23 (0.88)	-1.7	-0.20	1.4	0.71 (0.58)	[-0.42, 1.84]
		Week 24	12	9	-0.17 (1.01)	-2.0	-0.20	1.3	0.26 (0.56)	[-0.84, 1.35]
	Placebo	Week 4	9	6	-0.07 (0.29)	-0.3	-0.20	0.3		
		Week 8	9	5	-0.40 (0.48)	-0.7	-0.70	0.4		
		Week 16	9	5	-0.82 (0.72)	-2.0	-0.80	-0.2		
		Week 24	9	5	-0.42 (0.95)	-1.8	-0.40	0.6		
Female	Dapa 10mg	Week 4	17	14	-0.36 (0.74)	-1.7	-0.50	1.6	-0.73 (0.39)	[-1.50, 0.04]
		Week 8	17	16	-0.54 (0.96)	-3.0	-0.65	1.8	-0.97 (0.39)	[-1.73, -0.21]
		Week 16	17	13	-0.50 (1.23)	-3.0	-0.60	1.9	-0.71 (0.42)	[-1.54, 0.12]
		Week 24	17	13	0.03 (1.58)	-2.6	-0.20	2.6	-0.47 (0.41)	[-1.26, 0.33]
	Placebo	Week 4	15	14	0.04 (0.29)	-0.4	0.05	0.7		
		Week 8	15	14	0.48 (1.13)	-0.5	0.05	3.9		
		Week 16	15	11	0.25 (0.82)	-0.7	-0.10	1.8		
		Week 24	15	12	0.95 (2.32)	-0.8	-0.25	6.1		

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group,
 n = Number of valid observations, Q50 = Median, SD = Standard deviation, CI = Confidence interval,
 HbA1c = Glycated haemoglobin.
 Source Data: alb, created on: 30SEP2021

Table T2HAMC_FSHS: Hedges G for Change in censored HbA1c at Week 24 by subgroup
PFAS

Hedges G for Change in censored HbA1c at Week 24	Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max	Hedges G	
									Effect size (SD)	95% CI
C: Race										
White	Dapa 10mg	Week 4	23	19	-0.63 (0.39)	-1.7	-0.60	0.1	-2.31 (0.55)	[-3.39, -1.22]
		Week 8	23	20	-0.70 (0.73)	-3.0	-0.70	0.5	-0.92 (0.46)	[-1.82, -0.02]
		Week 16	23	17	-0.71 (0.91)	-3.0	-0.60	0.4	-0.51 (0.48)	[-1.45, 0.43]
		Week 24	23	17	-0.29 (1.35)	-2.6	-0.50	2.1	0.09 (0.51)	[-0.91, 1.09]
	Placebo	Week 4	9	7	0.17 (0.18)	-0.1	0.20	0.4		
		Week 8	9	7	-0.07 (0.53)	-0.7	-0.10	0.6		
		Week 16	9	6	-0.28 (0.58)	-0.8	-0.45	0.5		
		Week 24	9	5	-0.40 (0.42)	-0.8	-0.50	0.3		
Non-White	Dapa 10mg	Week 4	6	6	0.23 (0.72)	-0.4	0.00	1.6	0.67 (0.51)	[-0.33, 1.66]
		Week 8	6	6	0.45 (0.91)	-0.4	0.10	1.8	0.01 (0.50)	[-0.97, 0.99]
		Week 16	6	5	0.70 (1.00)	-0.6	0.70	1.9	0.62 (0.56)	[-0.48, 1.72]
		Week 24	6	5	0.76 (1.13)	-0.2	0.60	2.6	-0.09 (0.53)	[-1.13, 0.96]
	Placebo	Week 4	15	13	-0.08 (0.30)	-0.4	-0.10	0.7		
		Week 8	15	12	0.43 (1.27)	-0.7	-0.05	3.9		
		Week 16	15	10	0.04 (1.09)	-2.0	-0.15	1.8		
		Week 24	15	12	0.94 (2.39)	-1.8	0.15	6.1		

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group,
n = Number of valid observations, Q50 = Median, SD = Standard deviation, CI = Confidence interval,
HbA1c = Glycated haemoglobin.

