Table S-187 Shift of Laboratory Findings of Biochemistry in 52-Week Long-term Period with Monotherapy and Combination Therapy (PXL008-019; Long-term Safety Population)

Parameter / Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
Alanine Aminotransferase (U/L)													
Week 4	m		134	127	64	64	64	65	63	70	63	580	714
	Low	Normal	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
	Normal	Low	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
		Normal	114 (85.1%)	109 (85.8%)	56 (87.5%)	54 (84.4%)	54 (84.4%)	59 (90.8%)	52 (82.5%)	53 (75.7%)	53 (84.1%)	490 (84.5%)	604 (84.6%)
		High	5 (3.7%)	3 (2.4%)	1 (1.6%)	0	0	1 (1.5%)	3 (4.8%)	3 (4.3%)	2 (3.2%)	13 (2.2%)	18 (2.5%)
	High	Normal	6 (4.5%)	8 (6.3%)	2 (3.1%)	5 (7.8%)	3 (4.7%)	3 (4.6%)	3 (4.8%)	4 (5.7%)	4 (6.3%)	32 (5.5%)	38 (5.3%)
		High	9 (6.7%)	5 (3.9%)	5 (7.8%)	5 (7.8%)	7 (10.9%)	2 (3.1%)	5 (7.9%)	10 (14.3%)	4 (6.3%)	43 (7.4%)	52 (7.3%)
Week 8	m		132	124	63	64	64	65	62	69	62	573	705
	Low	Low	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
	Normal	Low	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
		Normal	115 (87.1%)	104 (83.9%)	57 (90.5%)	51 (79.7%)	54 (84.4%)	59 (90.8%)	54 (87.1%)	53 (76.8%)	51 (82.3%)	483 (84.3%)	598 (84.8%)
		High	2 (1.5%)	5 (4.0%)	0	3 (4.7%)	0	1 (1.5%)	0	2 (2.9%)	3 (4.8%)	14 (2.4%)	16 (2.3%)
	High	Normal	8 (6.1%)	7 (5.6%)	3 (4.8%)	4 (6.3%)	4 (6.3%)	5 (7.7%)	4 (6.5%)	7 (10.1%)	6 (9.7%)	40 (7.0%)	48 (6.8%)
		High	7 (5.3%)	6 (4.8%)	3 (4.8%)	6 (9.4%)	6 (9.4%)	0	4 (6.5%)	7 (10.1%)	2 (3.2%)	34 (5.9%)	41 (5.8%)
Week 12	m		131	122	63	64	64	65	62	68	63	571	702
	Low	Low	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
	Normal	Low	1 (0.8%)	1 (0.8%)	0	0	0	0	0	0	1 (1.6%)	2 (0.4%)	3 (0.4%)
		Normal	111 (84.7%)	102 (83.6%)	56 (88.9%)	53 (82.8%)	52 (81.3%)	57 (87.7%)	54 (87.1%)	52 (76.5%)	51 (81.0%)	477 (83.5%)	588 (83.8%)
		High	4 (3.1%)	6 (4.9%)	1 (1.6%)	1 (1.6%)	2 (3.1%)	3 (4.6%)	0	2 (2.9%)	3 (4.8%)	18 (3.2%)	22 (3.1%)
	High	Normal	8 (6.1%)	5 (4.1%)	2 (3.2%)	5 (7.8%)	6 (9.4%)	4 (6.2%)	4 (6.5%)	7 (10.3%)	5 (7.9%)	38 (6.7%)	46 (6.6%)
		High	7 (5.3%)	7 (5.7%)	4 (6.3%)	5 (7.8%)	4 (6.3%)	1 (1.5%)	4 (6.5%)	7 (10.3%)	3 (4.8%)	35 (6.1%)	42 (6.0%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
Week 16	m		130	123	63	64	64	64	62	69	63	572	702
	Low	Low	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
	Normal	Low	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
		Normal	111 (85.4%)	97 (78.9%)	56 (88.9%)	52 (81.3%)	53 (82.8%)	55 (85.9%)	53 (85.5%)	51 (73.9%)	54 (85.7%)	471 (82.3%)	582 (82.9%)
		High	4 (3.1%)	12 (9.8%)	1 (1.6%)	2 (3.1%)	1 (1.6%)	4 (6.3%)	1 (1.6%)	4 (5.8%)	1 (1.6%)	26 (4.5%)	30 (4.3%)
	High	Normal	8 (6.2%)	7 (5.7%)	4 (6.3%)	6 (9.4%)	6 (9.4%)	4 (6.3%)	3 (4.8%)	5 (7.2%)	4 (6.3%)	39 (6.8%)	47 (6.7%)
		High	7 (5.4%)	5 (4.1%)	2 (3.2%)	4 (6.3%)	4 (6.3%)	1 (1.6%)	5 (8.1%)	9 (13.0%)	4 (6.3%)	34 (5.9%)	41 (5.8%)
Week 20	m		130	123	62	63	64	65	61	69	63	570	700
	Low	Low	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
	Normal	Low	1 (0.8%)	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	2 (0.3%)
		Normal	111 (85.4%)	101 (82.1%)	54 (87.1%)	51 (81.0%)	52 (81.3%)	55 (84.6%)	51 (83.6%)	52 (75.4%)	50 (79.4%)	466 (81.8%)	577 (82.4%)
		High	3 (2.3%)	8 (6.5%)	2 (3.2%)	2 (3.2%)	2 (3.1%)	5 (7.7%)	3 (4.9%)	3 (4.3%)	5 (7.9%)	30 (5.3%)	33 (4.7%)
	High	Normal	7 (5.4%)	5 (4.1%)	3 (4.8%)	6 (9.5%)	2 (3.1%)	4 (6.2%)	2 (3.3%)	7 (10.1%)	4 (6.3%)	33 (5.8%)	40 (5.7%)
		High	8 (6.2%)	7 (5.7%)	3 (4.8%)	4 (6.3%)	8 (12.5%)	1 (1.5%)	5 (8.2%)	7 (10.1%)	4 (6.3%)	39 (6.8%)	47 (6.7%)
Week 24	m		130	122	62	63	64	65	61	69	63	569	699
	Low	Low	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
	Normal	Low	1 (0.8%)	1 (0.8%)	0	0	1 (1.6%)	0	0	0	0	2 (0.4%)	3 (0.4%)
		Normal	109 (83.8%)	98 (80.3%)	54 (87.1%)	50 (79.4%)	50 (78.1%)	54 (83.1%)	50 (82.0%)	52 (75.4%)	51 (81.0%)	459 (80.7%)	568 (81.3%)
		High	5 (3.8%)	11 (9.0%)	2 (3.2%)	3 (4.8%)	3 (4.7%)	6 (9.2%)	4 (6.6%)	3 (4.3%)	4 (6.3%)	36 (6.3%)	41 (5.9%)
	High	Normal	7 (5.4%)	5 (4.1%)	4 (6.5%)	5 (7.9%)	3 (4.7%)	3 (4.6%)	1 (1.6%)	8 (11.6%)	4 (6.3%)	33 (5.8%)	40 (5.7%)
		High	8 (6.2%)	6 (4.9%)	2 (3.2%)	5 (7.9%)	7 (10.9%)	2 (3.1%)	6 (9.8%)	6 (8.7%)	4 (6.3%)	38 (6.7%)	46 (6.6%)
Week 32	m		128	120	62	60	62	65	60	69	63	561	689
	Low	Low	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
	Normal	Normal	107 (83.6%)	99 (82.5%)	55 (88.7%)	48 (80.0%)	52 (83.9%)	56 (86.2%)	49 (81.7%)	51 (73.9%)	52 (82.5%)	462 (82.4%)	569 (82.6%)
		High	7 (5.5%)	9 (7.5%)	1 (1.6%)	2 (3.3%)	0	4 (6.2%)	4 (6.7%)	4 (5.8%)	3 (4.8%)	27 (4.8%)	34 (4.9%)
	High	Normal	5 (3.9%)	6 (5.0%)	2 (3.2%)	5 (8.3%)	3 (4.8%)	4 (6.2%)	1 (1.7%)	8 (11.6%)	4 (6.3%)	33 (5.9%)	38 (5.5%)
		High	9 (7.0%)	5 (4.2%)	4 (6.5%)	5 (8.3%)	7 (11.3%)	1 (1.5%)	6 (10.0%)	6 (8.7%)	4 (6.3%)	38 (6.8%)	47 (6.8%)
Week 40	m		128	120	60	59	62	65	60	69	63	558	686
	Low	Low	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
	Normal	Low	1 (0.8%)	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	2 (0.3%)
		Normal	108 (84.4%)	97 (80.8%)	52 (86.7%)	47 (79.7%)	49 (79.0%)	52 (80.0%)	50 (83.3%)	53 (76.8%)	51 (81.0%)	451 (80.8%)	559 (81.5%)
		High	5 (3.9%)	10 (8.3%)	2 (3.3%)	2 (3.4%)	3 (4.8%)	8 (12.3%)	3 (5.0%)	2 (2.9%)	4 (6.3%)	34 (6.1%)	39 (5.7%)
	High	Normal	4 (3.1%)	6 (5.0%)	4 (6.7%)	4 (6.8%)	3 (4.8%)	2 (3.1%)	2 (3.3%)	8 (11.6%)	3 (4.8%)	32 (5.7%)	36 (5.2%)
		High	10 (7.8%)	5 (4.2%)	2 (3.3%)	6 (10.2%)	7 (11.3%)	3 (4.6%)	5 (8.3%)	6 (8.7%)	5 (7.9%)	39 (7.0%)	49 (7.1%)
Week 48	m		127	117	60	59	62	65	60	66	63	552	679
	Low	Low	0	1 (0.9%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
	Normal	Low	1 (0.8%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
		Normal	108 (85.0%)	97 (82.9%)	52 (86.7%)	47 (79.7%)	49 (79.0%)	57 (87.7%)	53 (88.3%)	50 (75.8%)	51 (81.0%)	456 (82.6%)	564 (83.1%)
		High	4 (3.1%)	8 (6.8%)	2 (3.3%)	2 (3.4%)	3 (4.8%)	3 (4.6%)	0	2 (3.0%)	4 (6.3%)	24 (4.3%)	28 (4.1%)
	High	Normal	7 (5.5%)	6 (5.1%)	4 (6.7%)	6 (10.2%)	4 (6.5%)	3 (4.6%)	2 (3.3%)	9 (13.6%)	4 (6.3%)	38 (6.9%)	45 (6.6%)
		High	7 (5.5%)	5 (4.3%)	2 (3.3%)	4 (6.8%)	6 (9.7%)	2 (3.1%)	5 (8.3%)	5 (7.6%)	4 (6.3%)	33 (6.0%)	40 (5.9%)
Week 52	m		126	116	59	58	62	65	60	67	62	549	675
	Low	Normal	0	1 (0.9%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
	Normal	Low	1 (0.8%)	1 (0.9%)	0	0	0	0	0	0	0	1 (0.2%)	2 (0.3%)
		Normal	106 (84.1%)	97 (83.6%)	52 (88.1%)	47 (81.0%)	50 (80.6%)	57 (87.7%)	51 (85.0%)	51 (76.1%)	51 (82.3%)	456 (83.1%)	562 (83.3%)
		High	5 (4.0%)	6 (5.2%)	1 (1.7%)	1 (1.7%)	2 (3.2%)	3 (4.6%)	2 (3.3%)	2 (3.0%)	3 (4.8%)	20 (3.6%)	25 (3.7%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
	High	Normal	7 (5.6%)	7 (6.0%)	4 (6.8%)	7 (12.1%)	3 (4.8%)	3 (4.6%)	2 (3.3%)	7 (10.4%)	1 (1.6%)	34 (6.2%)	41 (6.1%)
		High	7 (5.6%)	4 (3.4%)	2 (3.4%)	3 (5.2%)	7 (11.3%)	2 (3.1%)	5 (8.3%)	7 (10.4%)	7 (11.3%)	37 (6.7%)	44 (6.5%)
LOCF Endpoint	m		134	127	64	64	64	65	63	70	63	580	714
	Low	Normal	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
	Normal	Low	1 (0.7%)	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	2 (0.3%)
		Normal	112 (83.6%)	105 (82.7%)	56 (87.5%)	50 (78.1%)	51 (79.7%)	57 (87.7%)	52 (82.5%)	54 (77.1%)	51 (81.0%)	476 (82.1%)	588 (82.4%)
		High	6 (4.5%)	7 (5.5%)	1 (1.6%)	4 (6.3%)	3 (4.7%)	3 (4.6%)	3 (4.8%)	2 (2.9%)	4 (6.3%)	27 (4.7%)	33 (4.6%)
	High	Normal	8 (6.0%)	9 (7.1%)	4 (6.3%)	7 (10.9%)	3 (4.7%)	3 (4.6%)	3 (4.8%)	7 (10.0%)	1 (1.6%)	37 (6.4%)	45 (6.3%)
		High	7 (5.2%)	4 (3.1%)	3 (4.7%)	3 (4.7%)	7 (10.9%)	2 (3.1%)	5 (7.9%)	7 (10.0%)	7 (11.1%)	38 (6.6%)	45 (6.3%)
Albumin (g/L)													
Week 4	m		134	127	64	64	64	65	63	70	63	580	714
	Normal	Normal	121 (90.3%)	109 (85.8%)	60 (93.8%)	59 (92.2%)	58 (90.6%)	64 (98.5%)	57 (90.5%)	66 (94.3%)	55 (87.3%)	528 (91.0%)	649 (90.9%)
		High	2 (1.5%)	5 (3.9%)	1 (1.6%)	1 (1.6%)	4 (6.3%)	1 (1.5%)	2 (3.2%)	2 (2.9%)	2 (3.2%)	18 (3.1%)	20 (2.8%)
	High	Normal	10 (7.5%)	9 (7.1%)	1 (1.6%)	4 (6.3%)	1 (1.6%)	0	3 (4.8%)	1 (1.4%)	4 (6.3%)	23 (4.0%)	33 (4.6%)
		High	1 (0.7%)	4 (3.1%)	2 (3.1%)	0	1 (1.6%)	0	1 (1.6%)	1 (1.4%)	2 (3.2%)	11 (1.9%)	12 (1.7%)
Week 8	m		132	125	63	64	64	65	62	69	63	575	707
	Normal	Normal	119 (90.2%)	106 (84.8%)	59 (93.7%)	57 (89.1%)	60 (93.8%)	64 (98.5%)	53 (85.5%)	64 (92.8%)	55 (87.3%)	518 (90.1%)	637 (90.1%)
		High	2 (1.5%)	6 (4.8%)	1 (1.6%)	3 (4.7%)	2 (3.1%)	1 (1.5%)	5 (8.1%)	3 (4.3%)	2 (3.2%)	23 (4.0%)	25 (3.5%)
	High	Normal	11 (8.3%)	9 (7.2%)	1 (1.6%)	4 (6.3%)	1 (1.6%)	0	4 (6.5%)	1 (1.4%)	4 (6.3%)	24 (4.2%)	35 (5.0%)
		High	0	4 (3.2%)	2 (3.2%)	0	1 (1.6%)	0	0	1 (1.4%)	2 (3.2%)	10 (1.7%)	10 (1.4%)
Week 12	m		131	123	63	64	64	65	62	68	63	572	703
	Normal	Normal	118 (90.1%)	106 (86.2%)	60 (95.2%)	58 (90.6%)	59 (92.2%)	61 (93.8%)	54 (87.1%)	62 (91.2%)	54 (85.7%)	514 (89.9%)	632 (89.9%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
		High	2 (1.5%)	4 (3.3%)	0	2 (3.1%)	3 (4.7%)	4 (6.2%)	4 (6.5%)	4 (5.9%)	3 (4.8%)	24 (4.2%)	26 (3.7%)
	High	Normal	7 (5.3%)	9 (7.3%)	1 (1.6%)	4 (6.3%)	0	0	3 (4.8%)	1 (1.5%)	3 (4.8%)	21 (3.7%)	28 (4.0%)
		High	4 (3.1%)	4 (3.3%)	2 (3.2%)	0	2 (3.1%)	0	1 (1.6%)	1 (1.5%)	3 (4.8%)	13 (2.3%)	17 (2.4%)
Week 16	m		130	123	63	64	64	64	62	69	63	572	702
	Normal	Normal	114 (87.7%)	108 (87.8%)	57 (90.5%)	55 (85.9%)	61 (95.3%)	64 (100.0%)	57 (91.9%)	64 (92.8%)	55 (87.3%)	521 (91.1%)	635 (90.5%)
		High	5 (3.8%)	2 (1.6%)	3 (4.8%)	5 (7.8%)	1 (1.6%)	0	1 (1.6%)	3 (4.3%)	2 (3.2%)	17 (3.0%)	22 (3.1%)
	High	Normal	10 (7.7%)	8 (6.5%)	2 (3.2%)	3 (4.7%)	2 (3.1%)	0	4 (6.5%)	0	6 (9.5%)	25 (4.4%)	35 (5.0%)
		High	1 (0.8%)	5 (4.1%)	1 (1.6%)	1 (1.6%)	0	0	0	2 (2.9%)	0	9 (1.6%)	10 (1.4%)
Week 20	m		130	123	62	63	64	65	61	69	63	570	700
	Normal	Normal	115 (88.5%)	104 (84.6%)	58 (93.5%)	58 (92.1%)	57 (89.1%)	64 (98.5%)	56 (91.8%)	64 (92.8%)	52 (82.5%)	513 (90.0%)	628 (89.7%)
		High	4 (3.1%)	6 (4.9%)	1 (1.6%)	1 (1.6%)	5 (7.8%)	1 (1.5%)	1 (1.6%)	3 (4.3%)	5 (7.9%)	23 (4.0%)	27 (3.9%)
	High	Normal	11 (8.5%)	8 (6.5%)	0	4 (6.3%)	2 (3.1%)	0	2 (3.3%)	2 (2.9%)	5 (7.9%)	23 (4.0%)	34 (4.9%)
		High	0	5 (4.1%)	3 (4.8%)	0	0	0	2 (3.3%)	0	1 (1.6%)	11 (1.9%)	11 (1.6%)
Week 24	m		130	122	62	63	64	65	61	69	63	569	699
	Normal	Normal	116 (89.2%)	101 (82.8%)	51 (82.3%)	56 (88.9%)	61 (95.3%)	62 (95.4%)	53 (86.9%)	65 (94.2%)	51 (81.0%)	500 (87.9%)	616 (88.1%)
		High	3 (2.3%)	8 (6.6%)	8 (12.9%)	3 (4.8%)	1 (1.6%)	3 (4.6%)	4 (6.6%)	2 (2.9%)	6 (9.5%)	35 (6.2%)	38 (5.4%)
	High	Normal	6 (4.6%)	7 (5.7%)	1 (1.6%)	3 (4.8%)	2 (3.1%)	0	3 (4.9%)	0	2 (3.2%)	18 (3.2%)	24 (3.4%)
		High	5 (3.8%)	6 (4.9%)	2 (3.2%)	1 (1.6%)	0	0	1 (1.6%)	2 (2.9%)	4 (6.3%)	16 (2.8%)	21 (3.0%)
Week 32	m		128	120	62	60	62	65	60	69	63	561	689
	Normal	Normal	112 (87.5%)	103 (85.8%)	57 (91.9%)	51 (85.0%)	57 (91.9%)	61 (93.8%)	51 (85.0%)	63 (91.3%)	52 (82.5%)	495 (88.2%)	607 (88.1%)
		High	5 (3.9%)	4 (3.3%)	2 (3.2%)	5 (8.3%)	3 (4.8%)	4 (6.2%)	5 (8.3%)	4 (5.8%)	5 (7.9%)	32 (5.7%)	37 (5.4%)
	High	Normal	8 (6.3%)	8 (6.7%)	1 (1.6%)	4 (6.7%)	1 (1.6%)	0	4 (6.7%)	1 (1.4%)	4 (6.3%)	23 (4.1%)	31 (4.5%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
		High	3 (2.3%)	5 (4.2%)	2 (3.2%)	0	1 (1.6%)	0	0	1 (1.4%)	2 (3.2%)	11 (2.0%)	14 (2.0%)
Week 40	m		128	120	60	59	62	65	60	69	63	558	686
	Normal	Normal	114 (89.1%)	104 (86.7%)	50 (83.3%)	53 (89.8%)	57 (91.9%)	61 (93.8%)	51 (85.0%)	64 (92.8%)	51 (81.0%)	491 (88.0%)	605 (88.2%)
		High	3 (2.3%)	3 (2.5%)	7 (11.7%)	3 (5.1%)	3 (4.8%)	4 (6.2%)	5 (8.3%)	3 (4.3%)	6 (9.5%)	34 (6.1%)	37 (5.4%)
	High	Normal	7 (5.5%)	5 (4.2%)	2 (3.3%)	2 (3.4%)	0	0	4 (6.7%)	1 (1.4%)	4 (6.3%)	18 (3.2%)	25 (3.6%)
		High	4 (3.1%)	8 (6.7%)	1 (1.7%)	1 (1.7%)	2 (3.2%)	0	0	1 (1.4%)	2 (3.2%)	15 (2.7%)	19 (2.8%)
Week 48	m		127	118	60	59	62	65	60	66	63	553	680
	Normal	Low	0	0	0	0	1 (1.6%)	0	0	0	0	1 (0.2%)	1 (0.1%)
		Normal	111 (87.4%)	98 (83.1%)	55 (91.7%)	54 (91.5%)	58 (93.5%)	63 (96.9%)	52 (86.7%)	61 (92.4%)	53 (84.1%)	494 (89.3%)	605 (89.0%)
		High	5 (3.9%)	7 (5.9%)	2 (3.3%)	2 (3.4%)	1 (1.6%)	2 (3.1%)	4 (6.7%)	3 (4.5%)	4 (6.3%)	25 (4.5%)	30 (4.4%)
	High	Normal	10 (7.9%)	8 (6.8%)	2 (3.3%)	2 (3.4%)	1 (1.6%)	0	3 (5.0%)	2 (3.0%)	4 (6.3%)	22 (4.0%)	32 (4.7%)
		High	1 (0.8%)	5 (4.2%)	1 (1.7%)	1 (1.7%)	1 (1.6%)	0	1 (1.7%)	0	2 (3.2%)	11 (2.0%)	12 (1.8%)
Week 52	m		126	116	59	58	62	65	60	67	62	549	675
	Normal	Normal	105 (83.3%)	99 (85.3%)	51 (86.4%)	53 (91.4%)	55 (88.7%)	62 (95.4%)	47 (78.3%)	57 (85.1%)	50 (80.6%)	474 (86.3%)	579 (85.8%)
		High	10 (7.9%)	4 (3.4%)	5 (8.5%)	2 (3.4%)	5 (8.1%)	3 (4.6%)	9 (15.0%)	8 (11.9%)	6 (9.7%)	42 (7.7%)	52 (7.7%)
	High	Normal	3 (2.4%)	8 (6.9%)	1 (1.7%)	1 (1.7%)	0	0	4 (6.7%)	0	4 (6.5%)	18 (3.3%)	21 (3.1%)
		High	8 (6.3%)	5 (4.3%)	2 (3.4%)	2 (3.4%)	2 (3.2%)	0	0	2 (3.0%)	2 (3.2%)	15 (2.7%)	23 (3.4%)
LOCF Endpoint	m		134	127	64	64	64	65	63	70	63	580	714
	Normal	Normal	113 (84.3%)	109 (85.8%)	55 (85.9%)	58 (90.6%)	57 (89.1%)	62 (95.4%)	50 (79.4%)	60 (85.7%)	51 (81.0%)	502 (86.6%)	615 (86.1%)
		High	10 (7.5%)	5 (3.9%)	6 (9.4%)	2 (3.1%)	5 (7.8%)	3 (4.6%)	9 (14.3%)	8 (11.4%)	6 (9.5%)	44 (7.6%)	54 (7.6%)
	High	Normal	3 (2.2%)	8 (6.3%)	1 (1.6%)	2 (3.1%)	0	0	4 (6.3%)	0	4 (6.3%)	19 (3.3%)	22 (3.1%)
		High	8 (6.0%)	5 (3.9%)	2 (3.1%)	2 (3.1%)	2 (3.1%)	0	0	2 (2.9%)	2 (3.2%)	15 (2.6%)	23 (3.2%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
Alkaline Phosphatase (U/L)													
Week 4	m		134	127	64	64	64	65	63	70	63	580	714
	Low	Low	1 (0.7%)	0	0	0	0	3 (4.6%)	0	1 (1.4%)	2 (3.2%)	6 (1.0%)	7 (1.0%)
		Normal	1 (0.7%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
	Normal	Low	2 (1.5%)	0	0	1 (1.6%)	1 (1.6%)	1 (1.5%)	0	1 (1.4%)	0	4 (0.7%)	6 (0.8%)
		Normal	130 (97.0%)	123 (96.9%)	63 (98.4%)	63 (98.4%)	61 (95.3%)	59 (90.8%)	61 (96.8%)	65 (92.9%)	61 (96.8%)	556 (95.9%)	686 (96.1%)
		High	0	0	0	0	0	1 (1.5%)	0	0	0	1 (0.2%)	1 (0.1%)
	High	Normal	0	2 (1.6%)	0	0	2 (3.1%)	0	2 (3.2%)	1 (1.4%)	0	7 (1.2%)	7 (1.0%)
		High	0	2 (1.6%)	1 (1.6%)	0	0	1 (1.5%)	0	2 (2.9%)	0	6 (1.0%)	6 (0.8%)
Week 8	m		132	125	63	64	64	65	62	69	63	575	707
	Low	Low	1 (0.8%)	0	0	0	0	3 (4.6%)	0	1 (1.4%)	2 (3.2%)	6 (1.0%)	7 (1.0%)
		Normal	1 (0.8%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
	Normal	Low	3 (2.3%)	0	0	1 (1.6%)	1 (1.6%)	2 (3.1%)	0	1 (1.4%)	0	5 (0.9%)	8 (1.1%)
		Normal	127 (96.2%)	121 (96.8%)	62 (98.4%)	63 (98.4%)	61 (95.3%)	58 (89.2%)	60 (96.8%)	64 (92.8%)	61 (96.8%)	550 (95.7%)	677 (95.8%)
		High	0	0	0	0	0	1 (1.5%)	0	0	0	1 (0.2%)	1 (0.1%)
	High	Normal	0	4 (3.2%)	0	0	2 (3.1%)	0	2 (3.2%)	2 (2.9%)	0	10 (1.7%)	10 (1.4%)
		High	0	0	1 (1.6%)	0	0	1 (1.5%)	0	1 (1.4%)	0	3 (0.5%)	3 (0.4%)
Week 12	m		131	123	63	64	64	65	62	68	63	572	703
	Low	Low	0	0	0	0	0	3 (4.6%)	0	1 (1.5%)	2 (3.2%)	6 (1.0%)	6 (0.9%)
		Normal	2 (1.5%)	0	0	0	0	0	0	0	0	0	2 (0.3%)
	Normal	Low	4 (3.1%)	0	0	1 (1.6%)	2 (3.1%)	0	0	1 (1.5%)	0	4 (0.7%)	8 (1.1%)
		Normal	125 (95.4%)	119 (96.7%)	62 (98.4%)	63 (98.4%)	60 (93.8%)	60 (92.3%)	60 (96.8%)	63 (92.6%)	61 (96.8%)	548 (95.8%)	673 (95.7%)
		High	0	0	0	0	0	1 (1.5%)	0	0	0	1 (0.2%)	1 (0.1%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
	High	Normal	0	3 (2.4%)	0	0	2 (3.1%)	0	2 (3.2%)	1 (1.5%)	0	8 (1.4%)	8 (1.1%)
		High	0	1 (0.8%)	1 (1.6%)	0	0	1 (1.5%)	0	2 (2.9%)	0	5 (0.9%)	5 (0.7%)
Week 16	m		130	123	63	64	64	64	62	69	63	572	702
	Low	Low	0	0	0	0	0	3 (4.7%)	0	1 (1.4%)	2 (3.2%)	6 (1.0%)	6 (0.9%)
		Normal	2 (1.5%)	0	0	0	0	0	0	0	0	0	2 (0.3%)
	Normal	Low	4 (3.1%)	0	0	2 (3.1%)	2 (3.1%)	1 (1.6%)	0	1 (1.4%)	0	6 (1.0%)	10 (1.4%)
		Normal	124 (95.4%)	118 (95.9%)	62 (98.4%)	62 (96.9%)	60 (93.8%)	58 (90.6%)	60 (96.8%)	63 (91.3%)	61 (96.8%)	544 (95.1%)	668 (95.2%)
		High	0	1 (0.8%)	0	0	0	1 (1.6%)	0	1 (1.4%)	0	3 (0.5%)	3 (0.4%)
	High	Normal	0	3 (2.4%)	0	0	2 (3.1%)	0	2 (3.2%)	1 (1.4%)	0	8 (1.4%)	8 (1.1%)
		High	0	1 (0.8%)	1 (1.6%)	0	0	1 (1.6%)	0	2 (2.9%)	0	5 (0.9%)	5 (0.7%)
Week 20	m		130	123	62	63	64	65	61	69	63	570	700
	Low	Low	2 (1.5%)	0	0	0	0	3 (4.6%)	0	1 (1.4%)	2 (3.2%)	6 (1.1%)	8 (1.1%)
	Normal	Low	3 (2.3%)	0	0	1 (1.6%)	2 (3.1%)	1 (1.5%)	0	1 (1.4%)	0	5 (0.9%)	8 (1.1%)
		Normal	125 (96.2%)	119 (96.7%)	61 (98.4%)	62 (98.4%)	60 (93.8%)	59 (90.8%)	59 (96.7%)	64 (92.8%)	61 (96.8%)	545 (95.6%)	670 (95.7%)
		High	0	0	0	0	0	1 (1.5%)	0	0	0	1 (0.2%)	1 (0.1%)
	High	Normal	0	2 (1.6%)	0	0	2 (3.1%)	0	2 (3.3%)	1 (1.4%)	0	7 (1.2%)	7 (1.0%)
		High	0	2 (1.6%)	1 (1.6%)	0	0	1 (1.5%)	0	2 (2.9%)	0	6 (1.1%)	6 (0.9%)
Week 24	m		130	122	62	63	64	65	61	69	63	569	699
	Low	Low	0	0	0	0	0	3 (4.6%)	0	1 (1.4%)	2 (3.2%)	6 (1.1%)	6 (0.9%)
		Normal	2 (1.5%)	0	0	0	0	0	0	0	0	0	2 (0.3%)
	Normal	Low	3 (2.3%)	0	0	1 (1.6%)	1 (1.6%)	1 (1.5%)	0	1 (1.4%)	0	4 (0.7%)	7 (1.0%)
		Normal	125 (96.2%)	117 (95.9%)	61 (98.4%)	61 (96.8%)	61 (95.3%)	59 (90.8%)	59 (96.7%)	64 (92.8%)	61 (96.8%)	543 (95.4%)	668 (95.6%)
		High	0	1 (0.8%)	0	1 (1.6%)	0	1 (1.5%)	0	0	0	3 (0.5%)	3 (0.4%)
	High	Normal	0	3 (2.5%)	0	0	2 (3.1%)	0	2 (3.3%)	2 (2.9%)	0	9 (1.6%)	9 (1.3%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
		High	0	1 (0.8%)	1 (1.6%)	0	0	1 (1.5%)	0	1 (1.4%)	0	4 (0.7%)	4 (0.6%)
Week 32	m		128	120	62	60	62	65	60	69	63	561	689
	Low	Low	1 (0.8%)	0	0	0	0	3 (4.6%)	0	1 (1.4%)	2 (3.2%)	6 (1.1%)	7 (1.0%)
		Normal	1 (0.8%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
	Normal	Low	2 (1.6%)	0	0	1 (1.7%)	1 (1.6%)	2 (3.1%)	0	1 (1.4%)	0	5 (0.9%)	7 (1.0%)
		Normal	124 (96.9%)	117 (97.5%)	61 (98.4%)	58 (96.7%)	59 (95.2%)	59 (90.8%)	58 (96.7%)	64 (92.8%)	60 (95.2%)	536 (95.5%)	660 (95.8%)
		High	0	0	0	1 (1.7%)	0	0	0	0	1 (1.6%)	2 (0.4%)	2 (0.3%)
	High	Normal	0	3 (2.5%)	0	0	2 (3.2%)	1 (1.5%)	2 (3.3%)	2 (2.9%)	0	10 (1.8%)	10 (1.5%)
		High	0	0	1 (1.6%)	0	0	0	0	1 (1.4%)	0	2 (0.4%)	2 (0.3%)
Week 40	m		128	120	60	59	62	65	60	69	63	558	686
	Low	Low	0	0	0	0	0	3 (4.6%)	0	1 (1.4%)	2 (3.2%)	6 (1.1%)	6 (0.9%)
		Normal	2 (1.6%)	0	0	0	0	0	0	0	0	0	2 (0.3%)
	Normal	Low	3 (2.3%)	1 (0.8%)	0	0	2 (3.2%)	0	0	1 (1.4%)	0	4 (0.7%)	7 (1.0%)
		Normal	122 (95.3%)	116 (96.7%)	59 (98.3%)	59 (100.0%)	58 (93.5%)	60 (92.3%)	58 (96.7%)	64 (92.8%)	60 (95.2%)	534 (95.7%)	656 (95.6%)
		High	1 (0.8%)	0	0	0	0	1 (1.5%)	0	0	1 (1.6%)	2 (0.4%)	3 (0.4%)
	High	Normal	0	3 (2.5%)	0	0	2 (3.2%)	1 (1.5%)	2 (3.3%)	2 (2.9%)	0	10 (1.8%)	10 (1.5%)
		High	0	0	1 (1.7%)	0	0	0	0	1 (1.4%)	0	2 (0.4%)	2 (0.3%)
Week 48	m		127	118	60	59	62	65	60	66	63	553	680
	Low	Low	0	0	0	0	0	2 (3.1%)	0	1 (1.5%)	2 (3.2%)	5 (0.9%)	5 (0.7%)
		Normal	2 (1.6%)	0	0	0	0	1 (1.5%)	0	0	0	1 (0.2%)	3 (0.4%)
	Normal	Low	2 (1.6%)	0	0	1 (1.7%)	0	1 (1.5%)	0	1 (1.5%)	0	3 (0.5%)	5 (0.7%)
		Normal	122 (96.1%)	115 (97.5%)	59 (98.3%)	58 (98.3%)	59 (95.2%)	59 (90.8%)	57 (95.0%)	60 (90.9%)	60 (95.2%)	527 (95.3%)	649 (95.4%)
		High	1 (0.8%)	0	0	0	1 (1.6%)	1 (1.5%)	1 (1.7%)	1 (1.5%)	1 (1.6%)	5 (0.9%)	6 (0.9%)
	High	Normal	0	3 (2.5%)	0	0	2 (3.2%)	1 (1.5%)	2 (3.3%)	2 (3.0%)	0	10 (1.8%)	10 (1.5%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
		High	0	0	1 (1.7%)	0	0	0	0	1 (1.5%)	0	2 (0.4%)	2 (0.3%)
Week 52	m		126	116	59	58	62	65	60	67	62	549	675
	Low	Low	0	0	0	0	0	3 (4.6%)	0	1 (1.5%)	2 (3.2%)	6 (1.1%)	6 (0.9%)
		Normal	2 (1.6%)	0	0	0	0	0	0	0	0	0	2 (0.3%)
	Normal	Low	3 (2.4%)	0	0	0	1 (1.6%)	1 (1.5%)	0	0	0	2 (0.4%)	5 (0.7%)
		Normal	119 (94.4%)	112 (96.6%)	58 (98.3%)	58 (100.0%)	59 (95.2%)	58 (89.2%)	58 (96.7%)	63 (94.0%)	60 (96.8%)	526 (95.8%)	645 (95.6%)
		High	2 (1.6%)	1 (0.9%)	0	0	0	2 (3.1%)	0	0	0	3 (0.5%)	5 (0.7%)
	High	Normal	0	2 (1.7%)	0	0	2 (3.2%)	1 (1.5%)	2 (3.3%)	3 (4.5%)	0	10 (1.8%)	10 (1.5%)
		High	0	1 (0.9%)	1 (1.7%)	0	0	0	0	0	0	2 (0.4%)	2 (0.3%)
LOCF Endpoint	m		134	127	64	64	64	65	63	70	63	580	714
	Low	Low	0	0	0	0	0	3 (4.6%)	0	1 (1.4%)	2 (3.2%)	6 (1.0%)	6 (0.8%)
		Normal	2 (1.5%)	0	0	0	0	0	0	0	0	0	2 (0.3%)
	Normal	Low	3 (2.2%)	0	0	0	1 (1.6%)	1 (1.5%)	0	0	0	2 (0.3%)	5 (0.7%)
		Normal	127 (94.8%)	122 (96.1%)	63 (98.4%)	63 (98.4%)	61 (95.3%)	58 (89.2%)	61 (96.8%)	66 (94.3%)	61 (96.8%)	555 (95.7%)	682 (95.5%)
		High	2 (1.5%)	1 (0.8%)	0	1 (1.6%)	0	2 (3.1%)	0	0	0	4 (0.7%)	6 (0.8%)
	High	Normal	0	2 (1.6%)	0	0	2 (3.1%)	1 (1.5%)	2 (3.2%)	3 (4.3%)	0	10 (1.7%)	10 (1.4%)
		High	0	2 (1.6%)	1 (1.6%)	0	0	0	0	0	0	3 (0.5%)	3 (0.4%)
Amylase (U/L)													
Week 4	m		134	127	64	64	64	65	63	70	63	580	714
	Low	Low	2 (1.5%)	3 (2.4%)	4 (6.3%)	1 (1.6%)	5 (7.8%)	4 (6.2%)	3 (4.8%)	3 (4.3%)	2 (3.2%)	25 (4.3%)	27 (3.8%)
		Normal	2 (1.5%)	4 (3.1%)	2 (3.1%)	0	5 (7.8%)	2 (3.1%)	0	1 (1.4%)	2 (3.2%)	16 (2.8%)	18 (2.5%)
	Normal	Low	1 (0.7%)	0	1 (1.6%)	0	0	0	1 (1.6%)	0	0	2 (0.3%)	3 (0.4%)
		Normal	127 (94.8%)	116 (91.3%)	57 (89.1%)	63 (98.4%)	49 (76.6%)	57 (87.7%)	57 (90.5%)	61 (87.1%)	57 (90.5%)	517 (89.1%)	644 (90.2%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
		High	1 (0.7%)	3 (2.4%)	0	0	3 (4.7%)	0	1 (1.6%)	3 (4.3%)	1 (1.6%)	11 (1.9%)	12 (1.7%)
	High	Normal	0	0	0	0	2 (3.1%)	2 (3.1%)	0	1 (1.4%)	0	5 (0.9%)	5 (0.7%)
		High	1 (0.7%)	1 (0.8%)	0	0	0	0	1 (1.6%)	1 (1.4%)	1 (1.6%)	4 (0.7%)	5 (0.7%)
Week 8	m		132	125	63	64	64	65	62	69	63	575	707
	Low	Low	2 (1.5%)	4 (3.2%)	4 (6.3%)	1 (1.6%)	8 (12.5%)	4 (6.2%)	1 (1.6%)	2 (2.9%)	4 (6.3%)	28 (4.9%)	30 (4.2%)
		Normal	2 (1.5%)	3 (2.4%)	2 (3.2%)	0	2 (3.1%)	2 (3.1%)	1 (1.6%)	2 (2.9%)	0	12 (2.1%)	14 (2.0%)
	Normal	Low	4 (3.0%)	0	1 (1.6%)	0	0	0	1 (1.6%)	0	0	2 (0.3%)	6 (0.8%)
		Normal	123 (93.2%)	116 (92.8%)	56 (88.9%)	62 (96.9%)	52 (81.3%)	57 (87.7%)	57 (91.9%)	63 (91.3%)	56 (88.9%)	519 (90.3%)	642 (90.8%)
		High	0	1 (0.8%)	0	1 (1.6%)	0	0	1 (1.6%)	1 (1.4%)	2 (3.2%)	6 (1.0%)	6 (0.8%)
	High	Normal	1 (0.8%)	1 (0.8%)	0	0	2 (3.1%)	0	1 (1.6%)	0	0	4 (0.7%)	5 (0.7%)
		High	0	0	0	0	0	2 (3.1%)	0	1 (1.4%)	1 (1.6%)	4 (0.7%)	4 (0.6%)
Week 12	m		131	123	63	64	64	65	62	68	63	572	703
	Low	Low	2 (1.5%)	5 (4.1%)	4 (6.3%)	1 (1.6%)	7 (10.9%)	4 (6.2%)	2 (3.2%)	1 (1.5%)	3 (4.8%)	27 (4.7%)	29 (4.1%)
		Normal	2 (1.5%)	2 (1.6%)	2 (3.2%)	0	3 (4.7%)	2 (3.1%)	0	2 (2.9%)	1 (1.6%)	12 (2.1%)	14 (2.0%)
	Normal	Low	2 (1.5%)	3 (2.4%)	1 (1.6%)	2 (3.1%)	2 (3.1%)	1 (1.5%)	0	0	1 (1.6%)	10 (1.7%)	12 (1.7%)
		Normal	123 (93.9%)	111 (90.2%)	55 (87.3%)	59 (92.2%)	49 (76.6%)	56 (86.2%)	56 (90.3%)	64 (94.1%)	55 (87.3%)	505 (88.3%)	628 (89.3%)
		High	1 (0.8%)	1 (0.8%)	1 (1.6%)	2 (3.1%)	1 (1.6%)	0	3 (4.8%)	0	2 (3.2%)	10 (1.7%)	11 (1.6%)
	High	Normal	1 (0.8%)	1 (0.8%)	0	0	2 (3.1%)	2 (3.1%)	0	0	0	5 (0.9%)	6 (0.9%)
		High	0	0	0	0	0	0	1 (1.6%)	1 (1.5%)	1 (1.6%)	3 (0.5%)	3 (0.4%)
Week 16	m		130	123	63	64	64	64	62	69	63	572	702
	Low	Low	2 (1.5%)	4 (3.3%)	4 (6.3%)	1 (1.6%)	6 (9.4%)	4 (6.3%)	1 (1.6%)	2 (2.9%)	4 (6.3%)	26 (4.5%)	28 (4.0%)
		Normal	2 (1.5%)	3 (2.4%)	2 (3.2%)	0	4 (6.3%)	2 (3.1%)	1 (1.6%)	2 (2.9%)	0	14 (2.4%)	16 (2.3%)
	Normal	Low	2 (1.5%)	3 (2.4%)	0	1 (1.6%)	1 (1.6%)	2 (3.1%)	1 (1.6%)	0	3 (4.8%)	11 (1.9%)	13 (1.9%)
		Normal	123 (94.6%)	110 (89.4%)	57 (90.5%)	61 (95.3%)	49 (76.6%)	54 (84.4%)	57 (91.9%)	61 (88.4%)	54 (85.7%)	503 (87.9%)	626 (89.2%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
		High	0	2 (1.6%)	0	1 (1.6%)	2 (3.1%)	0	1 (1.6%)	3 (4.3%)	1 (1.6%)	10 (1.7%)	10 (1.4%)
	High	Normal	1 (0.8%)	1 (0.8%)	0	0	2 (3.1%)	2 (3.1%)	0	0	0	5 (0.9%)	6 (0.9%)
		High	0	0	0	0	0	0	1 (1.6%)	1 (1.4%)	1 (1.6%)	3 (0.5%)	3 (0.4%)
Week 20	m		130	123	62	63	64	65	61	69	63	570	700
	Low	Low	2 (1.5%)	2 (1.6%)	3 (4.8%)	1 (1.6%)	6 (9.4%)	4 (6.2%)	1 (1.6%)	2 (2.9%)	4 (6.3%)	23 (4.0%)	25 (3.6%)
		Normal	2 (1.5%)	5 (4.1%)	3 (4.8%)	0	4 (6.3%)	2 (3.1%)	1 (1.6%)	2 (2.9%)	0	17 (3.0%)	19 (2.7%)
	Normal	Low	4 (3.1%)	4 (3.3%)	1 (1.6%)	1 (1.6%)	1 (1.6%)	3 (4.6%)	1 (1.6%)	0	2 (3.2%)	13 (2.3%)	17 (2.4%)
		Normal	120 (92.3%)	110 (89.4%)	55 (88.7%)	61 (96.8%)	50 (78.1%)	54 (83.1%)	55 (90.2%)	63 (91.3%)	56 (88.9%)	504 (88.4%)	624 (89.1%)
		High	1 (0.8%)	1 (0.8%)	0	0	1 (1.6%)	0	2 (3.3%)	1 (1.4%)	0	5 (0.9%)	6 (0.9%)
	High	Normal	1 (0.8%)	0	0	0	2 (3.1%)	2 (3.1%)	1 (1.6%)	0	0	5 (0.9%)	6 (0.9%)
		High	0	1 (0.8%)	0	0	0	0	0	1 (1.4%)	1 (1.6%)	3 (0.5%)	3 (0.4%)
Week 24	m		130	122	62	63	64	65	61	69	63	569	699
	Low	Low	2 (1.5%)	1 (0.8%)	3 (4.8%)	1 (1.6%)	5 (7.8%)	4 (6.2%)	1 (1.6%)	2 (2.9%)	4 (6.3%)	21 (3.7%)	23 (3.3%)
		Normal	2 (1.5%)	5 (4.1%)	3 (4.8%)	0	5 (7.8%)	2 (3.1%)	1 (1.6%)	2 (2.9%)	0	18 (3.2%)	20 (2.9%)
	Normal	Low	2 (1.5%)	5 (4.1%)	0	2 (3.2%)	2 (3.1%)	3 (4.6%)	2 (3.3%)	0	1 (1.6%)	15 (2.6%)	17 (2.4%)
		Normal	121 (93.1%)	108 (88.5%)	55 (88.7%)	60 (95.2%)	48 (75.0%)	54 (83.1%)	54 (88.5%)	63 (91.3%)	56 (88.9%)	498 (87.5%)	619 (88.6%)
		High	2 (1.5%)	2 (1.6%)	1 (1.6%)	0	2 (3.1%)	0	2 (3.3%)	1 (1.4%)	1 (1.6%)	9 (1.6%)	11 (1.6%)
	High	Normal	1 (0.8%)	1 (0.8%)	0	0	2 (3.1%)	1 (1.5%)	1 (1.6%)	0	0	5 (0.9%)	6 (0.9%)
		High	0	0	0	0	0	1 (1.5%)	0	1 (1.4%)	1 (1.6%)	3 (0.5%)	3 (0.4%)
Week 32	m		128	120	62	60	62	65	60	69	63	561	689
	Low	Low	2 (1.6%)	2 (1.7%)	2 (3.2%)	1 (1.7%)	7 (11.3%)	3 (4.6%)	1 (1.7%)	1 (1.4%)	3 (4.8%)	20 (3.6%)	22 (3.2%)
		Normal	2 (1.6%)	4 (3.3%)	4 (6.5%)	0	3 (4.8%)	3 (4.6%)	1 (1.7%)	3 (4.3%)	1 (1.6%)	19 (3.4%)	21 (3.0%)
	Normal	Low	3 (2.3%)	3 (2.5%)	0	1 (1.7%)	1 (1.6%)	2 (3.1%)	3 (5.0%)	1 (1.4%)	1 (1.6%)	12 (2.1%)	15 (2.2%)
		Normal	120 (93.8%)	107 (89.2%)	56 (90.3%)	58 (96.7%)	48 (77.4%)	55 (84.6%)	52 (86.7%)	62 (89.9%)	56 (88.9%)	494 (88.1%)	614 (89.1%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
		High	0	3 (2.5%)	0	0	1 (1.6%)	0	2 (3.3%)	1 (1.4%)	1 (1.6%)	8 (1.4%)	8 (1.2%)
	High	Normal	1 (0.8%)	1 (0.8%)	0	0	2 (3.2%)	2 (3.1%)	0	0	0	5 (0.9%)	6 (0.9%)
		High	0	0	0	0	0	0	1 (1.7%)	1 (1.4%)	1 (1.6%)	3 (0.5%)	3 (0.4%)
Week 40	m		128	120	60	59	62	65	60	69	63	558	686
	Low	Low	2 (1.6%)	3 (2.5%)	3 (5.0%)	1 (1.7%)	7 (11.3%)	4 (6.2%)	2 (3.3%)	2 (2.9%)	3 (4.8%)	25 (4.5%)	27 (3.9%)
		Normal	2 (1.6%)	3 (2.5%)	3 (5.0%)	0	3 (4.8%)	2 (3.1%)	0	2 (2.9%)	1 (1.6%)	14 (2.5%)	16 (2.3%)
	Normal	Low	1 (0.8%)	3 (2.5%)	0	2 (3.4%)	0	2 (3.1%)	2 (3.3%)	0	1 (1.6%)	10 (1.8%)	11 (1.6%)
		Normal	121 (94.5%)	109 (90.8%)	54 (90.0%)	54 (91.5%)	50 (80.6%)	55 (84.6%)	54 (90.0%)	62 (89.9%)	57 (90.5%)	495 (88.7%)	616 (89.8%)
		High	1 (0.8%)	1 (0.8%)	0	2 (3.4%)	0	0	1 (1.7%)	2 (2.9%)	0	6 (1.1%)	7 (1.0%)
	High	Normal	1 (0.8%)	1 (0.8%)	0	0	2 (3.2%)	1 (1.5%)	1 (1.7%)	1 (1.4%)	0	6 (1.1%)	7 (1.0%)
		High	0	0	0	0	0	1 (1.5%)	0	0	1 (1.6%)	2 (0.4%)	2 (0.3%)
Week 48	m		127	118	60	59	62	65	60	66	63	553	680
	Low	Low	2 (1.6%)	3 (2.5%)	3 (5.0%)	1 (1.7%)	4 (6.5%)	4 (6.2%)	1 (1.7%)	1 (1.5%)	3 (4.8%)	20 (3.6%)	22 (3.2%)
		Normal	2 (1.6%)	3 (2.5%)	3 (5.0%)	0	6 (9.7%)	2 (3.1%)	1 (1.7%)	1 (1.5%)	1 (1.6%)	17 (3.1%)	19 (2.8%)
	Normal	Low	1 (0.8%)	3 (2.5%)	0	1 (1.7%)	1 (1.6%)	1 (1.5%)	2 (3.3%)	0	3 (4.8%)	11 (2.0%)	12 (1.8%)
		Normal	120 (94.5%)	106 (89.8%)	54 (90.0%)	57 (96.6%)	49 (79.0%)	55 (84.6%)	54 (90.0%)	62 (93.9%)	53 (84.1%)	490 (88.6%)	610 (89.7%)
		High	1 (0.8%)	2 (1.7%)	0	0	0	1 (1.5%)	1 (1.7%)	1 (1.5%)	2 (3.2%)	7 (1.3%)	8 (1.2%)
	High	Normal	1 (0.8%)	1 (0.8%)	0	0	2 (3.2%)	2 (3.1%)	1 (1.7%)	1 (1.5%)	0	7 (1.3%)	8 (1.2%)
		High	0	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	1 (0.1%)
Week 52	m		126	116	59	58	62	65	60	67	62	549	675
	Low	Low	2 (1.6%)	3 (2.6%)	2 (3.4%)	1 (1.7%)	5 (8.1%)	4 (6.2%)	2 (3.3%)	0	3 (4.8%)	20 (3.6%)	22 (3.3%)
		Normal	2 (1.6%)	3 (2.6%)	3 (5.1%)	0	5 (8.1%)	2 (3.1%)	0	3 (4.5%)	1 (1.6%)	17 (3.1%)	19 (2.8%)
	Normal	Low	1 (0.8%)	4 (3.4%)	0	1 (1.7%)	0	1 (1.5%)	2 (3.3%)	0	3 (4.8%)	11 (2.0%)	12 (1.8%)
		Normal	119 (94.4%)	105 (90.5%)	52 (88.1%)	56 (96.6%)	50 (80.6%)	55 (84.6%)	51 (85.0%)	62 (92.5%)	53 (85.5%)	484 (88.2%)	603 (89.3%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
		High	1 (0.8%)	0	2 (3.4%)	0	0	1 (1.5%)	4 (6.7%)	1 (1.5%)	1 (1.6%)	9 (1.6%)	10 (1.5%)
	High	Normal	1 (0.8%)	1 (0.9%)	0	0	2 (3.2%)	2 (3.1%)	1 (1.7%)	1 (1.5%)	0	7 (1.3%)	8 (1.2%)
		High	0	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	1 (0.1%)
LOCF Endpoint	m		134	127	64	64	64	65	63	70	63	580	714
	Low	Low	2 (1.5%)	3 (2.4%)	3 (4.7%)	1 (1.6%)	5 (7.8%)	4 (6.2%)	3 (4.8%)	0	3 (4.8%)	22 (3.8%)	24 (3.4%)
		Normal	2 (1.5%)	4 (3.1%)	3 (4.7%)	0	5 (7.8%)	2 (3.1%)	0	4 (5.7%)	1 (1.6%)	19 (3.3%)	21 (2.9%)
	Normal	Low	2 (1.5%)	5 (3.9%)	0	1 (1.6%)	0	1 (1.5%)	2 (3.2%)	0	3 (4.8%)	12 (2.1%)	14 (2.0%)
		Normal	126 (94.0%)	114 (89.8%)	56 (87.5%)	62 (96.9%)	52 (81.3%)	55 (84.6%)	53 (84.1%)	63 (90.0%)	53 (84.1%)	508 (87.6%)	634 (88.8%)
		High	1 (0.7%)	0	2 (3.1%)	0	0	1 (1.5%)	4 (6.3%)	1 (1.4%)	2 (3.2%)	10 (1.7%)	11 (1.5%)
	High	Normal	1 (0.7%)	1 (0.8%)	0	0	2 (3.1%)	2 (3.1%)	1 (1.6%)	2 (2.9%)	0	8 (1.4%)	9 (1.3%)
		High	0	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	1 (0.1%)
Aspartate Aminotransferase (U/L)													
Week 4	m		131	126	64	64	62	65	63	69	62	575	706
	Low	Low	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
		Normal	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
	Normal	Low	1 (0.8%)	1 (0.8%)	0	1 (1.6%)	1 (1.6%)	0	0	0	0	3 (0.5%)	4 (0.6%)
		Normal	116 (88.5%)	114 (90.5%)	58 (90.6%)	56 (87.5%)	56 (90.3%)	57 (87.7%)	54 (85.7%)	59 (85.5%)	56 (90.3%)	510 (88.7%)	626 (88.7%)
		High	3 (2.3%)	1 (0.8%)	0	1 (1.6%)	1 (1.6%)	3 (4.6%)	3 (4.8%)	1 (1.4%)	1 (1.6%)	11 (1.9%)	14 (2.0%)
	High	Normal	5 (3.8%)	2 (1.6%)	3 (4.7%)	4 (6.3%)	2 (3.2%)	2 (3.1%)	2 (3.2%)	4 (5.8%)	1 (1.6%)	20 (3.5%)	25 (3.5%)
		High	6 (4.6%)	6 (4.8%)	3 (4.7%)	2 (3.1%)	2 (3.2%)	3 (4.6%)	4 (6.3%)	5 (7.2%)	4 (6.5%)	29 (5.0%)	35 (5.0%)
Week 8	m		130	124	63	64	63	64	62	69	60	569	699
	Low	Low	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
		Normal	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
	Normal	Low	1 (0.8%)	0	0	1 (1.6%)	0	0	0	0	0	1 (0.2%)	2 (0.3%)
		Normal	116 (89.2%)	111 (89.5%)	57 (90.5%)	54 (84.4%)	58 (92.1%)	57 (89.1%)	56 (90.3%)	58 (84.1%)	52 (86.7%)	503 (88.4%)	619 (88.6%)
		High	2 (1.5%)	3 (2.4%)	1 (1.6%)	3 (4.7%)	2 (3.2%)	2 (3.1%)	0	1 (1.4%)	3 (5.0%)	15 (2.6%)	17 (2.4%)
	High	Normal	5 (3.8%)	4 (3.2%)	3 (4.8%)	3 (4.7%)	1 (1.6%)	2 (3.1%)	3 (4.8%)	6 (8.7%)	4 (6.7%)	26 (4.6%)	31 (4.4%)
		High	6 (4.6%)	4 (3.2%)	2 (3.2%)	3 (4.7%)	2 (3.2%)	3 (4.7%)	3 (4.8%)	4 (5.8%)	1 (1.7%)	22 (3.9%)	28 (4.0%)
Week 12	m		131	121	63	64	64	65	61	68	61	567	698
	Low	Low	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
	Normal	Low	1 (0.8%)	0	0	1 (1.6%)	1 (1.6%)	1 (1.5%)	0	0	0	3 (0.5%)	4 (0.6%)
		Normal	116 (88.5%)	106 (87.6%)	58 (92.1%)	56 (87.5%)	56 (87.5%)	56 (86.2%)	54 (88.5%)	57 (83.8%)	54 (88.5%)	497 (87.7%)	613 (87.8%)
		High	3 (2.3%)	6 (5.0%)	0	1 (1.6%)	3 (4.7%)	3 (4.6%)	1 (1.6%)	1 (1.5%)	2 (3.3%)	17 (3.0%)	20 (2.9%)
	High	Normal	5 (3.8%)	3 (2.5%)	3 (4.8%)	3 (4.7%)	2 (3.1%)	4 (6.2%)	2 (3.3%)	5 (7.4%)	3 (4.9%)	25 (4.4%)	30 (4.3%)
		High	6 (4.6%)	5 (4.1%)	2 (3.2%)	3 (4.7%)	2 (3.1%)	1 (1.5%)	4 (6.6%)	5 (7.4%)	2 (3.3%)	24 (4.2%)	30 (4.3%)
Week 16	m		130	123	61	64	64	63	62	69	63	569	699
	Low	Low	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
		Normal	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
	Normal	Low	1 (0.8%)	0	0	0	1 (1.6%)	0	0	0	0	1 (0.2%)	2 (0.3%)