Source Data: alb, created on: 30SEP2021

Table T2HAMC_FSHS: Hedges G for Change in censored HbA1c at Week 24 by subgroup
 PFAS

Hedges G for Change in censored HbA1c at Week 24	Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max	Hedges G	
									Effect size (SD)	95% CI
D: Baseline BMI										
< 30 kg/m**2	Dapa 10mg	Week 4	15	14	-0.36 (0.77)	-1.7	-0.50	1.6	-0.93 (0.54)	[-2.00, 0.14]
		Week 8	15	13	-0.40 (1.08)	-3.0	-0.40	1.8	-0.67 (0.58)	[-1.81, 0.48]
		Week 16	15	11	-0.52 (1.36)	-3.0	-0.60	1.9	-0.75 (0.60)	[-1.93, 0.43]
		Week 24	15	11	-0.42 (1.38)	-2.6	-0.20	2.6	-0.74 (0.60)	[-1.92, 0.44]
	Placebo	Week 4	7	5	0.28 (0.25)	0.1	0.20	0.7		
		Week 8	7	4	0.30 (0.91)	-0.7	0.20	1.5		
		Week 16	7	4	0.45 (1.07)	-0.8	0.40	1.8		
		Week 24	7	4	0.80 (2.31)	-0.8	-0.10	4.2		
>= 30 kg/m**2	Dapa 10mg	Week 4	14	11	-0.50 (0.28)	-1.0	-0.50	0.0	-1.63 (0.46)	[-2.54, -0.73]
		Week 8	14	13	-0.48 (0.73)	-1.7	-0.60	1.3	-0.74 (0.39)	[-1.50, 0.03]
		Week 16	14	11	-0.26 (0.78)	-1.7	-0.40	1.4	-0.01 (0.42)	[-0.82, 0.81]
		Week 24	14	11	0.32 (1.28)	-2.0	0.60	2.1	-0.08 (0.41)	[-0.89, 0.72]
	Placebo	Week 4	17	15	-0.08 (0.24)	-0.4	-0.10	0.4		
		Week 8	17	15	0.23 (1.13)	-0.7	-0.10	3.9		
		Week 16	17	12	-0.26 (0.84)	-2.0	-0.25	1.7		
		Week 24	17	13	0.47 (2.11)	-1.8	-0.40	6.1		

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group,
 n = Number of valid observations, Q50 = Median, SD = Standard deviation, CI = Confidence interval,
 HbA1c = Glycated haemoglobin.
 Source Data: alb, created on: 30SEP2021

Table T2HAMC_FSHS: Hedges G for Change in censored HbA1c at Week 24 by subgroup
 PFAS

Hedges G for Change in censored HbA1c at Week 24	Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max	Hedges G	
									Effect size (SD)	95% CI
E: Baseline HbA1c										
< 8 %	Dapa 10mg	Week 4	19	17	-0.36 (0.59)	-1.0	-0.50	1.6	-0.92 (0.42)	[-1.74, -0.10]
		Week 8	19	18	-0.38 (0.69)	-1.0	-0.55	1.8	-0.90 (0.43)	[-1.74, -0.06]
		Week 16	19	18	-0.26 (0.87)	-2.4	-0.35	1.9	-0.60 (0.42)	[-1.42, 0.21]
		Week 24	19	17	-0.11 (1.12)	-2.6	-0.20	2.6	-0.52 (0.42)	[-1.34, 0.30]
	Placebo	Week 4	12	10	0.10 (0.26)	-0.2	0.05	0.7		
		Week 8	12	9	0.22 (0.64)	-0.7	0.10	1.5		
		Week 16	12	9	0.28 (0.92)	-0.8	-0.10	1.8		
		Week 24	12	9	0.63 (1.92)	-0.8	-0.40	4.2		
>= 8 %	Dapa 10mg	Week 4	10	8	-0.55 (0.64)	-1.7	-0.50	0.4	-0.98 (0.51)	[-1.97, 0.01]
		Week 8	10	8	-0.56 (1.32)	-3.0	-0.40	1.3	-0.61 (0.49)	[-1.57, 0.34]
		Week 16	10	4	-1.00 (1.86)	-3.0	-1.20	1.4	-0.37 (0.63)	[-1.61, 0.87]
		Week 24	10	5	0.16 (2.12)	-2.2	0.90	2.1	-0.13 (0.57)	[-1.24, 0.99]
	Placebo	Week 4	12	10	-0.08 (0.30)	-0.4	-0.15	0.4		
		Week 8	12	10	0.27 (1.38)	-0.7	-0.20	3.9		
		Week 16	12	7	-0.54 (0.74)	-2.0	-0.30	0.3		
		Week 24	12	8	0.45 (2.39)	-1.8	-0.25	6.1		

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group,
 n = Number of valid observations, Q50 = Median, SD = Standard deviation, CI = Confidence interval,
 HbA1c = Glycated haemoglobin.
 Source Data: alb, created on: 30SEP2021

Table T2HAMC_FSHS: Hedges G for Change in censored HbA1c at Week 24 by subgroup
 PFAS

Hedges G for Change in censored HbA1c at Week 24	Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max	Hedges G	
									Effect size (SD)	95% CI
F: Background diabetic medication										
Metformin only	Dapa 10mg	Week 4	11	9	-0.59 (0.30)	-1.0	-0.70	0.0	-1.79 (0.54)	[-2.85, -0.73]
		Week 8	11	10	-0.50 (0.36)	-1.0	-0.55	-0.1	-0.96 (0.46)	[-1.87, -0.05]
		Week 16	11	10	-0.32 (0.49)	-0.9	-0.40	0.7	-0.39 (0.45)	[-1.27, 0.50]
		Week 24	11	9	-0.29 (0.66)	-0.9	-0.50	1.3	-0.37 (0.45)	[-1.26, 0.52]
	Placebo	Week 4	14	11	-0.03 (0.33)	-0.4	-0.10	0.7		
		Week 8	14	11	-0.03 (0.59)	-0.7	-0.10	1.5		
		Week 16	14	10	-0.08 (0.73)	-0.8	-0.25	1.8		
		Week 24	14	11	0.15 (1.44)	-0.8	-0.50	4.2		
Insulin or insulin + metformin	Dapa 10mg	Week 4	18	16	-0.33 (0.71)	-1.7	-0.50	1.6	-0.65 (0.43)	[-1.48, 0.19]
		Week 8	18	16	-0.40 (1.13)	-3.0	-0.50	1.8	-0.82 (0.45)	[-1.70, 0.06]
		Week 16	18	12	-0.45 (1.43)	-3.0	-0.45	1.9	-0.27 (0.50)	[-1.25, 0.72]
		Week 24	18	13	0.12 (1.68)	-2.6	0.60	2.6	-0.55 (0.50)	[-1.53, 0.44]
	Placebo	Week 4	10	9	0.06 (0.24)	-0.3	0.10	0.4		
		Week 8	10	8	0.63 (1.46)	-0.7	0.45	3.9		
		Week 16	10	6	-0.08 (1.25)	-2.0	0.05	1.7		
		Week 24	10	6	1.28 (2.96)	-1.8	0.15	6.1		

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group,
 n = Number of valid observations, Q50 = Median, SD = Standard deviation, CI = Confidence interval,
 HbA1c = Glycated haemoglobin.
 Source Data: alb, created on: 30SEP2021

Table T2HAMC_FSHS: Hedges G for Change in censored HbA1c at Week 24 by subgroup
 PFAS

Hedges G for Change in censored HbA1c at Week 24	Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max	Hedges G		
									Effect size (SD)	95% CI	
G: Geographic region											
Europe	Dapa 10mg	Week 4	12	10	-0.70 (0.45)	-1.7	-0.65	0.0	-1.99 (0.89)	[-3.74, -0.24]	
		Week 8	12	11	-0.86 (0.79)	-3.0	-0.70	0.1	-1.13 (0.81)	[-2.71, 0.45]	
		Week 16	12	9	-1.01 (1.01)	-3.0	-0.80	-0.1	-0.92 (0.81)	[-2.51, 0.67]	
		Week 24	12	11	-0.40 (1.44)	-2.6	-0.50	2.1	0.11 (0.77)	[-1.40, 1.62]	
	Placebo	Week 4	3	2	0.15 (0.07)	0.1	0.15	0.2			
		Week 8	3	2	0.00 (0.42)	-0.3	0.00	0.3			
		Week 16	3	2	-0.10 (0.85)	-0.7	-0.10	0.5			
		Week 24	3	2	-0.55 (0.07)	-0.6	-0.55	-0.5			
Non-Europe	Dapa 10mg	Week 4	17	15	-0.23 (0.63)	-1.0	-0.40	1.6	-0.48 (0.35)	[-1.17, 0.22]	
		Week 8	17	15	-0.13 (0.88)	-1.7	-0.20	1.8	-0.40 (0.36)	[-1.10, 0.30]	
		Week 16	17	13	0.04 (0.95)	-1.7	0.10	1.9	0.12 (0.39)	[-0.63, 0.88]	
		Week 24	17	11	0.30 (1.23)	-2.0	0.60	2.6	-0.21 (0.40)	[-0.99, 0.57]	
	Placebo	Week 4	21	18	-0.01 (0.30)	-0.4	0.00	0.7			
		Week 8	21	17	0.28 (1.12)	-0.7	-0.10	3.9			
		Week 16	21	14	-0.08 (0.96)	-2.0	-0.20	1.8			
		Week 24	21	15	0.69 (2.19)	-1.8	0.00	6.1			