		Normal	115 (88.5%)	102 (82.9%)	55 (90.2%)	55 (85.9%)	57 (89.1%)	55 (87.3%)	56 (90.3%)	55 (79.7%)	55 (87.3%)	490 (86.1%)	605 (86.6%)
		High	3 (2.3%)	11 (8.9%)	1 (1.6%)	3 (4.7%)	2 (3.1%)	3 (4.8%)	0	4 (5.8%)	3 (4.8%)	27 (4.7%)	30 (4.3%)
	High	Normal	4 (3.1%)	3 (2.4%)	3 (4.9%)	5 (7.8%)	2 (3.1%)	3 (4.8%)	3 (4.8%)	6 (8.7%)	3 (4.8%)	28 (4.9%)	32 (4.6%)
		High	7 (5.4%)	5 (4.1%)	2 (3.3%)	1 (1.6%)	2 (3.1%)	2 (3.2%)	3 (4.8%)	4 (5.8%)	2 (3.2%)	21 (3.7%)	28 (4.0%)
Week 20	m		128	122	62	63	64	65	60	68	63	567	695
	Low	Low	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
		Normal	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
	Normal	Normal	115 (89.8%)	106 (86.9%)	55 (88.7%)	55 (87.3%)	57 (89.1%)	58 (89.2%)	51 (85.0%)	57 (83.8%)	54 (85.7%)	493 (86.9%)	608 (87.5%)
		High	2 (1.6%)	6 (4.9%)	2 (3.2%)	2 (3.2%)	3 (4.7%)	2 (3.1%)	3 (5.0%)	1 (1.5%)	4 (6.3%)	23 (4.1%)	25 (3.6%)
	High	Normal	5 (3.9%)	4 (3.3%)	3 (4.8%)	4 (6.3%)	2 (3.1%)	4 (6.2%)	2 (3.3%)	4 (5.9%)	3 (4.8%)	26 (4.6%)	31 (4.5%)
		High	6 (4.7%)	4 (3.3%)	2 (3.2%)	2 (3.2%)	2 (3.1%)	1 (1.5%)	4 (6.7%)	6 (8.8%)	2 (3.2%)	23 (4.1%)	29 (4.2%)
Week 24	m		130	120	62	63	64	65	59	69	62	564	694
	Low	Normal	0	2 (1.7%)	0	0	0	0	0	0	0	2 (0.4%)	2 (0.3%)
	Normal	Low	1 (0.8%)	0	0	1 (1.6%)	1 (1.6%)	0	0	0	0	2 (0.4%)	3 (0.4%)
		Normal	114 (87.7%)	103 (85.8%)	54 (87.1%)	54 (85.7%)	55 (85.9%)	55 (84.6%)	50 (84.7%)	57 (82.6%)	48 (77.4%)	476 (84.4%)	590 (85.0%)
		High	4 (3.1%)	8 (6.7%)	3 (4.8%)	2 (3.2%)	4 (6.3%)	5 (7.7%)	4 (6.8%)	2 (2.9%)	9 (14.5%)	37 (6.6%)	41 (5.9%)
	High	Normal	4 (3.1%)	2 (1.7%)	3 (4.8%)	4 (6.3%)	2 (3.1%)	4 (6.2%)	1 (1.7%)	6 (8.7%)	3 (4.8%)	25 (4.4%)	29 (4.2%)
		High	7 (5.4%)	5 (4.2%)	2 (3.2%)	2 (3.2%)	2 (3.1%)	1 (1.5%)	4 (6.8%)	4 (5.8%)	2 (3.2%)	22 (3.9%)	29 (4.2%)
Week 32	m		127	121	62	60	61	65	60	69	62	560	687
	Low	Normal	0	2 (1.7%)	0	0	0	0	0	0	0	2 (0.4%)	2 (0.3%)
	Normal	Low	1 (0.8%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
		Normal	112 (88.2%)	102 (84.3%)	52 (83.9%)	50 (83.3%)	56 (91.8%)	57 (87.7%)	51 (85.0%)	58 (84.1%)	54 (87.1%)	480 (85.7%)	592 (86.2%)
		High	4 (3.1%)	10 (8.3%)	5 (8.1%)	4 (6.7%)	1 (1.6%)	3 (4.6%)	3 (5.0%)	1 (1.4%)	3 (4.8%)	30 (5.4%)	34 (4.9%)
	High	Normal	3 (2.4%)	2 (1.7%)	3 (4.8%)	4 (6.7%)	2 (3.3%)	4 (6.2%)	2 (3.3%)	5 (7.2%)	4 (6.5%)	26 (4.6%)	29 (4.2%)
		High	7 (5.5%)	5 (4.1%)	2 (3.2%)	2 (3.3%)	2 (3.3%)	1 (1.5%)	4 (6.7%)	5 (7.2%)	1 (1.6%)	22 (3.9%)	29 (4.2%)
Week 40	m		126	120	60	59	62	65	60	69	63	558	684
	Low	Normal	0	2 (1.7%)	0	0	0	0	0	0	0	2 (0.4%)	2 (0.3%)
	Normal	Normal	112 (88.9%)	104 (86.7%)	54 (90.0%)	51 (86.4%)	55 (88.7%)	56 (86.2%)	51 (85.0%)	58 (84.1%)	53 (84.1%)	482 (86.4%)	594 (86.8%)
		High	4 (3.2%)	7 (5.8%)	1 (1.7%)	2 (3.4%)	3 (4.8%)	4 (6.2%)	3 (5.0%)	1 (1.4%)	5 (7.9%)	26 (4.7%)	30 (4.4%)
	High	Normal	3 (2.4%)	2 (1.7%)	4 (6.7%)	4 (6.8%)	4 (6.5%)	4 (6.2%)	2 (3.3%)	5 (7.2%)	2 (3.2%)	27 (4.8%)	30 (4.4%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
		High	7 (5.6%)	5 (4.2%)	1 (1.7%)	2 (3.4%)	0	1 (1.5%)	4 (6.7%)	5 (7.2%)	3 (4.8%)	21 (3.8%)	28 (4.1%)
Week 48	m		125	116	59	59	61	65	60	66	62	548	673
	Low	Low	0	1 (0.9%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
		Normal	0	1 (0.9%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
	Normal	Low	2 (1.6%)	0	0	0	1 (1.6%)	0	0	1 (1.5%)	0	2 (0.4%)	4 (0.6%)
		Normal	110 (88.0%)	101 (87.1%)	53 (89.8%)	51 (86.4%)	56 (91.8%)	56 (86.2%)	51 (85.0%)	54 (81.8%)	53 (85.5%)	475 (86.7%)	585 (86.9%)
		High	3 (2.4%)	7 (6.0%)	2 (3.4%)	2 (3.4%)	1 (1.6%)	4 (6.2%)	3 (5.0%)	1 (1.5%)	4 (6.5%)	24 (4.4%)	27 (4.0%)
	High	Normal	5 (4.0%)	2 (1.7%)	4 (6.8%)	2 (3.4%)	2 (3.3%)	4 (6.2%)	2 (3.3%)	4 (6.1%)	2 (3.2%)	22 (4.0%)	27 (4.0%)
		High	5 (4.0%)	4 (3.4%)	0	4 (6.8%)	1 (1.6%)	1 (1.5%)	4 (6.7%)	6 (9.1%)	3 (4.8%)	23 (4.2%)	28 (4.2%)
Week 52	m		124	115	59	58	62	65	60	67	62	548	672
	Low	Normal	0	2 (1.7%)	0	0	0	0	0	0	0	2 (0.4%)	2 (0.3%)
	Normal	Low	1 (0.8%)	0	0	1 (1.7%)	1 (1.6%)	0	0	0	0	2 (0.4%)	3 (0.4%)
		Normal	110 (88.7%)	103 (89.6%)	53 (89.8%)	50 (86.2%)	56 (90.3%)	59 (90.8%)	53 (88.3%)	57 (85.1%)	54 (87.1%)	485 (88.5%)	595 (88.5%)
		High	3 (2.4%)	4 (3.5%)	1 (1.7%)	2 (3.4%)	1 (1.6%)	1 (1.5%)	1 (1.7%)	0	3 (4.8%)	13 (2.4%)	16 (2.4%)
	High	Normal	4 (3.2%)	4 (3.5%)	4 (6.8%)	3 (5.2%)	3 (4.8%)	4 (6.2%)	3 (5.0%)	5 (7.5%)	2 (3.2%)	28 (5.1%)	32 (4.8%)
		High	6 (4.8%)	2 (1.7%)	1 (1.7%)	2 (3.4%)	1 (1.6%)	1 (1.5%)	3 (5.0%)	5 (7.5%)	3 (4.8%)	18 (3.3%)	24 (3.6%)
LOCF Endpoint	m		134	127	64	64	64	65	63	70	63	580	714
	Low	Normal	0	2 (1.6%)	0	0	0	0	0	0	0	2 (0.3%)	2 (0.3%)
	Normal	Low	1 (0.7%)	0	0	1 (1.6%)	1 (1.6%)	0	0	0	0	2 (0.3%)	3 (0.4%)
		Normal	118 (88.1%)	112 (88.2%)	57 (89.1%)	53 (82.8%)	57 (89.1%)	59 (90.8%)	55 (87.3%)	60 (85.7%)	55 (87.3%)	508 (87.6%)	626 (87.7%)
		High	4 (3.0%)	5 (3.9%)	1 (1.6%)	4 (6.3%)	2 (3.1%)	1 (1.5%)	2 (3.2%)	0	3 (4.8%)	18 (3.1%)	22 (3.1%)
	High	Normal	5 (3.7%)	5 (3.9%)	5 (7.8%)	3 (4.7%)	3 (4.7%)	4 (6.2%)	3 (4.8%)	5 (7.1%)	2 (3.2%)	30 (5.2%)	35 (4.9%)
		High	6 (4.5%)	3 (2.4%)	1 (1.6%)	3 (4.7%)	1 (1.6%)	1 (1.5%)	3 (4.8%)	5 (7.1%)	3 (4.8%)	20 (3.4%)	26 (3.6%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
Bicarbonate (mmol/L)													
Week 4	m		134	127	64	64	64	65	63	70	63	580	714
	Normal	Low	0	1 (0.8%)	0	0	0	1 (1.5%)	0	0	0	2 (0.3%)	2 (0.3%)
		Normal	133 (99.3%)	126 (99.2%)	64 (100.0%)	64 (100.0%)	64 (100.0%)	63 (96.9%)	63 (100.0%)	70 (100.0%)	63 (100.0%)	577 (99.5%)	710 (99.4%)
		High	0	0	0	0	0	1 (1.5%)	0	0	0	1 (0.2%)	1 (0.1%)
	High	Normal	1 (0.7%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
Week 8	m		132	125	63	64	64	65	62	69	63	575	707
	Normal	Low	1 (0.8%)	2 (1.6%)	0	0	0	0	0	2 (2.9%)	2 (3.2%)	6 (1.0%)	7 (1.0%)
		Normal	130 (98.5%)	123 (98.4%)	63 (100.0%)	64 (100.0%)	64 (100.0%)	65 (100.0%)	62 (100.0%)	67 (97.1%)	61 (96.8%)	569 (99.0%)	699 (98.9%)
	High	Normal	1 (0.8%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
Week 12	m		131	122	63	64	64	65	62	68	63	571	702
	Normal	Low	1 (0.8%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
		Normal	129 (98.5%)	122 (100.0%)	63 (100.0%)	64 (100.0%)	64 (100.0%)	65 (100.0%)	62 (100.0%)	68 (100.0%)	63 (100.0%)	571 (100.0%)	700 (99.7%)
	High	Normal	1 (0.8%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
Week 16	m		130	123	63	64	64	64	62	69	63	572	702
	Normal	Low	0	1 (0.8%)	1 (1.6%)	0	0	0	0	1 (1.4%)	6 (9.5%)	9 (1.6%)	9 (1.3%)
		Normal	129 (99.2%)	122 (99.2%)	62 (98.4%)	64 (100.0%)	64 (100.0%)	64 (100.0%)	62 (100.0%)	68 (98.6%)	57 (90.5%)	563 (98.4%)	692 (98.6%)
	High	Normal	1 (0.8%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
Week 20	m		130	123	62	63	64	65	61	69	63	570	700
	Normal	Low	1 (0.8%)	0	1 (1.6%)	0	0	1 (1.5%)	0	0	4 (6.3%)	6 (1.1%)	7 (1.0%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
		Normal	128 (98.5%)	123 (100.0%)	61 (98.4%)	63 (100.0%)	64 (100.0%)	64 (98.5%)	61 (100.0%)	69 (100.0%)	59 (93.7%)	564 (98.9%)	692 (98.9%)
	High	Normal	1 (0.8%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
Week 24	m		130	122	62	63	64	65	61	69	63	569	699
	Normal	Low	0	0	0	0	0	0	1 (1.6%)	0	1 (1.6%)	2 (0.4%)	2 (0.3%)
		Normal	129 (99.2%)	122 (100.0%)	62 (100.0%)	63 (100.0%)	64 (100.0%)	64 (98.5%)	60 (98.4%)	69 (100.0%)	62 (98.4%)	566 (99.5%)	695 (99.4%)
		High	0	0	0	0	0	1 (1.5%)	0	0	0	1 (0.2%)	1 (0.1%)
	High	Normal	1 (0.8%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
Week 32	m		128	120	62	60	62	65	60	69	63	561	689
	Normal	Low	1 (0.8%)	0	0	0	0	0	0	0	3 (4.8%)	3 (0.5%)	4 (0.6%)
		Normal	126 (98.4%)	120 (100.0%)	62 (100.0%)	60 (100.0%)	62 (100.0%)	65 (100.0%)	60 (100.0%)	69 (100.0%)	60 (95.2%)	558 (99.5%)	684 (99.3%)
	High	Normal	1 (0.8%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
Week 40	m		128	120	60	59	62	65	60	69	63	558	686
	Normal	Normal	127 (99.2%)	120 (100.0%)	60 (100.0%)	59 (100.0%)	62 (100.0%)	65 (100.0%)	60 (100.0%)	69 (100.0%)	63 (100.0%)	558 (100.0%)	685 (99.9%)
	High	Normal	1 (0.8%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
Week 48	m		127	118	60	59	62	65	60	66	63	553	680
	Normal	Low	3 (2.4%)	2 (1.7%)	0	0	0	0	0	0	1 (1.6%)	3 (0.5%)	6 (0.9%)
		Normal	123 (96.9%)	116 (98.3%)	60 (100.0%)	59 (100.0%)	62 (100.0%)	65 (100.0%)	60 (100.0%)	66 (100.0%)	62 (98.4%)	550 (99.5%)	673 (99.0%)
	High	Normal	1 (0.8%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
Week 52	m		126	116	59	58	62	65	60	67	62	549	675
	Normal	Low	1 (0.8%)	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	2 (0.3%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
		Normal	124 (98.4%)	116 (100.0%)	59 (100.0%)	58 (100.0%)	62 (100.0%)	65 (100.0%)	60 (100.0%)	67 (100.0%)	61 (98.4%)	548 (99.8%)	672 (99.6%)
	High	Normal	1 (0.8%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
LOCF Endpoint	m		134	127	64	64	64	65	63	70	63	580	714
	Normal	Low	1 (0.7%)	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	2 (0.3%)
		Normal	132 (98.5%)	127 (100.0%)	64 (100.0%)	64 (100.0%)	64 (100.0%)	65 (100.0%)	63 (100.0%)	70 (100.0%)	62 (98.4%)	579 (99.8%)	711 (99.6%)
	High	Normal	1 (0.7%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
Bilirubin (umol/L)													
Week 4	m		134	127	64	64	64	65	63	70	63	580	714
	Low	Normal	2 (1.5%)	0	1 (1.6%)	3 (4.7%)	1 (1.6%)	0	0	0	0	5 (0.9%)	7 (1.0%)
	Normal	Low	2 (1.5%)	0	0	0	0	0	0	0	0	0	2 (0.3%)
		Normal	122 (91.0%)	119 (93.7%)	61 (95.3%)	57 (89.1%)	62 (96.9%)	64 (98.5%)	62 (98.4%)	69 (98.6%)	60 (95.2%)	554 (95.5%)	676 (94.7%)
		High	1 (0.7%)	2 (1.6%)	0	0	0	0	0	0	2 (3.2%)	4 (0.7%)	5 (0.7%)
	High	Normal	4 (3.0%)	4 (3.1%)	1 (1.6%)	4 (6.3%)	1 (1.6%)	1 (1.5%)	0	1 (1.4%)	1 (1.6%)	13 (2.2%)	17 (2.4%)
		High	3 (2.2%)	2 (1.6%)	1 (1.6%)	0	0	0	1 (1.6%)	0	0	4 (0.7%)	7 (1.0%)
Week 8	m		132	125	63	64	64	65	62	69	63	575	707
	Low	Low	0	0	0	1 (1.6%)	0	0	0	0	0	1 (0.2%)	1 (0.1%)
		Normal	2 (1.5%)	0	1 (1.6%)	2 (3.1%)	1 (1.6%)	0	0	0	0	4 (0.7%)	6 (0.8%)
	Normal	Low	1 (0.8%)	0	1 (1.6%)	0	0	0	0	0	1 (1.6%)	2 (0.3%)	3 (0.4%)
		Normal	121 (91.7%)	116 (92.8%)	58 (92.1%)	56 (87.5%)	62 (96.9%)	64 (98.5%)	61 (98.4%)	67 (97.1%)	61 (96.8%)	545 (94.8%)	666 (94.2%)
		High	1 (0.8%)	3 (2.4%)	1 (1.6%)	1 (1.6%)	0	0	0	1 (1.4%)	0	6 (1.0%)	7 (1.0%)
	High	Normal	5 (3.8%)	4 (3.2%)	1 (1.6%)	3 (4.7%)	1 (1.6%)	1 (1.5%)	1 (1.6%)	1 (1.4%)	0	12 (2.1%)	17 (2.4%)
		High	2 (1.5%)	2 (1.6%)	1 (1.6%)	1 (1.6%)	0	0	0	0	1 (1.6%)	5 (0.9%)	7 (1.0%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
Week 12	m		131	122	63	64	64	65	62	68	63	571	702
	Low	Low	0	0	0	1 (1.6%)	0	0	0	0	0	1 (0.2%)	1 (0.1%)
		Normal	2 (1.5%)	0	1 (1.6%)	2 (3.1%)	1 (1.6%)	0	0	0	0	4 (0.7%)	6 (0.9%)
	Normal	Low	0	2 (1.6%)	0	0	0	0	0	0	0	2 (0.4%)	2 (0.3%)
		Normal	120 (91.6%)	108 (88.5%)	60 (95.2%)	57 (89.1%)	60 (93.8%)	64 (98.5%)	58 (93.5%)	67 (98.5%)	62 (98.4%)	536 (93.9%)	656 (93.4%)
		High	2 (1.5%)	6 (4.9%)	0	0	2 (3.1%)	0	3 (4.8%)	0	0	11 (1.9%)	13 (1.9%)
	High	Normal	3 (2.3%)	4 (3.3%)	1 (1.6%)	2 (3.1%)	1 (1.6%)	1 (1.5%)	1 (1.6%)	0	0	10 (1.8%)	13 (1.9%)
		High	4 (3.1%)	2 (1.6%)	1 (1.6%)	2 (3.1%)	0	0	0	1 (1.5%)	1 (1.6%)	7 (1.2%)	11 (1.6%)
Week 16	m		130	123	63	64	64	64	62	69	62	571	701
	Low	Low	0	0	0	1 (1.6%)	0	0	0	0	0	1 (0.2%)	1 (0.1%)
		Normal	2 (1.5%)	0	1 (1.6%)	2 (3.1%)	1 (1.6%)	0	0	0	0	4 (0.7%)	6 (0.9%)
	Normal	Low	2 (1.5%)	0	0	1 (1.6%)	0	1 (1.6%)	0	0	1 (1.6%)	3 (0.5%)	5 (0.7%)
		Normal	118 (90.8%)	113 (91.9%)	60 (95.2%)	56 (87.5%)	62 (96.9%)	62 (96.9%)	60 (96.8%)	67 (97.1%)	60 (96.8%)	540 (94.6%)	658 (93.9%)
		High	1 (0.8%)	4 (3.3%)	0	0	0	0	1 (1.6%)	1 (1.4%)	0	6 (1.1%)	7 (1.0%)
	High	Normal	4 (3.1%)	4 (3.3%)	1 (1.6%)	1 (1.6%)	1 (1.6%)	1 (1.6%)	1 (1.6%)	0	0	9 (1.6%)	13 (1.9%)
		High	3 (2.3%)	2 (1.6%)	1 (1.6%)	3 (4.7%)	0	0	0	1 (1.4%)	1 (1.6%)	8 (1.4%)	11 (1.6%)
Week 20	m		130	123	62	63	64	65	61	69	63	570	700
	Low	Low	0	0	0	1 (1.6%)	0	0	0	0	0	1 (0.2%)	1 (0.1%)
		Normal	2 (1.5%)	0	1 (1.6%)	2 (3.2%)	1 (1.6%)	0	0	0	0	4 (0.7%)	6 (0.9%)
	Normal	Low	1 (0.8%)	0	1 (1.6%)	0	0	1 (1.5%)	0	0	0	2 (0.4%)	3 (0.4%)
		Normal	120 (92.3%)	114 (92.7%)	56 (90.3%)	55 (87.3%)	62 (96.9%)	62 (95.4%)	60 (98.4%)	66 (95.7%)	62 (98.4%)	537 (94.2%)	657 (93.9%)
		High	0	3 (2.4%)	2 (3.2%)	1 (1.6%)	0	1 (1.5%)	0	2 (2.9%)	0	9 (1.6%)	9 (1.3%)
	High	Normal	4 (3.1%)	4 (3.3%)	0	3 (4.8%)	1 (1.6%)	1 (1.5%)	1 (1.6%)	0	0	10 (1.8%)	14 (2.0%)
		High	3 (2.3%)	2 (1.6%)	2 (3.2%)	1 (1.6%)	0	0	0	1 (1.4%)	1 (1.6%)	7 (1.2%)	10 (1.4%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
Week 24	m		130	122	62	63	64	65	61	69	63	569	699
	Low	Low	0	0	0	1 (1.6%)	0	0	0	0	0	1 (0.2%)	1 (0.1%)
		Normal	2 (1.5%)	0	1 (1.6%)	2 (3.2%)	1 (1.6%)	0	0	0	0	4 (0.7%)	6 (0.9%)
	Normal	Low	0	0	0	0	1 (1.6%)	0	1 (1.6%)	0	0	2 (0.4%)	2 (0.3%)
		Normal	117 (90.0%)	113 (92.6%)	59 (95.2%)	55 (87.3%)	60 (93.8%)	64 (98.5%)	59 (96.7%)	66 (95.7%)	62 (98.4%)	538 (94.6%)	655 (93.7%)
		High	4 (3.1%)	3 (2.5%)	0	1 (1.6%)	1 (1.6%)	0	0	2 (2.9%)	0	7 (1.2%)	11 (1.6%)
	High	Normal	3 (2.3%)	4 (3.3%)	1 (1.6%)	2 (3.2%)	1 (1.6%)	1 (1.5%)	1 (1.6%)	0	0	10 (1.8%)	13 (1.9%)
		High	4 (3.1%)	2 (1.6%)	1 (1.6%)	2 (3.2%)	0	0	0	1 (1.4%)	1 (1.6%)	7 (1.2%)	11 (1.6%)
Week 32	m		128	120	62	60	62	65	60	69	63	561	689
	Low	Low	0	0	0	1 (1.7%)	0	0	0	0	0	1 (0.2%)	1 (0.1%)
		Normal	2 (1.6%)	0	1 (1.6%)	2 (3.3%)	1 (1.6%)	0	0	0	0	4 (0.7%)	6 (0.9%)
	Normal	Low	0	0	0	0	1 (1.6%)	0	0	0	0	1 (0.2%)	1 (0.1%)
		Normal	119 (93.0%)	111 (92.5%)	59 (95.2%)	54 (90.0%)	58 (93.5%)	64 (98.5%)	58 (96.7%)	67 (97.1%)	62 (98.4%)	533 (95.0%)	652 (94.6%)
		High	1 (0.8%)	3 (2.5%)	0	0	1 (1.6%)	0	1 (1.7%)	1 (1.4%)	0	6 (1.1%)	7 (1.0%)
	High	Normal	3 (2.3%)	5 (4.2%)	1 (1.6%)	2 (3.3%)	1 (1.6%)	1 (1.5%)	1 (1.7%)	0	0	11 (2.0%)	14 (2.0%)
		High	3 (2.3%)	1 (0.8%)	1 (1.6%)	1 (1.7%)	0	0	0	1 (1.4%)	1 (1.6%)	5 (0.9%)	8 (1.2%)
Week 40	m		128	120	60	59	62	65	60	69	63	558	686
	Low	Low	0	0	0	1 (1.7%)	0	0	0	0	0	1 (0.2%)	1 (0.1%)
		Normal	2 (1.6%)	0	1 (1.7%)	2 (3.4%)	1 (1.6%)	0	0	0	0	4 (0.7%)	6 (0.9%)
	Normal	Normal	118 (92.2%)	112 (93.3%)	58 (96.7%)	53 (89.8%)	60 (96.8%)	64 (98.5%)	58 (96.7%)	64 (92.8%)	62 (98.4%)	531 (95.2%)	649 (94.6%)
		High	2 (1.6%)	2 (1.7%)	0	1 (1.7%)	0	0	1 (1.7%)	4 (5.8%)	0	8 (1.4%)	10 (1.5%)
	High	Normal	4 (3.1%)	4 (3.3%)	0	2 (3.4%)	1 (1.6%)	1 (1.5%)	0	0	0	8 (1.4%)	12 (1.7%)
		High	2 (1.6%)	2 (1.7%)	1 (1.7%)	0	0	0	1 (1.7%)	1 (1.4%)	1 (1.6%)	6 (1.1%)	8 (1.2%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
Week 48	m		127	118	60	59	62	65	60	66	63	553	680
	Low	Normal	2 (1.6%)	0	1 (1.7%)	3 (5.1%)	1 (1.6%)	0	0	0	0	5 (0.9%)	7 (1.0%)
	Normal	Low	0	0	0	0	1 (1.6%)	1 (1.5%)	1 (1.7%)	0	0	3 (0.5%)	3 (0.4%)
		Normal	118 (92.9%)	108 (91.5%)	57 (95.0%)	54 (91.5%)	59 (95.2%)	63 (96.9%)	57 (95.0%)	64 (97.0%)	62 (98.4%)	524 (94.8%)	642 (94.4%)
		High	1 (0.8%)	4 (3.4%)	1 (1.7%)	0	0	0	1 (1.7%)	1 (1.5%)	0	7 (1.3%)	8 (1.2%)
	High	Normal	4 (3.1%)	4 (3.4%)	0	2 (3.4%)	1 (1.6%)	1 (1.5%)	1 (1.7%)	0	0	9 (1.6%)	13 (1.9%)
		High	2 (1.6%)	2 (1.7%)	1 (1.7%)	0	0	0	0	1 (1.5%)	1 (1.6%)	5 (0.9%)	7 (1.0%)
Week 52	m		126	116	59	58	62	65	60	67	62	549	675
	Low	Low	1 (0.8%)	0	0	0	1 (1.6%)	0	0	0	0	1 (0.2%)	2 (0.3%)
		Normal	1 (0.8%)	0	1 (1.7%)	3 (5.2%)	0	0	0	0	0	4 (0.7%)	5 (0.7%)
	Normal	Low	0	0	0	0	0	0	1 (1.7%)	0	0	1 (0.2%)	1 (0.1%)
		Normal	117 (92.9%)	107 (92.2%)	57 (96.6%)	53 (91.4%)	60 (96.8%)	64 (98.5%)	57 (95.0%)	65 (97.0%)	61 (98.4%)	524 (95.4%)	641 (95.0%)
		High	1 (0.8%)	3 (2.6%)	0	0	0	0	1 (1.7%)	1 (1.5%)	0	5 (0.9%)	6 (0.9%)
	High	Normal	2 (1.6%)	3 (2.6%)	0	1 (1.7%)	1 (1.6%)	1 (1.5%)	0	0	0	6 (1.1%)	8 (1.2%)
		High	4 (3.2%)	3 (2.6%)	1 (1.7%)	1 (1.7%)	0	0	1 (1.7%)	1 (1.5%)	1 (1.6%)	8 (1.5%)	12 (1.8%)
LOCF Endpoint	m		134	127	64	64	64	65	63	70	63	580	714
	Low	Low	1 (0.7%)	0	0	0	1 (1.6%)	0	0	0	0	1 (0.2%)	2 (0.3%)
		Normal	1 (0.7%)	0	1 (1.6%)	3 (4.7%)	0	0	0	0	0	4 (0.7%)	5 (0.7%)
	Normal	Low	0	0	0	0	0	0	1 (1.6%)	0	0	1 (0.2%)	1 (0.1%)
		Normal	124 (92.5%)	117 (92.1%)	61 (95.3%)	57 (89.1%)	61 (95.3%)	64 (98.5%)	60 (95.2%)	68 (97.1%)	62 (98.4%)	550 (94.8%)	674 (94.4%)
		High	1 (0.7%)	4 (3.1%)	0	0	1 (1.6%)	0	1 (1.6%)	1 (1.4%)	0	7 (1.2%)	8 (1.1%)
	High	Normal	3 (2.2%)	3 (2.4%)	1 (1.6%)	2 (3.1%)	1 (1.6%)	1 (1.5%)	0	0	0	8 (1.4%)	11 (1.5%)
		High	4 (3.0%)	3 (2.4%)	1 (1.6%)	2 (3.1%)	0	0	1 (1.6%)	1 (1.4%)	1 (1.6%)	9 (1.6%)	13 (1.8%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
Calcium (mmol/L)													
Week 4	m		134	127	64	64	64	65	63	70	63	580	714
	Normal	Low	1 (0.7%)	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	2 (0.3%)
		Normal	133 (99.3%)	127 (100.0%)	64 (100.0%)	64 (100.0%)	64 (100.0%)	65 (100.0%)	63 (100.0%)	70 (100.0%)	62 (98.4%)	579 (99.8%)	712 (99.7%)
Week 8	m		132	125	63	64	64	65	62	69	63	575	707
	Normal	Low	0	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	1 (0.1%)
		Normal	132 (100.0%)	125 (100.0%)	63 (100.0%)	64 (100.0%)	64 (100.0%)	65 (100.0%)	62 (100.0%)	69 (100.0%)	62 (98.4%)	574 (99.8%)	706 (99.9%)
Week 12	m		131	123	63	64	64	65	62	68	63	572	703
	Normal	Low	0	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	1 (0.1%)
		Normal	131 (100.0%)	123 (100.0%)	63 (100.0%)	64 (100.0%)	64 (100.0%)	64 (98.5%)	62 (100.0%)	68 (100.0%)	62 (98.4%)	570 (99.7%)	701 (99.7%)
		High	0	0	0	0	0	1 (1.5%)	0	0	0	1 (0.2%)	1 (0.1%)
Week 16	m		130	123	63	64	64	64	62	69	63	572	702
	Normal	Normal	130 (100.0%)	123 (100.0%)	63 (100.0%)	64 (100.0%)	64 (100.0%)	64 (100.0%)	62 (100.0%)	69 (100.0%)	63 (100.0%)	572 (100.0%)	702 (100.0%)
Week 20	m		130	123	62	63	64	65	61	69	63	570	700
	Normal	Low	0	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	1 (0.1%)
		Normal	130 (100.0%)	123 (100.0%)	62 (100.0%)	63 (100.0%)	64 (100.0%)	65 (100.0%)	61 (100.0%)	69 (100.0%)	62 (98.4%)	569 (99.8%)	699 (99.9%)
Week 24	m		130	122	62	63	64	65	61	69	63	569	699
	Normal	Normal	130 (100.0%)	121 (99.2%)	62 (100.0%)	63 (100.0%)	64 (100.0%)	65 (100.0%)	61 (100.0%)	69 (100.0%)	63 (100.0%)	568 (99.8%)	698 (99.9%)
		High	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
Week 32	m		128	120	62	60	62	65	60	69	63	561	689
	Normal	Normal	128 (100.0%)	120 (100.0%)	62 (100.0%)	60 (100.0%)	62 (100.0%)	65 (100.0%)	60 (100.0%)	69 (100.0%)	63 (100.0%)	561 (100.0%)	689 (100.0%)
Week 40	m		128	120	60	59	62	65	60	69	63	558	686
	Normal	Normal	128 (100.0%)	120 (100.0%)	60 (100.0%)	59 (100.0%)	62 (100.0%)	65 (100.0%)	60 (100.0%)	69 (100.0%)	63 (100.0%)	558 (100.0%)	686 (100.0%)
Week 48	m		127	118	60	59	62	65	60	66	63	553	680
	Normal	Low	0	0	0	0	1 (1.6%)	0	0	0	0	1 (0.2%)	1 (0.1%)
		Normal	127 (100.0%)	118 (100.0%)	60 (100.0%)	59 (100.0%)	61 (98.4%)	65 (100.0%)	59 (98.3%)	66 (100.0%)	63 (100.0%)	551 (99.6%)	678 (99.7%)
		High	0	0	0	0	0	0	1 (1.7%)	0	0	1 (0.2%)	1 (0.1%)
Week 52	m		126	116	59	58	62	65	60	67	62	549	675
	Normal	Normal	126 (100.0%)	116 (100.0%)	58 (98.3%)	58 (100.0%)	62 (100.0%)	64 (98.5%)	60 (100.0%)	67 (100.0%)	62 (100.0%)	547 (99.6%)	673 (99.7%)
		High	0	0	1 (1.7%)	0	0	1 (1.5%)	0	0	0	2 (0.4%)	2 (0.3%)
LOCF Endpoint	m		134	127	64	64	64	65	63	70	63	580	714
	Normal	Normal	134 (100.0%)	127 (100.0%)	63 (98.4%)	64 (100.0%)	64 (100.0%)	64 (98.5%)	63 (100.0%)	70 (100.0%)	63 (100.0%)	578 (99.7%)	712 (99.7%)
		High	0	0	1 (1.6%)	0	0	1 (1.5%)	0	0	0	2 (0.3%)	2 (0.3%)
Chloride (mmol/L)													
Week 4	m		134	127	64	64	64	65	63	70	63	580	714
	Low	Normal	2 (1.5%)	1 (0.8%)	0	1 (1.6%)	0	0	1 (1.6%)	0	1 (1.6%)	4 (0.7%)	6 (0.8%)
	Normal	Low	0	2 (1.6%)	0	0	0	0	0	0	1 (1.6%)	3 (0.5%)	3 (0.4%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
		Normal	132 (98.5%)	124 (97.6%)	64 (100.0%)	63 (98.4%)	64 (100.0%)	65 (100.0%)	62 (98.4%)	70 (100.0%)	61 (96.8%)	573 (98.8%)	705 (98.7%)
Week 8	m		132	125	63	64	64	65	62	69	63	575	707
	Low	Normal	2 (1.5%)	1 (0.8%)	0	1 (1.6%)	0	0	1 (1.6%)	0	1 (1.6%)	4 (0.7%)	6 (0.8%)
	Normal	Low	0	1 (0.8%)	1 (1.6%)	0	1 (1.6%)	1 (1.5%)	0	0	1 (1.6%)	5 (0.9%)	5 (0.7%)
		Normal	130 (98.5%)	123 (98.4%)	62 (98.4%)	63 (98.4%)	63 (98.4%)	64 (98.5%)	61 (98.4%)	69 (100.0%)	61 (96.8%)	566 (98.4%)	696 (98.4%)
Week 12	m		131	123	63	64	64	65	62	68	63	572	703
	Low	Normal	2 (1.5%)	1 (0.8%)	0	1 (1.6%)	0	0	1 (1.6%)	0	1 (1.6%)	4 (0.7%)	6 (0.9%)
	Normal	Low	0	0	0	0	0	1 (1.5%)	0	0	1 (1.6%)	2 (0.3%)	2 (0.3%)
		Normal	129 (98.5%)	122 (99.2%)	63 (100.0%)	63 (98.4%)	64 (100.0%)	64 (98.5%)	61 (98.4%)	68 (100.0%)	61 (96.8%)	566 (99.0%)	695 (98.9%)
Week 16	m		130	123	63	64	64	64	62	69	63	572	702
	Low	Normal	2 (1.5%)	1 (0.8%)	0	1 (1.6%)	0	0	1 (1.6%)	0	1 (1.6%)	4 (0.7%)	6 (0.9%)
	Normal	Low	0	1 (0.8%)	0	0	0	0	0	1 (1.4%)	1 (1.6%)	3 (0.5%)	3 (0.4%)
		Normal	128 (98.5%)	121 (98.4%)	63 (100.0%)	63 (98.4%)	64 (100.0%)	64 (100.0%)	61 (98.4%)	68 (98.6%)	61 (96.8%)	565 (98.8%)	693 (98.7%)
Week 20	m		130	123	62	63	64	65	61	69	63	570	700
	Low	Low	0	0	0	1 (1.6%)	0	0	0	0	0	1 (0.2%)	1 (0.1%)
		Normal	2 (1.5%)	1 (0.8%)	0	0	0	0	1 (1.6%)	0	1 (1.6%)	3 (0.5%)	5 (0.7%)
	Normal	Low	0	2 (1.6%)	1 (1.6%)	0	0	0	0	1 (1.4%)	0	4 (0.7%)	4 (0.6%)
		Normal	128 (98.5%)	120 (97.6%)	61 (98.4%)	62 (98.4%)	64 (100.0%)	65 (100.0%)	60 (98.4%)	68 (98.6%)	62 (98.4%)	562 (98.6%)	690 (98.6%)
Week 24	m		130	122	62	63	64	65	61	69	63	569	699
	Low	Normal	2 (1.5%)	1 (0.8%)	0	1 (1.6%)	0	0	1 (1.6%)	0	1 (1.6%)	4 (0.7%)	6 (0.9%)
	Normal	Low	1 (0.8%)	0	0	0	0	1 (1.5%)	0	0	0	1 (0.2%)	2 (0.3%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
		Normal	127 (97.7%)	121 (99.2%)	62 (100.0%)	62 (98.4%)	64 (100.0%)	64 (98.5%)	60 (98.4%)	69 (100.0%)	62 (98.4%)	564 (99.1%)	691 (98.9%)
Week 32	m		128	120	62	60	62	65	60	69	63	561	689
	Low	Normal	2 (1.6%)	1 (0.8%)	0	0	0	0	1 (1.7%)	0	1 (1.6%)	3 (0.5%)	5 (0.7%)
	Normal	Low	0	0	1 (1.6%)	1 (1.7%)	0	0	0	0	2 (3.2%)	4 (0.7%)	4 (0.6%)
		Normal	126 (98.4%)	119 (99.2%)	61 (98.4%)	59 (98.3%)	62 (100.0%)	65 (100.0%)	59 (98.3%)	69 (100.0%)	60 (95.2%)	554 (98.8%)	680 (98.7%)
Week 40	m		128	120	60	59	62	65	60	69	63	558	686
	Low	Low	1 (0.8%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
		Normal	1 (0.8%)	1 (0.8%)	0	0	0	0	1 (1.7%)	0	1 (1.6%)	3 (0.5%)	4 (0.6%)
	Normal	Low	0	0	1 (1.7%)	0	1 (1.6%)	0	0	2 (2.9%)	1 (1.6%)	5 (0.9%)	5 (0.7%)
		Normal	126 (98.4%)	119 (99.2%)	59 (98.3%)	59 (100.0%)	61 (98.4%)	65 (100.0%)	59 (98.3%)	67 (97.1%)	61 (96.8%)	550 (98.6%)	676 (98.5%)
Week 48	m		127	118	60	59	62	65	60	66	63	553	680
	Low	Normal	2 (1.6%)	1 (0.8%)	0	0	0	0	1 (1.7%)	0	1 (1.6%)	3 (0.5%)	5 (0.7%)
	Normal	Low	0	0	0	0	0	0	0	1 (1.5%)	1 (1.6%)	2 (0.4%)	2 (0.3%)
		Normal	125 (98.4%)	117 (99.2%)	60 (100.0%)	59 (100.0%)	62 (100.0%)	65 (100.0%)	59 (98.3%)	65 (98.5%)	61 (96.8%)	548 (99.1%)	673 (99.0%)
Week 52	m		126	116	59	58	62	65	60	67	62	549	675
	Low	Normal	2 (1.6%)	1 (0.9%)	0	0	0	0	1 (1.7%)	0	1 (1.6%)	3 (0.5%)	5 (0.7%)
	Normal	Low	0	0	1 (1.7%)	0	0	0	0	0	1 (1.6%)	2 (0.4%)	2 (0.3%)
		Normal	124 (98.4%)	115 (99.1%)	58 (98.3%)	58 (100.0%)	62 (100.0%)	65 (100.0%)	59 (98.3%)	67 (100.0%)	60 (96.8%)	544 (99.1%)	668 (99.0%)
LOCF Endpoint	m		134	127	64	64	64	65	63	70	63	580	714
	Low	Normal	2 (1.5%)	1 (0.8%)	0	1 (1.6%)	0	0	1 (1.6%)	0	1 (1.6%)	4 (0.7%)	6 (0.8%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
	Normal	Low	0	0	1 (1.6%)	1 (1.6%)	0	0	0	0	1 (1.6%)	3 (0.5%)	3 (0.4%)
		Normal	132 (98.5%)	126 (99.2%)	63 (98.4%)	62 (96.9%)	64 (100.0%)	65 (100.0%)	62 (98.4%)	70 (100.0%)	61 (96.8%)	573 (98.8%)	705 (98.7%)
Creatine Kinase (U/L)													
Week 4	m		134	127	64	64	64	65	63	70	63	580	714
	Low	Low	0	0	0	1 (1.6%)	0	0	0	0	1 (1.6%)	2 (0.3%)	2 (0.3%)
		Normal	0	0	0	1 (1.6%)	1 (1.6%)	0	0	0	0	2 (0.3%)	2 (0.3%)
	Normal	Normal	126 (94.0%)	124 (97.6%)	64 (100.0%)	60 (93.8%)	59 (92.2%)	58 (89.2%)	61 (96.8%)	65 (92.9%)	60 (95.2%)	551 (95.0%)	677 (94.8%)
		High	2 (1.5%)	2 (1.6%)	0	1 (1.6%)	0	3 (4.6%)	1 (1.6%)	2 (2.9%)	1 (1.6%)	10 (1.7%)	12 (1.7%)
	High	Normal	4 (3.0%)	1 (0.8%)	0	0	3 (4.7%)	3 (4.6%)	0	2 (2.9%)	1 (1.6%)	10 (1.7%)	14 (2.0%)
		High	2 (1.5%)	0	0	1 (1.6%)	1 (1.6%)	1 (1.5%)	1 (1.6%)	1 (1.4%)	0	5 (0.9%)	7 (1.0%)
Week 8	m		132	124	63	64	64	65	62	69	62	573	705
	Low	Low	0	0	0	1 (1.6%)	0	0	0	0	1 (1.6%)	2 (0.3%)	2 (0.3%)
		Normal	0	0	0	1 (1.6%)	1 (1.6%)	0	0	0	0	2 (0.3%)	2 (0.3%)
	Normal	Low	0	0	0	0	0	0	0	1 (1.4%)	0	1 (0.2%)	1 (0.1%)
		Normal	126 (95.5%)	120 (96.8%)	63 (100.0%)	60 (93.8%)	57 (89.1%)	57 (87.7%)	60 (96.8%)	63 (91.3%)	57 (91.9%)	537 (93.7%)	663 (94.0%)
		High	1 (0.8%)	3 (2.4%)	0	1 (1.6%)	2 (3.1%)	4 (6.2%)	1 (1.6%)	2 (2.9%)	3 (4.8%)	16 (2.8%)	17 (2.4%)
	High	Normal	4 (3.0%)	1 (0.8%)	0	0	1 (1.6%)	3 (4.6%)	1 (1.6%)	2 (2.9%)	1 (1.6%)	9 (1.6%)	13 (1.8%)
		High	1 (0.8%)	0	0	1 (1.6%)	3 (4.7%)	1 (1.5%)	0	1 (1.4%)	0	6 (1.0%)	7 (1.0%)
Week 12	m		131	122	63	64	64	65	62	68	63	571	702
	Low	Low	0	0	0	1 (1.6%)	0	0	0	0	1 (1.6%)	2 (0.4%)	2 (0.3%)
		Normal	0	0	0	1 (1.6%)	1 (1.6%)	0	0	0	0	2 (0.4%)	2 (0.3%)
	Normal	Low	0	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	1 (0.1%)
		Normal	125 (95.4%)	118 (96.7%)	61 (96.8%)	59 (92.2%)	58 (90.6%)	58 (89.2%)	59 (95.2%)	63 (92.6%)	59 (93.7%)	535 (93.7%)	660 (94.0%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
		High	1 (0.8%)	3 (2.5%)	2 (3.2%)	2 (3.1%)	1 (1.6%)	3 (4.6%)	2 (3.2%)	2 (2.9%)	1 (1.6%)	16 (2.8%)	17 (2.4%)
	High	Normal	3 (2.3%)	0	0	0	2 (3.1%)	3 (4.6%)	0	2 (2.9%)	1 (1.6%)	8 (1.4%)	11 (1.6%)
		High	2 (1.5%)	1 (0.8%)	0	1 (1.6%)	2 (3.1%)	1 (1.5%)	1 (1.6%)	1 (1.5%)	0	7 (1.2%)	9 (1.3%)
Week 16	m		130	123	63	64	64	64	62	69	63	572	702
	Low	Low	0	0	0	2 (3.1%)	0	0	0	0	1 (1.6%)	3 (0.5%)	3 (0.4%)
		Normal	0	0	0	0	1 (1.6%)	0	0	0	0	1 (0.2%)	1 (0.1%)
	Normal	Low	0	0	0	0	0	1 (1.6%)	0	1 (1.4%)	0	2 (0.3%)	2 (0.3%)
		Normal	122 (93.8%)	122 (99.2%)	63 (100.0%)	59 (92.2%)	58 (90.6%)	55 (85.9%)	60 (96.8%)	64 (92.8%)	60 (95.2%)	541 (94.6%)	663 (94.4%)
		High	3 (2.3%)	0	0	2 (3.1%)	1 (1.6%)	4 (6.3%)	1 (1.6%)	1 (1.4%)	1 (1.6%)	10 (1.7%)	13 (1.9%)
	High	Normal	4 (3.1%)	0	0	0	2 (3.1%)	3 (4.7%)	0	2 (2.9%)	1 (1.6%)	8 (1.4%)	12 (1.7%)
		High	1 (0.8%)	1 (0.8%)	0	1 (1.6%)	2 (3.1%)	1 (1.6%)	1 (1.6%)	1 (1.4%)	0	7 (1.2%)	8 (1.1%)
Week 20	m		130	123	62	63	64	65	61	69	63	570	700
	Low	Low	0	0	0	2 (3.2%)	0	0	0	0	1 (1.6%)	3 (0.5%)	3 (0.4%)
		Normal	0	0	0	0	1 (1.6%)	0	0	0	0	1 (0.2%)	1 (0.1%)
	Normal	Low	0	0	0	1 (1.6%)	0	1 (1.5%)	0	0	0	2 (0.4%)	2 (0.3%)
		Normal	122 (93.8%)	116 (94.3%)	59 (95.2%)	58 (92.1%)	59 (92.2%)	57 (87.7%)	60 (98.4%)	65 (94.2%)	61 (96.8%)	535 (93.9%)	657 (93.9%)
		High	3 (2.3%)	6 (4.9%)	3 (4.8%)	1 (1.6%)	0	3 (4.6%)	0	1 (1.4%)	0	14 (2.5%)	17 (2.4%)
	High	Normal	4 (3.1%)	1 (0.8%)	0	0	1 (1.6%)	3 (4.6%)	1 (1.6%)	2 (2.9%)	1 (1.6%)	9 (1.6%)	13 (1.9%)
		High	1 (0.8%)	0	0	1 (1.6%)	3 (4.7%)	1 (1.5%)	0	1 (1.4%)	0	6 (1.1%)	7 (1.0%)
Week 24	m		130	122	62	63	64	65	61	69	63	569	699
	Low	Normal	0	0	0	2 (3.2%)	1 (1.6%)	0	0	0	1 (1.6%)	4 (0.7%)	4 (0.6%)
	Normal	Low	0	0	0	0	1 (1.6%)	1 (1.5%)	0	0	0	2 (0.4%)	2 (0.3%)
		Normal	120 (92.3%)	119 (97.5%)	59 (95.2%)	59 (93.7%)	58 (90.6%)	59 (90.8%)	58 (95.1%)	64 (92.8%)	60 (95.2%)	536 (94.2%)	656 (93.8%)
		High	5 (3.8%)	2 (1.6%)	3 (4.8%)	1 (1.6%)	0	1 (1.5%)	2 (3.3%)	2 (2.9%)	1 (1.6%)	12 (2.1%)	17 (2.4%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
	High	Normal	4 (3.1%)	1 (0.8%)	0	0	2 (3.1%)	3 (4.6%)	1 (1.6%)	2 (2.9%)	1 (1.6%)	10 (1.8%)	14 (2.0%)
		High	1 (0.8%)	0	0	1 (1.6%)	2 (3.1%)	1 (1.5%)	0	1 (1.4%)	0	5 (0.9%)	6 (0.9%)
Week 32	m		128	120	62	60	62	65	60	69	63	561	689
	Low	Low	0	0	0	1 (1.7%)	0	0	0	0	0	1 (0.2%)	1 (0.1%)
		Normal	0	0	0	1 (1.7%)	1 (1.6%)	0	0	0	1 (1.6%)	3 (0.5%)	3 (0.4%)
	Normal	Low	0	1 (0.8%)	0	1 (1.7%)	1 (1.6%)	0	0	1 (1.4%)	1 (1.6%)	5 (0.9%)	5 (0.7%)
		Normal	120 (93.8%)	115 (95.8%)	62 (100.0%)	54 (90.0%)	55 (88.7%)	60 (92.3%)	58 (96.7%)	65 (94.2%)	59 (93.7%)	528 (94.1%)	648 (94.0%)
		High	3 (2.3%)	3 (2.5%)	0	2 (3.3%)	2 (3.2%)	1 (1.5%)	1 (1.7%)	0	1 (1.6%)	10 (1.8%)	13 (1.9%)
	High	Normal	4 (3.1%)	0	0	0	2 (3.2%)	4 (6.2%)	1 (1.7%)	2 (2.9%)	1 (1.6%)	10 (1.8%)	14 (2.0%)
		High	1 (0.8%)	1 (0.8%)	0	1 (1.7%)	1 (1.6%)	0	0	1 (1.4%)	0	4 (0.7%)	5 (0.7%)
Week 40	m		128	120	60	59	62	65	60	69	63	558	686
	Low	Low	0	0	0	1 (1.7%)	0	0	0	0	1 (1.6%)	2 (0.4%)	2 (0.3%)
		Normal	0	0	0	1 (1.7%)	1 (1.6%)	0	0	0	0	2 (0.4%)	2 (0.3%)
	Normal	Low	0	0	0	0	1 (1.6%)	0	0	0	0	1 (0.2%)	1 (0.1%)
		Normal	119 (93.0%)	119 (99.2%)	58 (96.7%)	55 (93.2%)	57 (91.9%)	58 (89.2%)	58 (96.7%)	64 (92.8%)	58 (92.1%)	527 (94.4%)	646 (94.2%)
		High	4 (3.1%)	0	2 (3.3%)	1 (1.7%)	0	3 (4.6%)	1 (1.7%)	2 (2.9%)	3 (4.8%)	12 (2.2%)	16 (2.3%)
	High	Normal	3 (2.3%)	0	0	0	2 (3.2%)	2 (3.1%)	1 (1.7%)	3 (4.3%)	1 (1.6%)	9 (1.6%)	12 (1.7%)
		High	2 (1.6%)	1 (0.8%)	0	1 (1.7%)	1 (1.6%)	2 (3.1%)	0	0	0	5 (0.9%)	7 (1.0%)
Week 48	m		127	117	60	59	62	65	60	66	63	552	679
	Low	Low	0	0	0	1 (1.7%)	0	0	0	0	1 (1.6%)	2 (0.4%)	2 (0.3%)
		Normal	0	0	0	1 (1.7%)	1 (1.6%)	0	0	0	0	2 (0.4%)	2 (0.3%)
	Normal	Low	1 (0.8%)	0	0	1 (1.7%)	0	1 (1.5%)	0	1 (1.5%)	0	3 (0.5%)	4 (0.6%)
		Normal	120 (94.5%)	113 (96.6%)	58 (96.7%)	54 (91.5%)	56 (90.3%)	57 (87.7%)	57 (95.0%)	60 (90.9%)	56 (88.9%)	511 (92.6%)	631 (92.9%)
		High	1 (0.8%)	3 (2.6%)	2 (3.3%)	1 (1.7%)	2 (3.2%)	3 (4.6%)	2 (3.3%)	2 (3.0%)	5 (7.9%)	20 (3.6%)	21 (3.1%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
	High	Normal	4 (3.1%)	0	0	0	2 (3.2%)	3 (4.6%)	1 (1.7%)	1 (1.5%)	1 (1.6%)	8 (1.4%)	12 (1.8%)
		High	1 (0.8%)	1 (0.9%)	0	1 (1.7%)	1 (1.6%)	1 (1.5%)	0	2 (3.0%)	0	6 (1.1%)	7 (1.0%)
Week 52	m		126	116	59	58	62	65	60	67	62	549	675
	Low	Low	0	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	1 (0.1%)
		Normal	0	0	0	2 (3.4%)	1 (1.6%)	0	0	0	0	3 (0.5%)	3 (0.4%)
	Normal	Low	0	0	0	1 (1.7%)	1 (1.6%)	0	0	0	0	2 (0.4%)	2 (0.3%)
		Normal	119 (94.4%)	114 (98.3%)	56 (94.9%)	53 (91.4%)	56 (90.3%)	60 (92.3%)	58 (96.7%)	61 (91.0%)	59 (95.2%)	517 (94.2%)	636 (94.2%)
		High	2 (1.6%)	1 (0.9%)	3 (5.1%)	1 (1.7%)	1 (1.6%)	1 (1.5%)	1 (1.7%)	3 (4.5%)	1 (1.6%)	12 (2.2%)	14 (2.1%)
	High	Normal	4 (3.2%)	0	0	0	2 (3.2%)	3 (4.6%)	1 (1.7%)	3 (4.5%)	1 (1.6%)	10 (1.8%)	14 (2.1%)
		High	1 (0.8%)	1 (0.9%)	0	1 (1.7%)	1 (1.6%)	1 (1.5%)	0	0	0	4 (0.7%)	5 (0.7%)
LOCF Endpoint	m		134	127	64	64	64	65	63	70	63	580	714
	Low	Low	0	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	1 (0.1%)
		Normal	0	0	0	2 (3.1%)	1 (1.6%)	0	0	0	0	3 (0.5%)	3 (0.4%)
	Normal	Low	0	0	0	1 (1.6%)	1 (1.6%)	0	0	0	0	2 (0.3%)	2 (0.3%)
		Normal	126 (94.0%)	124 (97.6%)	61 (95.3%)	59 (92.2%)	57 (89.1%)	60 (92.3%)	61 (96.8%)	64 (91.4%)	60 (95.2%)	546 (94.1%)	672 (94.1%)
		High	2 (1.5%)	2 (1.6%)	3 (4.7%)	1 (1.6%)	1 (1.6%)	1 (1.5%)	1 (1.6%)	3 (4.3%)	1 (1.6%)	13 (2.2%)	15 (2.1%)
	High	Normal	5 (3.7%)	0	0	0	2 (3.1%)	3 (4.6%)	1 (1.6%)	3 (4.3%)	1 (1.6%)	10 (1.7%)	15 (2.1%)
		High	1 (0.7%)	1 (0.8%)	0	1 (1.6%)	2 (3.1%)	1 (1.5%)	0	0	0	5 (0.9%)	6 (0.8%)
Creatinine (umol/L)													
Week 4	m		134	127	64	64	64	65	63	70	63	580	714
	Normal	Normal	134 (100.0%)	127 (100.0%)	64 (100.0%)	64 (100.0%)	64 (100.0%)	65 (100.0%)	63 (100.0%)	70 (100.0%)	63 (100.0%)	580 (100.0%)	714 (100.0%)
Week 8	m		132	125	63	64	64	65	62	69	63	575	707