Note: Dapa = Dapagliflozin, PFAS = Pediatric full analysis set, N = Number of subjects in treatment group,
 n = Number of valid observations, Q50 = Median, SD = Standard deviation, CI = Confidence interval,
 HbA1c = Glycated haemoglobin.
 Source Data: alb, created on: 30SEP2021

Table T2HA_PSFs: Course of HbA1c up to Week 24 by subgroup
PPPS

Course of HbA1c up to Week 24	Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max
A: Age								
<= 15 years	Dapa 10mg	Day 1	14	14	7.49 (1.37)	5.4	7.05	10.4
		Week 4	14	12	7.14 (1.66)	5.0	6.70	10.8
		Week 8	14	13	6.97 (1.59)	5.2	6.50	10.8
		Week 16	14	14	7.11 (1.38)	5.0	7.00	9.9
		Week 24	14	13	7.31 (1.94)	4.9	7.00	12.3
	Placebo	Day 1	10	10	7.85 (1.02)	6.5	7.85	9.7
		Week 4	10	9	7.64 (0.83)	6.5	7.60	9.1
		Week 8	10	9	7.63 (0.82)	6.3	7.90	8.4
		Week 16	10	8	7.74 (1.18)	6.2	7.95	9.2
		Week 24	10	9	8.46 (1.99)	6.1	7.80	12.1
> 15 and < 18 years	Dapa 10mg	Day 1	11	11	7.25 (0.86)	5.7	7.30	8.5
		Week 4	11	10	6.66 (0.86)	5.5	6.75	8.2
		Week 8	11	11	6.86 (1.10)	5.5	6.70	9.5
		Week 16	11	10	6.79 (1.30)	5.2	6.60	9.6
		Week 24	11	11	7.12 (1.64)	5.0	6.70	10.5
	Placebo	Day 1	7	7	8.46 (1.36)	6.7	8.50	10.5
		Week 4	7	6	8.35 (1.33)	7.0	8.00	10.2
		Week 8	7	7	9.06 (2.19)	7.1	8.20	13.1
		Week 16	7	6	7.85 (0.96)	6.5	7.70	9.3
		Week 24	7	7	8.84 (3.10)	5.9	8.10	15.3

Note: Dapa = Dapagliflozin, PPPS = Pediatric per protocol set, N = Number of subjects in treatment group, n = Number of valid observations, SD = Standard deviation, Q50 = median, HbA1c = Glycated haemoglobin, FPG = Fasting plasma glucose, BMI = Body mass index, Europe = Hungary, Israel, Russian Federation.
Source Data: alb, created on: 30SEP2021

Table T2HA_PSFs: Course of HbA1c up to Week 24 by subgroup
 PPPS

Course of HbA1c up to Week 24	Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max
B: Sex								
Male	Dapa 10mg	Day 1	11	11	7.29 (1.31)	5.4	7.10	9.5
		Week 4	11	10	6.65 (1.18)	5.0	6.50	8.7
		Week 8	11	10	6.75 (1.26)	5.3	6.35	9.5
		Week 16	11	11	6.88 (1.38)	5.0	6.80	9.6
		Week 24	11	10	6.74 (1.26)	4.9	6.55	9.1
	Placebo	Day 1	5	5	8.68 (1.52)	6.7	8.80	10.5
		Week 4	5	4	8.48 (1.45)	7.0	8.35	10.2
		Week 8	5	4	8.00 (1.30)	7.0	7.60	9.8
		Week 16	5	4	7.48 (0.93)	6.5	7.45	8.5
		Week 24	5	4	7.75 (1.45)	5.9	8.00	9.1
Female	Dapa 10mg	Day 1	14	14	7.45 (1.07)	6.2	7.15	10.4
		Week 4	14	12	7.15 (1.48)	5.4	6.95	10.8
		Week 8	14	14	7.04 (1.46)	5.2	6.85	10.8
		Week 16	14	13	7.06 (1.34)	5.2	6.90	9.9
		Week 24	14	14	7.56 (2.04)	5.0	7.25	12.3
	Placebo	Day 1	12	12	7.86 (0.97)	6.5	7.75	9.5
		Week 4	12	11	7.73 (0.91)	6.5	7.60	9.6
		Week 8	12	12	8.34 (1.83)	6.3	8.05	13.1
		Week 16	12	10	7.91 (1.12)	6.2	7.85	9.3
		Week 24	12	12	8.92 (2.69)	6.1	8.00	15.3

Note: Dapa = Dapagliflozin, PPPS = Pediatric per protocol set, N = Number of subjects in treatment group, n = Number of valid observations, SD = Standard deviation, Q50 = median, HbA1c = Glycated haemoglobin, FPG = Fasting plasma glucose, BMI = Body mass index, Europe = Hungary, Israel, Russian Federation.
 Source Data: alb, created on: 30SEP2021

Table T2HA_PSF.S: Course of HbA1c up to Week 24 by subgroup
 PPPS

Course of HbA1c up to Week 24	Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max
C: Race								
White	Dapa 10mg	Day 1	19	19	7.20 (1.10)	5.4	6.90	9.5
		Week 4	19	16	6.45 (0.98)	5.0	6.20	8.7
		Week 8	19	18	6.43 (0.86)	5.2	6.25	8.2
		Week 16	19	18	6.49 (0.96)	5.0	6.35	8.9
		Week 24	19	18	6.66 (1.35)	4.9	6.30	10.5
	Placebo	Day 1	6	6	8.32 (1.02)	6.7	8.50	9.7
		Week 4	6	5	8.16 (0.84)	7.0	8.50	9.1
		Week 8	6	5	7.76 (0.66)	7.0	8.10	8.4
		Week 16	6	5	7.60 (0.91)	6.5	7.80	8.8
		Week 24	6	5	7.70 (1.20)	5.9	7.90	9.1
Non-White	Dapa 10mg	Day 1	6	6	7.95 (1.26)	7.1	7.40	10.4
		Week 4	6	6	8.18 (1.46)	6.9	7.85	10.8
		Week 8	6	6	8.40 (1.58)	7.0	8.00	10.8
		Week 16	6	6	8.45 (1.24)	6.9	8.50	9.9
		Week 24	6	6	8.90 (1.94)	7.2	8.45	12.3
	Placebo	Day 1	11	11	7.98 (1.28)	6.5	7.50	10.5
		Week 4	11	10	7.81 (1.20)	6.5	7.55	10.2
		Week 8	11	11	8.48 (1.97)	6.3	7.90	13.1
		Week 16	11	9	7.89 (1.16)	6.2	7.90	9.3
		Week 24	11	11	9.05 (2.79)	6.1	8.10	15.3

Note: Dapa = Dapagliflozin, PPPS = Pediatric per protocol set, N = Number of subjects in treatment group, n = Number of valid observations, SD = Standard deviation, Q50 = median, HbA1c = Glycated haemoglobin, FPG = Fasting plasma glucose, BMI = Body mass index, Europe = Hungary, Israel, Russian Federation.
 Source Data: alb, created on: 30SEP2021

Table T2HA_PSF.S: Course of HbA1c up to Week 24 by subgroup
 PPPS

Course of HbA1c up to Week 24	Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max
D: Baseline BMI								
< 30 kg/m**2	Dapa 10mg	Day 1	13	13	7.48 (1.34)	5.7	7.10	10.4
		Week 4	13	12	7.13 (1.57)	5.5	6.65	10.8
		Week 8	13	12	7.09 (1.52)	5.5	6.50	10.8
		Week 16	13	13	7.05 (1.48)	5.2	6.80	9.9
		Week 24	13	12	7.12 (2.01)	5.0	6.55	12.3
	Placebo	Day 1	4	4	8.18 (1.30)	6.9	8.05	9.7
		Week 4	4	3	8.03 (0.93)	7.4	7.60	9.1
		Week 8	4	3	7.97 (0.51)	7.4	8.10	8.4
		Week 16	4	3	8.10 (0.56)	7.6	8.00	8.7
		Week 24	4	3	8.90 (2.31)	6.5	9.10	11.1
>= 30 kg/m**2	Dapa 10mg	Day 1	12	12	7.28 (0.98)	5.4	7.15	8.5
		Week 4	12	10	6.67 (1.05)	5.0	6.80	8.2
		Week 8	12	12	6.75 (1.22)	5.2	6.70	9.5
		Week 16	12	11	6.90 (1.21)	5.0	7.00	9.6
		Week 24	12	12	7.33 (1.58)	4.9	7.35	10.5
	Placebo	Day 1	13	13	8.08 (1.19)	6.5	8.00	10.5
		Week 4	13	12	7.90 (1.15)	6.5	7.60	10.2
		Week 8	13	13	8.32 (1.86)	6.3	7.90	13.1
		Week 16	13	11	7.70 (1.16)	6.2	7.80	9.3
		Week 24	13	13	8.56 (2.57)	5.9	7.90	15.3