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
	Normal	Normal	132 (100.0%)	125 (100.0%)	63 (100.0%)	64 (100.0%)	64 (100.0%)	65 (100.0%)	62 (100.0%)	69 (100.0%)	63 (100.0%)	575 (100.0%)	707 (100.0%)
Week 12	m		131	123	63	64	64	65	62	68	63	572	703
	Normal	Normal	131 (100.0%)	123 (100.0%)	63 (100.0%)	64 (100.0%)	64 (100.0%)	65 (100.0%)	62 (100.0%)	68 (100.0%)	63 (100.0%)	572 (100.0%)	703 (100.0%)
Week 16	m		130	123	63	64	64	64	62	69	63	572	702
	Normal	Normal	130 (100.0%)	123 (100.0%)	63 (100.0%)	64 (100.0%)	64 (100.0%)	64 (100.0%)	62 (100.0%)	69 (100.0%)	63 (100.0%)	572 (100.0%)	702 (100.0%)
Week 20	m		130	123	62	63	64	65	61	69	63	570	700
	Normal	Normal	130 (100.0%)	123 (100.0%)	62 (100.0%)	63 (100.0%)	64 (100.0%)	65 (100.0%)	61 (100.0%)	69 (100.0%)	63 (100.0%)	570 (100.0%)	700 (100.0%)
Week 24	m		130	122	62	63	64	65	61	69	63	569	699
	Normal	Normal	130 (100.0%)	122 (100.0%)	62 (100.0%)	62 (98.4%)	64 (100.0%)	65 (100.0%)	60 (98.4%)	69 (100.0%)	63 (100.0%)	567 (99.6%)	697 (99.7%)
		High	0	0	0	1 (1.6%)	0	0	1 (1.6%)	0	0	2 (0.4%)	2 (0.3%)
Week 32	m		128	120	62	60	62	65	60	69	63	561	689
	Normal	Normal	128 (100.0%)	120 (100.0%)	62 (100.0%)	60 (100.0%)	62 (100.0%)	65 (100.0%)	60 (100.0%)	69 (100.0%)	63 (100.0%)	561 (100.0%)	689 (100.0%)
Week 40	m		128	120	60	59	62	65	60	69	63	558	686
	Normal	Normal	128 (100.0%)	120 (100.0%)	60 (100.0%)	59 (100.0%)	62 (100.0%)	65 (100.0%)	60 (100.0%)	69 (100.0%)	63 (100.0%)	558 (100.0%)	686 (100.0%)
Week 48	m		127	118	60	59	62	65	60	66	63	553	680
	Normal	Normal	126 (99.2%)	118 (100.0%)	60 (100.0%)	59 (100.0%)	62 (100.0%)	65 (100.0%)	60 (100.0%)	66 (100.0%)	63 (100.0%)	553 (100.0%)	679 (99.9%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
		High	1 (0.8%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
Week 52	m		126	116	59	58	62	65	60	67	62	549	675
	Normal	Normal	126 (100.0%)	116 (100.0%)	59 (100.0%)	58 (100.0%)	62 (100.0%)	65 (100.0%)	60 (100.0%)	67 (100.0%)	62 (100.0%)	549 (100.0%)	675 (100.0%)
LOCF Endpoint	m		134	127	64	64	64	65	63	70	63	580	714
	Normal	Normal	134 (100.0%)	127 (100.0%)	64 (100.0%)	64 (100.0%)	64 (100.0%)	65 (100.0%)	63 (100.0%)	70 (100.0%)	63 (100.0%)	580 (100.0%)	714 (100.0%)
Gamma Glutamyl Transferase (U/L)													
Week 4	m		134	127	64	64	64	65	63	70	63	580	714
	Low	Low	0	0	0	0	1 (1.6%)	1 (1.5%)	1 (1.6%)	0	0	3 (0.5%)	3 (0.4%)
		Normal	1 (0.7%)	0	0	0	0	1 (1.5%)	0	0	0	1 (0.2%)	2 (0.3%)
	Normal	Low	1 (0.7%)	0	1 (1.6%)	0	0	0	0	0	0	1 (0.2%)	2 (0.3%)
		Normal	112 (83.6%)	99 (78.0%)	49 (76.6%)	52 (81.3%)	47 (73.4%)	55 (84.6%)	45 (71.4%)	53 (75.7%)	48 (76.2%)	448 (77.2%)	560 (78.4%)
		High	0	1 (0.8%)	1 (1.6%)	2 (3.1%)	1 (1.6%)	0	1 (1.6%)	1 (1.4%)	1 (1.6%)	8 (1.4%)	8 (1.1%)
	High	Normal	5 (3.7%)	5 (3.9%)	4 (6.3%)	4 (6.3%)	5 (7.8%)	1 (1.5%)	6 (9.5%)	4 (5.7%)	1 (1.6%)	30 (5.2%)	35 (4.9%)
		High	15 (11.2%)	22 (17.3%)	9 (14.1%)	6 (9.4%)	10 (15.6%)	7 (10.8%)	10 (15.9%)	12 (17.1%)	13 (20.6%)	89 (15.3%)	104 (14.6%)
Week 8	m		132	125	63	64	64	65	62	69	63	575	707
	Low	Low	1 (0.8%)	0	0	0	1 (1.6%)	1 (1.5%)	0	0	0	2 (0.3%)	3 (0.4%)
		Normal	0	0	0	0	0	1 (1.5%)	1 (1.6%)	0	0	2 (0.3%)	2 (0.3%)
	Normal	Low	1 (0.8%)	1 (0.8%)	1 (1.6%)	0	1 (1.6%)	0	0	0	0	3 (0.5%)	4 (0.6%)
		Normal	110 (83.3%)	95 (76.0%)	48 (76.2%)	53 (82.8%)	45 (70.3%)	55 (84.6%)	45 (72.6%)	52 (75.4%)	49 (77.8%)	442 (76.9%)	552 (78.1%)
		High	1 (0.8%)	2 (1.6%)	1 (1.6%)	1 (1.6%)	2 (3.1%)	0	1 (1.6%)	1 (1.4%)	0	8 (1.4%)	9 (1.3%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
	High	Normal	5 (3.8%)	9 (7.2%)	4 (6.3%)	6 (9.4%)	6 (9.4%)	3 (4.6%)	5 (8.1%)	6 (8.7%)	3 (4.8%)	42 (7.3%)	47 (6.6%)
		High	14 (10.6%)	18 (14.4%)	9 (14.3%)	4 (6.3%)	9 (14.1%)	5 (7.7%)	10 (16.1%)	10 (14.5%)	11 (17.5%)	76 (13.2%)	90 (12.7%)
Week 12	m		131	123	63	64	64	65	62	68	63	572	703
	Low	Low	0	0	0	0	1 (1.6%)	1 (1.5%)	0	0	0	2 (0.3%)	2 (0.3%)
		Normal	1 (0.8%)	0	0	0	0	1 (1.5%)	1 (1.6%)	0	0	2 (0.3%)	3 (0.4%)
	Normal	Low	2 (1.5%)	1 (0.8%)	1 (1.6%)	1 (1.6%)	0	0	0	1 (1.5%)	0	4 (0.7%)	6 (0.9%)
		Normal	108 (82.4%)	95 (77.2%)	48 (76.2%)	51 (79.7%)	46 (71.9%)	55 (84.6%)	45 (72.6%)	51 (75.0%)	48 (76.2%)	439 (76.7%)	547 (77.8%)
		High	1 (0.8%)	0	1 (1.6%)	2 (3.1%)	2 (3.1%)	0	1 (1.6%)	0	1 (1.6%)	7 (1.2%)	8 (1.1%)
	High	Normal	5 (3.8%)	9 (7.3%)	5 (7.9%)	5 (7.8%)	7 (10.9%)	4 (6.2%)	5 (8.1%)	4 (5.9%)	4 (6.3%)	43 (7.5%)	48 (6.8%)
		High	14 (10.7%)	18 (14.6%)	8 (12.7%)	5 (7.8%)	8 (12.5%)	4 (6.2%)	10 (16.1%)	12 (17.6%)	10 (15.9%)	75 (13.1%)	89 (12.7%)
Week 16	m		130	123	63	64	64	64	62	69	63	572	702
	Low	Low	0	0	0	0	1 (1.6%)	1 (1.6%)	0	0	0	2 (0.3%)	2 (0.3%)
		Normal	1 (0.8%)	0	0	0	0	1 (1.6%)	1 (1.6%)	0	0	2 (0.3%)	3 (0.4%)
	Normal	Low	2 (1.5%)	1 (0.8%)	0	2 (3.1%)	0	0	0	0	0	3 (0.5%)	5 (0.7%)
		Normal	104 (80.0%)	93 (75.6%)	49 (77.8%)	49 (76.6%)	46 (71.9%)	52 (81.3%)	45 (72.6%)	53 (76.8%)	48 (76.2%)	435 (76.0%)	539 (76.8%)
		High	4 (3.1%)	2 (1.6%)	1 (1.6%)	3 (4.7%)	2 (3.1%)	2 (3.1%)	1 (1.6%)	0	1 (1.6%)	12 (2.1%)	16 (2.3%)
	High	Normal	6 (4.6%)	10 (8.1%)	5 (7.9%)	5 (7.8%)	7 (10.9%)	2 (3.1%)	5 (8.1%)	2 (2.9%)	4 (6.3%)	40 (7.0%)	46 (6.6%)
		High	13 (10.0%)	17 (13.8%)	8 (12.7%)	5 (7.8%)	8 (12.5%)	6 (9.4%)	10 (16.1%)	14 (20.3%)	10 (15.9%)	78 (13.6%)	91 (13.0%)
Week 20	m		130	123	62	63	64	65	61	69	63	570	700
	Low	Low	0	0	0	0	1 (1.6%)	1 (1.5%)	1 (1.6%)	0	0	3 (0.5%)	3 (0.4%)
		Normal	1 (0.8%)	0	0	0	0	1 (1.5%)	0	0	0	1 (0.2%)	2 (0.3%)
	Normal	Low	1 (0.8%)	1 (0.8%)	0	2 (3.2%)	0	0	0	0	0	3 (0.5%)	4 (0.6%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
		Normal	104 (80.0%)	91 (74.0%)	46 (74.2%)	49 (77.8%)	47 (73.4%)	53 (81.5%)	45 (73.8%)	52 (75.4%)	48 (76.2%)	431 (75.6%)	535 (76.4%)
		High	5 (3.8%)	4 (3.3%)	3 (4.8%)	2 (3.2%)	1 (1.6%)	2 (3.1%)	0	1 (1.4%)	1 (1.6%)	14 (2.5%)	19 (2.7%)
	High	Normal	6 (4.6%)	7 (5.7%)	5 (8.1%)	5 (7.9%)	7 (10.9%)	3 (4.6%)	3 (4.9%)	3 (4.3%)	4 (6.3%)	37 (6.5%)	43 (6.1%)
		High	13 (10.0%)	20 (16.3%)	8 (12.9%)	5 (7.9%)	8 (12.5%)	5 (7.7%)	12 (19.7%)	13 (18.8%)	10 (15.9%)	81 (14.2%)	94 (13.4%)
Week 24	m		130	122	62	63	64	65	61	69	63	569	699
	Low	Low	0	0	0	0	1 (1.6%)	1 (1.5%)	0	0	0	2 (0.4%)	2 (0.3%)
		Normal	1 (0.8%)	0	0	0	0	1 (1.5%)	1 (1.6%)	0	0	2 (0.4%)	3 (0.4%)
	Normal	Low	0	1 (0.8%)	0	1 (1.6%)	1 (1.6%)	1 (1.5%)	0	0	0	4 (0.7%)	4 (0.6%)
		Normal	105 (80.8%)	94 (77.0%)	47 (75.8%)	51 (81.0%)	45 (70.3%)	53 (81.5%)	44 (72.1%)	51 (73.9%)	48 (76.2%)	433 (76.1%)	538 (77.0%)
		High	5 (3.8%)	1 (0.8%)	2 (3.2%)	1 (1.6%)	2 (3.1%)	1 (1.5%)	1 (1.6%)	2 (2.9%)	1 (1.6%)	11 (1.9%)	16 (2.3%)
	High	Normal	7 (5.4%)	6 (4.9%)	4 (6.5%)	4 (6.3%)	8 (12.5%)	2 (3.1%)	3 (4.9%)	6 (8.7%)	3 (4.8%)	36 (6.3%)	43 (6.2%)
		High	12 (9.2%)	20 (16.4%)	9 (14.5%)	6 (9.5%)	7 (10.9%)	6 (9.2%)	12 (19.7%)	10 (14.5%)	11 (17.5%)	81 (14.2%)	93 (13.3%)
Week 32	m		128	120	62	60	62	65	60	69	63	561	689
	Low	Low	1 (0.8%)	0	0	0	1 (1.6%)	1 (1.5%)	1 (1.7%)	0	0	3 (0.5%)	4 (0.6%)
		Normal	0	0	0	0	0	1 (1.5%)	0	0	0	1 (0.2%)	1 (0.1%)
	Normal	Low	1 (0.8%)	1 (0.8%)	0	1 (1.7%)	0	1 (1.5%)	0	0	0	3 (0.5%)	4 (0.6%)
		Normal	101 (78.9%)	92 (76.7%)	47 (75.8%)	48 (80.0%)	45 (72.6%)	52 (80.0%)	45 (75.0%)	52 (75.4%)	48 (76.2%)	429 (76.5%)	530 (76.9%)
		High	6 (4.7%)	3 (2.5%)	2 (3.2%)	1 (1.7%)	1 (1.6%)	2 (3.1%)	0	1 (1.4%)	1 (1.6%)	11 (2.0%)	17 (2.5%)
	High	Normal	3 (2.3%)	5 (4.2%)	5 (8.1%)	2 (3.3%)	8 (12.9%)	2 (3.1%)	4 (6.7%)	5 (7.2%)	3 (4.8%)	34 (6.1%)	37 (5.4%)
		High	16 (12.5%)	19 (15.8%)	8 (12.9%)	8 (13.3%)	7 (11.3%)	6 (9.2%)	10 (16.7%)	11 (15.9%)	11 (17.5%)	80 (14.3%)	96 (13.9%)
Week 40	m		128	120	60	59	62	65	60	69	63	558	686
	Low	Low	1 (0.8%)	0	0	0	1 (1.6%)	1 (1.5%)	0	0	0	2 (0.4%)	3 (0.4%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
		Normal	0	0	0	0	0	1 (1.5%)	1 (1.7%)	0	0	2 (0.4%)	2 (0.3%)
	Normal	Low	1 (0.8%)	1 (0.8%)	0	1 (1.7%)	0	0	0	0	0	2 (0.4%)	3 (0.4%)
		Normal	102 (79.7%)	91 (75.8%)	46 (76.7%)	47 (79.7%)	45 (72.6%)	52 (80.0%)	44 (73.3%)	53 (76.8%)	47 (74.6%)	425 (76.2%)	527 (76.8%)
		High	5 (3.9%)	4 (3.3%)	2 (3.3%)	1 (1.7%)	1 (1.6%)	3 (4.6%)	0	0	2 (3.2%)	13 (2.3%)	18 (2.6%)
	High	Normal	5 (3.9%)	8 (6.7%)	7 (11.7%)	5 (8.5%)	8 (12.9%)	2 (3.1%)	6 (10.0%)	7 (10.1%)	6 (9.5%)	49 (8.8%)	54 (7.9%)
		High	14 (10.9%)	16 (13.3%)	5 (8.3%)	5 (8.5%)	7 (11.3%)	6 (9.2%)	9 (15.0%)	9 (13.0%)	8 (12.7%)	65 (11.6%)	79 (11.5%)
Week 48	m		127	118	60	59	62	65	60	66	63	553	680
	Low	Low	0	0	0	0	1 (1.6%)	1 (1.5%)	0	0	0	2 (0.4%)	2 (0.3%)
		Normal	1 (0.8%)	0	0	0	0	1 (1.5%)	1 (1.7%)	0	0	2 (0.4%)	3 (0.4%)
	Normal	Low	3 (2.4%)	1 (0.8%)	0	1 (1.7%)	0	1 (1.5%)	0	1 (1.5%)	0	4 (0.7%)	7 (1.0%)
		Normal	102 (80.3%)	92 (78.0%)	47 (78.3%)	48 (81.4%)	44 (71.0%)	53 (81.5%)	43 (71.7%)	49 (74.2%)	49 (77.8%)	425 (76.9%)	527 (77.5%)
		High	2 (1.6%)	1 (0.8%)	1 (1.7%)	0	2 (3.2%)	1 (1.5%)	1 (1.7%)	0	0	6 (1.1%)	8 (1.2%)
	High	Normal	8 (6.3%)	8 (6.8%)	5 (8.3%)	3 (5.1%)	8 (12.9%)	4 (6.2%)	6 (10.0%)	8 (12.1%)	6 (9.5%)	48 (8.7%)	56 (8.2%)
		High	11 (8.7%)	16 (13.6%)	7 (11.7%)	7 (11.9%)	7 (11.3%)	4 (6.2%)	9 (15.0%)	8 (12.1%)	8 (12.7%)	66 (11.9%)	77 (11.3%)
Week 52	m		126	116	59	58	62	65	60	67	62	549	675
	Low	Low	0	0	0	0	1 (1.6%)	1 (1.5%)	0	0	0	2 (0.4%)	2 (0.3%)
		Normal	1 (0.8%)	0	0	0	0	1 (1.5%)	1 (1.7%)	0	0	2 (0.4%)	3 (0.4%)
	Normal	Low	3 (2.4%)	1 (0.9%)	0	2 (3.4%)	1 (1.6%)	0	0	0	0	4 (0.7%)	7 (1.0%)
		Normal	102 (81.0%)	89 (76.7%)	46 (78.0%)	45 (77.6%)	45 (72.6%)	53 (81.5%)	43 (71.7%)	51 (76.1%)	49 (79.0%)	421 (76.7%)	523 (77.5%)
		High	1 (0.8%)	3 (2.6%)	1 (1.7%)	2 (3.4%)	0	2 (3.1%)	1 (1.7%)	0	0	9 (1.6%)	10 (1.5%)
	High	Normal	7 (5.6%)	8 (6.9%)	5 (8.5%)	4 (6.9%)	10 (16.1%)	3 (4.6%)	6 (10.0%)	6 (9.0%)	4 (6.5%)	46 (8.4%)	53 (7.9%)
		High	12 (9.5%)	15 (12.9%)	7 (11.9%)	5 (8.6%)	5 (8.1%)	5 (7.7%)	9 (15.0%)	10 (14.9%)	9 (14.5%)	65 (11.8%)	77 (11.4%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
LOCF Endpoint													
LOCF	m		134	127	64	64	64	65	63	70	63	580	714
	Low	Low	0	0	0	0	1 (1.6%)	1 (1.5%)	0	0	0	2 (0.3%)	2 (0.3%)
		Normal	1 (0.7%)	0	0	0	0	1 (1.5%)	1 (1.6%)	0	0	2 (0.3%)	3 (0.4%)
	Normal	Low	3 (2.2%)	1 (0.8%)	0	2 (3.1%)	1 (1.6%)	0	0	0	0	4 (0.7%)	7 (1.0%)
		Normal	109 (81.3%)	96 (75.6%)	50 (78.1%)	49 (76.6%)	46 (71.9%)	53 (81.5%)	45 (71.4%)	54 (77.1%)	49 (77.8%)	442 (76.2%)	551 (77.2%)
		High	1 (0.7%)	3 (2.4%)	1 (1.6%)	3 (4.7%)	1 (1.6%)	2 (3.1%)	1 (1.6%)	0	0	11 (1.9%)	12 (1.7%)
	High	Normal	8 (6.0%)	9 (7.1%)	6 (9.4%)	4 (6.3%)	10 (15.6%)	3 (4.6%)	7 (11.1%)	6 (8.6%)	4 (6.3%)	49 (8.4%)	57 (8.0%)
		High	12 (9.0%)	18 (14.2%)	7 (10.9%)	6 (9.4%)	5 (7.8%)	5 (7.7%)	9 (14.3%)	10 (14.3%)	10 (15.9%)	70 (12.1%)	82 (11.5%)
Lipase (U/L)													
Week 4	m		134	127	64	64	64	65	63	70	63	580	714
	Normal	Normal	129 (96.3%)	123 (96.9%)	62 (96.9%)	62 (96.9%)	63 (98.4%)	62 (95.4%)	59 (93.7%)	64 (91.4%)	62 (98.4%)	557 (96.0%)	686 (96.1%)
		High	3 (2.2%)	1 (0.8%)	1 (1.6%)	2 (3.1%)	1 (1.6%)	1 (1.5%)	3 (4.8%)	3 (4.3%)	1 (1.6%)	13 (2.2%)	16 (2.2%)
	High	Normal	1 (0.7%)	2 (1.6%)	1 (1.6%)	0	0	1 (1.5%)	1 (1.6%)	3 (4.3%)	0	8 (1.4%)	9 (1.3%)
		High	1 (0.7%)	1 (0.8%)	0	0	0	1 (1.5%)	0	0	0	2 (0.3%)	3 (0.4%)
Week 8	m		132	125	63	64	64	65	62	69	63	575	707
	Normal	Normal	129 (97.7%)	120 (96.0%)	62 (98.4%)	60 (93.8%)	64 (100.0%)	62 (95.4%)	59 (95.2%)	64 (92.8%)	62 (98.4%)	553 (96.2%)	682 (96.5%)
		High	1 (0.8%)	2 (1.6%)	0	4 (6.3%)	0	1 (1.5%)	2 (3.2%)	2 (2.9%)	1 (1.6%)	12 (2.1%)	13 (1.8%)
	High	Normal	2 (1.5%)	3 (2.4%)	1 (1.6%)	0	0	0	1 (1.6%)	1 (1.4%)	0	6 (1.0%)	8 (1.1%)
		High	0	0	0	0	0	2 (3.1%)	0	2 (2.9%)	0	4 (0.7%)	4 (0.6%)
Week 12	m		131	123	63	64	64	65	62	68	63	572	703