Note: Dapa = Dapagliflozin, PPPS = Pediatric per protocol set, N = Number of subjects in treatment group, n = Number of valid observations, SD = Standard deviation, Q50 = median, HbA1c = Glycated haemoglobin, FPG = Fasting plasma glucose, BMI = Body mass index, Europe = Hungary, Israel, Russian Federation.
 Source Data: alb, created on: 30SEP2021

Table T2HA_PSFs: Course of HbA1c up to Week 24 by subgroup
PPPS

Course of HbA1c up to Week 24	Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max
E: Baseline HbA1c								
< 8 %	Dapa 10mg	Day 1	18	18	6.81 (0.65)	5.4	6.90	7.9
		Week 4	18	17	6.44 (0.91)	5.0	6.30	8.7
		Week 8	18	18	6.42 (0.87)	5.2	6.25	8.9
		Week 16	18	18	6.55 (1.01)	5.0	6.40	9.0
		Week 24	18	18	6.68 (1.21)	4.9	6.45	9.7
	Placebo	Day 1	8	8	7.09 (0.47)	6.5	7.10	7.7
		Week 4	8	8	7.18 (0.46)	6.5	7.35	7.6
		Week 8	8	8	7.30 (0.76)	6.3	7.25	8.4
		Week 16	8	8	7.34 (1.13)	6.2	7.15	9.2
		Week 24	8	8	7.99 (2.35)	5.9	7.05	12.1
>= 8 %	Dapa 10mg	Day 1	7	7	8.86 (0.82)	8.1	8.50	10.4
		Week 4	7	5	8.56 (1.38)	7.1	8.20	10.8
		Week 8	7	6	8.42 (1.53)	6.4	8.05	10.8
		Week 16	7	6	8.27 (1.43)	6.4	8.35	9.9
		Week 24	7	6	8.85 (2.29)	6.1	8.60	12.3
	Placebo	Day 1	9	9	9.00 (0.80)	8.0	8.80	10.5
		Week 4	9	7	8.79 (0.92)	7.6	8.60	10.2
		Week 8	9	8	9.21 (1.83)	7.8	8.30	13.1
		Week 16	9	6	8.38 (0.59)	7.8	8.25	9.3
		Week 24	9	8	9.26 (2.53)	7.5	8.50	15.3

Note: Dapa = Dapagliflozin, PPPS = Pediatric per protocol set, N = Number of subjects in treatment group, n = Number of valid observations, SD = Standard deviation, Q50 = median, HbA1c = Glycated haemoglobin, FPG = Fasting plasma glucose, BMI = Body mass index, Europe = Hungary, Israel, Russian Federation.
Source Data: alb, created on: 30SEP2021

Table T2HA_PSFs: Course of HbA1c up to Week 24 by subgroup
 PPPS

Course of HbA1c up to Week 24	Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max
F: Background diabetic medication								
Metformin only	Dapa 10mg	Day 1	10	10	6.62 (0.57)	5.4	6.85	7.3
		Week 4	10	9	6.00 (0.62)	5.0	6.00	6.9
		Week 8	10	10	6.12 (0.66)	5.2	6.20	7.1
		Week 16	10	10	6.30 (0.91)	5.0	6.25	8.0
		Week 24	10	10	6.32 (0.97)	4.9	6.15	8.4
	Placebo	Day 1	11	11	7.61 (0.97)	6.5	7.50	9.7
		Week 4	11	10	7.40 (0.63)	6.5	7.50	8.6
		Week 8	11	10	7.40 (0.69)	6.3	7.40	8.4
		Week 16	11	9	7.24 (0.86)	6.2	7.40	8.7
		Week 24	11	10	7.50 (1.48)	5.9	7.40	11.1
Insulin or insulin + metformin	Dapa 10mg	Day 1	15	15	7.89 (1.19)	5.7	7.90	10.4
		Week 4	15	13	7.56 (1.36)	5.8	7.30	10.8
		Week 8	15	14	7.49 (1.46)	5.7	7.05	10.8
		Week 16	15	14	7.46 (1.40)	5.2	7.05	9.9
		Week 24	15	14	7.86 (1.96)	5.0	7.45	12.3
	Placebo	Day 1	6	6	9.00 (1.01)	7.5	9.00	10.5
		Week 4	6	5	8.98 (1.04)	7.5	9.10	10.2
		Week 8	6	6	9.68 (1.91)	8.1	9.10	13.1
		Week 16	6	5	8.76 (0.53)	8.0	8.80	9.3
		Week 24	6	6	10.50 (2.71)	8.3	9.30	15.3

Note: Dapa = Dapagliflozin, PPPS = Pediatric per protocol set, N = Number of subjects in treatment group, n = Number of valid observations, SD = Standard deviation, Q50 = median, HbA1c = Glycated haemoglobin, FPG = Fasting plasma glucose, BMI = Body mass index, Europe = Hungary, Israel, Russian Federation.
 Source Data: alb, created on: 30SEP2021

Table T2HA_PSFs: Course of HbA1c up to Week 24 by subgroup
 PPPS

Course of HbA1c up to Week 24	Treatment	Time point	N	n	Mean (SD)	Min	Q50	Max
G: Geographic region								
Europe	Dapa 10mg	Day 1	9	9	7.01 (0.81)	6.2	6.80	8.5
		Week 4	9	8	6.20 (0.69)	5.4	6.00	7.3
		Week 8	9	9	6.28 (0.81)	5.2	6.20	7.9
		Week 16	9	8	6.06 (0.68)	5.2	6.10	7.1
		Week 24	9	9	6.53 (1.61)	5.0	6.10	10.5
	Placebo	Day 1	2	2	9.10 (0.85)	8.5	9.10	9.7
		Week 4	2	1	8.60 ()	8.6	8.60	8.6
		Week 8	2	1	8.20 ()	8.2	8.20	8.2
		Week 16	2	1	7.80 ()	7.8	7.80	7.8
		Week 24	2	1	7.90 ()	7.9	7.90	7.9
Non-Europe	Dapa 10mg	Day 1	16	16	7.59 (1.30)	5.4	7.25	10.4
		Week 4	16	14	7.34 (1.47)	5.0	7.05	10.8
		Week 8	16	15	7.31 (1.50)	5.3	7.00	10.8
		Week 16	16	16	7.44 (1.35)	5.0	7.15	9.9
		Week 24	16	15	7.63 (1.79)	4.9	7.30	12.3
	Placebo	Day 1	15	15	7.97 (1.17)	6.5	7.70	10.5
		Week 4	15	14	7.88 (1.10)	6.5	7.60	10.2
		Week 8	15	15	8.26 (1.73)	6.3	7.90	13.1
		Week 16	15	13	7.78 (1.09)	6.2	7.90	9.3
		Week 24	15	15	8.67 (2.53)	5.9	8.10	15.3

Note: Dapa = Dapagliflozin, PPPS = Pediatric per protocol set, N = Number of subjects in treatment group, n = Number of valid observations, SD = Standard deviation, Q50 = median, HbA1c = Glycated haemoglobin, FPG = Fasting plasma glucose, BMI = Body mass index, Europe = Hungary, Israel, Russian Federation.
 Source Data: alb, created on: 30SEP2021

Table T2HAC_PSCS: Change in HbA1c at Week 24 by subgroup
 PPPS

Subgroup	Treatment	Time point	N	n (%)	Repeated measures analysis				
					Change from Baseline		Treatment Difference		p-value
					LS-Mean (SE)	95% CI	LS-Mean (SE)	95% CI	
A: Age	Dapa 10mg	Week 24							0.675
<= 15 years	Dapa 10mg	Week 24	14	13 (92.9)	0.02 (0.45)	(-0.93, 0.96)	-0.80 (0.72)	(-2.31, 0.71)	0.282
	Placebo	Week 24	10	9 (90.0)	0.82 (0.56)	(-0.36, 1.99)			
> 15 and < 18 years	Dapa 10mg	Week 24	11	11 (100.0)	-0.06 (0.63)	(-1.40, 1.28)	-0.31 (1.11)	(-2.68, 2.06)	0.784
	Placebo	Week 24	7	7 (100.0)	0.25 (0.84)	(-1.54, 2.04)			
B: Sex	Dapa 10mg	Week 24							0.201
Male	Dapa 10mg	Week 24	11	10 (90.9)	-0.42 (0.33)	(-1.14, 0.30)	-0.03 (0.67)	(-1.50, 1.44)	0.969
	Placebo	Week 24	5	4 (80.0)	-0.40 (0.56)	(-1.63, 0.84)			
Female	Dapa 10mg	Week 24	14	14 (100.0)	0.17 (0.52)	(-0.91, 1.24)	-0.79 (0.78)	(-2.39, 0.81)	0.318
	Placebo	Week 24	12	12 (100.0)	0.96 (0.57)	(-0.21, 2.13)			
C: Race	Dapa 10mg	Week 24							0.108
White	Dapa 10mg	Week 24	19	18 (94.7)	-0.40 (0.26)	(-0.93, 0.14)	-0.15 (0.59)	(-1.38, 1.09)	0.809
	Placebo	Week 24	6	5 (83.3)	-0.25 (0.53)	(-1.35, 0.85)			
Non-White	Dapa 10mg	Week 24	6	6 (100.0)	0.95 (0.94)	(-1.07, 2.97)	-0.12 (1.17)	(-2.63, 2.40)	0.923
	Placebo	Week 24	11	11 (100.0)	1.07 (0.70)	(-0.43, 2.56)			
D: Baseline BMI	Dapa 10mg	Week 24							0.613
< 30 kg/m**2	Dapa 10mg	Week 24	13	12 (92.3)	-0.14 (0.50)	(-1.22, 0.95)	-1.38 (1.15)	(-3.87, 1.11)	0.253
	Placebo	Week 24	4	3 (75.0)	1.24 (1.04)	(-1.00, 3.49)			
>= 30 kg/m**2	Dapa 10mg	Week 24	12	12 (100.0)	0.08 (0.55)	(-1.05, 1.21)	-0.36 (0.79)	(-2.00, 1.27)	0.648
	Placebo	Week 24	13	13 (100.0)	0.45 (0.53)	(-0.65, 1.55)			