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
	Normal	Normal	127 (96.9%)	119 (96.7%)	62 (98.4%)	61 (95.3%)	63 (98.4%)	63 (96.9%)	55 (88.7%)	65 (95.6%)	61 (96.8%)	549 (96.0%)	676 (96.2%)
		High	2 (1.5%)	1 (0.8%)	0	3 (4.7%)	1 (1.6%)	0	6 (9.7%)	0	2 (3.2%)	13 (2.3%)	15 (2.1%)
	High	Normal	2 (1.5%)	2 (1.6%)	1 (1.6%)	0	0	1 (1.5%)	1 (1.6%)	1 (1.5%)	0	6 (1.0%)	8 (1.1%)
		High	0	1 (0.8%)	0	0	0	1 (1.5%)	0	2 (2.9%)	0	4 (0.7%)	4 (0.6%)
Week 16	m		130	123	63	64	64	64	62	69	63	572	702
	Normal	Normal	125 (96.2%)	120 (97.6%)	62 (98.4%)	62 (96.9%)	63 (98.4%)	62 (96.9%)	61 (98.4%)	64 (92.8%)	61 (96.8%)	555 (97.0%)	680 (96.9%)
		High	3 (2.3%)	0	0	2 (3.1%)	1 (1.6%)	0	0	2 (2.9%)	2 (3.2%)	7 (1.2%)	10 (1.4%)
	High	Normal	2 (1.5%)	3 (2.4%)	1 (1.6%)	0	0	2 (3.1%)	1 (1.6%)	1 (1.4%)	0	8 (1.4%)	10 (1.4%)
		High	0	0	0	0	0	0	0	2 (2.9%)	0	2 (0.3%)	2 (0.3%)
Week 20	m		130	123	62	63	64	65	61	69	63	570	700
	Normal	Normal	126 (96.9%)	119 (96.7%)	61 (98.4%)	62 (98.4%)	62 (96.9%)	63 (96.9%)	58 (95.1%)	63 (91.3%)	62 (98.4%)	550 (96.5%)	676 (96.6%)
		High	2 (1.5%)	1 (0.8%)	0	1 (1.6%)	2 (3.1%)	0	2 (3.3%)	3 (4.3%)	1 (1.6%)	10 (1.8%)	12 (1.7%)
	High	Normal	2 (1.5%)	1 (0.8%)	1 (1.6%)	0	0	2 (3.1%)	1 (1.6%)	2 (2.9%)	0	7 (1.2%)	9 (1.3%)
		High	0	2 (1.6%)	0	0	0	0	0	1 (1.4%)	0	3 (0.5%)	3 (0.4%)
Week 24	m		130	122	62	63	64	65	61	69	63	569	699
	Normal	Normal	125 (96.2%)	119 (97.5%)	61 (98.4%)	60 (95.2%)	61 (95.3%)	63 (96.9%)	59 (96.7%)	65 (94.2%)	61 (96.8%)	549 (96.5%)	674 (96.4%)
		High	3 (2.3%)	0	0	3 (4.8%)	3 (4.7%)	0	1 (1.6%)	1 (1.4%)	2 (3.2%)	10 (1.8%)	13 (1.9%)
	High	Normal	2 (1.5%)	3 (2.5%)	1 (1.6%)	0	0	1 (1.5%)	1 (1.6%)	1 (1.4%)	0	7 (1.2%)	9 (1.3%)
		High	0	0	0	0	0	1 (1.5%)	0	2 (2.9%)	0	3 (0.5%)	3 (0.4%)
Week 32	m		128	120	62	60	62	65	60	69	63	561	689
	Normal	Normal	125 (97.7%)	115 (95.8%)	61 (98.4%)	59 (98.3%)	61 (98.4%)	62 (95.4%)	56 (93.3%)	66 (95.7%)	63 (100.0%)	543 (96.8%)	668 (97.0%)
		High	1 (0.8%)	2 (1.7%)	0	1 (1.7%)	1 (1.6%)	1 (1.5%)	3 (5.0%)	0	0	8 (1.4%)	9 (1.3%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
	High	Normal	2 (1.6%)	3 (2.5%)	1 (1.6%)	0	0	1 (1.5%)	1 (1.7%)	3 (4.3%)	0	9 (1.6%)	11 (1.6%)
		High	0	0	0	0	0	1 (1.5%)	0	0	0	1 (0.2%)	1 (0.1%)
Week 40	m		128	120	60	59	62	65	60	69	63	558	686
	Normal	Normal	126 (98.4%)	116 (96.7%)	59 (98.3%)	55 (93.2%)	62 (100.0%)	61 (93.8%)	55 (91.7%)	64 (92.8%)	61 (96.8%)	533 (95.5%)	659 (96.1%)
		High	0	1 (0.8%)	0	4 (6.8%)	0	2 (3.1%)	4 (6.7%)	2 (2.9%)	2 (3.2%)	15 (2.7%)	15 (2.2%)
	High	Normal	2 (1.6%)	3 (2.5%)	1 (1.7%)	0	0	1 (1.5%)	1 (1.7%)	2 (2.9%)	0	8 (1.4%)	10 (1.5%)
		High	0	0	0	0	0	1 (1.5%)	0	1 (1.4%)	0	2 (0.4%)	2 (0.3%)
Week 48	m		127	118	60	59	62	65	60	66	63	553	680
	Normal	Normal	123 (96.9%)	113 (95.8%)	59 (98.3%)	57 (96.6%)	62 (100.0%)	62 (95.4%)	58 (96.7%)	62 (93.9%)	61 (96.8%)	534 (96.6%)	657 (96.6%)
		High	2 (1.6%)	2 (1.7%)	0	2 (3.4%)	0	1 (1.5%)	1 (1.7%)	1 (1.5%)	2 (3.2%)	9 (1.6%)	11 (1.6%)
	High	Normal	2 (1.6%)	2 (1.7%)	1 (1.7%)	0	0	2 (3.1%)	1 (1.7%)	2 (3.0%)	0	8 (1.4%)	10 (1.5%)
		High	0	1 (0.8%)	0	0	0	0	0	1 (1.5%)	0	2 (0.4%)	2 (0.3%)
Week 52	m		126	116	59	58	62	65	60	67	62	549	675
	Normal	Normal	122 (96.8%)	113 (97.4%)	58 (98.3%)	53 (91.4%)	62 (100.0%)	62 (95.4%)	57 (95.0%)	62 (92.5%)	61 (98.4%)	528 (96.2%)	650 (96.3%)
		High	2 (1.6%)	0	0	5 (8.6%)	0	1 (1.5%)	2 (3.3%)	2 (3.0%)	1 (1.6%)	11 (2.0%)	13 (1.9%)
	High	Normal	2 (1.6%)	3 (2.6%)	1 (1.7%)	0	0	2 (3.1%)	1 (1.7%)	2 (3.0%)	0	9 (1.6%)	11 (1.6%)
		High	0	0	0	0	0	0	0	1 (1.5%)	0	1 (0.2%)	1 (0.1%)
LOCF Endpoint	m		134	127	64	64	64	65	63	70	63	580	714
	Normal	Normal	130 (97.0%)	124 (97.6%)	63 (98.4%)	59 (92.2%)	64 (100.0%)	62 (95.4%)	60 (95.2%)	64 (91.4%)	62 (98.4%)	558 (96.2%)	688 (96.4%)
		High	2 (1.5%)	0	0	5 (7.8%)	0	1 (1.5%)	2 (3.2%)	3 (4.3%)	1 (1.6%)	12 (2.1%)	14 (2.0%)
	High	Normal	2 (1.5%)	3 (2.4%)	1 (1.6%)	0	0	2 (3.1%)	1 (1.6%)	2 (2.9%)	0	9 (1.6%)	11 (1.5%)
		High	0	0	0	0	0	0	0	1 (1.4%)	0	1 (0.2%)	1 (0.1%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
Phosphate (mmol/L)													
Week 4	m		134	127	64	64	64	65	63	70	63	580	714
	Low	Normal	0	0	1 (1.6%)	0	0	0	0	1 (1.4%)	0	2 (0.3%)	2 (0.3%)
	Normal	Low	0	1 (0.8%)	0	0	1 (1.6%)	0	1 (1.6%)	0	0	3 (0.5%)	3 (0.4%)
		Normal	134 (100.0%)	126 (99.2%)	63 (98.4%)	64 (100.0%)	63 (98.4%)	65 (100.0%)	62 (98.4%)	69 (98.6%)	63 (100.0%)	575 (99.1%)	709 (99.3%)
Week 8	m		132	125	63	64	64	65	62	69	63	575	707
	Low	Normal	0	0	1 (1.6%)	0	0	0	0	1 (1.4%)	0	2 (0.3%)	2 (0.3%)
	Normal	Low	0	0	0	0	0	0	1 (1.6%)	0	1 (1.6%)	2 (0.3%)	2 (0.3%)
		Normal	132 (100.0%)	125 (100.0%)	62 (98.4%)	64 (100.0%)	64 (100.0%)	65 (100.0%)	61 (98.4%)	68 (98.6%)	62 (98.4%)	571 (99.3%)	703 (99.4%)
Week 12	m		131	123	63	64	64	65	62	68	63	572	703
	Low	Normal	0	0	1 (1.6%)	0	0	0	0	1 (1.5%)	0	2 (0.3%)	2 (0.3%)
	Normal	Low	0	0	0	0	0	0	0	1 (1.5%)	0	1 (0.2%)	1 (0.1%)
		Normal	131 (100.0%)	123 (100.0%)	62 (98.4%)	64 (100.0%)	64 (100.0%)	65 (100.0%)	61 (98.4%)	66 (97.1%)	63 (100.0%)	568 (99.3%)	699 (99.4%)
		High	0	0	0	0	0	0	1 (1.6%)	0	0	1 (0.2%)	1 (0.1%)
Week 16	m		130	123	63	64	64	64	62	69	63	572	702
	Low	Normal	0	0	1 (1.6%)	0	0	0	0	1 (1.4%)	0	2 (0.3%)	2 (0.3%)
	Normal	Low	0	0	0	0	1 (1.6%)	0	0	0	0	1 (0.2%)	1 (0.1%)
		Normal	130 (100.0%)	123 (100.0%)	62 (98.4%)	64 (100.0%)	63 (98.4%)	64 (100.0%)	62 (100.0%)	68 (98.6%)	63 (100.0%)	569 (99.5%)	699 (99.6%)
Week 20	m		130	123	62	63	64	65	61	69	63	570	700
	Low	Normal	0	0	1 (1.6%)	0	0	0	0	1 (1.4%)	0	2 (0.4%)	2 (0.3%)
	Normal	Low	0	0	0	1 (1.6%)	1 (1.6%)	0	0	1 (1.4%)	0	3 (0.5%)	3 (0.4%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
		Normal	130 (100.0%)	123 (100.0%)	61 (98.4%)	62 (98.4%)	63 (98.4%)	65 (100.0%)	61 (100.0%)	67 (97.1%)	63 (100.0%)	565 (99.1%)	695 (99.3%)
Week 24	m		130	122	62	63	64	65	61	69	63	569	699
	Low	Normal	0	0	1 (1.6%)	0	0	0	0	1 (1.4%)	0	2 (0.4%)	2 (0.3%)
	Normal	Normal	130 (100.0%)	122 (100.0%)	61 (98.4%)	63 (100.0%)	64 (100.0%)	65 (100.0%)	61 (100.0%)	68 (98.6%)	63 (100.0%)	567 (99.6%)	697 (99.7%)
Week 32	m		128	120	62	60	62	65	60	69	63	561	689
	Low	Normal	0	0	1 (1.6%)	0	0	0	0	1 (1.4%)	0	2 (0.4%)	2 (0.3%)
	Normal	Normal	128 (100.0%)	120 (100.0%)	61 (98.4%)	60 (100.0%)	62 (100.0%)	65 (100.0%)	60 (100.0%)	68 (98.6%)	63 (100.0%)	559 (99.6%)	687 (99.7%)
Week 40	m		128	120	60	59	62	65	60	69	63	558	686
	Low	Normal	0	0	1 (1.7%)	0	0	0	0	1 (1.4%)	0	2 (0.4%)	2 (0.3%)
	Normal	Normal	128 (100.0%)	120 (100.0%)	59 (98.3%)	58 (98.3%)	62 (100.0%)	65 (100.0%)	60 (100.0%)	68 (98.6%)	63 (100.0%)	555 (99.5%)	683 (99.6%)
		High	0	0	0	1 (1.7%)	0	0	0	0	0	1 (0.2%)	1 (0.1%)
Week 48	m		127	118	60	59	62	65	60	66	63	553	680
	Low	Low	0	0	0	0	0	0	0	1 (1.5%)	0	1 (0.2%)	1 (0.1%)
		Normal	0	0	1 (1.7%)	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
	Normal	Low	0	0	0	0	1 (1.6%)	0	0	0	0	1 (0.2%)	1 (0.1%)
		Normal	127 (100.0%)	118 (100.0%)	59 (98.3%)	59 (100.0%)	61 (98.4%)	65 (100.0%)	60 (100.0%)	65 (98.5%)	63 (100.0%)	550 (99.5%)	677 (99.6%)
Week 52	m		126	116	59	58	62	65	60	67	62	549	675
	Low	Normal	0	0	1 (1.7%)	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
		High	0	0	0	0	0	0	0	1 (1.5%)	0	1 (0.2%)	1 (0.1%)
	Normal	Normal	126 (100.0%)	116 (100.0%)	58 (98.3%)	58 (100.0%)	62 (100.0%)	65 (100.0%)	59 (98.3%)	66 (98.5%)	62 (100.0%)	546 (99.5%)	672 (99.6%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
		High	0	0	0	0	0	0	1 (1.7%)	0	0	1 (0.2%)	1 (0.1%)
LOCF Endpoint	m		134	127	64	64	64	65	63	70	63	580	714
	Low	Normal	0	0	1 (1.6%)	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
		High	0	0	0	0	0	0	0	1 (1.4%)	0	1 (0.2%)	1 (0.1%)
	Normal	Normal	134 (100.0%)	127 (100.0%)	63 (98.4%)	64 (100.0%)	64 (100.0%)	65 (100.0%)	62 (98.4%)	69 (98.6%)	63 (100.0%)	577 (99.5%)	711 (99.6%)
		High	0	0	0	0	0	0	1 (1.6%)	0	0	1 (0.2%)	1 (0.1%)
Potassium (mmol/L)													
Week 4	m		134	127	64	64	64	65	63	70	63	580	714
	Normal	Normal	130 (97.0%)	124 (97.6%)	63 (98.4%)	64 (100.0%)	64 (100.0%)	65 (100.0%)	61 (96.8%)	69 (98.6%)	62 (98.4%)	572 (98.6%)	702 (98.3%)
		High	3 (2.2%)	3 (2.4%)	1 (1.6%)	0	0	0	2 (3.2%)	1 (1.4%)	1 (1.6%)	8 (1.4%)	11 (1.5%)
	High	Normal	1 (0.7%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
Week 8	m		132	124	63	64	64	65	62	69	62	573	705
	Normal	Low	0	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	1 (0.1%)
		Normal	129 (97.7%)	121 (97.6%)	61 (96.8%)	62 (96.9%)	64 (100.0%)	64 (98.5%)	61 (98.4%)	69 (100.0%)	61 (98.4%)	563 (98.3%)	692 (98.2%)
		High	2 (1.5%)	3 (2.4%)	2 (3.2%)	2 (3.1%)	0	1 (1.5%)	1 (1.6%)	0	0	9 (1.6%)	11 (1.6%)
	High	Normal	1 (0.8%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
Week 12	m		131	123	63	64	64	65	62	68	63	572	703
	Normal	Normal	130 (99.2%)	123 (100.0%)	62 (98.4%)	63 (98.4%)	64 (100.0%)	64 (98.5%)	62 (100.0%)	68 (100.0%)	63 (100.0%)	569 (99.5%)	699 (99.4%)
		High	0	0	1 (1.6%)	1 (1.6%)	0	1 (1.5%)	0	0	0	3 (0.5%)	3 (0.4%)
	High	Normal	1 (0.8%)	0	0	0	0	0	0	0	0	0	1 (0.1%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
Week 16	m		130	123	63	64	64	64	62	69	63	572	702
	Normal	Low	1 (0.8%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
		Normal	127 (97.7%)	120 (97.6%)	63 (100.0%)	64 (100.0%)	64 (100.0%)	63 (98.4%)	60 (96.8%)	69 (100.0%)	62 (98.4%)	565 (98.8%)	692 (98.6%)
		High	1 (0.8%)	3 (2.4%)	0	0	0	1 (1.6%)	2 (3.2%)	0	1 (1.6%)	7 (1.2%)	8 (1.1%)
	High	Normal	1 (0.8%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
Week 20	m		130	123	62	63	64	65	61	69	63	570	700
	Normal	Low	0	0	0	0	0	1 (1.5%)	0	0	0	1 (0.2%)	1 (0.1%)
		Normal	129 (99.2%)	122 (99.2%)	60 (96.8%)	63 (100.0%)	63 (98.4%)	62 (95.4%)	60 (98.4%)	69 (100.0%)	61 (96.8%)	560 (98.2%)	689 (98.4%)
		High	0	1 (0.8%)	2 (3.2%)	0	1 (1.6%)	2 (3.1%)	1 (1.6%)	0	2 (3.2%)	9 (1.6%)	9 (1.3%)
	High	Normal	1 (0.8%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
Week 24	m		130	122	62	63	64	65	61	69	63	569	699
	Normal	Low	0	0	0	0	0	0	0	0	2 (3.2%)	2 (0.4%)	2 (0.3%)
		Normal	128 (98.5%)	121 (99.2%)	62 (100.0%)	62 (98.4%)	63 (98.4%)	65 (100.0%)	60 (98.4%)	69 (100.0%)	61 (96.8%)	563 (98.9%)	691 (98.9%)
		High	1 (0.8%)	1 (0.8%)	0	1 (1.6%)	1 (1.6%)	0	1 (1.6%)	0	0	4 (0.7%)	5 (0.7%)
	High	Normal	1 (0.8%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
Week 32	m		128	120	62	60	62	65	60	69	63	561	689
	Normal	Low	0	0	0	0	0	0	0	1 (1.4%)	0	1 (0.2%)	1 (0.1%)
		Normal	125 (97.7%)	116 (96.7%)	62 (100.0%)	60 (100.0%)	62 (100.0%)	65 (100.0%)	58 (96.7%)	66 (95.7%)	63 (100.0%)	552 (98.4%)	677 (98.3%)
		High	2 (1.6%)	4 (3.3%)	0	0	0	0	2 (3.3%)	2 (2.9%)	0	8 (1.4%)	10 (1.5%)
	High	Normal	1 (0.8%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
Week 40	m		128	120	60	59	62	65	60	69	63	558	686
	Normal	Normal	124 (96.9%)	119 (99.2%)	60 (100.0%)	59 (100.0%)	62 (100.0%)	63 (96.9%)	60 (100.0%)	67 (97.1%)	63 (100.0%)	553 (99.1%)	677 (98.7%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
		High	3 (2.3%)	1 (0.8%)	0	0	0	2 (3.1%)	0	2 (2.9%)	0	5 (0.9%)	8 (1.2%)
	High	Normal	1 (0.8%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
Week 48	m		127	117	60	59	62	65	60	66	63	552	679
	Normal	Low	0	0	0	0	0	1 (1.5%)	0	0	0	1 (0.2%)	1 (0.1%)
		Normal	124 (97.6%)	115 (98.3%)	58 (96.7%)	57 (96.6%)	61 (98.4%)	64 (98.5%)	59 (98.3%)	65 (98.5%)	61 (96.8%)	540 (97.8%)	664 (97.8%)
		High	2 (1.6%)	2 (1.7%)	2 (3.3%)	2 (3.4%)	1 (1.6%)	0	1 (1.7%)	1 (1.5%)	2 (3.2%)	11 (2.0%)	13 (1.9%)
	High	Normal	1 (0.8%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
Week 52	m		126	116	59	58	62	65	60	67	62	549	675
	Normal	Low	0	0	0	0	0	1 (1.5%)	0	0	0	1 (0.2%)	1 (0.1%)
		Normal	124 (98.4%)	114 (98.3%)	59 (100.0%)	58 (100.0%)	62 (100.0%)	64 (98.5%)	60 (100.0%)	66 (98.5%)	62 (100.0%)	545 (99.3%)	669 (99.1%)
		High	1 (0.8%)	2 (1.7%)	0	0	0	0	0	1 (1.5%)	0	3 (0.5%)	4 (0.6%)
	High	Normal	1 (0.8%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
LOCF Endpoint	m		134	127	64	64	64	65	63	70	63	580	714
	Normal	Low	0	0	0	0	0	1 (1.5%)	0	0	0	1 (0.2%)	1 (0.1%)
		Normal	132 (98.5%)	124 (97.6%)	64 (100.0%)	64 (100.0%)	64 (100.0%)	64 (98.5%)	63 (100.0%)	69 (98.6%)	63 (100.0%)	575 (99.1%)	707 (99.0%)
		High	1 (0.7%)	3 (2.4%)	0	0	0	0	0	1 (1.4%)	0	4 (0.7%)	5 (0.7%)
	High	Normal	1 (0.7%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
Protein (g/L)													
Week 4	m		134	127	64	64	64	65	63	70	63	580	714
	Low	Low	0	0	1 (1.6%)	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
		Normal	0	0	0	0	0	1 (1.5%)	0	0	0	1 (0.2%)	1 (0.1%)
	Normal	Normal	131 (97.8%)	122 (96.1%)	61 (95.3%)	63 (98.4%)	63 (98.4%)	64 (98.5%)	61 (96.8%)	68 (97.1%)	63 (100.0%)	565 (97.4%)	696 (97.5%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
		High	1 (0.7%)	1 (0.8%)	1 (1.6%)	0	0	0	0	1 (1.4%)	0	3 (0.5%)	4 (0.6%)
	High	Normal	2 (1.5%)	4 (3.1%)	0	1 (1.6%)	1 (1.6%)	0	1 (1.6%)	0	0	7 (1.2%)	9 (1.3%)
		High	0	0	1 (1.6%)	0	0	0	1 (1.6%)	1 (1.4%)	0	3 (0.5%)	3 (0.4%)
Week 8	m		132	125	63	64	64	65	62	69	63	575	707
	Low	Low	0	0	1 (1.6%)	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
		Normal	0	0	0	0	0	1 (1.5%)	0	0	0	1 (0.2%)	1 (0.1%)
	Normal	Normal	130 (98.5%)	119 (95.2%)	61 (96.8%)	63 (98.4%)	63 (98.4%)	64 (98.5%)	60 (96.8%)	67 (97.1%)	63 (100.0%)	560 (97.4%)	690 (97.6%)
		High	0	2 (1.6%)	0	0	0	0	0	1 (1.4%)	0	3 (0.5%)	3 (0.4%)
	High	Normal	2 (1.5%)	4 (3.2%)	1 (1.6%)	1 (1.6%)	0	0	1 (1.6%)	0	0	7 (1.2%)	9 (1.3%)
		High	0	0	0	0	1 (1.6%)	0	1 (1.6%)	1 (1.4%)	0	3 (0.5%)	3 (0.4%)
Week 12	m		131	123	63	64	64	65	62	68	63	572	703
	Low	Low	0	0	1 (1.6%)	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
		Normal	0	0	0	0	0	1 (1.5%)	0	0	0	1 (0.2%)	1 (0.1%)
	Normal	Normal	129 (98.5%)	118 (95.9%)	61 (96.8%)	63 (98.4%)	63 (98.4%)	63 (96.9%)	60 (96.8%)	66 (97.1%)	63 (100.0%)	557 (97.4%)	686 (97.6%)
		High	0	1 (0.8%)	0	0	0	1 (1.5%)	0	1 (1.5%)	0	3 (0.5%)	3 (0.4%)
	High	Normal	2 (1.5%)	3 (2.4%)	1 (1.6%)	1 (1.6%)	1 (1.6%)	0	1 (1.6%)	0	0	7 (1.2%)	9 (1.3%)
		High	0	1 (0.8%)	0	0	0	0	1 (1.6%)	1 (1.5%)	0	3 (0.5%)	3 (0.4%)
Week 16	m		130	123	63	64	64	64	62	69	63	572	702
	Low	Low	0	0	1 (1.6%)	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
		Normal	0	0	0	0	0	1 (1.6%)	0	0	0	1 (0.2%)	1 (0.1%)
	Normal	Normal	128 (98.5%)	118 (95.9%)	61 (96.8%)	63 (98.4%)	63 (98.4%)	63 (98.4%)	60 (96.8%)	67 (97.1%)	62 (98.4%)	557 (97.4%)	685 (97.6%)
		High	0	1 (0.8%)	0	0	0	0	0	1 (1.4%)	1 (1.6%)	3 (0.5%)	3 (0.4%)
	High	Normal	2 (1.5%)	4 (3.3%)	1 (1.6%)	1 (1.6%)	1 (1.6%)	0	2 (3.2%)	0	0	9 (1.6%)	11 (1.6%)
		High	0	0	0	0	0	0	0	1 (1.4%)	0	1 (0.2%)	1 (0.1%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
Week 20	m		130	123	62	63	64	65	61	69	63	570	700
	Low	Low	0	0	0	0	0	1 (1.5%)	0	0	0	1 (0.2%)	1 (0.1%)
		Normal	0	0	1 (1.6%)	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
	Normal	Low	1 (0.8%)	0	0	0	1 (1.6%)	0	0	0	0	1 (0.2%)	2 (0.3%)
		Normal	127 (97.7%)	117 (95.1%)	60 (96.8%)	62 (98.4%)	62 (96.9%)	63 (96.9%)	59 (96.7%)	67 (97.1%)	63 (100.0%)	553 (97.0%)	680 (97.1%)
		High	0	2 (1.6%)	0	0	0	1 (1.5%)	0	1 (1.4%)	0	4 (0.7%)	4 (0.6%)
	High	Normal	2 (1.5%)	3 (2.4%)	0	1 (1.6%)	1 (1.6%)	0	2 (3.3%)	0	0	7 (1.2%)	9 (1.3%)
		High	0	1 (0.8%)	1 (1.6%)	0	0	0	0	1 (1.4%)	0	3 (0.5%)	3 (0.4%)
Week 24	m		130	122	62	63	64	65	61	69	63	569	699
	Low	Normal	0	0	1 (1.6%)	0	0	1 (1.5%)	0	0	0	2 (0.4%)	2 (0.3%)
	Normal	Low	1 (0.8%)	0	0	0	0	1 (1.5%)	0	0	0	1 (0.2%)	2 (0.3%)
		Normal	127 (97.7%)	113 (92.6%)	57 (91.9%)	60 (95.2%)	63 (98.4%)	63 (96.9%)	58 (95.1%)	66 (95.7%)	61 (96.8%)	541 (95.1%)	668 (95.6%)
		High	0	5 (4.1%)	3 (4.8%)	2 (3.2%)	0	0	1 (1.6%)	2 (2.9%)	2 (3.2%)	15 (2.6%)	15 (2.1%)
	High	Normal	1 (0.8%)	1 (0.8%)	0	1 (1.6%)	1 (1.6%)	0	1 (1.6%)	0	0	4 (0.7%)	5 (0.7%)
		High	1 (0.8%)	3 (2.5%)	1 (1.6%)	0	0	0	1 (1.6%)	1 (1.4%)	0	6 (1.1%)	7 (1.0%)
Week 32	m		128	120	62	60	62	65	60	69	63	561	689
	Low	Normal	0	0	1 (1.6%)	0	0	1 (1.5%)	0	0	0	2 (0.4%)	2 (0.3%)
	Normal	Low	0	0	0	0	0	1 (1.5%)	0	0	0	1 (0.2%)	1 (0.1%)
		Normal	126 (98.4%)	116 (96.7%)	60 (96.8%)	59 (98.3%)	61 (98.4%)	62 (95.4%)	58 (96.7%)	67 (97.1%)	62 (98.4%)	545 (97.1%)	671 (97.4%)
		High	0	0	0	0	0	1 (1.5%)	0	1 (1.4%)	1 (1.6%)	3 (0.5%)	3 (0.4%)
	High	Normal	2 (1.6%)	4 (3.3%)	0	1 (1.7%)	1 (1.6%)	0	1 (1.7%)	0	0	7 (1.2%)	9 (1.3%)
		High	0	0	1 (1.6%)	0	0	0	1 (1.7%)	1 (1.4%)	0	3 (0.5%)	3 (0.4%)
Week 40	m		128	120	60	59	62	65	60	69	63	558	686

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
	Low	Low	0	0	1 (1.7%)	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
		Normal	0	0	0	0	0	1 (1.5%)	0	0	0	1 (0.2%)	1 (0.1%)
	Normal	Low	1 (0.8%)	0	1 (1.7%)	1 (1.7%)	0	0	0	0	0	2 (0.4%)	3 (0.4%)
		Normal	124 (96.9%)	115 (95.8%)	56 (93.3%)	56 (94.9%)	61 (98.4%)	63 (96.9%)	58 (96.7%)	67 (97.1%)	62 (98.4%)	538 (96.4%)	662 (96.5%)
		High	1 (0.8%)	1 (0.8%)	1 (1.7%)	1 (1.7%)	0	1 (1.5%)	1 (1.7%)	1 (1.4%)	1 (1.6%)	7 (1.3%)	8 (1.2%)
	High	Normal	2 (1.6%)	2 (1.7%)	1 (1.7%)	1 (1.7%)	0	0	1 (1.7%)	0	0	5 (0.9%)	7 (1.0%)
		High	0	2 (1.7%)	0	0	1 (1.6%)	0	0	1 (1.4%)	0	4 (0.7%)	4 (0.6%)
Week 48	m		127	118	60	59	62	65	60	66	63	553	680
	Low	Normal	0	0	1 (1.7%)	0	0	1 (1.5%)	0	0	0	2 (0.4%)	2 (0.3%)
	Normal	Normal	125 (98.4%)	113 (95.8%)	58 (96.7%)	58 (98.3%)	61 (98.4%)	64 (98.5%)	59 (98.3%)	64 (97.0%)	61 (96.8%)	538 (97.3%)	663 (97.5%)
		High	0	1 (0.8%)	0	0	0	0	0	1 (1.5%)	2 (3.2%)	4 (0.7%)	4 (0.6%)
	High	Normal	2 (1.6%)	3 (2.5%)	1 (1.7%)	1 (1.7%)	0	0	0	0	0	5 (0.9%)	7 (1.0%)
		High	0	1 (0.8%)	0	0	1 (1.6%)	0	1 (1.7%)	1 (1.5%)	0	4 (0.7%)	4 (0.6%)
Week 52	m		126	116	59	58	62	65	60	67	62	549	675
	Low	Normal	0	0	1 (1.7%)	0	0	1 (1.5%)	0	0	0	2 (0.4%)	2 (0.3%)
	Normal	Low	1 (0.8%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
		Normal	122 (96.8%)	110 (94.8%)	57 (96.6%)	54 (93.1%)	60 (96.8%)	63 (96.9%)	59 (98.3%)	66 (98.5%)	62 (100.0%)	531 (96.7%)	653 (96.7%)
		High	1 (0.8%)	2 (1.7%)	0	3 (5.2%)	1 (1.6%)	1 (1.5%)	0	0	0	7 (1.3%)	8 (1.2%)
	High	Normal	2 (1.6%)	3 (2.6%)	0	1 (1.7%)	1 (1.6%)	0	0	0	0	5 (0.9%)	7 (1.0%)
		High	0	1 (0.9%)	1 (1.7%)	0	0	0	1 (1.7%)	1 (1.5%)	0	4 (0.7%)	4 (0.6%)
LOCF Endpoint	m		134	127	64	64	64	65	63	70	63	580	714
	Low	Normal	0	0	1 (1.6%)	0	0	1 (1.5%)	0	0	0	2 (0.3%)	2 (0.3%)
	Normal	Low	1 (0.7%)	0	0	0	0	0	0	0	0	0	1 (0.1%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
		Normal	130 (97.0%)	120 (94.5%)	62 (96.9%)	60 (93.8%)	62 (96.9%)	63 (96.9%)	61 (96.8%)	69 (98.6%)	63 (100.0%)	560 (96.6%)	690 (96.6%)
		High	1 (0.7%)	3 (2.4%)	0	3 (4.7%)	1 (1.6%)	1 (1.5%)	0	0	0	8 (1.4%)	9 (1.3%)
	High	Normal	2 (1.5%)	3 (2.4%)	0	1 (1.6%)	1 (1.6%)	0	1 (1.6%)	0	0	6 (1.0%)	8 (1.1%)
		High	0	1 (0.8%)	1 (1.6%)	0	0	0	1 (1.6%)	1 (1.4%)	0	4 (0.7%)	4 (0.6%)
Sodium (mmol/L)													
Week 4	m		134	127	64	64	64	65	63	70	63	580	714
	Low	Normal	1 (0.7%)	0	0	0	1 (1.6%)	0	0	0	2 (3.2%)	3 (0.5%)	4 (0.6%)
	Normal	Low	0	1 (0.8%)	0	0	0	0	0	0	1 (1.6%)	2 (0.3%)	2 (0.3%)
		Normal	132 (98.5%)	126 (99.2%)	64 (100.0%)	64 (100.0%)	62 (96.9%)	65 (100.0%)	63 (100.0%)	70 (100.0%)	60 (95.2%)	574 (99.0%)	706 (98.9%)
		High	1 (0.7%)	0	0	0	1 (1.6%)	0	0	0	0	1 (0.2%)	2 (0.3%)
Week 8	m		132	125	63	64	64	65	62	69	63	575	707
	Low	Normal	1 (0.8%)	0	0	0	1 (1.6%)	0	0	0	2 (3.2%)	3 (0.5%)	4 (0.6%)
	Normal	Low	0	0	1 (1.6%)	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
		Normal	131 (99.2%)	124 (99.2%)	62 (98.4%)	64 (100.0%)	63 (98.4%)	65 (100.0%)	62 (100.0%)	69 (100.0%)	61 (96.8%)	570 (99.1%)	701 (99.2%)
		High	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
Week 12	m		131	123	63	64	64	65	62	68	63	572	703
	Low	Normal	1 (0.8%)	0	0	0	1 (1.6%)	0	0	0	2 (3.2%)	3 (0.5%)	4 (0.6%)
	Normal	Low	0	1 (0.8%)	0	0	0	0	0	0	1 (1.6%)	2 (0.3%)	2 (0.3%)
		Normal	130 (99.2%)	122 (99.2%)	63 (100.0%)	64 (100.0%)	63 (98.4%)	65 (100.0%)	62 (100.0%)	68 (100.0%)	60 (95.2%)	567 (99.1%)	697 (99.1%)
Week 16	m		130	123	63	64	64	64	62	69	63	572	702
	Low	Normal	1 (0.8%)	0	0	0	1 (1.6%)	0	0	0	2 (3.2%)	3 (0.5%)	4 (0.6%)
	Normal	Low	0	1 (0.8%)	0	0	0	0	0	0	1 (1.6%)	2 (0.3%)	2 (0.3%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
		Normal	129 (99.2%)	121 (98.4%)	63 (100.0%)	64 (100.0%)	63 (98.4%)	64 (100.0%)	62 (100.0%)	69 (100.0%)	59 (93.7%)	565 (98.8%)	694 (98.9%)
		High	0	1 (0.8%)	0	0	0	0	0	0	1 (1.6%)	2 (0.3%)	2 (0.3%)
Week 20	m		130	123	62	63	64	65	61	69	63	570	700
	Low	Normal	1 (0.8%)	0	0	0	1 (1.6%)	0	0	0	2 (3.2%)	3 (0.5%)	4 (0.6%)
	Normal	Low	0	1 (0.8%)	1 (1.6%)	1 (1.6%)	0	0	0	0	1 (1.6%)	4 (0.7%)	4 (0.6%)
		Normal	129 (99.2%)	122 (99.2%)	61 (98.4%)	62 (98.4%)	63 (98.4%)	65 (100.0%)	61 (100.0%)	69 (100.0%)	60 (95.2%)	563 (98.8%)	692 (98.9%)
Week 24	m		130	122	62	63	64	65	61	69	63	569	699
	Low	Normal	1 (0.8%)	0	0	0	1 (1.6%)	0	0	0	2 (3.2%)	3 (0.5%)	4 (0.6%)
	Normal	Low	1 (0.8%)	1 (0.8%)	0	0	0	0	1 (1.6%)	0	0	2 (0.4%)	3 (0.4%)
		Normal	128 (98.5%)	121 (99.2%)	62 (100.0%)	63 (100.0%)	63 (98.4%)	65 (100.0%)	60 (98.4%)	69 (100.0%)	60 (95.2%)	563 (98.9%)	691 (98.9%)
		High	0	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	1 (0.1%)
Week 32	m		128	120	62	60	62	65	60	69	63	561	689
	Low	Normal	1 (0.8%)	0	0	0	1 (1.6%)	0	0	0	2 (3.2%)	3 (0.5%)	4 (0.6%)
	Normal	Low	0	2 (1.7%)	0	0	0	0	0	0	1 (1.6%)	3 (0.5%)	3 (0.4%)
		Normal	127 (99.2%)	118 (98.3%)	62 (100.0%)	60 (100.0%)	61 (98.4%)	65 (100.0%)	60 (100.0%)	69 (100.0%)	60 (95.2%)	555 (98.9%)	682 (99.0%)
Week 40	m		128	120	60	59	62	65	60	69	63	558	686
	Low	Normal	1 (0.8%)	0	0	0	1 (1.6%)	0	0	0	2 (3.2%)	3 (0.5%)	4 (0.6%)
	Normal	Normal	127 (99.2%)	120 (100.0%)	60 (100.0%)	59 (100.0%)	61 (98.4%)	65 (100.0%)	60 (100.0%)	69 (100.0%)	61 (96.8%)	555 (99.5%)	682 (99.4%)
Week 48	m		127	118	60	59	62	65	60	66	63	553	680
	Low	Normal	1 (0.8%)	0	0	0	1 (1.6%)	0	0	0	2 (3.2%)	3 (0.5%)	4 (0.6%)
	Normal	Low	0	1 (0.8%)	1 (1.7%)	0	0	0	0	0	1 (1.6%)	3 (0.5%)	3 (0.4%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
		Normal	125 (98.4%)	117 (99.2%)	59 (98.3%)	58 (98.3%)	61 (98.4%)	64 (98.5%)	60 (100.0%)	66 (100.0%)	60 (95.2%)	545 (98.6%)	670 (98.5%)
		High	1 (0.8%)	0	0	1 (1.7%)	0	1 (1.5%)	0	0	0	2 (0.4%)	3 (0.4%)
Week 52	m		126	116	59	58	62	65	60	67	62	549	675
	Low	Normal	1 (0.8%)	0	0	0	1 (1.6%)	0	0	0	2 (3.2%)	3 (0.5%)	4 (0.6%)
	Normal	Low	0	1 (0.9%)	0	1 (1.7%)	0	0	0	0	2 (3.2%)	4 (0.7%)	4 (0.6%)
		Normal	125 (99.2%)	114 (98.3%)	59 (100.0%)	57 (98.3%)	61 (98.4%)	65 (100.0%)	60 (100.0%)	67 (100.0%)	58 (93.5%)	541 (98.5%)	666 (98.7%)
		High	0	1 (0.9%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
LOCF Endpoint	m		134	127	64	64	64	65	63	70	63	580	714
	Low	Normal	1 (0.7%)	0	0	0	1 (1.6%)	0	0	0	2 (3.2%)	3 (0.5%)	4 (0.6%)
	Normal	Low	0	1 (0.8%)	0	1 (1.6%)	0	0	0	0	2 (3.2%)	4 (0.7%)	4 (0.6%)
		Normal	133 (99.3%)	125 (98.4%)	64 (100.0%)	62 (96.9%)	63 (98.4%)	65 (100.0%)	63 (100.0%)	70 (100.0%)	59 (93.7%)	571 (98.4%)	704 (98.6%)
		High	0	1 (0.8%)	0	1 (1.6%)	0	0	0	0	0	2 (0.3%)	2 (0.3%)
Urate (umol/L)													
Week 4	m		134	127	64	64	64	65	63	70	63	580	714
	Low	Low	1 (0.7%)	0	1 (1.6%)	0	3 (4.7%)	0	0	0	1 (1.6%)	5 (0.9%)	6 (0.8%)
		Normal	1 (0.7%)	1 (0.8%)	1 (1.6%)	1 (1.6%)	0	2 (3.1%)	0	1 (1.4%)	0	6 (1.0%)	7 (1.0%)
	Normal	Low	0	0	0	0	0	0	0	1 (1.4%)	0	1 (0.2%)	1 (0.1%)
		Normal	130 (97.0%)	124 (97.6%)	61 (95.3%)	63 (98.4%)	61 (95.3%)	63 (96.9%)	63 (100.0%)	64 (91.4%)	60 (95.2%)	559 (96.4%)	689 (96.5%)
		High	1 (0.7%)	2 (1.6%)	1 (1.6%)	0	0	0	0	2 (2.9%)	0	5 (0.9%)	6 (0.8%)
	High	Normal	1 (0.7%)	0	0	0	0	0	0	1 (1.4%)	0	1 (0.2%)	2 (0.3%)
		High	0	0	0	0	0	0	0	1 (1.4%)	2 (3.2%)	3 (0.5%)	3 (0.4%)
Week 8	m		132	125	63	64	64	65	62	69	63	575	707

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
	Low	Low	0	1 (0.8%)	1 (1.6%)	0	3 (4.7%)	1 (1.5%)	0	0	0	6 (1.0%)	6 (0.8%)
		Normal	1 (0.8%)	0	1 (1.6%)	1 (1.6%)	0	1 (1.5%)	0	1 (1.4%)	1 (1.6%)	5 (0.9%)	6 (0.8%)
	Normal	Normal	128 (97.0%)	122 (97.6%)	60 (95.2%)	62 (96.9%)	59 (92.2%)	63 (96.9%)	62 (100.0%)	64 (92.8%)	60 (95.2%)	552 (96.0%)	680 (96.2%)
		High	2 (1.5%)	2 (1.6%)	1 (1.6%)	1 (1.6%)	2 (3.1%)	0	0	2 (2.9%)	0	8 (1.4%)	10 (1.4%)
	High	High	1 (0.8%)	0	0	0	0	0	0	2 (2.9%)	2 (3.2%)	4 (0.7%)	5 (0.7%)
Week 12	m		131	123	63	64	64	65	62	68	63	572	703
	Low	Low	1 (0.8%)	0	1 (1.6%)	0	3 (4.7%)	1 (1.5%)	0	0	0	5 (0.9%)	6 (0.9%)
		Normal	0	1 (0.8%)	1 (1.6%)	1 (1.6%)	0	1 (1.5%)	0	1 (1.5%)	1 (1.6%)	6 (1.0%)	6 (0.9%)
	Normal	Low	0	0	0	0	0	1 (1.5%)	0	1 (1.5%)	0	2 (0.3%)	2 (0.3%)
		Normal	127 (96.9%)	120 (97.6%)	60 (95.2%)	60 (93.8%)	61 (95.3%)	61 (93.8%)	62 (100.0%)	64 (94.1%)	60 (95.2%)	548 (95.8%)	675 (96.0%)
		High	2 (1.5%)	2 (1.6%)	1 (1.6%)	3 (4.7%)	0	1 (1.5%)	0	0	0	7 (1.2%)	9 (1.3%)
	High	Normal	1 (0.8%)	0	0	0	0	0	0	1 (1.5%)	2 (3.2%)	3 (0.5%)	4 (0.6%)
		High	0	0	0	0	0	0	0	1 (1.5%)	0	1 (0.2%)	1 (0.1%)
Week 16	m		130	123	63	64	64	64	62	69	63	572	702
	Low	Low	1 (0.8%)	0	2 (3.2%)	0	3 (4.7%)	2 (3.1%)	0	0	0	7 (1.2%)	8 (1.1%)
		Normal	0	1 (0.8%)	0	1 (1.6%)	0	0	0	1 (1.4%)	1 (1.6%)	4 (0.7%)	4 (0.6%)
	Normal	Low	0	0	0	0	0	1 (1.6%)	0	0	0	1 (0.2%)	1 (0.1%)
		Normal	125 (96.2%)	121 (98.4%)	61 (96.8%)	61 (95.3%)	60 (93.8%)	61 (95.3%)	62 (100.0%)	64 (92.8%)	60 (95.2%)	550 (96.2%)	675 (96.2%)
		High	3 (2.3%)	1 (0.8%)	0	2 (3.1%)	1 (1.6%)	0	0	2 (2.9%)	0	6 (1.0%)	9 (1.3%)
	High	Normal	0	0	0	0	0	0	0	0	2 (3.2%)	2 (0.3%)	2 (0.3%)
		High	1 (0.8%)	0	0	0	0	0	0	2 (2.9%)	0	2 (0.3%)	3 (0.4%)
Week 20	m		130	123	62	63	64	65	61	69	63	570	700
	Low	Low	1 (0.8%)	1 (0.8%)	1 (1.6%)	0	2 (3.1%)	0	0	0	0	4 (0.7%)	5 (0.7%)
		Normal	0	0	1 (1.6%)	1 (1.6%)	1 (1.6%)	2 (3.1%)	0	1 (1.4%)	1 (1.6%)	7 (1.2%)	7 (1.0%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
	Normal	Low	0	0	0	0	0	2 (3.1%)	1 (1.6%)	1 (1.4%)	0	4 (0.7%)	4 (0.6%)
		Normal	126 (96.9%)	122 (99.2%)	60 (96.8%)	62 (98.4%)	60 (93.8%)	60 (92.3%)	60 (98.4%)	65 (94.2%)	60 (95.2%)	549 (96.3%)	675 (96.4%)
		High	2 (1.5%)	0	0	0	1 (1.6%)	1 (1.5%)	0	0	0	2 (0.4%)	4 (0.6%)
	High	Normal	0	0	0	0	0	0	0	1 (1.4%)	2 (3.2%)	3 (0.5%)	3 (0.4%)
		High	1 (0.8%)	0	0	0	0	0	0	1 (1.4%)	0	1 (0.2%)	2 (0.3%)
Week 24	m		130	122	62	63	64	65	61	69	63	569	699
	Low	Low	1 (0.8%)	1 (0.8%)	1 (1.6%)	1 (1.6%)	3 (4.7%)	2 (3.1%)	0	0	0	8 (1.4%)	9 (1.3%)
		Normal	0	0	1 (1.6%)	0	0	0	0	1 (1.4%)	1 (1.6%)	3 (0.5%)	3 (0.4%)
	Normal	Normal	125 (96.2%)	121 (99.2%)	60 (96.8%)	60 (95.2%)	60 (93.8%)	62 (95.4%)	60 (98.4%)	66 (95.7%)	60 (95.2%)	549 (96.5%)	674 (96.4%)
		High	3 (2.3%)	0	0	2 (3.2%)	1 (1.6%)	1 (1.5%)	1 (1.6%)	0	0	5 (0.9%)	8 (1.1%)
	High	Normal	1 (0.8%)	0	0	0	0	0	0	2 (2.9%)	1 (1.6%)	3 (0.5%)	4 (0.6%)
		High	0	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	1 (0.1%)
Week 32	m		128	120	62	60	62	65	60	69	63	561	689
	Low	Low	0	1 (0.8%)	2 (3.2%)	0	3 (4.8%)	2 (3.1%)	0	0	0	8 (1.4%)	8 (1.2%)
		Normal	1 (0.8%)	0	0	1 (1.7%)	0	0	0	1 (1.4%)	1 (1.6%)	3 (0.5%)	4 (0.6%)
	Normal	Low	0	0	0	0	0	0	0	1 (1.4%)	0	1 (0.2%)	1 (0.1%)
		Normal	124 (96.9%)	118 (98.3%)	59 (95.2%)	59 (98.3%)	59 (95.2%)	63 (96.9%)	59 (98.3%)	65 (94.2%)	59 (93.7%)	541 (96.4%)	665 (96.5%)
		High	2 (1.6%)	1 (0.8%)	1 (1.6%)	0	0	0	1 (1.7%)	0	1 (1.6%)	4 (0.7%)	6 (0.9%)
	High	Normal	0	0	0	0	0	0	0	1 (1.4%)	1 (1.6%)	2 (0.4%)	2 (0.3%)
		High	1 (0.8%)	0	0	0	0	0	0	1 (1.4%)	1 (1.6%)	2 (0.4%)	3 (0.4%)
Week 40	m		128	120	60	59	62	65	60	69	63	558	686
	Low	Low	1 (0.8%)	1 (0.8%)	1 (1.7%)	0	2 (3.2%)	1 (1.5%)	0	0	0	5 (0.9%)	6 (0.9%)
		Normal	0	0	1 (1.7%)	1 (1.7%)	1 (1.6%)	1 (1.5%)	0	1 (1.4%)	1 (1.6%)	6 (1.1%)	6 (0.9%)
	Normal	Low	0	0	0	0	0	0	0	1 (1.4%)	1 (1.6%)	2 (0.4%)	2 (0.3%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
		Normal	125 (97.7%)	118 (98.3%)	58 (96.7%)	57 (96.6%)	58 (93.5%)	61 (93.8%)	60 (100.0%)	64 (92.8%)	59 (93.7%)	535 (95.9%)	660 (96.2%)
		High	1 (0.8%)	1 (0.8%)	0	1 (1.7%)	1 (1.6%)	2 (3.1%)	0	1 (1.4%)	0	6 (1.1%)	7 (1.0%)
	High	Normal	0	0	0	0	0	0	0	1 (1.4%)	1 (1.6%)	2 (0.4%)	2 (0.3%)
		High	1 (0.8%)	0	0	0	0	0	0	1 (1.4%)	1 (1.6%)	2 (0.4%)	3 (0.4%)
Week 48	m		127	118	60	59	62	65	60	66	63	553	680
	Low	Low	1 (0.8%)	0	1 (1.7%)	0	2 (3.2%)	1 (1.5%)	0	0	0	4 (0.7%)	5 (0.7%)
		Normal	0	1 (0.8%)	1 (1.7%)	1 (1.7%)	1 (1.6%)	1 (1.5%)	0	0	1 (1.6%)	6 (1.1%)	6 (0.9%)
	Normal	Low	0	0	0	0	0	0	0	1 (1.5%)	1 (1.6%)	2 (0.4%)	2 (0.3%)
		Normal	123 (96.9%)	114 (96.6%)	58 (96.7%)	57 (96.6%)	59 (95.2%)	63 (96.9%)	60 (100.0%)	62 (93.9%)	58 (92.1%)	531 (96.0%)	654 (96.2%)
		High	2 (1.6%)	3 (2.5%)	0	1 (1.7%)	0	0	0	1 (1.5%)	1 (1.6%)	6 (1.1%)	8 (1.2%)
	High	Normal	0	0	0	0	0	0	0	2 (3.0%)	1 (1.6%)	3 (0.5%)	3 (0.4%)
		High	1 (0.8%)	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	2 (0.3%)
Week 52	m		126	116	59	58	62	65	60	67	62	549	675
	Low	Low	1 (0.8%)	0	2 (3.4%)	0	2 (3.2%)	2 (3.1%)	0	1 (1.5%)	0	7 (1.3%)	8 (1.2%)
		Normal	0	1 (0.9%)	0	1 (1.7%)	1 (1.6%)	0	0	0	1 (1.6%)	4 (0.7%)	4 (0.6%)
	Normal	Low	0	0	0	0	0	0	0	1 (1.5%)	1 (1.6%)	2 (0.4%)	2 (0.3%)
		Normal	124 (98.4%)	114 (98.3%)	56 (94.9%)	57 (98.3%)	59 (95.2%)	62 (95.4%)	60 (100.0%)	63 (94.0%)	58 (93.5%)	529 (96.4%)	653 (96.7%)
		High	0	1 (0.9%)	1 (1.7%)	0	0	1 (1.5%)	0	0	0	3 (0.5%)	3 (0.4%)
	High	Normal	0	0	0	0	0	0	0	2 (3.0%)	2 (3.2%)	4 (0.7%)	4 (0.6%)
		High	1 (0.8%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
LOCF Endpoint	m		134	127	64	64	64	65	63	70	63	580	714
	Low	Low	2 (1.5%)	0	2 (3.1%)	0	2 (3.1%)	2 (3.1%)	0	1 (1.4%)	0	7 (1.2%)	9 (1.3%)
		Normal	0	1 (0.8%)	0	1 (1.6%)	1 (1.6%)	0	0	0	1 (1.6%)	4 (0.7%)	4 (0.6%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
	Normal	Low	0	1 (0.8%)	0	0	0	0	0	1 (1.4%)	1 (1.6%)	3 (0.5%)	3 (0.4%)
		Normal	131 (97.8%)	124 (97.6%)	61 (95.3%)	63 (98.4%)	61 (95.3%)	62 (95.4%)	63 (100.0%)	66 (94.3%)	58 (92.1%)	558 (96.2%)	689 (96.5%)
		High	0	1 (0.8%)	1 (1.6%)	0	0	1 (1.5%)	0	0	1 (1.6%)	4 (0.7%)	4 (0.6%)
	High	Normal	0	0	0	0	0	0	0	2 (2.9%)	2 (3.2%)	4 (0.7%)	4 (0.6%)
		High	1 (0.7%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
Urea Nitrogen (mmol/L)													
Week 4	m		134	127	64	64	64	65	63	70	63	580	714
	Normal	Normal	134 (100.0%)	127 (100.0%)	63 (98.4%)	63 (98.4%)	64 (100.0%)	63 (96.9%)	63 (100.0%)	69 (98.6%)	63 (100.0%)	575 (99.1%)	709 (99.3%)
		High	0	0	1 (1.6%)	0	0	2 (3.1%)	0	0	0	3 (0.5%)	3 (0.4%)
	High	Normal	0	0	0	0	0	0	0	1 (1.4%)	0	1 (0.2%)	1 (0.1%)
		High	0	0	0	1 (1.6%)	0	0	0	0	0	1 (0.2%)	1 (0.1%)
Week 8	m		132	125	63	64	64	65	62	69	63	575	707
	Normal	Normal	131 (99.2%)	124 (99.2%)	62 (98.4%)	63 (98.4%)	64 (100.0%)	63 (96.9%)	62 (100.0%)	68 (98.6%)	62 (98.4%)	568 (98.8%)	699 (98.9%)
		High	1 (0.8%)	1 (0.8%)	1 (1.6%)	0	0	2 (3.1%)	0	0	1 (1.6%)	5 (0.9%)	6 (0.8%)
	High	Normal	0	0	0	1 (1.6%)	0	0	0	1 (1.4%)	0	2 (0.3%)	2 (0.3%)
Week 12	m		131	123	63	64	64	65	62	68	63	572	703
	Normal	Low	0	0	0	0	1 (1.6%)	0	0	0	0	1 (0.2%)	1 (0.1%)
		Normal	130 (99.2%)	120 (97.6%)	62 (98.4%)	62 (96.9%)	63 (98.4%)	64 (98.5%)	62 (100.0%)	67 (98.5%)	62 (98.4%)	562 (98.3%)	692 (98.4%)
		High	1 (0.8%)	3 (2.4%)	1 (1.6%)	1 (1.6%)	0	1 (1.5%)	0	0	1 (1.6%)	7 (1.2%)	8 (1.1%)
	High	Normal	0	0	0	1 (1.6%)	0	0	0	1 (1.5%)	0	2 (0.3%)	2 (0.3%)
Week 16	m		130	123	63	64	64	64	62	69	63	572	702

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
	Normal	Normal	129 (99.2%)	123 (100.0%)	63 (100.0%)	62 (96.9%)	63 (98.4%)	63 (98.4%)	62 (100.0%)	67 (97.1%)	63 (100.0%)	566 (99.0%)	695 (99.0%)
		High	1 (0.8%)	0	0	1 (1.6%)	1 (1.6%)	1 (1.6%)	0	1 (1.4%)	0	4 (0.7%)	5 (0.7%)
	High	Normal	0	0	0	0	0	0	0	1 (1.4%)	0	1 (0.2%)	1 (0.1%)
		High	0	0	0	1 (1.6%)	0	0	0	0	0	1 (0.2%)	1 (0.1%)
Week 20	m		130	123	62	63	64	65	61	69	63	570	700
	Normal	Normal	127 (97.7%)	121 (98.4%)	62 (100.0%)	61 (96.8%)	64 (100.0%)	64 (98.5%)	61 (100.0%)	68 (98.6%)	62 (98.4%)	563 (98.8%)	690 (98.6%)
		High	3 (2.3%)	2 (1.6%)	0	1 (1.6%)	0	1 (1.5%)	0	0	1 (1.6%)	5 (0.9%)	8 (1.1%)
	High	Normal	0	0	0	1 (1.6%)	0	0	0	1 (1.4%)	0	2 (0.4%)	2 (0.3%)
Week 24	m		130	122	62	63	64	65	61	69	63	569	699
	Normal	Normal	130 (100.0%)	122 (100.0%)	62 (100.0%)	61 (96.8%)	64 (100.0%)	65 (100.0%)	61 (100.0%)	68 (98.6%)	62 (98.4%)	565 (99.3%)	695 (99.4%)
		High	0	0	0	1 (1.6%)	0	0	0	0	1 (1.6%)	2 (0.4%)	2 (0.3%)
	High	High	0	0	0	1 (1.6%)	0	0	0	1 (1.4%)	0	2 (0.4%)	2 (0.3%)
Week 32	m		128	120	62	60	62	65	60	69	63	561	689
	Normal	Normal	127 (99.2%)	118 (98.3%)	62 (100.0%)	59 (98.3%)	62 (100.0%)	65 (100.0%)	59 (98.3%)	68 (98.6%)	63 (100.0%)	556 (99.1%)	683 (99.1%)
		High	1 (0.8%)	2 (1.7%)	0	0	0	0	1 (1.7%)	0	0	3 (0.5%)	4 (0.6%)
	High	Normal	0	0	0	1 (1.7%)	0	0	0	1 (1.4%)	0	2 (0.4%)	2 (0.3%)
Week 40	m		128	120	60	59	62	65	60	69	63	558	686
	Normal	Normal	127 (99.2%)	118 (98.3%)	60 (100.0%)	58 (98.3%)	61 (98.4%)	65 (100.0%)	59 (98.3%)	68 (98.6%)	62 (98.4%)	551 (98.7%)	678 (98.8%)
		High	1 (0.8%)	2 (1.7%)	0	0	1 (1.6%)	0	1 (1.7%)	0	1 (1.6%)	5 (0.9%)	6 (0.9%)
	High	Normal	0	0	0	0	0	0	0	1 (1.4%)	0	1 (0.2%)	1 (0.1%)
		High	0	0	0	1 (1.7%)	0	0	0	0	0	1 (0.2%)	1 (0.1%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
Week 48	m		127	118	60	59	62	65	60	66	63	553	680
	Normal	Normal	126 (99.2%)	117 (99.2%)	60 (100.0%)	58 (98.3%)	61 (98.4%)	65 (100.0%)	60 (100.0%)	65 (98.5%)	62 (98.4%)	548 (99.1%)	674 (99.1%)
		High	1 (0.8%)	1 (0.8%)	0	0	1 (1.6%)	0	0	0	1 (1.6%)	3 (0.5%)	4 (0.6%)
	High	Normal	0	0	0	1 (1.7%)	0	0	0	1 (1.5%)	0	2 (0.4%)	2 (0.3%)
Week 52	m		126	116	59	58	62	65	60	67	62	549	675
	Normal	Normal	125 (99.2%)	113 (97.4%)	59 (100.0%)	56 (96.6%)	61 (98.4%)	65 (100.0%)	60 (100.0%)	66 (98.5%)	62 (100.0%)	542 (98.7%)	667 (98.8%)
		High	1 (0.8%)	3 (2.6%)	0	1 (1.7%)	1 (1.6%)	0	0	0	0	5 (0.9%)	6 (0.9%)
	High	Normal	0	0	0	1 (1.7%)	0	0	0	1 (1.5%)	0	2 (0.4%)	2 (0.3%)
LOCF Endpoint	m		134	127	64	64	64	65	63	70	63	580	714
	Normal	Normal	133 (99.3%)	124 (97.6%)	64 (100.0%)	62 (96.9%)	63 (98.4%)	65 (100.0%)	63 (100.0%)	69 (98.6%)	63 (100.0%)	573 (98.8%)	706 (98.9%)
		High	1 (0.7%)	3 (2.4%)	0	1 (1.6%)	1 (1.6%)	0	0	0	0	5 (0.9%)	6 (0.8%)
	High	Normal	0	0	0	1 (1.6%)	0	0	0	1 (1.4%)	0	2 (0.3%)	2 (0.3%)

- Abbreviations: LOCF, Last Observation Carried Forward; SU, Sulphonylurea; GLIN, Glinide; BIG, Biguanide; AGI, Alpha glucosidase inhibitor; TZD, Thiazolidinedione; DPP4-I, Dipeptidyl peptidase-4 inhibitor; GLP1-RA, Glucagon-like peptide 1 receptor agonist; SGLT2-I, Sodium glucose cotransporter 2 inhibitor
- "Imeglimin" in this table means "Imeglimin 1000 mg twice daily".
- "Combination Total" is the sum of the subjects excluding monotherapy "Imeglimin".
- "Imeglimin Total" is the sum of all subjects in Imeglimin treatment groups.
- m in row headings is the total number of subjects with both baseline and the corresponding visit values available, and is used as the denominator to calculate percentages.

Control No:<<t-s-187-labot-019lt.sas, 2020-03-06T00:15:20>>

Table S-188 Shift of Laboratory Findings of Urinalysis in 52-Week Long-term Period with Monotherapy and Combination Therapy (PXL008-019; Long-term Safety Population)

Parameter / Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
Ketones													
Week 4	m		134	127	64	64	64	65	63	70	63	580	714
	Negative	Negative	123 (91.8%)	110 (86.6%)	57 (89.1%)	54 (84.4%)	52 (81.3%)	60 (92.3%)	54 (85.7%)	61 (87.1%)	34 (54.0%)	482 (83.1%)	605 (84.7%)
		Trace	1 (0.7%)	2 (1.6%)	1 (1.6%)	4 (6.3%)	1 (1.6%)	1 (1.5%)	1 (1.6%)	1 (1.4%)	4 (6.3%)	15 (2.6%)	16 (2.2%)
		Positive	1 (0.7%)	0	0	1 (1.6%)	2 (3.1%)	1 (1.5%)	1 (1.6%)	1 (1.4%)	3 (4.8%)	9 (1.6%)	10 (1.4%)
	Trace	Negative	3 (2.2%)	5 (3.9%)	3 (4.7%)	3 (4.7%)	2 (3.1%)	2 (3.1%)	4 (6.3%)	2 (2.9%)	5 (7.9%)	26 (4.5%)	29 (4.1%)
		Trace	1 (0.7%)	0	0	0	1 (1.6%)	0	1 (1.6%)	0	1 (1.6%)	3 (0.5%)	4 (0.6%)
		Positive	1 (0.7%)	0	0	0	1 (1.6%)	0	0	0	4 (6.3%)	5 (0.9%)	6 (0.8%)
	Positive	Negative	2 (1.5%)	7 (5.5%)	2 (3.1%)	1 (1.6%)	4 (6.3%)	1 (1.5%)	2 (3.2%)	3 (4.3%)	7 (11.1%)	27 (4.7%)	29 (4.1%)
		Trace	0	0	1 (1.6%)	1 (1.6%)	0	0	0	0	4 (6.3%)	6 (1.0%)	6 (0.8%)
		Positive	2 (1.5%)	3 (2.4%)	0	0	1 (1.6%)	0	0	2 (2.9%)	1 (1.6%)	7 (1.2%)	9 (1.3%)
Week 8	m		132	126	63	64	64	65	62	69	63	576	708
	Negative	Negative	121 (91.7%)	104 (82.5%)	56 (88.9%)	51 (79.7%)	50 (78.1%)	59 (90.8%)	55 (88.7%)	57 (82.6%)	37 (58.7%)	469 (81.4%)	590 (83.3%)
		Trace	1 (0.8%)	5 (4.0%)	1 (1.6%)	4 (6.3%)	3 (4.7%)	2 (3.1%)	0	3 (4.3%)	1 (1.6%)	19 (3.3%)	20 (2.8%)
		Positive	1 (0.8%)	2 (1.6%)	0	4 (6.3%)	2 (3.1%)	1 (1.5%)	1 (1.6%)	2 (2.9%)	3 (4.8%)	15 (2.6%)	16 (2.3%)
	Trace	Negative	4 (3.0%)	3 (2.4%)	2 (3.2%)	2 (3.1%)	3 (4.7%)	2 (3.1%)	3 (4.8%)	2 (2.9%)	7 (11.1%)	24 (4.2%)	28 (4.0%)
		Trace	0	2 (1.6%)	1 (1.6%)	0	0	0	1 (1.6%)	0	1 (1.6%)	5 (0.9%)	5 (0.7%)
		Positive	1 (0.8%)	0	0	1 (1.6%)	1 (1.6%)	0	0	0	2 (3.2%)	4 (0.7%)	5 (0.7%)
	Positive	Negative	2 (1.5%)	4 (3.2%)	3 (4.8%)	1 (1.6%)	0	1 (1.5%)	2 (3.2%)	2 (2.9%)	6 (9.5%)	19 (3.3%)	21 (3.0%)
		Trace	0	2 (1.6%)	0	0	2 (3.1%)	0	0	0	2 (3.2%)	6 (1.0%)	6 (0.8%)
		Positive	2 (1.5%)	4 (3.2%)	0	1 (1.6%)	3 (4.7%)	0	0	3 (4.3%)	4 (6.3%)	15 (2.6%)	17 (2.4%)
Week 12	m		131	123	63	64	64	65	62	68	63	572	703
	Negative	Negative	116 (88.5%)	102 (82.9%)	55 (87.3%)	56 (87.5%)	51 (79.7%)	61 (93.8%)	56 (90.3%)	58 (85.3%)	37 (58.7%)	476 (83.2%)	592 (84.2%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
		Trace	5 (3.8%)	3 (2.4%)	2 (3.2%)	2 (3.1%)	2 (3.1%)	1 (1.5%)	0	1 (1.5%)	3 (4.8%)	14 (2.4%)	19 (2.7%)
		Positive	2 (1.5%)	3 (2.4%)	0	1 (1.6%)	2 (3.1%)	0	0	2 (2.9%)	1 (1.6%)	9 (1.6%)	11 (1.6%)
	Trace	Negative	4 (3.1%)	3 (2.4%)	3 (4.8%)	3 (4.7%)	3 (4.7%)	1 (1.5%)	4 (6.5%)	1 (1.5%)	9 (14.3%)	27 (4.7%)	31 (4.4%)
		Trace	0	1 (0.8%)	0	0	0	0	0	1 (1.5%)	0	2 (0.3%)	2 (0.3%)
		Positive	0	1 (0.8%)	0	0	1 (1.6%)	1 (1.5%)	0	0	1 (1.6%)	4 (0.7%)	4 (0.6%)
	Positive	Negative	1 (0.8%)	5 (4.1%)	3 (4.8%)	1 (1.6%)	3 (4.7%)	1 (1.5%)	0	4 (5.9%)	8 (12.7%)	25 (4.4%)	26 (3.7%)
		Trace	2 (1.5%)	2 (1.6%)	0	1 (1.6%)	1 (1.6%)	0	0	1 (1.5%)	1 (1.6%)	6 (1.0%)	8 (1.1%)
		Positive	1 (0.8%)	3 (2.4%)	0	0	1 (1.6%)	0	2 (3.2%)	0	3 (4.8%)	9 (1.6%)	10 (1.4%)
Week 16	m		130	123	63	64	64	64	62	69	63	572	702
	Negative	Negative	114 (87.7%)	95 (77.2%)	55 (87.3%)	57 (89.1%)	51 (79.7%)	59 (92.2%)	55 (88.7%)	56 (81.2%)	36 (57.1%)	464 (81.1%)	578 (82.3%)
		Trace	4 (3.1%)	7 (5.7%)	0	2 (3.1%)	1 (1.6%)	1 (1.6%)	1 (1.6%)	3 (4.3%)	4 (6.3%)	19 (3.3%)	23 (3.3%)
		Positive	4 (3.1%)	6 (4.9%)	2 (3.2%)	0	3 (4.7%)	1 (1.6%)	0	3 (4.3%)	1 (1.6%)	16 (2.8%)	20 (2.8%)
	Trace	Negative	2 (1.5%)	4 (3.3%)	3 (4.8%)	3 (4.7%)	3 (4.7%)	2 (3.1%)	4 (6.5%)	1 (1.4%)	9 (14.3%)	29 (5.1%)	31 (4.4%)
		Trace	1 (0.8%)	0	0	0	0	0	0	1 (1.4%)	0	1 (0.2%)	2 (0.3%)
		Positive	1 (0.8%)	1 (0.8%)	0	0	1 (1.6%)	0	0	0	1 (1.6%)	3 (0.5%)	4 (0.6%)
	Positive	Negative	1 (0.8%)	4 (3.3%)	3 (4.8%)	1 (1.6%)	1 (1.6%)	0	0	4 (5.8%)	9 (14.3%)	22 (3.8%)	23 (3.3%)
		Trace	2 (1.5%)	3 (2.4%)	0	1 (1.6%)	3 (4.7%)	0	1 (1.6%)	0	1 (1.6%)	9 (1.6%)	11 (1.6%)
		Positive	1 (0.8%)	3 (2.4%)	0	0	1 (1.6%)	1 (1.6%)	1 (1.6%)	1 (1.4%)	2 (3.2%)	9 (1.6%)	10 (1.4%)
Week 20	m		130	123	62	63	64	65	61	69	63	570	700
	Negative	Negative	113 (86.9%)	104 (84.6%)	50 (80.6%)	54 (85.7%)	51 (79.7%)	60 (92.3%)	53 (86.9%)	57 (82.6%)	39 (61.9%)	468 (82.1%)	581 (83.0%)
		Trace	1 (0.8%)	2 (1.6%)	4 (6.5%)	2 (3.2%)	3 (4.7%)	1 (1.5%)	1 (1.6%)	2 (2.9%)	1 (1.6%)	16 (2.8%)	17 (2.4%)
		Positive	8 (6.2%)	2 (1.6%)	2 (3.2%)	2 (3.2%)	1 (1.6%)	1 (1.5%)	1 (1.6%)	3 (4.3%)	1 (1.6%)	13 (2.3%)	21 (3.0%)
	Trace	Negative	3 (2.3%)	4 (3.3%)	3 (4.8%)	2 (3.2%)	3 (4.7%)	1 (1.5%)	4 (6.6%)	1 (1.4%)	8 (12.7%)	26 (4.6%)	29 (4.1%)
		Trace	0	1 (0.8%)	0	1 (1.6%)	0	1 (1.5%)	0	1 (1.4%)	0	4 (0.7%)	4 (0.6%)
		Positive	1 (0.8%)	0	0	0	1 (1.6%)	0	0	0	2 (3.2%)	3 (0.5%)	4 (0.6%)
	Positive	Negative	1 (0.8%)	6 (4.9%)	3 (4.8%)	2 (3.2%)	3 (4.7%)	1 (1.5%)	1 (1.6%)	3 (4.3%)	7 (11.1%)	26 (4.6%)	27 (3.9%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
		Trace	0	0	0	0	1 (1.6%)	0	0	0	2 (3.2%)	3 (0.5%)	3 (0.4%)
		Positive	3 (2.3%)	4 (3.3%)	0	0	1 (1.6%)	0	1 (1.6%)	2 (2.9%)	3 (4.8%)	11 (1.9%)	14 (2.0%)
Week 24	m		130	122	62	63	64	65	61	69	63	569	699
	Negative	Negative	113 (86.9%)	98 (80.3%)	53 (85.5%)	53 (84.1%)	50 (78.1%)	56 (86.2%)	53 (86.9%)	58 (84.1%)	35 (55.6%)	456 (80.1%)	569 (81.4%)
		Trace	3 (2.3%)	4 (3.3%)	2 (3.2%)	3 (4.8%)	3 (4.7%)	4 (6.2%)	2 (3.3%)	3 (4.3%)	2 (3.2%)	23 (4.0%)	26 (3.7%)
		Positive	6 (4.6%)	5 (4.1%)	1 (1.6%)	2 (3.2%)	2 (3.1%)	2 (3.1%)	0	1 (1.4%)	4 (6.3%)	17 (3.0%)	23 (3.3%)
	Trace	Negative	1 (0.8%)	4 (3.3%)	2 (3.2%)	2 (3.2%)	3 (4.7%)	2 (3.1%)	4 (6.6%)	2 (2.9%)	7 (11.1%)	26 (4.6%)	27 (3.9%)
		Trace	1 (0.8%)	1 (0.8%)	1 (1.6%)	0	0	0	0	0	2 (3.2%)	4 (0.7%)	5 (0.7%)
		Positive	2 (1.5%)	0	0	1 (1.6%)	1 (1.6%)	0	0	0	1 (1.6%)	3 (0.5%)	5 (0.7%)
	Positive	Negative	3 (2.3%)	6 (4.9%)	3 (4.8%)	2 (3.2%)	2 (3.1%)	0	2 (3.3%)	3 (4.3%)	8 (12.7%)	26 (4.6%)	29 (4.1%)
		Trace	0	1 (0.8%)	0	0	2 (3.1%)	1 (1.5%)	0	1 (1.4%)	0	5 (0.9%)	5 (0.7%)
		Positive	1 (0.8%)	3 (2.5%)	0	0	1 (1.6%)	0	0	1 (1.4%)	4 (6.3%)	9 (1.6%)	10 (1.4%)
Week 32	m		128	120	62	60	62	65	60	69	63	561	689
	Negative	Negative	113 (88.3%)	100 (83.3%)	51 (82.3%)	50 (83.3%)	50 (80.6%)	56 (86.2%)	51 (85.0%)	54 (78.3%)	37 (58.7%)	449 (80.0%)	562 (81.6%)
		Trace	4 (3.1%)	5 (4.2%)	1 (1.6%)	2 (3.3%)	2 (3.2%)	3 (4.6%)	2 (3.3%)	5 (7.2%)	4 (6.3%)	24 (4.3%)	28 (4.1%)
		Positive	3 (2.3%)	0	4 (6.5%)	3 (5.0%)	2 (3.2%)	3 (4.6%)	1 (1.7%)	3 (4.3%)	0	16 (2.9%)	19 (2.8%)
	Trace	Negative	3 (2.3%)	4 (3.3%)	3 (4.8%)	3 (5.0%)	3 (4.8%)	2 (3.1%)	3 (5.0%)	2 (2.9%)	6 (9.5%)	26 (4.6%)	29 (4.2%)
		Trace	1 (0.8%)	0	0	0	1 (1.6%)	0	0	0	3 (4.8%)	4 (0.7%)	5 (0.7%)
		Positive	0	1 (0.8%)	0	0	0	0	1 (1.7%)	0	1 (1.6%)	3 (0.5%)	3 (0.4%)
	Positive	Negative	0	5 (4.2%)	3 (4.8%)	0	3 (4.8%)	1 (1.5%)	1 (1.7%)	4 (5.8%)	8 (12.7%)	25 (4.5%)	25 (3.6%)
		Trace	2 (1.6%)	2 (1.7%)	0	1 (1.7%)	0	0	0	1 (1.4%)	1 (1.6%)	5 (0.9%)	7 (1.0%)
		Positive	2 (1.6%)	3 (2.5%)	0	1 (1.7%)	1 (1.6%)	0	1 (1.7%)	0	3 (4.8%)	9 (1.6%)	11 (1.6%)
Week 40	m		128	120	60	59	62	65	60	69	63	558	686
	Negative	Negative	116 (90.6%)	93 (77.5%)	50 (83.3%)	49 (83.1%)	48 (77.4%)	56 (86.2%)	54 (90.0%)	56 (81.2%)	36 (57.1%)	442 (79.2%)	558 (81.3%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
		Trace	3 (2.3%)	6 (5.0%)	2 (3.3%)	3 (5.1%)	3 (4.8%)	4 (6.2%)	0	3 (4.3%)	2 (3.2%)	23 (4.1%)	26 (3.8%)
		Positive	1 (0.8%)	6 (5.0%)	2 (3.3%)	3 (5.1%)	3 (4.8%)	2 (3.1%)	1 (1.7%)	3 (4.3%)	3 (4.8%)	23 (4.1%)	24 (3.5%)
	Trace	Negative	2 (1.6%)	2 (1.7%)	3 (5.0%)	3 (5.1%)	3 (4.8%)	2 (3.1%)	4 (6.7%)	2 (2.9%)	6 (9.5%)	25 (4.5%)	27 (3.9%)
		Trace	1 (0.8%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
		Positive	1 (0.8%)	3 (2.5%)	0	0	1 (1.6%)	0	0	0	4 (6.3%)	8 (1.4%)	9 (1.3%)
	Positive	Negative	2 (1.6%)	7 (5.8%)	2 (3.3%)	0	1 (1.6%)	0	1 (1.7%)	2 (2.9%)	7 (11.1%)	20 (3.6%)	22 (3.2%)
		Trace	1 (0.8%)	1 (0.8%)	0	0	2 (3.2%)	0	0	0	0	3 (0.5%)	4 (0.6%)
		Positive	1 (0.8%)	2 (1.7%)	1 (1.7%)	1 (1.7%)	1 (1.6%)	1 (1.5%)	0	3 (4.3%)	5 (7.9%)	14 (2.5%)	15 (2.2%)
Week 48	m		127	118	60	59	62	65	60	66	63	553	680
	Negative	Negative	109 (85.8%)	92 (78.0%)	53 (88.3%)	50 (84.7%)	49 (79.0%)	60 (92.3%)	53 (88.3%)	55 (83.3%)	35 (55.6%)	447 (80.8%)	556 (81.8%)
		Trace	6 (4.7%)	8 (6.8%)	0	2 (3.4%)	4 (6.5%)	2 (3.1%)	0	4 (6.1%)	3 (4.8%)	23 (4.2%)	29 (4.3%)
		Positive	4 (3.1%)	3 (2.5%)	1 (1.7%)	3 (5.1%)	1 (1.6%)	0	2 (3.3%)	1 (1.5%)	3 (4.8%)	14 (2.5%)	18 (2.6%)
	Trace	Negative	1 (0.8%)	4 (3.4%)	3 (5.0%)	3 (5.1%)	3 (4.8%)	1 (1.5%)	3 (5.0%)	2 (3.0%)	5 (7.9%)	24 (4.3%)	25 (3.7%)
		Trace	1 (0.8%)	0	0	0	1 (1.6%)	0	0	0	1 (1.6%)	2 (0.4%)	3 (0.4%)
		Positive	2 (1.6%)	1 (0.8%)	0	0	0	1 (1.5%)	1 (1.7%)	0	4 (6.3%)	7 (1.3%)	9 (1.3%)
	Positive	Negative	1 (0.8%)	5 (4.2%)	3 (5.0%)	1 (1.7%)	2 (3.2%)	1 (1.5%)	0	2 (3.0%)	7 (11.1%)	21 (3.8%)	22 (3.2%)
		Trace	1 (0.8%)	0	0	0	0	0	0	1 (1.5%)	3 (4.8%)	4 (0.7%)	5 (0.7%)
		Positive	2 (1.6%)	5 (4.2%)	0	0	2 (3.2%)	0	1 (1.7%)	1 (1.5%)	2 (3.2%)	11 (2.0%)	13 (1.9%)
Week 52	m		126	116	59	58	62	65	60	67	62	549	675
	Negative	Negative	111 (88.1%)	90 (77.6%)	51 (86.4%)	52 (89.7%)	47 (75.8%)	57 (87.7%)	52 (86.7%)	53 (79.1%)	34 (54.8%)	436 (79.4%)	547 (81.0%)
		Trace	3 (2.4%)	5 (4.3%)	2 (3.4%)	0	4 (6.5%)	2 (3.1%)	1 (1.7%)	6 (9.0%)	1 (1.6%)	21 (3.8%)	24 (3.6%)
		Positive	4 (3.2%)	6 (5.2%)	0	2 (3.4%)	3 (4.8%)	3 (4.6%)	2 (3.3%)	1 (1.5%)	5 (8.1%)	22 (4.0%)	26 (3.9%)
	Trace	Negative	2 (1.6%)	2 (1.7%)	2 (3.4%)	2 (3.4%)	3 (4.8%)	2 (3.1%)	4 (6.7%)	2 (3.0%)	9 (14.5%)	26 (4.7%)	28 (4.1%)
		Trace	0	2 (1.7%)	1 (1.7%)	1 (1.7%)	1 (1.6%)	0	0	0	1 (1.6%)	6 (1.1%)	6 (0.9%)
		Positive	2 (1.6%)	1 (0.9%)	0	0	0	0	0	0	0	1 (0.2%)	3 (0.4%)
	Positive	Negative	3 (2.4%)	4 (3.4%)	2 (3.4%)	0	2 (3.2%)	1 (1.5%)	0	4 (6.0%)	5 (8.1%)	18 (3.3%)	21 (3.1%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
		Trace	0	5 (4.3%)	1 (1.7%)	0	0	0	1 (1.7%)	0	1 (1.6%)	8 (1.5%)	8 (1.2%)
		Positive	1 (0.8%)	1 (0.9%)	0	1 (1.7%)	2 (3.2%)	0	0	1 (1.5%)	6 (9.7%)	11 (2.0%)	12 (1.8%)
LOCF Endpoint	m		134	127	64	64	64	65	63	70	63	580	714
	Negative	Negative	116 (86.6%)	99 (78.0%)	56 (87.5%)	57 (89.1%)	47 (73.4%)	57 (87.7%)	53 (84.1%)	56 (80.0%)	35 (55.6%)	460 (79.3%)	576 (80.7%)
		Trace	3 (2.2%)	6 (4.7%)	2 (3.1%)	0	5 (7.8%)	2 (3.1%)	1 (1.6%)	6 (8.6%)	1 (1.6%)	23 (4.0%)	26 (3.6%)
		Positive	6 (4.5%)	7 (5.5%)	0	2 (3.1%)	3 (4.7%)	3 (4.6%)	2 (3.2%)	1 (1.4%)	5 (7.9%)	23 (4.0%)	29 (4.1%)
	Trace	Negative	3 (2.2%)	2 (1.6%)	2 (3.1%)	2 (3.1%)	3 (4.7%)	2 (3.1%)	5 (7.9%)	2 (2.9%)	9 (14.3%)	27 (4.7%)	30 (4.2%)
		Trace	0	2 (1.6%)	1 (1.6%)	1 (1.6%)	1 (1.6%)	0	0	0	1 (1.6%)	6 (1.0%)	6 (0.8%)
		Positive	2 (1.5%)	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	3 (0.4%)
	Positive	Negative	3 (2.2%)	4 (3.1%)	2 (3.1%)	0	2 (3.1%)	1 (1.5%)	1 (1.6%)	4 (5.7%)	5 (7.9%)	19 (3.3%)	22 (3.1%)
		Trace	0	5 (3.9%)	1 (1.6%)	1 (1.6%)	1 (1.6%)	0	1 (1.6%)	0	1 (1.6%)	10 (1.7%)	10 (1.4%)
		Positive	1 (0.7%)	1 (0.8%)	0	1 (1.6%)	2 (3.1%)	0	0	1 (1.4%)	6 (9.5%)	11 (1.9%)	12 (1.7%)
Leukocyte Esterase													
Week 4	m		134	127	64	64	64	65	63	70	63	580	714
	Negative	Negative	120 (89.6%)	112 (88.2%)	51 (79.7%)	57 (89.1%)	54 (84.4%)	59 (90.8%)	56 (88.9%)	58 (82.9%)	57 (90.5%)	504 (86.9%)	624 (87.4%)
		Trace	1 (0.7%)	0	0	3 (4.7%)	0	0	1 (1.6%)	1 (1.4%)	1 (1.6%)	6 (1.0%)	7 (1.0%)
		Positive	5 (3.7%)	2 (1.6%)	2 (3.1%)	0	1 (1.6%)	2 (3.1%)	1 (1.6%)	1 (1.4%)	2 (3.2%)	11 (1.9%)	16 (2.2%)
	Trace	Negative	0	2 (1.6%)	1 (1.6%)	3 (4.7%)	0	1 (1.5%)	1 (1.6%)	2 (2.9%)	0	10 (1.7%)	10 (1.4%)
		Trace	0	0	0	0	0	0	0	1 (1.4%)	1 (1.6%)	2 (0.3%)	2 (0.3%)
		Positive	1 (0.7%)	1 (0.8%)	0	0	0	0	0	1 (1.4%)	0	2 (0.3%)	3 (0.4%)
	Positive	Negative	3 (2.2%)	3 (2.4%)	6 (9.4%)	0	7 (10.9%)	1 (1.5%)	0	0	1 (1.6%)	18 (3.1%)	21 (2.9%)
		Trace	1 (0.7%)	0	1 (1.6%)	0	0	0	1 (1.6%)	0	0	2 (0.3%)	3 (0.4%)
		Positive	3 (2.2%)	7 (5.5%)	3 (4.7%)	1 (1.6%)	2 (3.1%)	2 (3.1%)	3 (4.8%)	6 (8.6%)	1 (1.6%)	25 (4.3%)	28 (3.9%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
Week 8	m		132	126	63	64	64	65	62	69	63	576	708
	Negative	Negative	119 (90.2%)	109 (86.5%)	48 (76.2%)	57 (89.1%)	52 (81.3%)	58 (89.2%)	53 (85.5%)	58 (84.1%)	58 (92.1%)	493 (85.6%)	612 (86.4%)
		Trace	2 (1.5%)	2 (1.6%)	0	2 (3.1%)	1 (1.6%)	1 (1.5%)	1 (1.6%)	0	1 (1.6%)	8 (1.4%)	10 (1.4%)
		Positive	3 (2.3%)	2 (1.6%)	4 (6.3%)	1 (1.6%)	2 (3.1%)	2 (3.1%)	3 (4.8%)	1 (1.4%)	1 (1.6%)	16 (2.8%)	19 (2.7%)
	Trace	Negative	0	3 (2.4%)	1 (1.6%)	2 (3.1%)	0	1 (1.5%)	0	2 (2.9%)	1 (1.6%)	10 (1.7%)	10 (1.4%)
		Positive	1 (0.8%)	0	0	1 (1.6%)	0	0	1 (1.6%)	2 (2.9%)	0	4 (0.7%)	5 (0.7%)
	Positive	Negative	4 (3.0%)	4 (3.2%)	5 (7.9%)	0	7 (10.9%)	3 (4.6%)	1 (1.6%)	0	0	20 (3.5%)	24 (3.4%)
		Trace	0	0	2 (3.2%)	1 (1.6%)	1 (1.6%)	0	1 (1.6%)	0	0	5 (0.9%)	5 (0.7%)
		Positive	3 (2.3%)	6 (4.8%)	3 (4.8%)	0	1 (1.6%)	0	2 (3.2%)	6 (8.7%)	2 (3.2%)	20 (3.5%)	23 (3.2%)
Week 12	m		131	123	63	64	64	65	62	68	63	572	703
	Negative	Negative	120 (91.6%)	107 (87.0%)	49 (77.8%)	57 (89.1%)	52 (81.3%)	59 (90.8%)	54 (87.1%)	54 (79.4%)	56 (88.9%)	488 (85.3%)	608 (86.5%)
		Trace	0	0	0	0	3 (4.7%)	1 (1.5%)	1 (1.6%)	3 (4.4%)	1 (1.6%)	9 (1.6%)	9 (1.3%)
		Positive	3 (2.3%)	3 (2.4%)	3 (4.8%)	3 (4.7%)	0	1 (1.5%)	2 (3.2%)	2 (2.9%)	3 (4.8%)	17 (3.0%)	20 (2.8%)
	Trace	Negative	1 (0.8%)	2 (1.6%)	1 (1.6%)	1 (1.6%)	0	1 (1.5%)	0	1 (1.5%)	0	6 (1.0%)	7 (1.0%)
		Trace	0	0	0	1 (1.6%)	0	0	0	0	1 (1.6%)	2 (0.3%)	2 (0.3%)
		Positive	0	1 (0.8%)	0	1 (1.6%)	0	0	1 (1.6%)	3 (4.4%)	0	6 (1.0%)	6 (0.9%)
	Positive	Negative	4 (3.1%)	2 (1.6%)	6 (9.5%)	0	7 (10.9%)	1 (1.5%)	0	0	1 (1.6%)	17 (3.0%)	21 (3.0%)
		Trace	0	1 (0.8%)	0	1 (1.6%)	0	0	0	0	0	2 (0.3%)	2 (0.3%)
		Positive	3 (2.3%)	7 (5.7%)	4 (6.3%)	0	2 (3.1%)	2 (3.1%)	4 (6.5%)	5 (7.4%)	1 (1.6%)	25 (4.4%)	28 (4.0%)
Week 16	m		130	123	63	64	64	64	62	69	63	572	702
	Negative	Negative	117 (90.0%)	106 (86.2%)	47 (74.6%)	54 (84.4%)	53 (82.8%)	59 (92.2%)	54 (87.1%)	57 (82.6%)	57 (90.5%)	487 (85.1%)	604 (86.0%)
		Trace	1 (0.8%)	3 (2.4%)	1 (1.6%)	2 (3.1%)	0	0	1 (1.6%)	0	0	7 (1.2%)	8 (1.1%)
		Positive	5 (3.8%)	1 (0.8%)	4 (6.3%)	4 (6.3%)	2 (3.1%)	1 (1.6%)	2 (3.2%)	2 (2.9%)	3 (4.8%)	19 (3.3%)	24 (3.4%)
	Trace	Negative	0	2 (1.6%)	1 (1.6%)	0	0	1 (1.6%)	0	2 (2.9%)	0	6 (1.0%)	6 (0.9%)
		Trace	0	1 (0.8%)	0	0	0	0	0	0	1 (1.6%)	2 (0.3%)	2 (0.3%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
		Positive	0	0	0	3 (4.7%)	0	0	1 (1.6%)	2 (2.9%)	0	6 (1.0%)	6 (0.9%)
	Positive	Negative	4 (3.1%)	4 (3.3%)	6 (9.5%)	0	4 (6.3%)	1 (1.6%)	1 (1.6%)	0	1 (1.6%)	17 (3.0%)	21 (3.0%)
		Trace	1 (0.8%)	0	1 (1.6%)	0	1 (1.6%)	0	0	1 (1.4%)	0	3 (0.5%)	4 (0.6%)
		Positive	2 (1.5%)	6 (4.9%)	3 (4.8%)	1 (1.6%)	4 (6.3%)	2 (3.1%)	3 (4.8%)	5 (7.2%)	1 (1.6%)	25 (4.4%)	27 (3.8%)
Week 20	m		130	123	62	63	64	65	61	69	63	570	700
	Negative	Negative	115 (88.5%)	106 (86.2%)	47 (75.8%)	54 (85.7%)	51 (79.7%)	59 (90.8%)	52 (85.2%)	59 (85.5%)	57 (90.5%)	485 (85.1%)	600 (85.7%)
		Trace	1 (0.8%)	1 (0.8%)	1 (1.6%)	3 (4.8%)	2 (3.1%)	1 (1.5%)	2 (3.3%)	0	1 (1.6%)	11 (1.9%)	12 (1.7%)
		Positive	7 (5.4%)	3 (2.4%)	3 (4.8%)	3 (4.8%)	2 (3.1%)	1 (1.5%)	2 (3.3%)	0	2 (3.2%)	16 (2.8%)	23 (3.3%)
	Trace	Negative	0	1 (0.8%)	1 (1.6%)	2 (3.2%)	0	1 (1.5%)	0	2 (2.9%)	0	7 (1.2%)	7 (1.0%)
		Positive	0	2 (1.6%)	0	0	0	0	1 (1.6%)	2 (2.9%)	1 (1.6%)	6 (1.1%)	6 (0.9%)
	Positive	Negative	2 (1.5%)	5 (4.1%)	6 (9.7%)	0	4 (6.3%)	1 (1.5%)	1 (1.6%)	2 (2.9%)	1 (1.6%)	20 (3.5%)	22 (3.1%)
		Trace	2 (1.5%)	1 (0.8%)	0	1 (1.6%)	0	0	0	0	1 (1.6%)	3 (0.5%)	5 (0.7%)
		Positive	3 (2.3%)	4 (3.3%)	4 (6.5%)	0	5 (7.8%)	2 (3.1%)	3 (4.9%)	4 (5.8%)	0	22 (3.9%)	25 (3.6%)
Week 24	m		130	122	62	63	64	65	61	69	63	569	699
	Negative	Negative	118 (90.8%)	105 (86.1%)	49 (79.0%)	55 (87.3%)	52 (81.3%)	58 (89.2%)	50 (82.0%)	57 (82.6%)	59 (93.7%)	485 (85.2%)	603 (86.3%)
		Trace	1 (0.8%)	0	1 (1.6%)	2 (3.2%)	1 (1.6%)	1 (1.5%)	3 (4.9%)	2 (2.9%)	0	10 (1.8%)	11 (1.6%)
		Positive	4 (3.1%)	4 (3.3%)	1 (1.6%)	3 (4.8%)	2 (3.1%)	2 (3.1%)	3 (4.9%)	0	1 (1.6%)	16 (2.8%)	20 (2.9%)
	Trace	Negative	0	2 (1.6%)	1 (1.6%)	2 (3.2%)	0	1 (1.5%)	0	1 (1.4%)	1 (1.6%)	8 (1.4%)	8 (1.1%)
		Trace	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
		Positive	0	0	0	0	0	0	1 (1.6%)	3 (4.3%)	0	4 (0.7%)	4 (0.6%)
	Positive	Negative	4 (3.1%)	4 (3.3%)	4 (6.5%)	0	4 (6.3%)	0	1 (1.6%)	0	2 (3.2%)	15 (2.6%)	19 (2.7%)
		Trace	1 (0.8%)	1 (0.8%)	0	0	2 (3.1%)	0	0	0	0	3 (0.5%)	4 (0.6%)
		Positive	2 (1.5%)	5 (4.1%)	6 (9.7%)	1 (1.6%)	3 (4.7%)	3 (4.6%)	3 (4.9%)	6 (8.7%)	0	27 (4.7%)	29 (4.1%)
Week 32	m		128	120	62	60	62	65	60	69	63	561	689

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
	Negative	Negative	116 (90.6%)	104 (86.7%)	49 (79.0%)	52 (86.7%)	52 (83.9%)	57 (87.7%)	52 (86.7%)	58 (84.1%)	56 (88.9%)	480 (85.6%)	596 (86.5%)
		Trace	2 (1.6%)	0	1 (1.6%)	2 (3.3%)	0	2 (3.1%)	0	0	2 (3.2%)	7 (1.2%)	9 (1.3%)
		Positive	3 (2.3%)	3 (2.5%)	1 (1.6%)	3 (5.0%)	1 (1.6%)	2 (3.1%)	3 (5.0%)	1 (1.4%)	2 (3.2%)	16 (2.9%)	19 (2.8%)
	Trace	Negative	0	1 (0.8%)	1 (1.6%)	2 (3.3%)	0	0	0	2 (2.9%)	0	6 (1.1%)	6 (0.9%)
		Trace	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
		Positive	0	1 (0.8%)	0	0	0	1 (1.5%)	1 (1.7%)	2 (2.9%)	1 (1.6%)	6 (1.1%)	6 (0.9%)
	Positive	Negative	4 (3.1%)	4 (3.3%)	6 (9.7%)	0	4 (6.5%)	2 (3.1%)	0	0	1 (1.6%)	17 (3.0%)	21 (3.0%)
		Trace	0	2 (1.7%)	2 (3.2%)	0	1 (1.6%)	1 (1.5%)	0	0	0	6 (1.1%)	6 (0.9%)
		Positive	3 (2.3%)	4 (3.3%)	2 (3.2%)	1 (1.7%)	4 (6.5%)	0	4 (6.7%)	6 (8.7%)	1 (1.6%)	22 (3.9%)	25 (3.6%)
Week 40	m		128	120	60	59	62	65	60	69	63	558	686
	Negative	Negative	113 (88.3%)	104 (86.7%)	45 (75.0%)	53 (89.8%)	52 (83.9%)	58 (89.2%)	54 (90.0%)	55 (79.7%)	55 (87.3%)	476 (85.3%)	589 (85.9%)
		Trace	2 (1.6%)	1 (0.8%)	1 (1.7%)	2 (3.4%)	0	2 (3.1%)	1 (1.7%)	2 (2.9%)	0	9 (1.6%)	11 (1.6%)
		Positive	6 (4.7%)	2 (1.7%)	3 (5.0%)	1 (1.7%)	1 (1.6%)	1 (1.5%)	1 (1.7%)	2 (2.9%)	5 (7.9%)	16 (2.9%)	22 (3.2%)
	Trace	Negative	0	2 (1.7%)	1 (1.7%)	1 (1.7%)	0	1 (1.5%)	1 (1.7%)	2 (2.9%)	0	8 (1.4%)	8 (1.2%)
		Trace	0	0	0	1 (1.7%)	0	0	0	1 (1.4%)	0	2 (0.4%)	2 (0.3%)
		Positive	0	1 (0.8%)	0	0	0	0	0	1 (1.4%)	1 (1.6%)	3 (0.5%)	3 (0.4%)
	Positive	Negative	4 (3.1%)	4 (3.3%)	5 (8.3%)	0	6 (9.7%)	0	1 (1.7%)	1 (1.4%)	2 (3.2%)	19 (3.4%)	23 (3.4%)
		Trace	0	2 (1.7%)	1 (1.7%)	0	0	0	0	1 (1.4%)	0	4 (0.7%)	4 (0.6%)
		Positive	3 (2.3%)	4 (3.3%)	4 (6.7%)	1 (1.7%)	3 (4.8%)	3 (4.6%)	2 (3.3%)	4 (5.8%)	0	21 (3.8%)	24 (3.5%)
Week 48	m		127	118	60	59	62	65	60	66	63	553	680
	Negative	Negative	112 (88.2%)	99 (83.9%)	45 (75.0%)	54 (91.5%)	50 (80.6%)	59 (90.8%)	53 (88.3%)	55 (83.3%)	54 (85.7%)	469 (84.8%)	581 (85.4%)
		Trace	5 (3.9%)	3 (2.5%)	2 (3.3%)	0	0	0	2 (3.3%)	1 (1.5%)	3 (4.8%)	11 (2.0%)	16 (2.4%)
		Positive	3 (2.4%)	4 (3.4%)	2 (3.3%)	2 (3.4%)	3 (4.8%)	2 (3.1%)	1 (1.7%)	1 (1.5%)	3 (4.8%)	18 (3.3%)	21 (3.1%)
	Trace	Negative	0	2 (1.7%)	1 (1.7%)	1 (1.7%)	0	1 (1.5%)	1 (1.7%)	3 (4.5%)	1 (1.6%)	10 (1.8%)	10 (1.5%)
		Positive	0	0	0	1 (1.7%)	0	0	0	1 (1.5%)	0	2 (0.4%)	2 (0.3%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
	Positive	Negative	5 (3.9%)	4 (3.4%)	6 (10.0%)	0	7 (11.3%)	1 (1.5%)	1 (1.7%)	1 (1.5%)	2 (3.2%)	22 (4.0%)	27 (4.0%)
		Trace	2 (1.6%)	2 (1.7%)	0	0	1 (1.6%)	0	1 (1.7%)	0	0	4 (0.7%)	6 (0.9%)
		Positive	0	4 (3.4%)	4 (6.7%)	1 (1.7%)	1 (1.6%)	2 (3.1%)	1 (1.7%)	4 (6.1%)	0	17 (3.1%)	17 (2.5%)
Week 52	m		126	116	59	58	62	65	60	67	62	549	675
	Negative	Negative	113 (89.7%)	101 (87.1%)	43 (72.9%)	52 (89.7%)	52 (83.9%)	58 (89.2%)	52 (86.7%)	57 (85.1%)	55 (88.7%)	470 (85.6%)	583 (86.4%)
		Trace	0	1 (0.9%)	2 (3.4%)	1 (1.7%)	0	1 (1.5%)	3 (5.0%)	1 (1.5%)	3 (4.8%)	12 (2.2%)	12 (1.8%)
		Positive	6 (4.8%)	2 (1.7%)	3 (5.1%)	2 (3.4%)	1 (1.6%)	2 (3.1%)	1 (1.7%)	0	1 (1.6%)	12 (2.2%)	18 (2.7%)
	Trace	Negative	0	2 (1.7%)	1 (1.7%)	1 (1.7%)	0	1 (1.5%)	0	4 (6.0%)	0	9 (1.6%)	9 (1.3%)
		Trace	0	0	0	1 (1.7%)	0	0	1 (1.7%)	0	0	2 (0.4%)	2 (0.3%)
		Positive	0	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	1 (0.1%)
	Positive	Negative	4 (3.2%)	4 (3.4%)	7 (11.9%)	0	5 (8.1%)	0	1 (1.7%)	0	2 (3.2%)	19 (3.5%)	23 (3.4%)
		Trace	0	2 (1.7%)	0	0	2 (3.2%)	1 (1.5%)	0	0	0	5 (0.9%)	5 (0.7%)
		Positive	3 (2.4%)	4 (3.4%)	3 (5.1%)	1 (1.7%)	2 (3.2%)	2 (3.1%)	2 (3.3%)	5 (7.5%)	0	19 (3.5%)	22 (3.3%)
LOCF Endpoint	m		134	127	64	64	64	65	63	70	63	580	714
	Negative	Negative	120 (89.6%)	110 (86.6%)	47 (73.4%)	57 (89.1%)	54 (84.4%)	58 (89.2%)	54 (85.7%)	59 (84.3%)	56 (88.9%)	495 (85.3%)	615 (86.1%)
		Trace	0	2 (1.6%)	2 (3.1%)	1 (1.6%)	0	1 (1.5%)	3 (4.8%)	1 (1.4%)	3 (4.8%)	13 (2.2%)	13 (1.8%)
		Positive	6 (4.5%)	2 (1.6%)	4 (6.3%)	2 (3.1%)	1 (1.6%)	2 (3.1%)	1 (1.6%)	0	1 (1.6%)	13 (2.2%)	19 (2.7%)
	Trace	Negative	1 (0.7%)	2 (1.6%)	1 (1.6%)	1 (1.6%)	0	1 (1.5%)	0	4 (5.7%)	0	9 (1.6%)	10 (1.4%)
		Trace	0	0	0	1 (1.6%)	0	0	1 (1.6%)	0	0	2 (0.3%)	2 (0.3%)
		Positive	0	1 (0.8%)	0	1 (1.6%)	0	0	0	0	1 (1.6%)	3 (0.5%)	3 (0.4%)
	Positive	Negative	4 (3.0%)	4 (3.1%)	7 (10.9%)	0	5 (7.8%)	0	1 (1.6%)	0	2 (3.2%)	19 (3.3%)	23 (3.2%)
		Trace	0	2 (1.6%)	0	0	2 (3.1%)	1 (1.5%)	0	0	0	5 (0.9%)	5 (0.7%)
		Positive	3 (2.2%)	4 (3.1%)	3 (4.7%)	1 (1.6%)	2 (3.1%)	2 (3.1%)	3 (4.8%)	6 (8.6%)	0	21 (3.6%)	24 (3.4%)
Nitrite													