Note: Dapa = Dapagliflozin, PPPS = Pediatric per protocol set, N = Number of subjects in treatment group, n = Number of valid observations, SE = Standard error, CI = Confidence interval, HbA1c = Glycated haemoglobin, LS-Mean = Least square mean. Only results for Week 24 printed. Per subgroup, a mixed repeated measures model was applied with fixed factors for treatment, week, interactions treatment-by-week, baseline-by-week and baseline as covariate. Interaction test utilizes same model with additional interaction effects for subgroup with treatment, subgroup with week and subgroup with week with treatment.
 Source Data: alb, created on: 30SEP2021

Table T2HAC_PSCS: Change in HbA1c at Week 24 by subgroup
 PPPS

Subgroup	Treatment	Time point	N	n (%)	Repeated measures analysis				
					Change from Baseline		Treatment Difference		
					LS-Mean (SE)	95% CI	LS-Mean (SE)	95% CI	p-value
E: Baseline HbA1c	Dapa 10mg	Week 24							0.612
< 8 %	Dapa 10mg	Week 24	18	18 (100.0)	-0.13 (0.37)	(-0.88, 0.63)	-1.02 (0.67)	(-2.41, 0.36)	0.141
	Placebo	Week 24	8	8 (100.0)	0.90 (0.55)	(-0.25, 2.05)			
>= 8 %	Dapa 10mg	Week 24	7	6 (85.7)	0.13 (0.86)	(-1.74, 2.00)	-0.22 (1.17)	(-2.76, 2.33)	0.855
	Placebo	Week 24	9	8 (88.9)	0.35 (0.79)	(-1.38, 2.08)			
F: Background diabetic medication	Dapa 10mg	Week 24							0.150
Metformin only	Dapa 10mg	Week 24	10	10 (100.0)	-0.39 (0.41)	(-1.24, 0.47)	-0.58 (0.62)	(-1.89, 0.74)	0.367
	Placebo	Week 24	11	10 (90.9)	0.19 (0.41)	(-0.67, 1.06)			
Insulin or insulin + metformin	Dapa 10mg	Week 24	15	14 (93.3)	0.01 (0.56)	(-1.18, 1.19)	-1.82 (1.14)	(-4.20, 0.57)	0.127
	Placebo	Week 24	6	6 (100.0)	1.82 (0.94)	(-0.15, 3.80)			
G: Geographic region	Dapa 10mg	Week 24							0.457
Europe	Dapa 10mg	Week 24	9	9 (100.0)	-0.44 (0.40)	(-1.40, 0.51)	0.75 (1.49)	(-2.77, 4.27)	0.629
	Placebo	Week 24	2	1 (50.0)	-1.20 (1.41)	(-4.53, 2.14)			
Non-Europe	Dapa 10mg	Week 24	16	15 (93.8)	0.16 (0.48)	(-0.83, 1.15)	-0.57 (0.70)	(-1.99, 0.86)	0.422
	Placebo	Week 24	15	15 (100.0)	0.73 (0.50)	(-0.29, 1.74)			

Note: Dapa = Dapagliflozin, PPPS = Pediatric per protocol set, N = Number of subjects in treatment group, n = Number of valid observations, SE = Standard error, CI = Confidence interval, HbA1c = Glycated haemoglobin, LS-Mean = Least square mean. Only results for Week 24 printed. Per subgroup, a mixed repeated measures model was applied with fixed factors for treatment, week, interactions treatment-by-week, baseline-by-week and baseline as covariate. Interaction test utilizes same model with additional interaction effects for subgroup with treatment, subgroup with week and subgroup with week with treatment.
 Source Data: alb, created on: 30SEP2021