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
Week 4	m		134	127	64	64	64	65	63	70	63	580	714
	Negative	Negative	133 (99.3%)	121 (95.3%)	62 (96.9%)	62 (96.9%)	61 (95.3%)	63 (96.9%)	60 (95.2%)	65 (92.9%)	63 (100.0%)	557 (96.0%)	690 (96.6%)
		Positive	0	1 (0.8%)	1 (1.6%)	1 (1.6%)	1 (1.6%)	1 (1.5%)	0	1 (1.4%)	0	6 (1.0%)	6 (0.8%)
	Positive	Negative	0	3 (2.4%)	0	0	1 (1.6%)	0	0	1 (1.4%)	0	5 (0.9%)	5 (0.7%)
		Positive	1 (0.7%)	2 (1.6%)	1 (1.6%)	1 (1.6%)	1 (1.6%)	1 (1.5%)	3 (4.8%)	3 (4.3%)	0	12 (2.1%)	13 (1.8%)
Week 8	m		132	126	63	64	64	65	62	69	63	576	708
	Negative	Negative	131 (99.2%)	122 (96.8%)	61 (96.8%)	63 (98.4%)	61 (95.3%)	64 (98.5%)	59 (95.2%)	65 (94.2%)	62 (98.4%)	557 (96.7%)	688 (97.2%)
		Positive	0	0	1 (1.6%)	0	1 (1.6%)	0	0	0	1 (1.6%)	3 (0.5%)	3 (0.4%)
	Positive	Negative	1 (0.8%)	2 (1.6%)	1 (1.6%)	0	1 (1.6%)	1 (1.5%)	0	2 (2.9%)	0	7 (1.2%)	8 (1.1%)
		Positive	0	2 (1.6%)	0	1 (1.6%)	1 (1.6%)	0	3 (4.8%)	2 (2.9%)	0	9 (1.6%)	9 (1.3%)
Week 12	m		131	123	63	64	64	65	62	68	63	572	703
	Negative	Negative	129 (98.5%)	118 (95.9%)	61 (96.8%)	62 (96.9%)	61 (95.3%)	63 (96.9%)	59 (95.2%)	64 (94.1%)	62 (98.4%)	550 (96.2%)	679 (96.6%)
		Positive	1 (0.8%)	1 (0.8%)	1 (1.6%)	1 (1.6%)	1 (1.6%)	1 (1.5%)	0	1 (1.5%)	1 (1.6%)	7 (1.2%)	8 (1.1%)
	Positive	Negative	1 (0.8%)	2 (1.6%)	1 (1.6%)	0	1 (1.6%)	0	0	0	0	4 (0.7%)	5 (0.7%)
		Positive	0	2 (1.6%)	0	1 (1.6%)	1 (1.6%)	1 (1.5%)	3 (4.8%)	3 (4.4%)	0	11 (1.9%)	11 (1.6%)
Week 16	m		130	123	63	64	64	64	62	69	63	572	702
	Negative	Negative	127 (97.7%)	119 (96.7%)	61 (96.8%)	62 (96.9%)	60 (93.8%)	62 (96.9%)	58 (93.5%)	64 (92.8%)	62 (98.4%)	548 (95.8%)	675 (96.2%)
		Positive	2 (1.5%)	0	1 (1.6%)	1 (1.6%)	2 (3.1%)	1 (1.6%)	1 (1.6%)	1 (1.4%)	1 (1.6%)	8 (1.4%)	10 (1.4%)
	Positive	Negative	1 (0.8%)	1 (0.8%)	0	0	0	1 (1.6%)	1 (1.6%)	4 (5.8%)	0	7 (1.2%)	8 (1.1%)
		Positive	0	3 (2.4%)	1 (1.6%)	1 (1.6%)	2 (3.1%)	0	2 (3.2%)	0	0	9 (1.6%)	9 (1.3%)
Week 20	m		130	123	62	63	64	65	61	69	63	570	700
	Negative	Negative	128 (98.5%)	119 (96.7%)	59 (95.2%)	60 (95.2%)	62 (96.9%)	63 (96.9%)	58 (95.1%)	65 (94.2%)	63 (100.0%)	549 (96.3%)	677 (96.7%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
		Positive	1 (0.8%)	0	2 (3.2%)	2 (3.2%)	0	1 (1.5%)	0	0	0	5 (0.9%)	6 (0.9%)
	Positive	Negative	1 (0.8%)	1 (0.8%)	0	0	0	1 (1.5%)	1 (1.6%)	2 (2.9%)	0	5 (0.9%)	6 (0.9%)
		Positive	0	3 (2.4%)	1 (1.6%)	1 (1.6%)	2 (3.1%)	0	2 (3.3%)	2 (2.9%)	0	11 (1.9%)	11 (1.6%)
Week 24	m		130	122	62	63	64	65	61	69	63	569	699
	Negative	Negative	128 (98.5%)	116 (95.1%)	60 (96.8%)	62 (98.4%)	60 (93.8%)	63 (96.9%)	58 (95.1%)	64 (92.8%)	62 (98.4%)	545 (95.8%)	673 (96.3%)
		Positive	1 (0.8%)	2 (1.6%)	1 (1.6%)	0	2 (3.1%)	1 (1.5%)	0	1 (1.4%)	1 (1.6%)	8 (1.4%)	9 (1.3%)
	Positive	Negative	0	2 (1.6%)	1 (1.6%)	0	0	1 (1.5%)	0	1 (1.4%)	0	5 (0.9%)	5 (0.7%)
		Positive	1 (0.8%)	2 (1.6%)	0	1 (1.6%)	2 (3.1%)	0	3 (4.9%)	3 (4.3%)	0	11 (1.9%)	12 (1.7%)
Week 32	m		128	120	62	60	62	65	60	69	63	561	689
	Negative	Negative	126 (98.4%)	115 (95.8%)	61 (98.4%)	59 (98.3%)	59 (95.2%)	63 (96.9%)	57 (95.0%)	64 (92.8%)	62 (98.4%)	540 (96.3%)	666 (96.7%)
		Positive	1 (0.8%)	1 (0.8%)	0	0	1 (1.6%)	1 (1.5%)	0	1 (1.4%)	1 (1.6%)	5 (0.9%)	6 (0.9%)
	Positive	Negative	0	2 (1.7%)	1 (1.6%)	0	0	1 (1.5%)	2 (3.3%)	1 (1.4%)	0	7 (1.2%)	7 (1.0%)
		Positive	1 (0.8%)	2 (1.7%)	0	1 (1.7%)	2 (3.2%)	0	1 (1.7%)	3 (4.3%)	0	9 (1.6%)	10 (1.5%)
Week 40	m		128	120	60	59	62	65	60	69	63	558	686
	Negative	Negative	127 (99.2%)	115 (95.8%)	59 (98.3%)	57 (96.6%)	59 (95.2%)	63 (96.9%)	58 (96.7%)	64 (92.8%)	63 (100.0%)	538 (96.4%)	665 (96.9%)
		Positive	0	1 (0.8%)	0	1 (1.7%)	1 (1.6%)	1 (1.5%)	0	1 (1.4%)	0	5 (0.9%)	5 (0.7%)
	Positive	Negative	0	1 (0.8%)	1 (1.7%)	0	1 (1.6%)	1 (1.5%)	0	2 (2.9%)	0	6 (1.1%)	6 (0.9%)
		Positive	1 (0.8%)	3 (2.5%)	0	1 (1.7%)	1 (1.6%)	0	2 (3.3%)	2 (2.9%)	0	9 (1.6%)	10 (1.5%)
Week 48	m		127	118	60	59	62	65	60	66	63	553	680
	Negative	Negative	125 (98.4%)	113 (95.8%)	58 (96.7%)	57 (96.6%)	59 (95.2%)	63 (96.9%)	58 (96.7%)	62 (93.9%)	62 (98.4%)	532 (96.2%)	657 (96.6%)
		Positive	1 (0.8%)	1 (0.8%)	1 (1.7%)	1 (1.7%)	1 (1.6%)	1 (1.5%)	0	1 (1.5%)	1 (1.6%)	7 (1.3%)	8 (1.2%)
	Positive	Negative	0	1 (0.8%)	0	1 (1.7%)	0	1 (1.5%)	0	0	0	3 (0.5%)	3 (0.4%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
		Positive	1 (0.8%)	3 (2.5%)	1 (1.7%)	0	2 (3.2%)	0	2 (3.3%)	3 (4.5%)	0	11 (2.0%)	12 (1.8%)
Week 52	m		126	116	59	58	62	65	60	67	62	549	675
	Negative	Negative	124 (98.4%)	112 (96.6%)	58 (98.3%)	56 (96.6%)	59 (95.2%)	64 (98.5%)	58 (96.7%)	63 (94.0%)	61 (98.4%)	531 (96.7%)	655 (97.0%)
		Positive	1 (0.8%)	0	0	1 (1.7%)	1 (1.6%)	0	0	1 (1.5%)	1 (1.6%)	4 (0.7%)	5 (0.7%)
	Positive	Negative	0	2 (1.7%)	0	0	0	0	0	1 (1.5%)	0	3 (0.5%)	3 (0.4%)
		Positive	1 (0.8%)	2 (1.7%)	1 (1.7%)	1 (1.7%)	2 (3.2%)	1 (1.5%)	2 (3.3%)	2 (3.0%)	0	11 (2.0%)	12 (1.8%)
LOCF Endpoint	m		134	127	64	64	64	65	63	70	63	580	714
	Negative	Negative	132 (98.5%)	122 (96.1%)	62 (96.9%)	62 (96.9%)	61 (95.3%)	64 (98.5%)	60 (95.2%)	65 (92.9%)	62 (98.4%)	558 (96.2%)	690 (96.6%)
		Positive	1 (0.7%)	0	1 (1.6%)	1 (1.6%)	1 (1.6%)	0	0	1 (1.4%)	1 (1.6%)	5 (0.9%)	6 (0.8%)
	Positive	Negative	0	3 (2.4%)	0	0	0	0	1 (1.6%)	2 (2.9%)	0	6 (1.0%)	6 (0.8%)
		Positive	1 (0.7%)	2 (1.6%)	1 (1.6%)	1 (1.6%)	2 (3.1%)	1 (1.5%)	2 (3.2%)	2 (2.9%)	0	11 (1.9%)	12 (1.7%)
Occult Blood													
Week 4	m		134	127	64	64	64	65	63	70	63	580	714
	Negative	Negative	132 (98.5%)	122 (96.1%)	63 (98.4%)	61 (95.3%)	58 (90.6%)	62 (95.4%)	59 (93.7%)	65 (92.9%)	63 (100.0%)	553 (95.3%)	685 (95.9%)
		Trace	1 (0.7%)	0	0	1 (1.6%)	2 (3.1%)	2 (3.1%)	0	0	0	5 (0.9%)	6 (0.8%)
		Positive	0	1 (0.8%)	0	0	2 (3.1%)	0	2 (3.2%)	1 (1.4%)	0	6 (1.0%)	6 (0.8%)
	Trace	Negative	1 (0.7%)	0	0	0	1 (1.6%)	0	1 (1.6%)	3 (4.3%)	0	5 (0.9%)	6 (0.8%)
		Trace	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
	Positive	Negative	0	3 (2.4%)	0	1 (1.6%)	0	1 (1.5%)	0	0	0	5 (0.9%)	5 (0.7%)
		Positive	0	0	1 (1.6%)	1 (1.6%)	1 (1.6%)	0	1 (1.6%)	1 (1.4%)	0	5 (0.9%)	5 (0.7%)
Week 8	m		132	126	63	64	64	65	62	69	63	576	708
	Negative	Negative	129 (97.7%)	121 (96.0%)	62 (98.4%)	62 (96.9%)	59 (92.2%)	63 (96.9%)	60 (96.8%)	64 (92.8%)	62 (98.4%)	553 (96.0%)	682 (96.3%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
		Trace	1 (0.8%)	0	0	0	1 (1.6%)	1 (1.5%)	0	1 (1.4%)	1 (1.6%)	4 (0.7%)	5 (0.7%)
		Positive	1 (0.8%)	1 (0.8%)	0	0	2 (3.1%)	0	0	0	0	3 (0.5%)	4 (0.6%)
	Trace	Negative	1 (0.8%)	1 (0.8%)	0	0	1 (1.6%)	0	1 (1.6%)	2 (2.9%)	0	5 (0.9%)	6 (0.8%)
		Trace	0	0	0	0	0	0	0	1 (1.4%)	0	1 (0.2%)	1 (0.1%)
	Positive	Negative	0	3 (2.4%)	0	1 (1.6%)	1 (1.6%)	1 (1.5%)	1 (1.6%)	0	0	7 (1.2%)	7 (1.0%)
		Trace	0	0	1 (1.6%)	1 (1.6%)	0	0	0	0	0	2 (0.3%)	2 (0.3%)
		Positive	0	0	0	0	0	0	0	1 (1.4%)	0	1 (0.2%)	1 (0.1%)
Week 12	m		131	123	63	64	64	65	62	68	63	572	703
	Negative	Negative	130 (99.2%)	119 (96.7%)	62 (98.4%)	61 (95.3%)	59 (92.2%)	64 (98.5%)	58 (93.5%)	62 (91.2%)	62 (98.4%)	547 (95.6%)	677 (96.3%)
		Trace	0	0	0	0	1 (1.6%)	0	2 (3.2%)	2 (2.9%)	0	5 (0.9%)	5 (0.7%)
		Positive	0	0	0	1 (1.6%)	2 (3.1%)	0	0	0	1 (1.6%)	4 (0.7%)	4 (0.6%)
	Trace	Negative	1 (0.8%)	1 (0.8%)	0	0	1 (1.6%)	0	1 (1.6%)	2 (2.9%)	0	5 (0.9%)	6 (0.9%)
		Trace	0	0	0	0	0	0	0	1 (1.5%)	0	1 (0.2%)	1 (0.1%)
	Positive	Negative	0	2 (1.6%)	0	1 (1.6%)	0	1 (1.5%)	0	0	0	4 (0.7%)	4 (0.6%)
		Trace	0	0	0	1 (1.6%)	0	0	0	0	0	1 (0.2%)	1 (0.1%)
		Positive	0	1 (0.8%)	1 (1.6%)	0	1 (1.6%)	0	1 (1.6%)	1 (1.5%)	0	5 (0.9%)	5 (0.7%)
Week 16	m		130	123	63	64	64	64	62	69	63	572	702
	Negative	Negative	129 (99.2%)	119 (96.7%)	61 (96.8%)	61 (95.3%)	58 (90.6%)	62 (96.9%)	59 (95.2%)	64 (92.8%)	63 (100.0%)	547 (95.6%)	676 (96.3%)
		Trace	0	0	1 (1.6%)	1 (1.6%)	2 (3.1%)	1 (1.6%)	0	0	0	5 (0.9%)	5 (0.7%)
		Positive	0	0	0	0	2 (3.1%)	0	1 (1.6%)	1 (1.4%)	0	4 (0.7%)	4 (0.6%)
	Trace	Negative	1 (0.8%)	0	0	0	1 (1.6%)	0	1 (1.6%)	2 (2.9%)	0	4 (0.7%)	5 (0.7%)
		Trace	0	1 (0.8%)	0	0	0	0	0	1 (1.4%)	0	2 (0.3%)	2 (0.3%)
	Positive	Negative	0	3 (2.4%)	1 (1.6%)	1 (1.6%)	0	1 (1.6%)	0	0	0	6 (1.0%)	6 (0.9%)
		Positive	0	0	0	1 (1.6%)	1 (1.6%)	0	1 (1.6%)	1 (1.4%)	0	4 (0.7%)	4 (0.6%)
Week 20	m		130	123	62	63	64	65	61	69	63	570	700

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
	Negative	Negative	128 (98.5%)	119 (96.7%)	58 (93.5%)	60 (95.2%)	61 (95.3%)	63 (96.9%)	58 (95.1%)	63 (91.3%)	63 (100.0%)	545 (95.6%)	673 (96.1%)
		Trace	1 (0.8%)	0	0	0	0	1 (1.5%)	1 (1.6%)	1 (1.4%)	0	3 (0.5%)	4 (0.6%)
		Positive	0	0	3 (4.8%)	1 (1.6%)	1 (1.6%)	0	0	1 (1.4%)	0	6 (1.1%)	6 (0.9%)
	Trace	Negative	1 (0.8%)	0	0	0	1 (1.6%)	0	1 (1.6%)	3 (4.3%)	0	5 (0.9%)	6 (0.9%)
		Trace	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
	Positive	Negative	0	2 (1.6%)	1 (1.6%)	1 (1.6%)	0	1 (1.5%)	0	0	0	5 (0.9%)	5 (0.7%)
		Trace	0	1 (0.8%)	0	1 (1.6%)	0	0	0	0	0	2 (0.4%)	2 (0.3%)
		Positive	0	0	0	0	1 (1.6%)	0	1 (1.6%)	1 (1.4%)	0	3 (0.5%)	3 (0.4%)
Week 24	m		130	122	62	63	64	65	61	69	63	569	699
	Negative	Negative	129 (99.2%)	116 (95.1%)	59 (95.2%)	59 (93.7%)	60 (93.8%)	60 (92.3%)	56 (91.8%)	63 (91.3%)	62 (98.4%)	535 (94.0%)	664 (95.0%)
		Trace	0	2 (1.6%)	0	0	1 (1.6%)	4 (6.2%)	2 (3.3%)	1 (1.4%)	0	10 (1.8%)	10 (1.4%)
		Positive	0	0	2 (3.2%)	2 (3.2%)	1 (1.6%)	0	1 (1.6%)	1 (1.4%)	1 (1.6%)	8 (1.4%)	8 (1.1%)
	Trace	Negative	1 (0.8%)	0	0	0	1 (1.6%)	0	1 (1.6%)	3 (4.3%)	0	5 (0.9%)	6 (0.9%)
		Trace	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
	Positive	Negative	0	3 (2.5%)	0	1 (1.6%)	0	1 (1.5%)	0	0	0	5 (0.9%)	5 (0.7%)
		Positive	0	0	1 (1.6%)	1 (1.6%)	1 (1.6%)	0	1 (1.6%)	1 (1.4%)	0	5 (0.9%)	5 (0.7%)
Week 32	m		128	120	62	60	62	65	60	69	63	561	689
	Negative	Negative	123 (96.1%)	116 (96.7%)	60 (96.8%)	57 (95.0%)	57 (91.9%)	63 (96.9%)	58 (96.7%)	64 (92.8%)	60 (95.2%)	535 (95.4%)	658 (95.5%)
		Trace	2 (1.6%)	0	0	0	3 (4.8%)	0	0	1 (1.4%)	1 (1.6%)	5 (0.9%)	7 (1.0%)
		Positive	2 (1.6%)	0	1 (1.6%)	1 (1.7%)	0	1 (1.5%)	0	0	2 (3.2%)	5 (0.9%)	7 (1.0%)
	Trace	Negative	1 (0.8%)	1 (0.8%)	0	0	1 (1.6%)	0	1 (1.7%)	3 (4.3%)	0	6 (1.1%)	7 (1.0%)
	Positive	Negative	0	3 (2.5%)	1 (1.6%)	1 (1.7%)	0	1 (1.5%)	0	0	0	6 (1.1%)	6 (0.9%)
		Trace	0	0	0	0	0	0	0	1 (1.4%)	0	1 (0.2%)	1 (0.1%)
		Positive	0	0	0	1 (1.7%)	1 (1.6%)	0	1 (1.7%)	0	0	3 (0.5%)	3 (0.4%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
Week 40	m		128	120	60	59	62	65	60	69	63	558	686
	Negative	Negative	125 (97.7%)	113 (94.2%)	59 (98.3%)	54 (91.5%)	60 (96.8%)	62 (95.4%)	57 (95.0%)	65 (94.2%)	61 (96.8%)	531 (95.2%)	656 (95.6%)
		Trace	2 (1.6%)	2 (1.7%)	0	1 (1.7%)	0	1 (1.5%)	1 (1.7%)	0	1 (1.6%)	6 (1.1%)	8 (1.2%)
		Positive	0	1 (0.8%)	0	2 (3.4%)	0	1 (1.5%)	1 (1.7%)	0	1 (1.6%)	6 (1.1%)	6 (0.9%)
	Trace	Negative	1 (0.8%)	1 (0.8%)	0	0	1 (1.6%)	0	1 (1.7%)	3 (4.3%)	0	6 (1.1%)	7 (1.0%)
	Positive	Negative	0	3 (2.5%)	1 (1.7%)	1 (1.7%)	0	1 (1.5%)	0	0	0	6 (1.1%)	6 (0.9%)
		Trace	0	0	0	1 (1.7%)	0	0	0	1 (1.4%)	0	2 (0.4%)	2 (0.3%)
		Positive	0	0	0	0	1 (1.6%)	0	0	0	0	1 (0.2%)	1 (0.1%)
Week 48	m		127	118	60	59	62	65	60	66	63	553	680
	Negative	Negative	125 (98.4%)	113 (95.8%)	58 (96.7%)	55 (93.2%)	60 (96.8%)	63 (96.9%)	57 (95.0%)	62 (93.9%)	61 (96.8%)	529 (95.7%)	654 (96.2%)
		Trace	1 (0.8%)	0	0	1 (1.7%)	0	0	1 (1.7%)	0	1 (1.6%)	3 (0.5%)	4 (0.6%)
		Positive	0	1 (0.8%)	1 (1.7%)	1 (1.7%)	0	1 (1.5%)	1 (1.7%)	1 (1.5%)	1 (1.6%)	7 (1.3%)	7 (1.0%)
	Trace	Negative	0	0	0	0	1 (1.6%)	0	1 (1.7%)	3 (4.5%)	0	5 (0.9%)	5 (0.7%)
		Trace	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
		Positive	1 (0.8%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
	Positive	Negative	0	2 (1.7%)	1 (1.7%)	2 (3.4%)	0	1 (1.5%)	0	0	0	6 (1.1%)	6 (0.9%)
		Positive	0	1 (0.8%)	0	0	1 (1.6%)	0	0	0	0	2 (0.4%)	2 (0.3%)
Week 52	m		126	116	59	58	62	65	60	67	62	549	675
	Negative	Negative	122 (96.8%)	110 (94.8%)	58 (98.3%)	54 (93.1%)	59 (95.2%)	64 (98.5%)	55 (91.7%)	62 (92.5%)	60 (96.8%)	522 (95.1%)	644 (95.4%)
		Trace	3 (2.4%)	0	0	0	1 (1.6%)	0	1 (1.7%)	2 (3.0%)	1 (1.6%)	5 (0.9%)	8 (1.2%)
		Positive	0	2 (1.7%)	0	2 (3.4%)	0	0	3 (5.0%)	0	1 (1.6%)	8 (1.5%)	8 (1.2%)
	Trace	Negative	1 (0.8%)	0	0	0	1 (1.6%)	0	0	2 (3.0%)	0	3 (0.5%)	4 (0.6%)
		Trace	0	1 (0.9%)	0	0	0	0	1 (1.7%)	0	0	2 (0.4%)	2 (0.3%)
		Positive	0	0	0	0	0	0	0	1 (1.5%)	0	1 (0.2%)	1 (0.1%)
	Positive	Negative	0	2 (1.7%)	1 (1.7%)	1 (1.7%)	0	1 (1.5%)	0	0	0	5 (0.9%)	5 (0.7%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
		Positive	0	1 (0.9%)	0	1 (1.7%)	1 (1.6%)	0	0	0	0	3 (0.5%)	3 (0.4%)
LOCF Endpoint	m		134	127	64	64	64	65	63	70	63	580	714
	Negative	Negative	130 (97.0%)	120 (94.5%)	63 (98.4%)	60 (93.8%)	61 (95.3%)	64 (98.5%)	57 (90.5%)	64 (91.4%)	61 (96.8%)	550 (94.8%)	680 (95.2%)
		Trace	3 (2.2%)	1 (0.8%)	0	0	1 (1.6%)	0	1 (1.6%)	2 (2.9%)	1 (1.6%)	6 (1.0%)	9 (1.3%)
		Positive	0	2 (1.6%)	0	2 (3.1%)	0	0	3 (4.8%)	0	1 (1.6%)	8 (1.4%)	8 (1.1%)
	Trace	Negative	1 (0.7%)	0	0	0	1 (1.6%)	0	0	2 (2.9%)	0	3 (0.5%)	4 (0.6%)
		Trace	0	1 (0.8%)	0	0	0	0	1 (1.6%)	0	0	2 (0.3%)	2 (0.3%)
		Positive	0	0	0	0	0	0	0	1 (1.4%)	0	1 (0.2%)	1 (0.1%)
	Positive	Negative	0	2 (1.6%)	1 (1.6%)	1 (1.6%)	0	1 (1.5%)	0	0	0	5 (0.9%)	5 (0.7%)
		Positive	0	1 (0.8%)	0	1 (1.6%)	1 (1.6%)	0	1 (1.6%)	1 (1.4%)	0	5 (0.9%)	5 (0.7%)
pH													
Week 4	m		134	127	64	64	64	65	63	70	63	580	714
	5.5	5.5	14 (10.4%)	15 (11.8%)	4 (6.3%)	10 (15.6%)	4 (6.3%)	6 (9.2%)	9 (14.3%)	9 (12.9%)	20 (31.7%)	77 (13.3%)	91 (12.7%)
		6	11 (8.2%)	11 (8.7%)	3 (4.7%)	2 (3.1%)	3 (4.7%)	4 (6.2%)	5 (7.9%)	3 (4.3%)	3 (4.8%)	34 (5.9%)	45 (6.3%)
		6.5	2 (1.5%)	2 (1.6%)	1 (1.6%)	1 (1.6%)	0	1 (1.5%)	1 (1.6%)	2 (2.9%)	2 (3.2%)	10 (1.7%)	12 (1.7%)
		7	0	0	1 (1.6%)	0	0	1 (1.5%)	0	0	0	2 (0.3%)	2 (0.3%)
		7.5	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
	6	5	1 (0.7%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
		5.5	7 (5.2%)	14 (11.0%)	7 (10.9%)	4 (6.3%)	2 (3.1%)	3 (4.6%)	7 (11.1%)	4 (5.7%)	4 (6.3%)	45 (7.8%)	52 (7.3%)
		6	34 (25.4%)	28 (22.0%)	13 (20.3%)	12 (18.8%)	15 (23.4%)	11 (16.9%)	16 (25.4%)	15 (21.4%)	14 (22.2%)	124 (21.4%)	158 (22.1%)
		6.5	13 (9.7%)	7 (5.5%)	4 (6.3%)	4 (6.3%)	9 (14.1%)	2 (3.1%)	2 (3.2%)	10 (14.3%)	3 (4.8%)	41 (7.1%)	54 (7.6%)
		7	0	8 (6.3%)	2 (3.1%)	1 (1.6%)	1 (1.6%)	2 (3.1%)	3 (4.8%)	3 (4.3%)	0	20 (3.4%)	20 (2.8%)
	6.5	5.5	2 (1.5%)	1 (0.8%)	1 (1.6%)	2 (3.1%)	1 (1.6%)	3 (4.6%)	0	1 (1.4%)	1 (1.6%)	10 (1.7%)	12 (1.7%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
		6	15 (11.2%)	13 (10.2%)	9 (14.1%)	6 (9.4%)	8 (12.5%)	10 (15.4%)	5 (7.9%)	6 (8.6%)	3 (4.8%)	60 (10.3%)	75 (10.5%)
		6.5	7 (5.2%)	8 (6.3%)	8 (12.5%)	3 (4.7%)	4 (6.3%)	6 (9.2%)	3 (4.8%)	9 (12.9%)	5 (7.9%)	46 (7.9%)	53 (7.4%)
		7	5 (3.7%)	4 (3.1%)	1 (1.6%)	6 (9.4%)	4 (6.3%)	1 (1.5%)	5 (7.9%)	0	2 (3.2%)	23 (4.0%)	28 (3.9%)
		7.5	3 (2.2%)	1 (0.8%)	1 (1.6%)	1 (1.6%)	0	1 (1.5%)	0	1 (1.4%)	1 (1.6%)	6 (1.0%)	9 (1.3%)
		8	0	0	0	0	0	1 (1.5%)	0	0	0	1 (0.2%)	1 (0.1%)
	7	5.5	2 (1.5%)	0	1 (1.6%)	0	1 (1.6%)	0	1 (1.6%)	0	0	3 (0.5%)	5 (0.7%)
		6	4 (3.0%)	2 (1.6%)	2 (3.1%)	2 (3.1%)	1 (1.6%)	2 (3.1%)	2 (3.2%)	0	1 (1.6%)	12 (2.1%)	16 (2.2%)
		6.5	6 (4.5%)	2 (1.6%)	1 (1.6%)	2 (3.1%)	1 (1.6%)	5 (7.7%)	0	2 (2.9%)	3 (4.8%)	16 (2.8%)	22 (3.1%)
		7	6 (4.5%)	3 (2.4%)	4 (6.3%)	3 (4.7%)	3 (4.7%)	3 (4.6%)	2 (3.2%)	1 (1.4%)	0	19 (3.3%)	25 (3.5%)
		7.5	1 (0.7%)	1 (0.8%)	0	1 (1.6%)	2 (3.1%)	0	0	1 (1.4%)	0	5 (0.9%)	6 (0.8%)
		8	0	0	0	1 (1.6%)	0	0	0	0	0	1 (0.2%)	1 (0.1%)
	7.5	5.5	0	0	1 (1.6%)	1 (1.6%)	0	0	0	0	0	2 (0.3%)	2 (0.3%)
		6	0	2 (1.6%)	0	0	0	0	1 (1.6%)	0	1 (1.6%)	4 (0.7%)	4 (0.6%)
		6.5	0	0	0	0	0	2 (3.1%)	0	1 (1.4%)	0	3 (0.5%)	3 (0.4%)
		7	0	2 (1.6%)	0	0	1 (1.6%)	1 (1.5%)	1 (1.6%)	0	0	5 (0.9%)	5 (0.7%)
		7.5	1 (0.7%)	0	0	1 (1.6%)	2 (3.1%)	0	0	0	0	3 (0.5%)	4 (0.6%)
	8	5.5	0	0	0	0	1 (1.6%)	0	0	0	0	1 (0.2%)	1 (0.1%)
		6.5	0	0	0	0	0	0	0	1 (1.4%)	0	1 (0.2%)	1 (0.1%)
		7	0	0	0	0	1 (1.6%)	0	0	0	0	1 (0.2%)	1 (0.1%)
		7.5	0	0	0	0	0	0	0	1 (1.4%)	0	1 (0.2%)	1 (0.1%)
		8	0	0	0	1 (1.6%)	0	0	0	0	0	1 (0.2%)	1 (0.1%)
	8.5	7.5	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
		8.5	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
Week 8	m		132	126	63	64	64	65	62	69	63	576	708
	5.5	5.5	12 (9.1%)	13 (10.3%)	5 (7.9%)	7 (10.9%)	3 (4.7%)	4 (6.2%)	9 (14.5%)	7 (10.1%)	12 (19.0%)	60 (10.4%)	72 (10.2%)
		6	12 (9.1%)	10 (7.9%)	2 (3.2%)	4 (6.3%)	3 (4.7%)	6 (9.2%)	3 (4.8%)	6 (8.7%)	11 (17.5%)	45 (7.8%)	57 (8.1%)
		6.5	3 (2.3%)	5 (4.0%)	1 (1.6%)	1 (1.6%)	0	1 (1.5%)	3 (4.8%)	1 (1.4%)	2 (3.2%)	14 (2.4%)	17 (2.4%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
		7	0	1 (0.8%)	0	0	1 (1.6%)	1 (1.5%)	0	0	0	3 (0.5%)	3 (0.4%)
		7.5	0	0	0	1 (1.6%)	0	0	0	0	0	1 (0.2%)	1 (0.1%)
	6	5.5	10 (7.6%)	16 (12.7%)	8 (12.7%)	5 (7.8%)	6 (9.4%)	2 (3.1%)	7 (11.3%)	4 (5.8%)	2 (3.2%)	50 (8.7%)	60 (8.5%)
		6	27 (20.5%)	27 (21.4%)	13 (20.6%)	8 (12.5%)	12 (18.8%)	8 (12.3%)	12 (19.4%)	19 (27.5%)	18 (28.6%)	117 (20.3%)	144 (20.3%)
		6.5	10 (7.6%)	9 (7.1%)	3 (4.8%)	5 (7.8%)	4 (6.3%)	7 (10.8%)	5 (8.1%)	6 (8.7%)	1 (1.6%)	40 (6.9%)	50 (7.1%)
		7	6 (4.5%)	4 (3.2%)	2 (3.2%)	2 (3.1%)	3 (4.7%)	0	3 (4.8%)	2 (2.9%)	0	16 (2.8%)	22 (3.1%)
		7.5	1 (0.8%)	1 (0.8%)	0	1 (1.6%)	2 (3.1%)	1 (1.5%)	1 (1.6%)	0	0	6 (1.0%)	7 (1.0%)
	6.5	5.5	1 (0.8%)	6 (4.8%)	2 (3.2%)	0	1 (1.6%)	4 (6.2%)	1 (1.6%)	1 (1.4%)	1 (1.6%)	16 (2.8%)	17 (2.4%)
		6	11 (8.3%)	10 (7.9%)	5 (7.9%)	6 (9.4%)	9 (14.1%)	7 (10.8%)	2 (3.2%)	10 (14.5%)	3 (4.8%)	52 (9.0%)	63 (8.9%)
		6.5	13 (9.8%)	7 (5.6%)	12 (19.0%)	3 (4.7%)	3 (4.7%)	8 (12.3%)	5 (8.1%)	6 (8.7%)	6 (9.5%)	50 (8.7%)	63 (8.9%)
		7	4 (3.0%)	4 (3.2%)	0	5 (7.8%)	3 (4.7%)	2 (3.1%)	5 (8.1%)	0	2 (3.2%)	21 (3.6%)	25 (3.5%)
		7.5	2 (1.5%)	0	1 (1.6%)	4 (6.3%)	1 (1.6%)	1 (1.5%)	0	0	0	7 (1.2%)	9 (1.3%)
	7	5.5	0	1 (0.8%)	0	1 (1.6%)	0	1 (1.5%)	0	0	0	3 (0.5%)	3 (0.4%)
		6	5 (3.8%)	1 (0.8%)	4 (6.3%)	4 (6.3%)	3 (4.7%)	2 (3.1%)	1 (1.6%)	2 (2.9%)	2 (3.2%)	19 (3.3%)	24 (3.4%)
		6.5	5 (3.8%)	2 (1.6%)	2 (3.2%)	0	3 (4.7%)	6 (9.2%)	3 (4.8%)	2 (2.9%)	1 (1.6%)	19 (3.3%)	24 (3.4%)
		7	6 (4.5%)	2 (1.6%)	1 (1.6%)	2 (3.1%)	2 (3.1%)	1 (1.5%)	0	0	0	8 (1.4%)	14 (2.0%)
		7.5	2 (1.5%)	1 (0.8%)	1 (1.6%)	1 (1.6%)	0	0	0	0	1 (1.6%)	4 (0.7%)	6 (0.8%)
		8	1 (0.8%)	0	0	1 (1.6%)	0	0	0	0	0	1 (0.2%)	2 (0.3%)
	7.5	6	0	0	0	0	0	1 (1.5%)	0	0	1 (1.6%)	2 (0.3%)	2 (0.3%)
		6.5	0	1 (0.8%)	1 (1.6%)	1 (1.6%)	2 (3.1%)	0	1 (1.6%)	0	0	6 (1.0%)	6 (0.8%)
		7	0	3 (2.4%)	0	0	0	0	1 (1.6%)	0	0	4 (0.7%)	4 (0.6%)
		7.5	1 (0.8%)	0	0	1 (1.6%)	1 (1.6%)	1 (1.5%)	0	1 (1.4%)	0	4 (0.7%)	5 (0.7%)
		8	0	0	0	0	0	1 (1.5%)	0	0	0	1 (0.2%)	1 (0.1%)
	8	5.5	0	0	0	0	1 (1.6%)	0	0	0	0	1 (0.2%)	1 (0.1%)
		6	0	0	0	0	1 (1.6%)	0	0	0	0	1 (0.2%)	1 (0.1%)
		7	0	0	0	0	0	0	0	2 (2.9%)	0	2 (0.3%)	2 (0.3%)
		8	0	0	0	1 (1.6%)	0	0	0	0	0	1 (0.2%)	1 (0.1%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
	8.5	8.5	0	2 (1.6%)	0	0	0	0	0	0	0	2 (0.3%)	2 (0.3%)
Week 12	m		131	123	63	64	64	65	62	68	63	572	703
	5.5	5.5	14 (10.7%)	16 (13.0%)	4 (6.3%)	7 (10.9%)	2 (3.1%)	3 (4.6%)	8 (12.9%)	4 (5.9%)	17 (27.0%)	61 (10.7%)	75 (10.7%)
		6	12 (9.2%)	9 (7.3%)	2 (3.2%)	4 (6.3%)	4 (6.3%)	6 (9.2%)	7 (11.3%)	5 (7.4%)	7 (11.1%)	44 (7.7%)	56 (8.0%)
		6.5	0	2 (1.6%)	2 (3.2%)	2 (3.1%)	1 (1.6%)	2 (3.1%)	0	3 (4.4%)	1 (1.6%)	13 (2.3%)	13 (1.8%)
		7	1 (0.8%)	0	0	0	0	0	0	1 (1.5%)	0	1 (0.2%)	2 (0.3%)
		7.5	0	0	0	0	0	1 (1.5%)	0	0	0	1 (0.2%)	1 (0.1%)
		8	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
	6	5.5	13 (9.9%)	9 (7.3%)	6 (9.5%)	4 (6.3%)	6 (9.4%)	6 (9.2%)	6 (9.7%)	4 (5.9%)	5 (7.9%)	46 (8.0%)	59 (8.4%)
		6	25 (19.1%)	29 (23.6%)	12 (19.0%)	9 (14.1%)	8 (12.5%)	8 (12.3%)	16 (25.8%)	18 (26.5%)	14 (22.2%)	114 (19.9%)	139 (19.8%)
		6.5	10 (7.6%)	12 (9.8%)	7 (11.1%)	6 (9.4%)	12 (18.8%)	3 (4.6%)	4 (6.5%)	8 (11.8%)	2 (3.2%)	54 (9.4%)	64 (9.1%)
		7	5 (3.8%)	6 (4.9%)	1 (1.6%)	2 (3.1%)	1 (1.6%)	1 (1.5%)	2 (3.2%)	1 (1.5%)	0	14 (2.4%)	19 (2.7%)
	6.5	5.5	1 (0.8%)	6 (4.9%)	1 (1.6%)	1 (1.6%)	1 (1.6%)	1 (1.5%)	0	0	1 (1.6%)	11 (1.9%)	12 (1.7%)
		6	14 (10.7%)	11 (8.9%)	9 (14.3%)	5 (7.8%)	5 (7.8%)	7 (10.8%)	4 (6.5%)	8 (11.8%)	7 (11.1%)	56 (9.8%)	70 (10.0%)
		6.5	9 (6.9%)	6 (4.9%)	10 (15.9%)	4 (6.3%)	7 (10.9%)	8 (12.3%)	4 (6.5%)	7 (10.3%)	4 (6.3%)	50 (8.7%)	59 (8.4%)
		7	3 (2.3%)	2 (1.6%)	0	6 (9.4%)	2 (3.1%)	3 (4.6%)	3 (4.8%)	1 (1.5%)	0	17 (3.0%)	20 (2.8%)
		7.5	4 (3.1%)	1 (0.8%)	0	1 (1.6%)	2 (3.1%)	3 (4.6%)	2 (3.2%)	1 (1.5%)	0	10 (1.7%)	14 (2.0%)
		8	0	0	0	1 (1.6%)	0	0	0	0	0	1 (0.2%)	1 (0.1%)
	7	5.5	1 (0.8%)	2 (1.6%)	2 (3.2%)	1 (1.6%)	1 (1.6%)	0	1 (1.6%)	1 (1.5%)	0	8 (1.4%)	9 (1.3%)
		6	3 (2.3%)	0	1 (1.6%)	4 (6.3%)	3 (4.7%)	4 (6.2%)	1 (1.6%)	2 (2.9%)	1 (1.6%)	16 (2.8%)	19 (2.7%)
		6.5	6 (4.6%)	2 (1.6%)	2 (3.2%)	2 (3.1%)	2 (3.1%)	2 (3.1%)	0	0	1 (1.6%)	11 (1.9%)	17 (2.4%)
		7	7 (5.3%)	1 (0.8%)	1 (1.6%)	0	1 (1.6%)	1 (1.5%)	2 (3.2%)	1 (1.5%)	2 (3.2%)	9 (1.6%)	16 (2.3%)
		7.5	1 (0.8%)	2 (1.6%)	1 (1.6%)	2 (3.1%)	1 (1.6%)	2 (3.1%)	0	0	0	8 (1.4%)	9 (1.3%)
		8	1 (0.8%)	0	1 (1.6%)	0	0	1 (1.5%)	0	0	0	2 (0.3%)	3 (0.4%)
	7.5	6	0	0	0	0	0	0	1 (1.6%)	0	0	1 (0.2%)	1 (0.1%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
		6.5	0	2 (1.6%)	1 (1.6%)	1 (1.6%)	1 (1.6%)	2 (3.1%)	0	0	1 (1.6%)	8 (1.4%)	8 (1.1%)
		7	1 (0.8%)	1 (0.8%)	0	0	2 (3.1%)	0	0	0	0	3 (0.5%)	4 (0.6%)
		7.5	0	1 (0.8%)	0	0	0	1 (1.5%)	1 (1.6%)	1 (1.5%)	0	4 (0.7%)	4 (0.6%)
		8	0	0	0	1 (1.6%)	0	0	0	0	0	1 (0.2%)	1 (0.1%)
	8	6	0	0	0	0	1 (1.6%)	0	0	0	0	1 (0.2%)	1 (0.1%)
		6.5	0	0	0	0	1 (1.6%)	0	0	0	0	1 (0.2%)	1 (0.1%)
		7	0	0	0	0	0	0	0	1 (1.5%)	0	1 (0.2%)	1 (0.1%)
		7.5	0	0	0	1 (1.6%)	0	0	0	1 (1.5%)	0	2 (0.3%)	2 (0.3%)
	8.5	8	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
		8.5	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
Week 16	m		130	123	63	64	64	64	62	69	63	572	702
	5.5	5.5	15 (11.5%)	15 (12.2%)	5 (7.9%)	8 (12.5%)	4 (6.3%)	3 (4.7%)	10 (16.1%)	4 (5.8%)	18 (28.6%)	67 (11.7%)	82 (11.7%)
		6	9 (6.9%)	11 (8.9%)	2 (3.2%)	4 (6.3%)	3 (4.7%)	4 (6.3%)	5 (8.1%)	9 (13.0%)	6 (9.5%)	44 (7.7%)	53 (7.5%)
		6.5	2 (1.5%)	1 (0.8%)	1 (1.6%)	1 (1.6%)	0	3 (4.7%)	0	1 (1.4%)	1 (1.6%)	8 (1.4%)	10 (1.4%)
		7	1 (0.8%)	1 (0.8%)	0	0	0	1 (1.6%)	0	0	0	2 (0.3%)	3 (0.4%)
	6	5.5	13 (10.0%)	9 (7.3%)	5 (7.9%)	4 (6.3%)	7 (10.9%)	5 (7.8%)	6 (9.7%)	6 (8.7%)	3 (4.8%)	45 (7.9%)	58 (8.3%)
		6	25 (19.2%)	31 (25.2%)	13 (20.6%)	12 (18.8%)	9 (14.1%)	8 (12.5%)	14 (22.6%)	14 (20.3%)	16 (25.4%)	117 (20.5%)	142 (20.2%)
		6.5	13 (10.0%)	13 (10.6%)	8 (12.7%)	3 (4.7%)	6 (9.4%)	4 (6.3%)	5 (8.1%)	11 (15.9%)	1 (1.6%)	51 (8.9%)	64 (9.1%)
		7	2 (1.5%)	3 (2.4%)	0	1 (1.6%)	4 (6.3%)	1 (1.6%)	2 (3.2%)	0	1 (1.6%)	12 (2.1%)	14 (2.0%)
		7.5	0	0	0	0	1 (1.6%)	0	1 (1.6%)	0	0	2 (0.3%)	2 (0.3%)
		8	0	0	0	1 (1.6%)	0	0	0	0	0	1 (0.2%)	1 (0.1%)
	6.5	5.5	3 (2.3%)	5 (4.1%)	1 (1.6%)	3 (4.7%)	1 (1.6%)	3 (4.7%)	0	1 (1.4%)	2 (3.2%)	16 (2.8%)	19 (2.7%)
		6	12 (9.2%)	10 (8.1%)	9 (14.3%)	7 (10.9%)	7 (10.9%)	8 (12.5%)	6 (9.7%)	12 (17.4%)	5 (7.9%)	64 (11.2%)	76 (10.8%)
		6.5	10 (7.7%)	10 (8.1%)	7 (11.1%)	5 (7.8%)	5 (7.8%)	4 (6.3%)	4 (6.5%)	3 (4.3%)	4 (6.3%)	42 (7.3%)	52 (7.4%)
		7	5 (3.8%)	1 (0.8%)	3 (4.8%)	2 (3.1%)	2 (3.1%)	6 (9.4%)	3 (4.8%)	0	1 (1.6%)	18 (3.1%)	23 (3.3%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
		7.5	0	0	0	0	2 (3.1%)	1 (1.6%)	0	0	0	3 (0.5%)	3 (0.4%)
		8	0	0	0	1 (1.6%)	0	0	0	1 (1.4%)	0	2 (0.3%)	2 (0.3%)
	7	5.5	1 (0.8%)	2 (1.6%)	2 (3.2%)	4 (6.3%)	0	1 (1.6%)	1 (1.6%)	0	1 (1.6%)	11 (1.9%)	12 (1.7%)
		6	4 (3.1%)	0	4 (6.3%)	1 (1.6%)	1 (1.6%)	1 (1.6%)	1 (1.6%)	2 (2.9%)	0	10 (1.7%)	14 (2.0%)
		6.5	8 (6.2%)	3 (2.4%)	0	0	4 (6.3%)	3 (4.7%)	1 (1.6%)	1 (1.4%)	1 (1.6%)	13 (2.3%)	21 (3.0%)
		7	4 (3.1%)	2 (1.6%)	2 (3.2%)	1 (1.6%)	2 (3.1%)	2 (3.1%)	1 (1.6%)	1 (1.4%)	2 (3.2%)	13 (2.3%)	17 (2.4%)
		7.5	2 (1.5%)	0	0	2 (3.1%)	0	3 (4.7%)	0	0	0	5 (0.9%)	7 (1.0%)
		8	0	0	0	1 (1.6%)	1 (1.6%)	0	0	0	0	2 (0.3%)	2 (0.3%)
	7.5	6.5	0	1 (0.8%)	1 (1.6%)	1 (1.6%)	1 (1.6%)	1 (1.6%)	1 (1.6%)	0	0	6 (1.0%)	6 (0.9%)
		7	1 (0.8%)	3 (2.4%)	0	1 (1.6%)	1 (1.6%)	1 (1.6%)	1 (1.6%)	0	1 (1.6%)	8 (1.4%)	9 (1.3%)
		7.5	0	0	0	0	1 (1.6%)	1 (1.6%)	0	0	0	2 (0.3%)	2 (0.3%)
		8	0	0	0	0	0	0	0	1 (1.4%)	0	1 (0.2%)	1 (0.1%)
	8	6.5	0	0	0	0	0	0	0	1 (1.4%)	0	1 (0.2%)	1 (0.1%)
		7	0	0	0	1 (1.6%)	2 (3.1%)	0	0	0	0	3 (0.5%)	3 (0.4%)
		8	0	0	0	0	0	0	0	1 (1.4%)	0	1 (0.2%)	1 (0.1%)
	8.5	6	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
		8.5	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
Week 20	m		130	123	62	63	64	65	61	69	63	570	700
	5.5	5.5	17 (13.1%)	12 (9.8%)	5 (8.1%)	8 (12.7%)	5 (7.8%)	5 (7.7%)	6 (9.8%)	7 (10.1%)	14 (22.2%)	62 (10.9%)	79 (11.3%)
		6	7 (5.4%)	14 (11.4%)	2 (3.2%)	4 (6.3%)	2 (3.1%)	5 (7.7%)	8 (13.1%)	5 (7.2%)	11 (17.5%)	51 (8.9%)	58 (8.3%)
		6.5	3 (2.3%)	1 (0.8%)	1 (1.6%)	1 (1.6%)	0	1 (1.5%)	0	2 (2.9%)	0	6 (1.1%)	9 (1.3%)
		7	0	1 (0.8%)	0	0	0	1 (1.5%)	1 (1.6%)	0	0	3 (0.5%)	3 (0.4%)
	6	5.5	15 (11.5%)	5 (4.1%)	5 (8.1%)	4 (6.3%)	2 (3.1%)	5 (7.7%)	9 (14.8%)	3 (4.3%)	3 (4.8%)	36 (6.3%)	51 (7.3%)
		6	26 (20.0%)	27 (22.0%)	13 (21.0%)	10 (15.9%)	16 (25.0%)	8 (12.3%)	13 (21.3%)	17 (24.6%)	16 (25.4%)	120 (21.1%)	146 (20.9%)
		6.5	11 (8.5%)	19 (15.4%)	7 (11.3%)	4 (6.3%)	5 (7.8%)	4 (6.2%)	4 (6.6%)	7 (10.1%)	2 (3.2%)	52 (9.1%)	63 (9.0%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
		7	1 (0.8%)	3 (2.4%)	1 (1.6%)	1 (1.6%)	3 (4.7%)	1 (1.5%)	1 (1.6%)	2 (2.9%)	0	12 (2.1%)	13 (1.9%)
		7.5	0	2 (1.6%)	0	1 (1.6%)	1 (1.6%)	0	0	2 (2.9%)	0	6 (1.1%)	6 (0.9%)
	6.5	5.5	3 (2.3%)	4 (3.3%)	1 (1.6%)	2 (3.2%)	2 (3.1%)	2 (3.1%)	1 (1.6%)	2 (2.9%)	2 (3.2%)	16 (2.8%)	19 (2.7%)
		6	12 (9.2%)	8 (6.5%)	7 (11.3%)	9 (14.3%)	5 (7.8%)	7 (10.8%)	5 (8.2%)	7 (10.1%)	7 (11.1%)	55 (9.6%)	67 (9.6%)
		6.5	11 (8.5%)	11 (8.9%)	4 (6.5%)	6 (9.5%)	5 (7.8%)	5 (7.7%)	3 (4.9%)	5 (7.2%)	2 (3.2%)	41 (7.2%)	52 (7.4%)
		7	4 (3.1%)	1 (0.8%)	6 (9.7%)	0	4 (6.3%)	5 (7.7%)	4 (6.6%)	3 (4.3%)	1 (1.6%)	24 (4.2%)	28 (4.0%)
		7.5	0	1 (0.8%)	1 (1.6%)	1 (1.6%)	1 (1.6%)	3 (4.6%)	0	0	0	7 (1.2%)	7 (1.0%)
		8	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
	7	5.5	2 (1.5%)	2 (1.6%)	0	2 (3.2%)	1 (1.6%)	0	1 (1.6%)	0	0	6 (1.1%)	8 (1.1%)
		6	5 (3.8%)	1 (0.8%)	3 (4.8%)	1 (1.6%)	0	2 (3.1%)	0	1 (1.4%)	1 (1.6%)	9 (1.6%)	14 (2.0%)
		6.5	6 (4.6%)	3 (2.4%)	2 (3.2%)	2 (3.2%)	3 (4.7%)	5 (7.7%)	3 (4.9%)	1 (1.4%)	1 (1.6%)	20 (3.5%)	26 (3.7%)
		7	5 (3.8%)	1 (0.8%)	3 (4.8%)	3 (4.8%)	3 (4.7%)	2 (3.1%)	0	2 (2.9%)	2 (3.2%)	16 (2.8%)	21 (3.0%)
		7.5	1 (0.8%)	0	0	0	1 (1.6%)	1 (1.5%)	0	0	0	2 (0.4%)	3 (0.4%)
		8.5	0	0	0	1 (1.6%)	0	0	0	0	0	1 (0.2%)	1 (0.1%)
	7.5	5.5	0	0	1 (1.6%)	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
		6	1 (0.8%)	2 (1.6%)	0	1 (1.6%)	0	0	1 (1.6%)	0	1 (1.6%)	5 (0.9%)	6 (0.9%)
		6.5	0	0	0	0	2 (3.1%)	2 (3.1%)	0	0	0	4 (0.7%)	4 (0.6%)
		7	0	2 (1.6%)	0	0	1 (1.6%)	0	0	0	0	3 (0.5%)	3 (0.4%)
		7.5	0	0	0	0	0	1 (1.5%)	1 (1.6%)	1 (1.4%)	0	3 (0.5%)	3 (0.4%)
		8	0	0	0	1 (1.6%)	0	0	0	0	0	1 (0.2%)	1 (0.1%)
	8	5.5	0	0	0	0	1 (1.6%)	0	0	0	0	1 (0.2%)	1 (0.1%)
		6.5	0	0	0	0	1 (1.6%)	0	0	1 (1.4%)	0	2 (0.4%)	2 (0.3%)
		7.5	0	0	0	0	0	0	0	1 (1.4%)	0	1 (0.2%)	1 (0.1%)
		8	0	0	0	1 (1.6%)	0	0	0	0	0	1 (0.2%)	1 (0.1%)
	8.5	5.5	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
		8.5	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
Week 24	m		130	122	62	63	64	65	61	69	63	569	699
	5.5	5.5	13 (10.0%)	13 (10.7%)	3 (4.8%)	8 (12.7%)	4 (6.3%)	3 (4.6%)	7 (11.5%)	5 (7.2%)	13 (20.6%)	56 (9.8%)	69 (9.9%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
		6	11 (8.5%)	11 (9.0%)	3 (4.8%)	2 (3.2%)	3 (4.7%)	4 (6.2%)	8 (13.1%)	7 (10.1%)	10 (15.9%)	48 (8.4%)	59 (8.4%)
		6.5	2 (1.5%)	2 (1.6%)	2 (3.2%)	3 (4.8%)	0	2 (3.1%)	0	1 (1.4%)	2 (3.2%)	12 (2.1%)	14 (2.0%)
		7	1 (0.8%)	1 (0.8%)	0	0	0	3 (4.6%)	0	0	0	4 (0.7%)	5 (0.7%)
		7.5	0	0	0	0	0	0	0	1 (1.4%)	0	1 (0.2%)	1 (0.1%)
		8	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
	6	5.5	12 (9.2%)	5 (4.1%)	7 (11.3%)	5 (7.9%)	4 (6.3%)	2 (3.1%)	4 (6.6%)	3 (4.3%)	2 (3.2%)	32 (5.6%)	44 (6.3%)
		6	26 (20.0%)	24 (19.7%)	6 (9.7%)	5 (7.9%)	7 (10.9%)	11 (16.9%)	7 (11.5%)	17 (24.6%)	16 (25.4%)	93 (16.3%)	119 (17.0%)
		6.5	8 (6.2%)	15 (12.3%)	10 (16.1%)	4 (6.3%)	12 (18.8%)	3 (4.6%)	10 (16.4%)	4 (5.8%)	2 (3.2%)	60 (10.5%)	68 (9.7%)
		7	6 (4.6%)	7 (5.7%)	3 (4.8%)	5 (7.9%)	3 (4.7%)	1 (1.5%)	5 (8.2%)	5 (7.2%)	1 (1.6%)	30 (5.3%)	36 (5.2%)
		7.5	1 (0.8%)	4 (3.3%)	0	1 (1.6%)	1 (1.6%)	1 (1.5%)	1 (1.6%)	2 (2.9%)	0	10 (1.8%)	11 (1.6%)
	6.5	5.5	1 (0.8%)	3 (2.5%)	1 (1.6%)	4 (6.3%)	0	2 (3.1%)	1 (1.6%)	2 (2.9%)	0	13 (2.3%)	14 (2.0%)
		6	14 (10.8%)	10 (8.2%)	6 (9.7%)	6 (9.5%)	4 (6.3%)	6 (9.2%)	4 (6.6%)	4 (5.8%)	6 (9.5%)	46 (8.1%)	60 (8.6%)
		6.5	5 (3.8%)	10 (8.2%)	7 (11.3%)	4 (6.3%)	7 (10.9%)	9 (13.8%)	5 (8.2%)	8 (11.6%)	4 (6.3%)	54 (9.5%)	59 (8.4%)
		7	10 (7.7%)	3 (2.5%)	4 (6.5%)	2 (3.2%)	5 (7.8%)	2 (3.1%)	3 (4.9%)	3 (4.3%)	1 (1.6%)	23 (4.0%)	33 (4.7%)
		7.5	0	0	1 (1.6%)	1 (1.6%)	0	2 (3.1%)	0	0	1 (1.6%)	5 (0.9%)	5 (0.7%)
		8	0	0	0	0	1 (1.6%)	1 (1.5%)	0	0	0	2 (0.4%)	2 (0.3%)
		8.5	0	0	0	1 (1.6%)	0	0	0	0	0	1 (0.2%)	1 (0.1%)
	7	5.5	1 (0.8%)	0	1 (1.6%)	0	0	0	0	0	0	1 (0.2%)	2 (0.3%)
		6	5 (3.8%)	2 (1.6%)	2 (3.2%)	2 (3.2%)	1 (1.6%)	3 (4.6%)	1 (1.6%)	0	0	11 (1.9%)	16 (2.3%)
		6.5	9 (6.9%)	2 (1.6%)	3 (4.8%)	4 (6.3%)	3 (4.7%)	1 (1.5%)	0	2 (2.9%)	2 (3.2%)	17 (3.0%)	26 (3.7%)
		7	3 (2.3%)	2 (1.6%)	1 (1.6%)	3 (4.8%)	2 (3.1%)	2 (3.1%)	2 (3.3%)	2 (2.9%)	0	14 (2.5%)	17 (2.4%)
		7.5	0	1 (0.8%)	1 (1.6%)	0	2 (3.1%)	4 (6.2%)	1 (1.6%)	0	2 (3.2%)	11 (1.9%)	11 (1.6%)
		8	1 (0.8%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
	7.5	6	0	1 (0.8%)	1 (1.6%)	1 (1.6%)	1 (1.6%)	0	1 (1.6%)	0	0	5 (0.9%)	5 (0.7%)
		6.5	0	1 (0.8%)	0	0	0	0	0	1 (1.4%)	0	2 (0.4%)	2 (0.3%)
		7	1 (0.8%)	2 (1.6%)	0	0	2 (3.1%)	2 (3.1%)	0	0	0	6 (1.1%)	7 (1.0%)
		7.5	0	0	0	0	0	0	1 (1.6%)	0	1 (1.6%)	2 (0.4%)	2 (0.3%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
		8	0	0	0	1 (1.6%)	0	1 (1.5%)	0	0	0	2 (0.4%)	2 (0.3%)
	8	6	0	0	0	0	1 (1.6%)	0	0	0	0	1 (0.2%)	1 (0.1%)
		6.5	0	0	0	0	1 (1.6%)	0	0	1 (1.4%)	0	2 (0.4%)	2 (0.3%)
		7	0	0	0	0	0	0	0	1 (1.4%)	0	1 (0.2%)	1 (0.1%)
		8	0	0	0	1 (1.6%)	0	0	0	0	0	1 (0.2%)	1 (0.1%)
	8.5	5.5	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
		8.5	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
Week 32	m		128	120	62	60	62	65	60	69	63	561	689
	5.5	5.5	11 (8.6%)	13 (10.8%)	5 (8.1%)	7 (11.7%)	4 (6.5%)	3 (4.6%)	5 (8.3%)	5 (7.2%)	13 (20.6%)	55 (9.8%)	66 (9.6%)
		6	13 (10.2%)	11 (9.2%)	2 (3.2%)	4 (6.7%)	2 (3.2%)	6 (9.2%)	9 (15.0%)	4 (5.8%)	8 (12.7%)	46 (8.2%)	59 (8.6%)
		6.5	1 (0.8%)	4 (3.3%)	1 (1.6%)	1 (1.7%)	1 (1.6%)	3 (4.6%)	1 (1.7%)	4 (5.8%)	4 (6.3%)	19 (3.4%)	20 (2.9%)
		7	1 (0.8%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
		7.5	0	0	0	0	0	0	0	1 (1.4%)	0	1 (0.2%)	1 (0.1%)
	6	5.5	7 (5.5%)	6 (5.0%)	3 (4.8%)	3 (5.0%)	1 (1.6%)	3 (4.6%)	2 (3.3%)	1 (1.4%)	4 (6.3%)	23 (4.1%)	30 (4.4%)
		6	25 (19.5%)	30 (25.0%)	12 (19.4%)	9 (15.0%)	10 (16.1%)	9 (13.8%)	9 (15.0%)	15 (21.7%)	11 (17.5%)	105 (18.7%)	130 (18.9%)
		6.5	14 (10.9%)	13 (10.8%)	9 (14.5%)	7 (11.7%)	12 (19.4%)	4 (6.2%)	10 (16.7%)	8 (11.6%)	5 (7.9%)	68 (12.1%)	82 (11.9%)
		7	5 (3.9%)	4 (3.3%)	2 (3.2%)	0	3 (4.8%)	2 (3.1%)	6 (10.0%)	4 (5.8%)	1 (1.6%)	22 (3.9%)	27 (3.9%)
		7.5	1 (0.8%)	1 (0.8%)	0	0	1 (1.6%)	0	0	1 (1.4%)	0	3 (0.5%)	4 (0.6%)
		8	1 (0.8%)	0	0	0	0	0	0	2 (2.9%)	0	2 (0.4%)	3 (0.4%)
	6.5	5.5	1 (0.8%)	3 (2.5%)	0	1 (1.7%)	0	2 (3.1%)	1 (1.7%)	1 (1.4%)	0	8 (1.4%)	9 (1.3%)
		6	13 (10.2%)	13 (10.8%)	7 (11.3%)	8 (13.3%)	5 (8.1%)	6 (9.2%)	3 (5.0%)	6 (8.7%)	5 (7.9%)	53 (9.4%)	66 (9.6%)
		6.5	9 (7.0%)	8 (6.7%)	9 (14.5%)	2 (3.3%)	7 (11.3%)	13 (20.0%)	3 (5.0%)	7 (10.1%)	2 (3.2%)	51 (9.1%)	60 (8.7%)
		7	4 (3.1%)	0	3 (4.8%)	6 (10.0%)	5 (8.1%)	0	5 (8.3%)	3 (4.3%)	5 (7.9%)	27 (4.8%)	31 (4.5%)
		7.5	0	1 (0.8%)	0	1 (1.7%)	0	1 (1.5%)	0	0	0	3 (0.5%)	3 (0.4%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
		8	2 (1.6%)	0	0	0	0	0	0	0	0	0	2 (0.3%)
	7	6	4 (3.1%)	3 (2.5%)	2 (3.2%)	3 (5.0%)	3 (4.8%)	2 (3.1%)	1 (1.7%)	0	0	14 (2.5%)	18 (2.6%)
		6.5	5 (3.9%)	1 (0.8%)	3 (4.8%)	1 (1.7%)	2 (3.2%)	4 (6.2%)	0	1 (1.4%)	3 (4.8%)	15 (2.7%)	20 (2.9%)
		7	9 (7.0%)	2 (1.7%)	2 (3.2%)	2 (3.3%)	2 (3.2%)	2 (3.1%)	2 (3.3%)	3 (4.3%)	1 (1.6%)	16 (2.9%)	25 (3.6%)
		7.5	1 (0.8%)	1 (0.8%)	1 (1.6%)	2 (3.3%)	1 (1.6%)	2 (3.1%)	0	0	0	7 (1.2%)	8 (1.2%)
		8	0	0	0	0	0	0	1 (1.7%)	0	0	1 (0.2%)	1 (0.1%)
	7.5	6	1 (0.8%)	1 (0.8%)	0	1 (1.7%)	0	1 (1.5%)	0	0	1 (1.6%)	4 (0.7%)	5 (0.7%)
		6.5	0	1 (0.8%)	0	0	0	0	2 (3.3%)	0	0	3 (0.5%)	3 (0.4%)
		7	0	1 (0.8%)	0	0	1 (1.6%)	1 (1.5%)	0	0	0	3 (0.5%)	3 (0.4%)
		7.5	0	1 (0.8%)	1 (1.6%)	0	1 (1.6%)	1 (1.5%)	0	0	0	4 (0.7%)	4 (0.6%)
		8	0	0	0	1 (1.7%)	0	0	0	0	0	1 (0.2%)	1 (0.1%)
		8.5	0	0	0	0	0	0	0	1 (1.4%)	0	1 (0.2%)	1 (0.1%)
	8	7.5	0	0	0	1 (1.7%)	1 (1.6%)	0	0	2 (2.9%)	0	4 (0.7%)	4 (0.6%)
	8.5	5.5	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
		8.5	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
Week 40	m		128	120	60	59	62	65	60	69	63	558	686
	5.5	5.5	8 (6.3%)	9 (7.5%)	2 (3.3%)	5 (8.5%)	1 (1.6%)	3 (4.6%)	6 (10.0%)	5 (7.2%)	10 (15.9%)	41 (7.3%)	49 (7.1%)
		6	14 (10.9%)	12 (10.0%)	4 (6.7%)	6 (10.2%)	4 (6.5%)	8 (12.3%)	4 (6.7%)	4 (5.8%)	10 (15.9%)	52 (9.3%)	66 (9.6%)
		6.5	3 (2.3%)	3 (2.5%)	1 (1.7%)	0	2 (3.2%)	0	4 (6.7%)	2 (2.9%)	3 (4.8%)	15 (2.7%)	18 (2.6%)
		7	1 (0.8%)	3 (2.5%)	0	1 (1.7%)	0	1 (1.5%)	1 (1.7%)	3 (4.3%)	2 (3.2%)	11 (2.0%)	12 (1.7%)
		7.5	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
	6	5.5	10 (7.8%)	2 (1.7%)	3 (5.0%)	3 (5.1%)	4 (6.5%)	1 (1.5%)	2 (3.3%)	2 (2.9%)	1 (1.6%)	18 (3.2%)	28 (4.1%)
		6	22 (17.2%)	25 (20.8%)	12 (20.0%)	7 (11.9%)	4 (6.5%)	11 (16.9%)	8 (13.3%)	18 (26.1%)	15 (23.8%)	100 (17.9%)	122 (17.8%)
		6.5	14 (10.9%)	21 (17.5%)	8 (13.3%)	4 (6.8%)	14 (22.6%)	4 (6.2%)	13 (21.7%)	4 (5.8%)	5 (7.9%)	73 (13.1%)	87 (12.7%)
		7	7 (5.5%)	5 (4.2%)	2 (3.3%)	3 (5.1%)	2 (3.2%)	2 (3.1%)	3 (5.0%)	5 (7.2%)	0	22 (3.9%)	29 (4.2%)
		7.5	0	1 (0.8%)	0	1 (1.7%)	2 (3.2%)	0	1 (1.7%)	2 (2.9%)	0	7 (1.3%)	7 (1.0%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
		8	0	0	0	0	1 (1.6%)	0	0	0	0	1 (0.2%)	1 (0.1%)
	6.5	5.5	0	2 (1.7%)	0	1 (1.7%)	1 (1.6%)	1 (1.5%)	1 (1.7%)	2 (2.9%)	0	8 (1.4%)	8 (1.2%)
		6	13 (10.2%)	8 (6.7%)	5 (8.3%)	8 (13.6%)	4 (6.5%)	9 (13.8%)	2 (3.3%)	7 (10.1%)	5 (7.9%)	48 (8.6%)	61 (8.9%)
		6.5	8 (6.3%)	11 (9.2%)	9 (15.0%)	7 (11.9%)	8 (12.9%)	9 (13.8%)	3 (5.0%)	4 (5.8%)	3 (4.8%)	54 (9.7%)	62 (9.0%)
		7	6 (4.7%)	4 (3.3%)	4 (6.7%)	2 (3.4%)	4 (6.5%)	2 (3.1%)	6 (10.0%)	2 (2.9%)	4 (6.3%)	28 (5.0%)	34 (5.0%)
		7.5	2 (1.6%)	0	1 (1.7%)	0	0	1 (1.5%)	0	2 (2.9%)	0	4 (0.7%)	6 (0.9%)
	7	6	5 (3.9%)	2 (1.7%)	1 (1.7%)	1 (1.7%)	3 (4.8%)	3 (4.6%)	1 (1.7%)	2 (2.9%)	0	13 (2.3%)	18 (2.6%)
		6.5	6 (4.7%)	1 (0.8%)	3 (5.0%)	5 (8.5%)	1 (1.6%)	3 (4.6%)	0	2 (2.9%)	1 (1.6%)	16 (2.9%)	22 (3.2%)
		7	3 (2.3%)	3 (2.5%)	2 (3.3%)	2 (3.4%)	1 (1.6%)	2 (3.1%)	2 (3.3%)	0	3 (4.8%)	15 (2.7%)	18 (2.6%)
		7.5	4 (3.1%)	1 (0.8%)	2 (3.3%)	0	3 (4.8%)	2 (3.1%)	1 (1.7%)	0	0	9 (1.6%)	13 (1.9%)
		8	1 (0.8%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
	7.5	5.5	0	0	1 (1.7%)	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
		6	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
		6.5	0	2 (1.7%)	0	1 (1.7%)	1 (1.6%)	1 (1.5%)	2 (3.3%)	0	1 (1.6%)	8 (1.4%)	8 (1.2%)
		7	1 (0.8%)	1 (0.8%)	0	0	1 (1.6%)	0	0	0	0	2 (0.4%)	3 (0.4%)
		7.5	0	0	0	1 (1.7%)	0	2 (3.1%)	0	0	0	3 (0.5%)	3 (0.4%)
		8	0	0	0	0	0	0	0	1 (1.4%)	0	1 (0.2%)	1 (0.1%)
	8	6.5	0	0	0	0	1 (1.6%)	0	0	0	0	1 (0.2%)	1 (0.1%)
		7	0	0	0	0	0	0	0	2 (2.9%)	0	2 (0.4%)	2 (0.3%)
		7.5	0	0	0	1 (1.7%)	0	0	0	0	0	1 (0.2%)	1 (0.1%)
	8.5	6	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
		8.5	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
Week 48	m		127	118	60	59	62	65	60	66	63	553	680
	5.5	5.5	7 (5.5%)	10 (8.5%)	4 (6.7%)	5 (8.5%)	1 (1.6%)	2 (3.1%)	8 (13.3%)	6 (9.1%)	14 (22.2%)	50 (9.0%)	57 (8.4%)
		6	16 (12.6%)	14 (11.9%)	3 (5.0%)	6 (10.2%)	5 (8.1%)	7 (10.8%)	4 (6.7%)	5 (7.6%)	11 (17.5%)	55 (9.9%)	71 (10.4%)
		6.5	3 (2.4%)	3 (2.5%)	0	0	1 (1.6%)	1 (1.5%)	3 (5.0%)	1 (1.5%)	0	9 (1.6%)	12 (1.8%)
		7	0	1 (0.8%)	0	1 (1.7%)	0	2 (3.1%)	0	0	0	4 (0.7%)	4 (0.6%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
		7.5	0	0	0	0	0	0	0	1 (1.5%)	0	1 (0.2%)	1 (0.1%)
	6	5.5	11 (8.7%)	6 (5.1%)	4 (6.7%)	2 (3.4%)	3 (4.8%)	3 (4.6%)	2 (3.3%)	3 (4.5%)	1 (1.6%)	24 (4.3%)	35 (5.1%)
		6	24 (18.9%)	25 (21.2%)	12 (20.0%)	7 (11.9%)	12 (19.4%)	9 (13.8%)	12 (20.0%)	15 (22.7%)	14 (22.2%)	106 (19.2%)	130 (19.1%)
		6.5	10 (7.9%)	18 (15.3%)	7 (11.7%)	4 (6.8%)	7 (11.3%)	3 (4.6%)	7 (11.7%)	10 (15.2%)	5 (7.9%)	61 (11.0%)	71 (10.4%)
		7	7 (5.5%)	3 (2.5%)	1 (1.7%)	3 (5.1%)	4 (6.5%)	3 (4.6%)	4 (6.7%)	2 (3.0%)	0	20 (3.6%)	27 (4.0%)
		7.5	0	1 (0.8%)	1 (1.7%)	2 (3.4%)	1 (1.6%)	0	2 (3.3%)	0	1 (1.6%)	8 (1.4%)	8 (1.2%)
		8	1 (0.8%)	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	2 (0.3%)
	6.5	5.5	3 (2.4%)	5 (4.2%)	1 (1.7%)	1 (1.7%)	0	3 (4.6%)	1 (1.7%)	0	1 (1.6%)	12 (2.2%)	15 (2.2%)
		6	7 (5.5%)	11 (9.3%)	6 (10.0%)	4 (6.8%)	4 (6.5%)	6 (9.2%)	2 (3.3%)	6 (9.1%)	3 (4.8%)	42 (7.6%)	49 (7.2%)
		6.5	12 (9.4%)	6 (5.1%)	6 (10.0%)	5 (8.5%)	7 (11.3%)	10 (15.4%)	4 (6.7%)	7 (10.6%)	6 (9.5%)	51 (9.2%)	63 (9.3%)
		7	4 (3.1%)	1 (0.8%)	5 (8.3%)	5 (8.5%)	2 (3.2%)	1 (1.5%)	4 (6.7%)	3 (4.5%)	1 (1.6%)	22 (4.0%)	26 (3.8%)
		7.5	1 (0.8%)	1 (0.8%)	1 (1.7%)	3 (5.1%)	4 (6.5%)	2 (3.1%)	1 (1.7%)	0	1 (1.6%)	13 (2.4%)	14 (2.1%)
		8	1 (0.8%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
	7	5.5	2 (1.6%)	1 (0.8%)	0	0	0	0	0	1 (1.5%)	0	2 (0.4%)	4 (0.6%)
		6	4 (3.1%)	1 (0.8%)	1 (1.7%)	2 (3.4%)	3 (4.8%)	2 (3.1%)	1 (1.7%)	0	0	10 (1.8%)	14 (2.1%)
		6.5	5 (3.9%)	2 (1.7%)	3 (5.0%)	4 (6.8%)	2 (3.2%)	3 (4.6%)	3 (5.0%)	3 (4.5%)	1 (1.6%)	21 (3.8%)	26 (3.8%)
		7	5 (3.9%)	2 (1.7%)	3 (5.0%)	2 (3.4%)	2 (3.2%)	3 (4.6%)	0	0	2 (3.2%)	14 (2.5%)	19 (2.8%)
		7.5	3 (2.4%)	0	0	0	1 (1.6%)	2 (3.1%)	0	0	1 (1.6%)	4 (0.7%)	7 (1.0%)
		8	0	0	1 (1.7%)	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
	7.5	6	0	1 (0.8%)	1 (1.7%)	1 (1.7%)	0	0	0	0	0	3 (0.5%)	3 (0.4%)
		6.5	0	2 (1.7%)	0	0	1 (1.6%)	1 (1.5%)	1 (1.7%)	0	0	5 (0.9%)	5 (0.7%)
		7	1 (0.8%)	1 (0.8%)	0	0	0	2 (3.1%)	0	0	1 (1.6%)	4 (0.7%)	5 (0.7%)
		7.5	0	0	0	0	1 (1.6%)	0	1 (1.7%)	0	0	2 (0.4%)	2 (0.3%)
		8	0	0	0	1 (1.7%)	0	0	0	1 (1.5%)	0	2 (0.4%)	2 (0.3%)
	8	6.5	0	0	0	0	0	0	0	2 (3.0%)	0	2 (0.4%)	2 (0.3%)
		7.5	0	0	0	1 (1.7%)	1 (1.6%)	0	0	0	0	2 (0.4%)	2 (0.3%)
	8.5	5.5	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
		8	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
Week 52	m		126	116	59	58	62	65	60	67	62	549	675
	5.5	5.5	7 (5.6%)	10 (8.6%)	4 (6.8%)	4 (6.9%)	4 (6.5%)	2 (3.1%)	8 (13.3%)	5 (7.5%)	11 (17.7%)	48 (8.7%)	55 (8.1%)
		6	16 (12.7%)	14 (12.1%)	1 (1.7%)	6 (10.3%)	3 (4.8%)	8 (12.3%)	6 (10.0%)	6 (9.0%)	10 (16.1%)	54 (9.8%)	70 (10.4%)
		6.5	2 (1.6%)	3 (2.6%)	2 (3.4%)	2 (3.4%)	0	1 (1.5%)	0	1 (1.5%)	2 (3.2%)	11 (2.0%)	13 (1.9%)
		7	0	0	0	0	0	1 (1.5%)	1 (1.7%)	0	1 (1.6%)	3 (0.5%)	3 (0.4%)
		7.5	1 (0.8%)	1 (0.9%)	0	0	0	0	0	0	0	1 (0.2%)	2 (0.3%)
		8	0	0	0	0	0	0	0	1 (1.5%)	0	1 (0.2%)	1 (0.1%)
	6	5.5	6 (4.8%)	2 (1.7%)	3 (5.1%)	1 (1.7%)	5 (8.1%)	2 (3.1%)	1 (1.7%)	4 (6.0%)	0	18 (3.3%)	24 (3.6%)
		6	25 (19.8%)	32 (27.6%)	14 (23.7%)	9 (15.5%)	12 (19.4%)	10 (15.4%)	12 (20.0%)	15 (22.4%)	15 (24.2%)	119 (21.7%)	144 (21.3%)
		6.5	13 (10.3%)	13 (11.2%)	4 (6.8%)	3 (5.2%)	7 (11.3%)	5 (7.7%)	9 (15.0%)	10 (14.9%)	4 (6.5%)	55 (10.0%)	68 (10.1%)
		7	4 (3.2%)	4 (3.4%)	3 (5.1%)	3 (5.2%)	2 (3.2%)	1 (1.5%)	5 (8.3%)	1 (1.5%)	2 (3.2%)	21 (3.8%)	25 (3.7%)
		7.5	3 (2.4%)	1 (0.9%)	1 (1.7%)	2 (3.4%)	1 (1.6%)	0	0	0	0	5 (0.9%)	8 (1.2%)
		8	1 (0.8%)	1 (0.9%)	0	0	0	0	0	0	0	1 (0.2%)	2 (0.3%)
	6.5	5.5	1 (0.8%)	1 (0.9%)	0	0	0	1 (1.5%)	1 (1.7%)	1 (1.5%)	1 (1.6%)	5 (0.9%)	6 (0.9%)
		6	9 (7.1%)	12 (10.3%)	5 (8.5%)	6 (10.3%)	7 (11.3%)	6 (9.2%)	4 (6.7%)	9 (13.4%)	3 (4.8%)	52 (9.5%)	61 (9.0%)
		6.5	9 (7.1%)	6 (5.2%)	7 (11.9%)	4 (6.9%)	8 (12.9%)	9 (13.8%)	4 (6.7%)	4 (6.0%)	4 (6.5%)	46 (8.4%)	55 (8.1%)
		7	6 (4.8%)	3 (2.6%)	7 (11.9%)	4 (6.9%)	0	6 (9.2%)	2 (3.3%)	3 (4.5%)	1 (1.6%)	26 (4.7%)	32 (4.7%)
		7.5	2 (1.6%)	1 (0.9%)	0	2 (3.4%)	1 (1.6%)	0	1 (1.7%)	0	3 (4.8%)	8 (1.5%)	10 (1.5%)
		8	1 (0.8%)	0	0	0	1 (1.6%)	0	0	0	0	1 (0.2%)	2 (0.3%)
		8.5	0	0	0	1 (1.7%)	0	0	0	0	0	1 (0.2%)	1 (0.1%)
	7	5.5	1 (0.8%)	0	0	0	0	0	1 (1.7%)	0	0	1 (0.2%)	2 (0.3%)
		6	3 (2.4%)	3 (2.6%)	2 (3.4%)	4 (6.9%)	1 (1.6%)	2 (3.1%)	0	1 (1.5%)	0	13 (2.4%)	16 (2.4%)
		6.5	6 (4.8%)	0	3 (5.1%)	1 (1.7%)	4 (6.5%)	4 (6.2%)	1 (1.7%)	2 (3.0%)	1 (1.6%)	16 (2.9%)	22 (3.3%)
		7	8 (6.3%)	1 (0.9%)	2 (3.4%)	3 (5.2%)	1 (1.6%)	3 (4.6%)	2 (3.3%)	1 (1.5%)	3 (4.8%)	16 (2.9%)	24 (3.6%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
		7.5	1 (0.8%)	2 (1.7%)	0	0	2 (3.2%)	1 (1.5%)	0	0	0	5 (0.9%)	6 (0.9%)
	7.5	5.5	0	0	1 (1.7%)	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
		6	0	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	1 (0.1%)
		6.5	0	1 (0.9%)	0	1 (1.7%)	0	0	0	0	0	2 (0.4%)	2 (0.3%)
		7	1 (0.8%)	2 (1.7%)	0	0	1 (1.6%)	1 (1.5%)	2 (3.3%)	0	0	6 (1.1%)	7 (1.0%)
		7.5	0	1 (0.9%)	0	0	1 (1.6%)	1 (1.5%)	0	0	0	3 (0.5%)	3 (0.4%)
		8	0	0	0	1 (1.7%)	0	1 (1.5%)	0	1 (1.5%)	0	3 (0.5%)	3 (0.4%)
	8	6	0	0	0	0	1 (1.6%)	0	0	0	0	1 (0.2%)	1 (0.1%)
		6.5	0	0	0	0	0	0	0	1 (1.5%)	0	1 (0.2%)	1 (0.1%)
		7	0	0	0	0	0	0	0	1 (1.5%)	0	1 (0.2%)	1 (0.1%)
		7.5	0	0	0	1 (1.7%)	0	0	0	0	0	1 (0.2%)	1 (0.1%)
	8.5	6	0	1 (0.9%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
		8.5	0	1 (0.9%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
LOCF Endpoint	m		134	127	64	64	64	65	63	70	63	580	714
	5.5	5.5	8 (6.0%)	10 (7.9%)	4 (6.3%)	4 (6.3%)	4 (6.3%)	2 (3.1%)	8 (12.7%)	5 (7.1%)	11 (17.5%)	48 (8.3%)	56 (7.8%)
		6	16 (11.9%)	15 (11.8%)	3 (4.7%)	6 (9.4%)	3 (4.7%)	8 (12.3%)	6 (9.5%)	6 (8.6%)	11 (17.5%)	58 (10.0%)	74 (10.4%)
		6.5	2 (1.5%)	3 (2.4%)	2 (3.1%)	3 (4.7%)	0	1 (1.5%)	0	1 (1.4%)	2 (3.2%)	12 (2.1%)	14 (2.0%)
		7	0	0	0	0	0	1 (1.5%)	1 (1.6%)	1 (1.4%)	1 (1.6%)	4 (0.7%)	4 (0.6%)
		7.5	1 (0.7%)	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	2 (0.3%)
		8	0	0	0	0	0	0	0	1 (1.4%)	0	1 (0.2%)	1 (0.1%)
	6	5.5	8 (6.0%)	3 (2.4%)	3 (4.7%)	2 (3.1%)	5 (7.8%)	2 (3.1%)	1 (1.6%)	4 (5.7%)	0	20 (3.4%)	28 (3.9%)
		6	26 (19.4%)	34 (26.8%)	14 (21.9%)	11 (17.2%)	12 (18.8%)	10 (15.4%)	13 (20.6%)	17 (24.3%)	15 (23.8%)	126 (21.7%)	152 (21.3%)
		6.5	13 (9.7%)	14 (11.0%)	5 (7.8%)	3 (4.7%)	7 (10.9%)	5 (7.7%)	9 (14.3%)	10 (14.3%)	4 (6.3%)	57 (9.8%)	70 (9.8%)
		7	4 (3.0%)	4 (3.1%)	3 (4.7%)	3 (4.7%)	2 (3.1%)	1 (1.5%)	5 (7.9%)	1 (1.4%)	2 (3.2%)	21 (3.6%)	25 (3.5%)
		7.5	3 (2.2%)	1 (0.8%)	1 (1.6%)	2 (3.1%)	1 (1.6%)	0	0	0	0	5 (0.9%)	8 (1.1%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
		8	1 (0.7%)	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	2 (0.3%)
	6.5	5.5	2 (1.5%)	1 (0.8%)	0	0	0	1 (1.5%)	1 (1.6%)	1 (1.4%)	1 (1.6%)	5 (0.9%)	7 (1.0%)
		6	10 (7.5%)	16 (12.6%)	6 (9.4%)	7 (10.9%)	7 (10.9%)	6 (9.2%)	4 (6.3%)	9 (12.9%)	3 (4.8%)	58 (10.0%)	68 (9.5%)
		6.5	10 (7.5%)	6 (4.7%)	7 (10.9%)	4 (6.3%)	8 (12.5%)	9 (13.8%)	4 (6.3%)	4 (5.7%)	4 (6.3%)	46 (7.9%)	56 (7.8%)
		7	7 (5.2%)	3 (2.4%)	7 (10.9%)	4 (6.3%)	0	6 (9.2%)	3 (4.8%)	3 (4.3%)	1 (1.6%)	27 (4.7%)	34 (4.8%)
		7.5	2 (1.5%)	1 (0.8%)	0	2 (3.1%)	1 (1.6%)	0	1 (1.6%)	0	3 (4.8%)	8 (1.4%)	10 (1.4%)
		8	1 (0.7%)	0	0	0	1 (1.6%)	0	0	0	0	1 (0.2%)	2 (0.3%)
		8.5	0	0	0	1 (1.6%)	0	0	0	0	0	1 (0.2%)	1 (0.1%)
	7	5.5	1 (0.7%)	0	0	0	0	0	1 (1.6%)	0	0	1 (0.2%)	2 (0.3%)
		6	3 (2.2%)	4 (3.1%)	2 (3.1%)	4 (6.3%)	1 (1.6%)	2 (3.1%)	0	1 (1.4%)	0	14 (2.4%)	17 (2.4%)
		6.5	6 (4.5%)	0	3 (4.7%)	2 (3.1%)	4 (6.3%)	4 (6.2%)	2 (3.2%)	2 (2.9%)	1 (1.6%)	18 (3.1%)	24 (3.4%)
		7	8 (6.0%)	2 (1.6%)	3 (4.7%)	3 (4.7%)	1 (1.6%)	3 (4.6%)	2 (3.2%)	1 (1.4%)	3 (4.8%)	18 (3.1%)	26 (3.6%)
		7.5	1 (0.7%)	2 (1.6%)	0	0	2 (3.1%)	1 (1.5%)	0	0	0	5 (0.9%)	6 (0.8%)
	7.5	5.5	0	0	1 (1.6%)	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
		6	0	0	0	0	1 (1.6%)	0	0	0	1 (1.6%)	2 (0.3%)	2 (0.3%)
		6.5	0	1 (0.8%)	0	1 (1.6%)	0	0	0	0	0	2 (0.3%)	2 (0.3%)
		7	1 (0.7%)	2 (1.6%)	0	0	1 (1.6%)	1 (1.5%)	2 (3.2%)	0	0	6 (1.0%)	7 (1.0%)
		7.5	0	1 (0.8%)	0	0	1 (1.6%)	1 (1.5%)	0	0	0	3 (0.5%)	3 (0.4%)
		8	0	0	0	1 (1.6%)	0	1 (1.5%)	0	1 (1.4%)	0	3 (0.5%)	3 (0.4%)
	8	6	0	0	0	0	2 (3.1%)	0	0	0	0	2 (0.3%)	2 (0.3%)
		6.5	0	0	0	0	0	0	0	1 (1.4%)	0	1 (0.2%)	1 (0.1%)
		7	0	0	0	0	0	0	0	1 (1.4%)	0	1 (0.2%)	1 (0.1%)
		7.5	0	0	0	1 (1.6%)	0	0	0	0	0	1 (0.2%)	1 (0.1%)
	8.5	6	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
		8.5	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
Specific Gravity													
Week 4	m		134	127	64	64	64	65	63	70	63	580	714
	Low	Low	1 (0.7%)	1 (0.8%)	0	0	1 (1.6%)	0	0	2 (2.9%)	0	4 (0.7%)	5 (0.7%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
		Normal	2 (1.5%)	0	0	1 (1.6%)	0	1 (1.5%)	1 (1.6%)	2 (2.9%)	0	5 (0.9%)	7 (1.0%)
	Normal	Low	3 (2.2%)	1 (0.8%)	0	1 (1.6%)	1 (1.6%)	1 (1.5%)	2 (3.2%)	0	1 (1.6%)	7 (1.2%)	10 (1.4%)
		Normal	128 (95.5%)	124 (97.6%)	64 (100.0%)	62 (96.9%)	62 (96.9%)	62 (95.4%)	59 (93.7%)	65 (92.9%)	40 (63.5%)	538 (92.8%)	666 (93.3%)
		High	0	0	0	0	0	0	0	0	10 (15.9%)	10 (1.7%)	10 (1.4%)
	High	Normal	0	1 (0.8%)	0	0	0	1 (1.5%)	1 (1.6%)	0	6 (9.5%)	9 (1.6%)	9 (1.3%)
		High	0	0	0	0	0	0	0	1 (1.4%)	6 (9.5%)	7 (1.2%)	7 (1.0%)
Week 8	m		132	126	63	64	64	65	62	69	63	576	708
	Low	Low	1 (0.8%)	1 (0.8%)	0	0	1 (1.6%)	1 (1.5%)	0	0	0	3 (0.5%)	4 (0.6%)
		Normal	2 (1.5%)	0	0	1 (1.6%)	0	0	1 (1.6%)	4 (5.8%)	0	6 (1.0%)	8 (1.1%)
	Normal	Low	2 (1.5%)	0	2 (3.2%)	0	0	3 (4.6%)	0	1 (1.4%)	1 (1.6%)	7 (1.2%)	9 (1.3%)
		Normal	127 (96.2%)	124 (98.4%)	61 (96.8%)	62 (96.9%)	63 (98.4%)	60 (92.3%)	60 (96.8%)	62 (89.9%)	45 (71.4%)	537 (93.2%)	664 (93.8%)
		High	0	0	0	1 (1.6%)	0	0	0	1 (1.4%)	5 (7.9%)	7 (1.2%)	7 (1.0%)
	High	Normal	0	1 (0.8%)	0	0	0	1 (1.5%)	1 (1.6%)	0	5 (7.9%)	8 (1.4%)	8 (1.1%)
		High	0	0	0	0	0	0	0	1 (1.4%)	7 (11.1%)	8 (1.4%)	8 (1.1%)
Week 12	m		131	123	63	64	64	65	62	68	63	572	703
	Low	Low	1 (0.8%)	1 (0.8%)	0	0	1 (1.6%)	1 (1.5%)	0	1 (1.5%)	0	4 (0.7%)	5 (0.7%)
		Normal	2 (1.5%)	0	0	1 (1.6%)	0	0	1 (1.6%)	3 (4.4%)	0	5 (0.9%)	7 (1.0%)
	Normal	Low	4 (3.1%)	1 (0.8%)	0	1 (1.6%)	0	2 (3.1%)	0	0	1 (1.6%)	5 (0.9%)	9 (1.3%)
		Normal	124 (94.7%)	119 (96.7%)	63 (100.0%)	61 (95.3%)	63 (98.4%)	61 (93.8%)	60 (96.8%)	63 (92.6%)	46 (73.0%)	536 (93.7%)	660 (93.9%)
		High	0	1 (0.8%)	0	1 (1.6%)	0	0	0	0	4 (6.3%)	6 (1.0%)	6 (0.9%)
	High	Normal	0	1 (0.8%)	0	0	0	1 (1.5%)	1 (1.6%)	1 (1.5%)	5 (7.9%)	9 (1.6%)	9 (1.3%)
		High	0	0	0	0	0	0	0	0	7 (11.1%)	7 (1.2%)	7 (1.0%)
Week 16	m		130	123	63	64	64	64	62	69	63	572	702
	Low	Low	0	1 (0.8%)	0	1 (1.6%)	0	0	0	0	0	2 (0.3%)	2 (0.3%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
		Normal	3 (2.3%)	0	0	0	1 (1.6%)	1 (1.6%)	1 (1.6%)	4 (5.8%)	0	7 (1.2%)	10 (1.4%)
	Normal	Low	4 (3.1%)	0	2 (3.2%)	0	0	2 (3.1%)	0	1 (1.4%)	1 (1.6%)	6 (1.0%)	10 (1.4%)
		Normal	123 (94.6%)	120 (97.6%)	61 (96.8%)	63 (98.4%)	63 (98.4%)	60 (93.8%)	60 (96.8%)	63 (91.3%)	46 (73.0%)	536 (93.7%)	659 (93.9%)
		High	0	1 (0.8%)	0	0	0	0	0	0	4 (6.3%)	5 (0.9%)	5 (0.7%)
	High	Normal	0	1 (0.8%)	0	0	0	1 (1.6%)	1 (1.6%)	1 (1.4%)	4 (6.3%)	8 (1.4%)	8 (1.1%)
		High	0	0	0	0	0	0	0	0	8 (12.7%)	8 (1.4%)	8 (1.1%)
Week 20	m		130	123	62	63	64	65	61	69	63	570	700
	Low	Low	1 (0.8%)	1 (0.8%)	0	0	1 (1.6%)	0	0	2 (2.9%)	0	4 (0.7%)	5 (0.7%)
		Normal	2 (1.5%)	0	0	1 (1.6%)	0	1 (1.5%)	1 (1.6%)	2 (2.9%)	0	5 (0.9%)	7 (1.0%)
	Normal	Low	0	0	2 (3.2%)	0	0	1 (1.5%)	0	1 (1.4%)	0	4 (0.7%)	4 (0.6%)
		Normal	127 (97.7%)	121 (98.4%)	60 (96.8%)	62 (98.4%)	63 (98.4%)	62 (95.4%)	59 (96.7%)	63 (91.3%)	45 (71.4%)	535 (93.9%)	662 (94.6%)
		High	0	0	0	0	0	0	0	0	6 (9.5%)	6 (1.1%)	6 (0.9%)
	High	Normal	0	1 (0.8%)	0	0	0	1 (1.5%)	1 (1.6%)	1 (1.4%)	6 (9.5%)	10 (1.8%)	10 (1.4%)
		High	0	0	0	0	0	0	0	0	6 (9.5%)	6 (1.1%)	6 (0.9%)
Week 24	m		130	122	62	63	64	65	61	69	63	569	699
	Low	Low	1 (0.8%)	1 (0.8%)	0	1 (1.6%)	0	0	0	1 (1.4%)	0	3 (0.5%)	4 (0.6%)
		Normal	2 (1.5%)	0	0	0	1 (1.6%)	1 (1.5%)	1 (1.6%)	3 (4.3%)	0	6 (1.1%)	8 (1.1%)
	Normal	Low	1 (0.8%)	2 (1.6%)	1 (1.6%)	0	1 (1.6%)	1 (1.5%)	0	0	1 (1.6%)	6 (1.1%)	7 (1.0%)
		Normal	126 (96.9%)	117 (95.9%)	61 (98.4%)	62 (98.4%)	62 (96.9%)	62 (95.4%)	59 (96.7%)	64 (92.8%)	46 (73.0%)	533 (93.7%)	659 (94.3%)
		High	0	1 (0.8%)	0	0	0	0	0	0	4 (6.3%)	5 (0.9%)	5 (0.7%)
	High	Normal	0	1 (0.8%)	0	0	0	1 (1.5%)	1 (1.6%)	1 (1.4%)	6 (9.5%)	10 (1.8%)	10 (1.4%)
		High	0	0	0	0	0	0	0	0	6 (9.5%)	6 (1.1%)	6 (0.9%)
Week 32	m		128	120	62	60	62	65	60	69	63	561	689
	Low	Low	0	1 (0.8%)	0	1 (1.7%)	0	1 (1.5%)	0	3 (4.3%)	0	6 (1.1%)	6 (0.9%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
		Normal	3 (2.3%)	0	0	0	1 (1.6%)	0	1 (1.7%)	1 (1.4%)	0	3 (0.5%)	6 (0.9%)
	Normal	Low	1 (0.8%)	1 (0.8%)	1 (1.6%)	0	1 (1.6%)	2 (3.1%)	2 (3.3%)	1 (1.4%)	1 (1.6%)	9 (1.6%)	10 (1.5%)
		Normal	124 (96.9%)	116 (96.7%)	61 (98.4%)	59 (98.3%)	60 (96.8%)	61 (93.8%)	56 (93.3%)	62 (89.9%)	48 (76.2%)	523 (93.2%)	647 (93.9%)
		High	0	1 (0.8%)	0	0	0	0	0	1 (1.4%)	2 (3.2%)	4 (0.7%)	4 (0.6%)
	High	Normal	0	1 (0.8%)	0	0	0	1 (1.5%)	1 (1.7%)	1 (1.4%)	7 (11.1%)	11 (2.0%)	11 (1.6%)
		High	0	0	0	0	0	0	0	0	5 (7.9%)	5 (0.9%)	5 (0.7%)
Week 40	m		128	120	60	59	62	65	60	69	63	558	686
	Low	Low	0	1 (0.8%)	0	0	1 (1.6%)	1 (1.5%)	0	2 (2.9%)	0	5 (0.9%)	5 (0.7%)
		Normal	3 (2.3%)	0	0	1 (1.7%)	0	0	1 (1.7%)	2 (2.9%)	0	4 (0.7%)	7 (1.0%)
	Normal	Low	2 (1.6%)	3 (2.5%)	2 (3.3%)	0	2 (3.2%)	4 (6.2%)	2 (3.3%)	0	2 (3.2%)	15 (2.7%)	17 (2.5%)
		Normal	122 (95.3%)	113 (94.2%)	58 (96.7%)	58 (98.3%)	58 (93.5%)	59 (90.8%)	56 (93.3%)	62 (89.9%)	40 (63.5%)	504 (90.3%)	626 (91.3%)
		High	1 (0.8%)	2 (1.7%)	0	0	1 (1.6%)	0	0	2 (2.9%)	9 (14.3%)	14 (2.5%)	15 (2.2%)
	High	Normal	0	1 (0.8%)	0	0	0	1 (1.5%)	1 (1.7%)	1 (1.4%)	5 (7.9%)	9 (1.6%)	9 (1.3%)
		High	0	0	0	0	0	0	0	0	7 (11.1%)	7 (1.3%)	7 (1.0%)
Week 48	m		127	118	60	59	62	65	60	66	63	553	680
	Low	Low	0	1 (0.8%)	0	1 (1.7%)	0	1 (1.5%)	0	0	0	3 (0.5%)	3 (0.4%)
		Normal	3 (2.4%)	0	0	0	1 (1.6%)	0	1 (1.7%)	4 (6.1%)	0	6 (1.1%)	9 (1.3%)
	Normal	Low	1 (0.8%)	1 (0.8%)	1 (1.7%)	0	1 (1.6%)	2 (3.1%)	1 (1.7%)	0	2 (3.2%)	8 (1.4%)	9 (1.3%)
		Normal	123 (96.9%)	114 (96.6%)	59 (98.3%)	58 (98.3%)	59 (95.2%)	61 (93.8%)	56 (93.3%)	60 (90.9%)	44 (69.8%)	511 (92.4%)	634 (93.2%)
		High	0	1 (0.8%)	0	0	1 (1.6%)	0	1 (1.7%)	1 (1.5%)	5 (7.9%)	9 (1.6%)	9 (1.3%)
	High	Normal	0	1 (0.8%)	0	0	0	1 (1.5%)	1 (1.7%)	1 (1.5%)	7 (11.1%)	11 (2.0%)	11 (1.6%)
		High	0	0	0	0	0	0	0	0	5 (7.9%)	5 (0.9%)	5 (0.7%)
Week 52	m		126	116	59	58	62	65	60	67	62	549	675
	Low	Low	0	1 (0.9%)	0	1 (1.7%)	0	0	0	2 (3.0%)	0	4 (0.7%)	4 (0.6%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
		Normal	3 (2.4%)	0	0	0	1 (1.6%)	1 (1.5%)	1 (1.7%)	2 (3.0%)	0	5 (0.9%)	8 (1.2%)
	Normal	Low	1 (0.8%)	0	4 (6.8%)	1 (1.7%)	1 (1.6%)	0	1 (1.7%)	0	2 (3.2%)	9 (1.6%)	10 (1.5%)
		Normal	121 (96.0%)	109 (94.0%)	54 (91.5%)	56 (96.6%)	60 (96.8%)	63 (96.9%)	57 (95.0%)	59 (88.1%)	43 (69.4%)	501 (91.3%)	622 (92.1%)
		High	1 (0.8%)	5 (4.3%)	1 (1.7%)	0	0	0	0	3 (4.5%)	5 (8.1%)	14 (2.6%)	15 (2.2%)
	High	Normal	0	1 (0.9%)	0	0	0	1 (1.5%)	1 (1.7%)	1 (1.5%)	7 (11.3%)	11 (2.0%)	11 (1.6%)
		High	0	0	0	0	0	0	0	0	5 (8.1%)	5 (0.9%)	5 (0.7%)
LOCF Endpoint	m		134	127	64	64	64	65	63	70	63	580	714
	Low	Low	0	1 (0.8%)	0	1 (1.6%)	0	0	0	2 (2.9%)	0	4 (0.7%)	4 (0.6%)
		Normal	3 (2.2%)	0	0	0	1 (1.6%)	1 (1.5%)	1 (1.6%)	2 (2.9%)	0	5 (0.9%)	8 (1.1%)
	Normal	Low	1 (0.7%)	1 (0.8%)	4 (6.3%)	1 (1.6%)	1 (1.6%)	0	1 (1.6%)	0	2 (3.2%)	10 (1.7%)	11 (1.5%)
		Normal	128 (95.5%)	119 (93.7%)	59 (92.2%)	61 (95.3%)	62 (96.9%)	63 (96.9%)	60 (95.2%)	62 (88.6%)	44 (69.8%)	530 (91.4%)	658 (92.2%)
		High	2 (1.5%)	5 (3.9%)	1 (1.6%)	1 (1.6%)	0	0	0	3 (4.3%)	5 (7.9%)	15 (2.6%)	17 (2.4%)
	High	Normal	0	1 (0.8%)	0	0	0	1 (1.5%)	1 (1.6%)	1 (1.4%)	7 (11.1%)	11 (1.9%)	11 (1.5%)
		High	0	0	0	0	0	0	0	0	5 (7.9%)	5 (0.9%)	5 (0.7%)
Urine Glucose Week 4	m		134	127	64	64	64	65	63	70	63	580	714
	Negative	Negative	78 (58.2%)	50 (39.4%)	28 (43.8%)	30 (46.9%)	28 (43.8%)	25 (38.5%)	29 (46.0%)	26 (37.1%)	0	216 (37.2%)	294 (41.2%)
		Trace	3 (2.2%)	6 (4.7%)	1 (1.6%)	4 (6.3%)	0	0	0	2 (2.9%)	0	13 (2.2%)	16 (2.2%)
		Positive	1 (0.7%)	1 (0.8%)	0	2 (3.1%)	2 (3.1%)	3 (4.6%)	1 (1.6%)	1 (1.4%)	0	10 (1.7%)	11 (1.5%)
	Trace	Negative	15 (11.2%)	8 (6.3%)	2 (3.1%)	6 (9.4%)	6 (9.4%)	4 (6.2%)	5 (7.9%)	1 (1.4%)	0	32 (5.5%)	47 (6.6%)
		Trace	5 (3.7%)	3 (2.4%)	2 (3.1%)	0	1 (1.6%)	2 (3.1%)	2 (3.2%)	0	0	10 (1.7%)	15 (2.1%)
		Positive	3 (2.2%)	3 (2.4%)	1 (1.6%)	2 (3.1%)	1 (1.6%)	3 (4.6%)	1 (1.6%)	2 (2.9%)	0	13 (2.2%)	16 (2.2%)
	Positive	Negative	9 (6.7%)	13 (10.2%)	11 (17.2%)	9 (14.1%)	13 (20.3%)	12 (18.5%)	9 (14.3%)	11 (15.7%)	0	78 (13.4%)	87 (12.2%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
		Trace	3 (2.2%)	5 (3.9%)	6 (9.4%)	3 (4.7%)	4 (6.3%)	1 (1.5%)	5 (7.9%)	5 (7.1%)	0	29 (5.0%)	32 (4.5%)
		Positive	17 (12.7%)	38 (29.9%)	13 (20.3%)	8 (12.5%)	9 (14.1%)	15 (23.1%)	11 (17.5%)	22 (31.4%)	63 (100.0%)	179 (30.9%)	196 (27.5%)
Week 8	m		132	126	63	64	64	65	62	69	63	576	708
	Negative	Negative	80 (60.6%)	52 (41.3%)	26 (41.3%)	31 (48.4%)	28 (43.8%)	24 (36.9%)	29 (46.8%)	23 (33.3%)	0	213 (37.0%)	293 (41.4%)
		Trace	0	1 (0.8%)	1 (1.6%)	5 (7.8%)	2 (3.1%)	4 (6.2%)	1 (1.6%)	4 (5.8%)	0	18 (3.1%)	18 (2.5%)
		Positive	2 (1.5%)	3 (2.4%)	2 (3.2%)	0	0	0	0	2 (2.9%)	0	7 (1.2%)	9 (1.3%)
	Trace	Negative	15 (11.4%)	12 (9.5%)	4 (6.3%)	7 (10.9%)	7 (10.9%)	4 (6.2%)	7 (11.3%)	1 (1.4%)	0	42 (7.3%)	57 (8.1%)
		Trace	4 (3.0%)	1 (0.8%)	1 (1.6%)	1 (1.6%)	0	2 (3.1%)	0	0	0	5 (0.9%)	9 (1.3%)
		Positive	2 (1.5%)	1 (0.8%)	0	0	1 (1.6%)	3 (4.6%)	1 (1.6%)	1 (1.4%)	0	7 (1.2%)	9 (1.3%)
	Positive	Negative	10 (7.6%)	10 (7.9%)	14 (22.2%)	13 (20.3%)	12 (18.8%)	13 (20.0%)	10 (16.1%)	10 (14.5%)	1 (1.6%)	83 (14.4%)	93 (13.1%)
		Trace	4 (3.0%)	6 (4.8%)	2 (3.2%)	2 (3.1%)	4 (6.3%)	4 (6.2%)	5 (8.1%)	8 (11.6%)	0	31 (5.4%)	35 (4.9%)
		Positive	15 (11.4%)	40 (31.7%)	13 (20.6%)	5 (7.8%)	10 (15.6%)	11 (16.9%)	9 (14.5%)	20 (29.0%)	62 (98.4%)	170 (29.5%)	185 (26.1%)
Week 12	m		131	123	63	64	64	65	62	68	63	572	703
	Negative	Negative	75 (57.3%)	48 (39.0%)	28 (44.4%)	32 (50.0%)	29 (45.3%)	25 (38.5%)	30 (48.4%)	23 (33.8%)	0	215 (37.6%)	290 (41.3%)
		Trace	4 (3.1%)	3 (2.4%)	0	3 (4.7%)	1 (1.6%)	3 (4.6%)	0	2 (2.9%)	0	12 (2.1%)	16 (2.3%)
		Positive	3 (2.3%)	3 (2.4%)	1 (1.6%)	1 (1.6%)	0	0	0	3 (4.4%)	0	8 (1.4%)	11 (1.6%)
	Trace	Negative	14 (10.7%)	9 (7.3%)	3 (4.8%)	6 (9.4%)	5 (7.8%)	5 (7.7%)	8 (12.9%)	1 (1.5%)	0	37 (6.5%)	51 (7.3%)
		Trace	5 (3.8%)	3 (2.4%)	1 (1.6%)	0	1 (1.6%)	4 (6.2%)	0	0	0	9 (1.6%)	14 (2.0%)
		Positive	1 (0.8%)	2 (1.6%)	1 (1.6%)	2 (3.1%)	2 (3.1%)	0	0	1 (1.5%)	0	8 (1.4%)	9 (1.3%)
	Positive	Negative	12 (9.2%)	17 (13.8%)	11 (17.5%)	8 (12.5%)	17 (26.6%)	14 (21.5%)	11 (17.7%)	9 (13.2%)	1 (1.6%)	88 (15.4%)	100 (14.2%)
		Trace	5 (3.8%)	6 (4.9%)	4 (6.3%)	5 (7.8%)	3 (4.7%)	4 (6.2%)	2 (3.2%)	7 (10.3%)	0	31 (5.4%)	36 (5.1%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
		Positive	12 (9.2%)	32 (26.0%)	14 (22.2%)	7 (10.9%)	6 (9.4%)	10 (15.4%)	11 (17.7%)	22 (32.4%)	62 (98.4%)	164 (28.7%)	176 (25.0%)
Week 16	m		130	123	63	64	64	64	62	69	63	572	702
	Negative	Negative	73 (56.2%)	44 (35.8%)	26 (41.3%)	34 (53.1%)	28 (43.8%)	25 (39.1%)	27 (43.5%)	25 (36.2%)	0	209 (36.5%)	282 (40.2%)
		Trace	5 (3.8%)	6 (4.9%)	0	1 (1.6%)	1 (1.6%)	2 (3.1%)	3 (4.8%)	3 (4.3%)	0	16 (2.8%)	21 (3.0%)
		Positive	3 (2.3%)	4 (3.3%)	3 (4.8%)	1 (1.6%)	1 (1.6%)	0	0	1 (1.4%)	0	10 (1.7%)	13 (1.9%)
	Trace	Negative	12 (9.2%)	8 (6.5%)	3 (4.8%)	6 (9.4%)	7 (10.9%)	5 (7.8%)	7 (11.3%)	1 (1.4%)	0	37 (6.5%)	49 (7.0%)
		Trace	4 (3.1%)	3 (2.4%)	0	0	0	2 (3.1%)	0	0	0	5 (0.9%)	9 (1.3%)
		Positive	4 (3.1%)	3 (2.4%)	2 (3.2%)	2 (3.1%)	1 (1.6%)	2 (3.1%)	1 (1.6%)	1 (1.4%)	0	12 (2.1%)	16 (2.3%)
	Positive	Negative	13 (10.0%)	18 (14.6%)	16 (25.4%)	11 (17.2%)	14 (21.9%)	14 (21.9%)	12 (19.4%)	10 (14.5%)	1 (1.6%)	96 (16.8%)	109 (15.5%)
		Trace	6 (4.6%)	9 (7.3%)	1 (1.6%)	3 (4.7%)	4 (6.3%)	2 (3.1%)	4 (6.5%)	9 (13.0%)	0	32 (5.6%)	38 (5.4%)
		Positive	10 (7.7%)	28 (22.8%)	12 (19.0%)	6 (9.4%)	8 (12.5%)	12 (18.8%)	8 (12.9%)	19 (27.5%)	62 (98.4%)	155 (27.1%)	165 (23.5%)
Week 20	m		130	123	62	63	64	65	61	69	63	570	700
	Negative	Negative	70 (53.8%)	44 (35.8%)	24 (38.7%)	32 (50.8%)	28 (43.8%)	27 (41.5%)	29 (47.5%)	25 (36.2%)	0	209 (36.7%)	279 (39.9%)
		Trace	7 (5.4%)	4 (3.3%)	3 (4.8%)	2 (3.2%)	2 (3.1%)	1 (1.5%)	1 (1.6%)	0	0	13 (2.3%)	20 (2.9%)
		Positive	4 (3.1%)	6 (4.9%)	1 (1.6%)	2 (3.2%)	0	0	0	4 (5.8%)	0	13 (2.3%)	17 (2.4%)
	Trace	Negative	15 (11.5%)	10 (8.1%)	3 (4.8%)	7 (11.1%)	7 (10.9%)	6 (9.2%)	7 (11.5%)	1 (1.4%)	0	41 (7.2%)	56 (8.0%)
		Trace	2 (1.5%)	1 (0.8%)	0	0	0	2 (3.1%)	1 (1.6%)	0	0	4 (0.7%)	6 (0.9%)
		Positive	3 (2.3%)	3 (2.4%)	2 (3.2%)	1 (1.6%)	1 (1.6%)	1 (1.5%)	0	1 (1.4%)	0	9 (1.6%)	12 (1.7%)
	Positive	Negative	16 (12.3%)	14 (11.4%)	12 (19.4%)	10 (15.9%)	11 (17.2%)	13 (20.0%)	11 (18.0%)	14 (20.3%)	0	85 (14.9%)	101 (14.4%)
		Trace	1 (0.8%)	6 (4.9%)	6 (9.7%)	1 (1.6%)	5 (7.8%)	7 (10.8%)	6 (9.8%)	7 (10.1%)	0	38 (6.7%)	39 (5.6%)
		Positive	12 (9.2%)	35 (28.5%)	11 (17.7%)	8 (12.7%)	10 (15.6%)	8 (12.3%)	6 (9.8%)	17 (24.6%)	63 (100.0%)	158 (27.7%)	170 (24.3%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
Week 24	m		130	122	62	63	64	65	61	69	63	569	699
	Negative	Negative	72 (55.4%)	46 (37.7%)	26 (41.9%)	33 (52.4%)	26 (40.6%)	27 (41.5%)	29 (47.5%)	22 (31.9%)	0	209 (36.7%)	281 (40.2%)
		Trace	6 (4.6%)	2 (1.6%)	0	1 (1.6%)	2 (3.1%)	0	1 (1.6%)	3 (4.3%)	0	9 (1.6%)	15 (2.1%)
		Positive	3 (2.3%)	6 (4.9%)	2 (3.2%)	2 (3.2%)	2 (3.1%)	1 (1.5%)	0	4 (5.8%)	0	17 (3.0%)	20 (2.9%)
	Trace	Negative	16 (12.3%)	10 (8.2%)	3 (4.8%)	7 (11.1%)	6 (9.4%)	8 (12.3%)	7 (11.5%)	1 (1.4%)	0	42 (7.4%)	58 (8.3%)
		Trace	1 (0.8%)	1 (0.8%)	1 (1.6%)	0	2 (3.1%)	0	0	0	0	4 (0.7%)	5 (0.7%)
		Positive	3 (2.3%)	3 (2.5%)	1 (1.6%)	1 (1.6%)	0	1 (1.5%)	1 (1.6%)	1 (1.4%)	0	8 (1.4%)	11 (1.6%)
	Positive	Negative	12 (9.2%)	14 (11.5%)	13 (21.0%)	10 (15.9%)	13 (20.3%)	12 (18.5%)	9 (14.8%)	16 (23.2%)	0	87 (15.3%)	99 (14.2%)
		Trace	5 (3.8%)	8 (6.6%)	2 (3.2%)	3 (4.8%)	3 (4.7%)	4 (6.2%)	6 (9.8%)	2 (2.9%)	0	28 (4.9%)	33 (4.7%)
		Positive	12 (9.2%)	32 (26.2%)	14 (22.6%)	6 (9.5%)	10 (15.6%)	12 (18.5%)	8 (13.1%)	20 (29.0%)	63 (100.0%)	165 (29.0%)	177 (25.3%)
Week 32	m		128	120	62	60	62	65	60	69	63	561	689
	Negative	Negative	70 (54.7%)	44 (36.7%)	26 (41.9%)	34 (56.7%)	28 (45.2%)	25 (38.5%)	27 (45.0%)	22 (31.9%)	0	206 (36.7%)	276 (40.1%)
		Trace	4 (3.1%)	3 (2.5%)	0	0	0	3 (4.6%)	0	3 (4.3%)	0	9 (1.6%)	13 (1.9%)
		Positive	5 (3.9%)	6 (5.0%)	2 (3.2%)	2 (3.3%)	1 (1.6%)	0	2 (3.3%)	4 (5.8%)	0	17 (3.0%)	22 (3.2%)
	Trace	Negative	14 (10.9%)	10 (8.3%)	4 (6.5%)	6 (10.0%)	8 (12.9%)	5 (7.7%)	6 (10.0%)	2 (2.9%)	0	41 (7.3%)	55 (8.0%)
		Trace	3 (2.3%)	1 (0.8%)	0	0	0	4 (6.2%)	2 (3.3%)	0	0	7 (1.2%)	10 (1.5%)
		Positive	3 (2.3%)	3 (2.5%)	1 (1.6%)	1 (1.7%)	0	0	0	0	0	5 (0.9%)	8 (1.2%)
	Positive	Negative	17 (13.3%)	12 (10.0%)	14 (22.6%)	8 (13.3%)	13 (21.0%)	13 (20.0%)	13 (21.7%)	13 (18.8%)	1 (1.6%)	87 (15.5%)	104 (15.1%)
		Trace	1 (0.8%)	8 (6.7%)	2 (3.2%)	1 (1.7%)	4 (6.5%)	5 (7.7%)	2 (3.3%)	3 (4.3%)	0	25 (4.5%)	26 (3.8%)
		Positive	11 (8.6%)	33 (27.5%)	13 (21.0%)	8 (13.3%)	8 (12.9%)	10 (15.4%)	8 (13.3%)	22 (31.9%)	62 (98.4%)	164 (29.2%)	175 (25.4%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
Week 40	m		128	120	60	59	62	65	60	69	63	558	686
	Negative	Negative	70 (54.7%)	43 (35.8%)	26 (43.3%)	34 (57.6%)	24 (38.7%)	25 (38.5%)	27 (45.0%)	21 (30.4%)	0	200 (35.8%)	270 (39.4%)
		Trace	1 (0.8%)	3 (2.5%)	1 (1.7%)	2 (3.4%)	2 (3.2%)	1 (1.5%)	1 (1.7%)	2 (2.9%)	0	12 (2.2%)	13 (1.9%)
		Positive	8 (6.3%)	7 (5.8%)	0	0	3 (4.8%)	2 (3.1%)	2 (3.3%)	6 (8.7%)	0	20 (3.6%)	28 (4.1%)
	Trace	Negative	14 (10.9%)	10 (8.3%)	2 (3.3%)	6 (10.2%)	7 (11.3%)	4 (6.2%)	7 (11.7%)	2 (2.9%)	0	38 (6.8%)	52 (7.6%)
		Trace	5 (3.9%)	0	1 (1.7%)	0	1 (1.6%)	3 (4.6%)	1 (1.7%)	0	0	6 (1.1%)	11 (1.6%)
		Positive	1 (0.8%)	4 (3.3%)	2 (3.3%)	1 (1.7%)	0	2 (3.1%)	0	0	0	9 (1.6%)	10 (1.5%)
	Positive	Negative	9 (7.0%)	8 (6.7%)	13 (21.7%)	8 (13.6%)	12 (19.4%)	13 (20.0%)	9 (15.0%)	11 (15.9%)	0	74 (13.3%)	83 (12.1%)
		Trace	7 (5.5%)	10 (8.3%)	1 (1.7%)	1 (1.7%)	3 (4.8%)	4 (6.2%)	4 (6.7%)	3 (4.3%)	0	26 (4.7%)	33 (4.8%)
		Positive	13 (10.2%)	35 (29.2%)	14 (23.3%)	7 (11.9%)	10 (16.1%)	11 (16.9%)	9 (15.0%)	24 (34.8%)	63 (100.0%)	173 (31.0%)	186 (27.1%)
Week 48	m		127	118	60	59	62	65	60	66	63	553	680
	Negative	Negative	72 (56.7%)	40 (33.9%)	25 (41.7%)	34 (57.6%)	27 (43.5%)	25 (38.5%)	26 (43.3%)	23 (34.8%)	0	200 (36.2%)	272 (40.0%)
		Trace	1 (0.8%)	7 (5.9%)	1 (1.7%)	2 (3.4%)	1 (1.6%)	1 (1.5%)	2 (3.3%)	1 (1.5%)	0	15 (2.7%)	16 (2.4%)
		Positive	6 (4.7%)	5 (4.2%)	1 (1.7%)	0	1 (1.6%)	2 (3.1%)	2 (3.3%)	4 (6.1%)	0	15 (2.7%)	21 (3.1%)
	Trace	Negative	17 (13.4%)	9 (7.6%)	4 (6.7%)	6 (10.2%)	6 (9.7%)	5 (7.7%)	7 (11.7%)	1 (1.5%)	0	38 (6.9%)	55 (8.1%)
		Trace	2 (1.6%)	2 (1.7%)	0	0	2 (3.2%)	2 (3.1%)	0	0	0	6 (1.1%)	8 (1.2%)
		Positive	1 (0.8%)	3 (2.5%)	1 (1.7%)	1 (1.7%)	0	2 (3.1%)	1 (1.7%)	1 (1.5%)	0	9 (1.6%)	10 (1.5%)
	Positive	Negative	12 (9.4%)	11 (9.3%)	14 (23.3%)	7 (11.9%)	12 (19.4%)	9 (13.8%)	9 (15.0%)	8 (12.1%)	0	70 (12.7%)	82 (12.1%)
		Trace	4 (3.1%)	7 (5.9%)	3 (5.0%)	4 (6.8%)	4 (6.5%)	2 (3.1%)	1 (1.7%)	5 (7.6%)	0	26 (4.7%)	30 (4.4%)
		Positive	12 (9.4%)	34 (28.8%)	11 (18.3%)	5 (8.5%)	9 (14.5%)	17 (26.2%)	12 (20.0%)	23 (34.8%)	63 (100.0%)	174 (31.5%)	186 (27.4%)
Week 52	m		126	116	59	58	62	65	60	67	62	549	675

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
	Negative	Negative	72 (57.1%)	41 (35.3%)	24 (40.7%)	32 (55.2%)	26 (41.9%)	25 (38.5%)	28 (46.7%)	18 (26.9%)	0	194 (35.3%)	266 (39.4%)
		Trace	2 (1.6%)	6 (5.2%)	1 (1.7%)	3 (5.2%)	1 (1.6%)	0	2 (3.3%)	5 (7.5%)	0	18 (3.3%)	20 (3.0%)
		Positive	4 (3.2%)	4 (3.4%)	1 (1.7%)	1 (1.7%)	2 (3.2%)	3 (4.6%)	0	5 (7.5%)	0	16 (2.9%)	20 (3.0%)
	Trace	Negative	15 (11.9%)	9 (7.8%)	3 (5.1%)	7 (12.1%)	6 (9.7%)	6 (9.2%)	8 (13.3%)	1 (1.5%)	0	40 (7.3%)	55 (8.1%)
		Trace	1 (0.8%)	3 (2.6%)	1 (1.7%)	0	2 (3.2%)	3 (4.6%)	0	0	0	9 (1.6%)	10 (1.5%)
		Positive	4 (3.2%)	2 (1.7%)	1 (1.7%)	0	0	0	0	1 (1.5%)	0	4 (0.7%)	8 (1.2%)
	Positive	Negative	16 (12.7%)	13 (11.2%)	9 (15.3%)	8 (13.8%)	15 (24.2%)	10 (15.4%)	10 (16.7%)	11 (16.4%)	0	76 (13.8%)	92 (13.6%)
		Trace	2 (1.6%)	1 (0.9%)	8 (13.6%)	0	1 (1.6%)	5 (7.7%)	1 (1.7%)	5 (7.5%)	1 (1.6%)	22 (4.0%)	24 (3.6%)
		Positive	10 (7.9%)	37 (31.9%)	11 (18.6%)	7 (12.1%)	9 (14.5%)	13 (20.0%)	11 (18.3%)	21 (31.3%)	61 (98.4%)	170 (31.0%)	180 (26.7%)
LOCF Endpoint	m		134	127	64	64	64	65	63	70	63	580	714
	Negative	Negative	76 (56.7%)	46 (36.2%)	26 (40.6%)	32 (50.0%)	27 (42.2%)	25 (38.5%)	28 (44.4%)	19 (27.1%)	0	203 (35.0%)	279 (39.1%)
		Trace	2 (1.5%)	7 (5.5%)	1 (1.6%)	3 (4.7%)	1 (1.6%)	0	2 (3.2%)	5 (7.1%)	0	19 (3.3%)	21 (2.9%)
		Positive	4 (3.0%)	4 (3.1%)	2 (3.1%)	1 (1.6%)	2 (3.1%)	3 (4.6%)	0	5 (7.1%)	0	17 (2.9%)	21 (2.9%)
	Trace	Negative	16 (11.9%)	9 (7.1%)	3 (4.7%)	8 (12.5%)	6 (9.4%)	6 (9.2%)	8 (12.7%)	1 (1.4%)	0	41 (7.1%)	57 (8.0%)
		Trace	1 (0.7%)	3 (2.4%)	1 (1.6%)	0	2 (3.1%)	3 (4.6%)	0	0	0	9 (1.6%)	10 (1.4%)
		Positive	6 (4.5%)	2 (1.6%)	1 (1.6%)	0	0	0	0	2 (2.9%)	0	5 (0.9%)	11 (1.5%)
	Positive	Negative	16 (11.9%)	14 (11.0%)	9 (14.1%)	12 (18.8%)	16 (25.0%)	10 (15.4%)	10 (15.9%)	11 (15.7%)	0	82 (14.1%)	98 (13.7%)
		Trace	2 (1.5%)	1 (0.8%)	9 (14.1%)	0	1 (1.6%)	5 (7.7%)	2 (3.2%)	5 (7.1%)	1 (1.6%)	24 (4.1%)	26 (3.6%)
		Positive	11 (8.2%)	41 (32.3%)	12 (18.8%)	8 (12.5%)	9 (14.1%)	13 (20.0%)	13 (20.6%)	22 (31.4%)	62 (98.4%)	180 (31.0%)	191 (26.8%)

Urine Protein

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
Week 4	m		134	127	64	64	64	65	63	70	63	580	714
	Negative	Negative	43 (32.1%)	23 (18.1%)	18 (28.1%)	19 (29.7%)	18 (28.1%)	12 (18.5%)	16 (25.4%)	21 (30.0%)	25 (39.7%)	152 (26.2%)	195 (27.3%)
		Trace	20 (14.9%)	12 (9.4%)	8 (12.5%)	3 (4.7%)	5 (7.8%)	7 (10.8%)	10 (15.9%)	7 (10.0%)	10 (15.9%)	62 (10.7%)	82 (11.5%)
		Positive	0	1 (0.8%)	3 (4.7%)	1 (1.6%)	0	2 (3.1%)	0	0	0	7 (1.2%)	7 (1.0%)
	Trace	Negative	24 (17.9%)	18 (14.2%)	8 (12.5%)	7 (10.9%)	9 (14.1%)	13 (20.0%)	11 (17.5%)	9 (12.9%)	5 (7.9%)	80 (13.8%)	104 (14.6%)
		Trace	25 (18.7%)	28 (22.0%)	13 (20.3%)	12 (18.8%)	18 (28.1%)	20 (30.8%)	9 (14.3%)	11 (15.7%)	14 (22.2%)	125 (21.6%)	150 (21.0%)
		Positive	3 (2.2%)	12 (9.4%)	1 (1.6%)	4 (6.3%)	2 (3.1%)	0	2 (3.2%)	5 (7.1%)	1 (1.6%)	27 (4.7%)	30 (4.2%)
	Positive	Negative	6 (4.5%)	2 (1.6%)	0	3 (4.7%)	1 (1.6%)	2 (3.1%)	1 (1.6%)	0	0	9 (1.6%)	15 (2.1%)
		Trace	5 (3.7%)	9 (7.1%)	5 (7.8%)	6 (9.4%)	4 (6.3%)	2 (3.1%)	4 (6.3%)	6 (8.6%)	1 (1.6%)	37 (6.4%)	42 (5.9%)
		Positive	8 (6.0%)	22 (17.3%)	8 (12.5%)	9 (14.1%)	7 (10.9%)	7 (10.8%)	10 (15.9%)	11 (15.7%)	7 (11.1%)	81 (14.0%)	89 (12.5%)
Week 8	m		132	126	63	64	64	65	62	69	63	576	708
	Negative	Negative	44 (33.3%)	24 (19.0%)	24 (38.1%)	15 (23.4%)	17 (26.6%)	12 (18.5%)	16 (25.8%)	21 (30.4%)	27 (42.9%)	156 (27.1%)	200 (28.2%)
		Trace	17 (12.9%)	10 (7.9%)	3 (4.8%)	6 (9.4%)	6 (9.4%)	8 (12.3%)	9 (14.5%)	5 (7.2%)	6 (9.5%)	53 (9.2%)	70 (9.9%)
		Positive	1 (0.8%)	1 (0.8%)	2 (3.2%)	2 (3.1%)	0	1 (1.5%)	1 (1.6%)	1 (1.4%)	2 (3.2%)	10 (1.7%)	11 (1.6%)
	Trace	Negative	22 (16.7%)	15 (11.9%)	5 (7.9%)	10 (15.6%)	12 (18.8%)	11 (16.9%)	13 (21.0%)	7 (10.1%)	8 (12.7%)	81 (14.1%)	103 (14.5%)
		Trace	25 (18.9%)	35 (27.8%)	15 (23.8%)	9 (14.1%)	12 (18.8%)	17 (26.2%)	9 (14.5%)	14 (20.3%)	9 (14.3%)	120 (20.8%)	145 (20.5%)
		Positive	5 (3.8%)	8 (6.3%)	1 (1.6%)	4 (6.3%)	5 (7.8%)	5 (7.7%)	0	4 (5.8%)	3 (4.8%)	30 (5.2%)	35 (4.9%)
	Positive	Negative	4 (3.0%)	4 (3.2%)	2 (3.2%)	2 (3.1%)	0	3 (4.6%)	0	0	1 (1.6%)	12 (2.1%)	16 (2.3%)
		Trace	6 (4.5%)	4 (3.2%)	2 (3.2%)	9 (14.1%)	4 (6.3%)	4 (6.2%)	5 (8.1%)	4 (5.8%)	1 (1.6%)	33 (5.7%)	39 (5.5%)
		Positive	8 (6.1%)	25 (19.8%)	9 (14.3%)	7 (10.9%)	8 (12.5%)	4 (6.2%)	9 (14.5%)	13 (18.8%)	6 (9.5%)	81 (14.1%)	89 (12.6%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
Week 12	m		131	123	63	64	64	65	62	68	63	572	703
	Negative	Negative	39 (29.8%)	21 (17.1%)	22 (34.9%)	14 (21.9%)	19 (29.7%)	14 (21.5%)	18 (29.0%)	12 (17.6%)	27 (42.9%)	147 (25.7%)	186 (26.5%)
		Trace	20 (15.3%)	11 (8.9%)	3 (4.8%)	8 (12.5%)	4 (6.3%)	7 (10.8%)	7 (11.3%)	14 (20.6%)	8 (12.7%)	62 (10.8%)	82 (11.7%)
		Positive	3 (2.3%)	1 (0.8%)	4 (6.3%)	1 (1.6%)	0	0	1 (1.6%)	1 (1.5%)	0	8 (1.4%)	11 (1.6%)
	Trace	Negative	23 (17.6%)	16 (13.0%)	4 (6.3%)	6 (9.4%)	14 (21.9%)	14 (21.5%)	7 (11.3%)	10 (14.7%)	12 (19.0%)	83 (14.5%)	106 (15.1%)
		Trace	25 (19.1%)	32 (26.0%)	15 (23.8%)	13 (20.3%)	12 (18.8%)	16 (24.6%)	14 (22.6%)	9 (13.2%)	8 (12.7%)	119 (20.8%)	144 (20.5%)
		Positive	4 (3.1%)	9 (7.3%)	2 (3.2%)	4 (6.3%)	3 (4.7%)	3 (4.6%)	1 (1.6%)	5 (7.4%)	0	27 (4.7%)	31 (4.4%)
	Positive	Negative	3 (2.3%)	2 (1.6%)	0	2 (3.1%)	1 (1.6%)	1 (1.5%)	1 (1.6%)	2 (2.9%)	1 (1.6%)	10 (1.7%)	13 (1.8%)
		Trace	7 (5.3%)	11 (8.9%)	5 (7.9%)	6 (9.4%)	2 (3.1%)	4 (6.2%)	1 (1.6%)	3 (4.4%)	1 (1.6%)	33 (5.8%)	40 (5.7%)
		Positive	7 (5.3%)	20 (16.3%)	8 (12.7%)	10 (15.6%)	9 (14.1%)	6 (9.2%)	12 (19.4%)	12 (17.6%)	6 (9.5%)	83 (14.5%)	90 (12.8%)
Week 16	m		130	123	63	64	64	64	62	69	63	572	702
	Negative	Negative	43 (33.1%)	24 (19.5%)	23 (36.5%)	10 (15.6%)	18 (28.1%)	14 (21.9%)	11 (17.7%)	17 (24.6%)	29 (46.0%)	146 (25.5%)	189 (26.9%)
		Trace	13 (10.0%)	8 (6.5%)	4 (6.3%)	12 (18.8%)	5 (7.8%)	6 (9.4%)	13 (21.0%)	8 (11.6%)	5 (7.9%)	61 (10.7%)	74 (10.5%)
		Positive	5 (3.8%)	1 (0.8%)	2 (3.2%)	1 (1.6%)	0	1 (1.6%)	2 (3.2%)	2 (2.9%)	1 (1.6%)	10 (1.7%)	15 (2.1%)
	Trace	Negative	18 (13.8%)	20 (16.3%)	11 (17.5%)	6 (9.4%)	13 (20.3%)	9 (14.1%)	12 (19.4%)	7 (10.1%)	10 (15.9%)	88 (15.4%)	106 (15.1%)
		Trace	25 (19.2%)	28 (22.8%)	9 (14.3%)	12 (18.8%)	13 (20.3%)	19 (29.7%)	9 (14.5%)	15 (21.7%)	10 (15.9%)	115 (20.1%)	140 (19.9%)
		Positive	9 (6.9%)	9 (7.3%)	1 (1.6%)	5 (7.8%)	3 (4.7%)	5 (7.8%)	1 (1.6%)	3 (4.3%)	0	27 (4.7%)	36 (5.1%)
	Positive	Negative	4 (3.1%)	5 (4.1%)	1 (1.6%)	6 (9.4%)	0	1 (1.6%)	0	1 (1.4%)	0	14 (2.4%)	18 (2.6%)
		Trace	7 (5.4%)	10 (8.1%)	3 (4.8%)	3 (4.7%)	4 (6.3%)	6 (9.4%)	7 (11.3%)	6 (8.7%)	0	39 (6.8%)	46 (6.6%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
		Positive	6 (4.6%)	18 (14.6%)	9 (14.3%)	9 (14.1%)	8 (12.5%)	3 (4.7%)	7 (11.3%)	10 (14.5%)	8 (12.7%)	72 (12.6%)	78 (11.1%)
Week 20	m		130	123	62	63	64	65	61	69	63	570	700
	Negative	Negative	38 (29.2%)	24 (19.5%)	19 (30.6%)	14 (22.2%)	20 (31.3%)	15 (23.1%)	15 (24.6%)	22 (31.9%)	29 (46.0%)	158 (27.7%)	196 (28.0%)
		Trace	19 (14.6%)	8 (6.5%)	6 (9.7%)	8 (12.7%)	3 (4.7%)	3 (4.6%)	10 (16.4%)	5 (7.2%)	5 (7.9%)	48 (8.4%)	67 (9.6%)
		Positive	4 (3.1%)	1 (0.8%)	3 (4.8%)	1 (1.6%)	0	3 (4.6%)	1 (1.6%)	0	1 (1.6%)	10 (1.8%)	14 (2.0%)
	Trace	Negative	21 (16.2%)	22 (17.9%)	10 (16.1%)	7 (11.1%)	10 (15.6%)	13 (20.0%)	12 (19.7%)	8 (11.6%)	5 (7.9%)	87 (15.3%)	108 (15.4%)
		Trace	24 (18.5%)	26 (21.1%)	11 (17.7%)	11 (17.5%)	15 (23.4%)	16 (24.6%)	5 (8.2%)	11 (15.9%)	15 (23.8%)	110 (19.3%)	134 (19.1%)
		Positive	7 (5.4%)	9 (7.3%)	0	5 (7.9%)	4 (6.3%)	4 (6.2%)	4 (6.6%)	6 (8.7%)	0	32 (5.6%)	39 (5.6%)
	Positive	Negative	3 (2.3%)	4 (3.3%)	3 (4.8%)	2 (3.2%)	2 (3.1%)	1 (1.5%)	0	2 (2.9%)	0	14 (2.5%)	17 (2.4%)
		Trace	9 (6.9%)	16 (13.0%)	4 (6.5%)	7 (11.1%)	3 (4.7%)	6 (9.2%)	7 (11.5%)	5 (7.2%)	1 (1.6%)	49 (8.6%)	58 (8.3%)
		Positive	5 (3.8%)	13 (10.6%)	6 (9.7%)	8 (12.7%)	7 (10.9%)	4 (6.2%)	7 (11.5%)	10 (14.5%)	7 (11.1%)	62 (10.9%)	67 (9.6%)
Week 24	m		130	122	62	63	64	65	61	69	63	569	699
	Negative	Negative	37 (28.5%)	22 (18.0%)	22 (35.5%)	16 (25.4%)	16 (25.0%)	15 (23.1%)	17 (27.9%)	23 (33.3%)	24 (38.1%)	155 (27.2%)	192 (27.5%)
		Trace	20 (15.4%)	9 (7.4%)	3 (4.8%)	5 (7.9%)	7 (10.9%)	6 (9.2%)	8 (13.1%)	2 (2.9%)	10 (15.9%)	50 (8.8%)	70 (10.0%)
		Positive	4 (3.1%)	2 (1.6%)	3 (4.8%)	2 (3.2%)	0	0	1 (1.6%)	2 (2.9%)	1 (1.6%)	11 (1.9%)	15 (2.1%)
	Trace	Negative	17 (13.1%)	27 (22.1%)	13 (21.0%)	10 (15.9%)	9 (14.1%)	13 (20.0%)	7 (11.5%)	9 (13.0%)	6 (9.5%)	94 (16.5%)	111 (15.9%)
		Trace	27 (20.8%)	19 (15.6%)	7 (11.3%)	9 (14.3%)	16 (25.0%)	14 (21.5%)	13 (21.3%)	12 (17.4%)	13 (20.6%)	103 (18.1%)	130 (18.6%)
		Positive	8 (6.2%)	10 (8.2%)	1 (1.6%)	4 (6.3%)	4 (6.3%)	6 (9.2%)	1 (1.6%)	4 (5.8%)	1 (1.6%)	31 (5.4%)	39 (5.6%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
	Positive	Negative	4 (3.1%)	1 (0.8%)	4 (6.5%)	3 (4.8%)	0	2 (3.1%)	0	3 (4.3%)	0	13 (2.3%)	17 (2.4%)
		Trace	8 (6.2%)	14 (11.5%)	0	5 (7.9%)	4 (6.3%)	6 (9.2%)	6 (9.8%)	5 (7.2%)	3 (4.8%)	43 (7.6%)	51 (7.3%)
		Positive	5 (3.8%)	18 (14.8%)	9 (14.5%)	9 (14.3%)	8 (12.5%)	3 (4.6%)	8 (13.1%)	9 (13.0%)	5 (7.9%)	69 (12.1%)	74 (10.6%)
Week 32	m		128	120	62	60	62	65	60	69	63	561	689
	Negative	Negative	48 (37.5%)	23 (19.2%)	19 (30.6%)	17 (28.3%)	17 (27.4%)	16 (24.6%)	18 (30.0%)	20 (29.0%)	32 (50.8%)	162 (28.9%)	210 (30.5%)
		Trace	11 (8.6%)	9 (7.5%)	7 (11.3%)	5 (8.3%)	6 (9.7%)	5 (7.7%)	6 (10.0%)	5 (7.2%)	2 (3.2%)	45 (8.0%)	56 (8.1%)
		Positive	2 (1.6%)	1 (0.8%)	2 (3.2%)	0	0	0	2 (3.3%)	2 (2.9%)	1 (1.6%)	8 (1.4%)	10 (1.5%)
	Trace	Negative	21 (16.4%)	29 (24.2%)	11 (17.7%)	11 (18.3%)	15 (24.2%)	13 (20.0%)	13 (21.7%)	10 (14.5%)	9 (14.3%)	111 (19.8%)	132 (19.2%)
		Trace	24 (18.8%)	19 (15.8%)	10 (16.1%)	8 (13.3%)	10 (16.1%)	17 (26.2%)	6 (10.0%)	10 (14.5%)	11 (17.5%)	91 (16.2%)	115 (16.7%)
		Positive	5 (3.9%)	7 (5.8%)	0	3 (5.0%)	2 (3.2%)	3 (4.6%)	1 (1.7%)	5 (7.2%)	0	21 (3.7%)	26 (3.8%)
	Positive	Negative	2 (1.6%)	5 (4.2%)	3 (4.8%)	1 (1.7%)	1 (1.6%)	5 (7.7%)	0	0	1 (1.6%)	16 (2.9%)	18 (2.6%)
		Trace	7 (5.5%)	10 (8.3%)	3 (4.8%)	6 (10.0%)	3 (4.8%)	4 (6.2%)	6 (10.0%)	8 (11.6%)	1 (1.6%)	41 (7.3%)	48 (7.0%)
		Positive	8 (6.3%)	17 (14.2%)	7 (11.3%)	9 (15.0%)	8 (12.9%)	2 (3.1%)	8 (13.3%)	9 (13.0%)	6 (9.5%)	66 (11.8%)	74 (10.7%)
Week 40	m		128	120	60	59	62	65	60	69	63	558	686
	Negative	Negative	43 (33.6%)	25 (20.8%)	23 (38.3%)	18 (30.5%)	15 (24.2%)	14 (21.5%)	22 (36.7%)	19 (27.5%)	30 (47.6%)	166 (29.7%)	209 (30.5%)
		Trace	17 (13.3%)	7 (5.8%)	4 (6.7%)	3 (5.1%)	7 (11.3%)	6 (9.2%)	3 (5.0%)	8 (11.6%)	4 (6.3%)	42 (7.5%)	59 (8.6%)
		Positive	1 (0.8%)	1 (0.8%)	0	1 (1.7%)	1 (1.6%)	1 (1.5%)	1 (1.7%)	0	1 (1.6%)	6 (1.1%)	7 (1.0%)
	Trace	Negative	26 (20.3%)	25 (20.8%)	10 (16.7%)	9 (15.3%)	14 (22.6%)	13 (20.0%)	10 (16.7%)	8 (11.6%)	9 (14.3%)	98 (17.6%)	124 (18.1%)
		Trace	17 (13.3%)	23 (19.2%)	10 (16.7%)	9 (15.3%)	9 (14.5%)	11 (16.9%)	10 (16.7%)	11 (15.9%)	10 (15.9%)	93 (16.7%)	110 (16.0%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
		Positive	7 (5.5%)	7 (5.8%)	1 (1.7%)	4 (6.8%)	4 (6.5%)	9 (13.8%)	1 (1.7%)	6 (8.7%)	1 (1.6%)	33 (5.9%)	40 (5.8%)
	Positive	Negative	4 (3.1%)	5 (4.2%)	3 (5.0%)	3 (5.1%)	0	4 (6.2%)	1 (1.7%)	2 (2.9%)	0	18 (3.2%)	22 (3.2%)
		Trace	6 (4.7%)	10 (8.3%)	5 (8.3%)	4 (6.8%)	7 (11.3%)	3 (4.6%)	2 (3.3%)	5 (7.2%)	5 (7.9%)	41 (7.3%)	47 (6.9%)
		Positive	7 (5.5%)	17 (14.2%)	4 (6.7%)	8 (13.6%)	5 (8.1%)	4 (6.2%)	10 (16.7%)	10 (14.5%)	3 (4.8%)	61 (10.9%)	68 (9.9%)
Week 48	m		127	118	60	59	62	65	60	66	63	553	680
	Negative	Negative	47 (37.0%)	20 (16.9%)	20 (33.3%)	15 (25.4%)	19 (30.6%)	15 (23.1%)	16 (26.7%)	21 (31.8%)	31 (49.2%)	157 (28.4%)	204 (30.0%)
		Trace	13 (10.2%)	11 (9.3%)	7 (11.7%)	6 (10.2%)	4 (6.5%)	3 (4.6%)	7 (11.7%)	5 (7.6%)	3 (4.8%)	46 (8.3%)	59 (8.7%)
		Positive	1 (0.8%)	1 (0.8%)	0	1 (1.7%)	0	3 (4.6%)	3 (5.0%)	1 (1.5%)	1 (1.6%)	10 (1.8%)	11 (1.6%)
	Trace	Negative	25 (19.7%)	25 (21.2%)	12 (20.0%)	7 (11.9%)	13 (21.0%)	12 (18.5%)	11 (18.3%)	8 (12.1%)	9 (14.3%)	97 (17.5%)	122 (17.9%)
		Trace	19 (15.0%)	18 (15.3%)	6 (10.0%)	12 (20.3%)	11 (17.7%)	12 (18.5%)	8 (13.3%)	12 (18.2%)	10 (15.9%)	89 (16.1%)	108 (15.9%)
		Positive	5 (3.9%)	11 (9.3%)	3 (5.0%)	3 (5.1%)	3 (4.8%)	9 (13.8%)	2 (3.3%)	3 (4.5%)	1 (1.6%)	35 (6.3%)	40 (5.9%)
	Positive	Negative	5 (3.9%)	4 (3.4%)	2 (3.3%)	3 (5.1%)	3 (4.8%)	1 (1.5%)	2 (3.3%)	3 (4.5%)	0	18 (3.3%)	23 (3.4%)
		Trace	5 (3.9%)	10 (8.5%)	4 (6.7%)	4 (6.8%)	3 (4.8%)	3 (4.6%)	2 (3.3%)	6 (9.1%)	2 (3.2%)	34 (6.1%)	39 (5.7%)
		Positive	7 (5.5%)	18 (15.3%)	6 (10.0%)	8 (13.6%)	6 (9.7%)	7 (10.8%)	9 (15.0%)	7 (10.6%)	6 (9.5%)	67 (12.1%)	74 (10.9%)
Week 52	m		126	116	59	58	62	65	60	67	62	549	675
	Negative	Negative	46 (36.5%)	19 (16.4%)	21 (35.6%)	17 (29.3%)	18 (29.0%)	13 (20.0%)	16 (26.7%)	20 (29.9%)	32 (51.6%)	156 (28.4%)	202 (29.9%)
		Trace	11 (8.7%)	10 (8.6%)	6 (10.2%)	3 (5.2%)	5 (8.1%)	7 (10.8%)	9 (15.0%)	5 (7.5%)	3 (4.8%)	48 (8.7%)	59 (8.7%)
		Positive	3 (2.4%)	3 (2.6%)	0	1 (1.7%)	0	1 (1.5%)	1 (1.7%)	2 (3.0%)	0	8 (1.5%)	11 (1.6%)
	Trace	Negative	25 (19.8%)	19 (16.4%)	6 (10.2%)	11 (19.0%)	13 (21.0%)	14 (21.5%)	9 (15.0%)	7 (10.4%)	10 (16.1%)	89 (16.2%)	114 (16.9%)
		Trace	19 (15.1%)	25 (21.6%)	14 (23.7%)	10 (17.2%)	13 (21.0%)	13 (20.0%)	10 (16.7%)	14 (20.9%)	9 (14.5%)	108 (19.7%)	127 (18.8%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
		Positive	5 (4.0%)	9 (7.8%)	0	1 (1.7%)	1 (1.6%)	6 (9.2%)	2 (3.3%)	3 (4.5%)	0	22 (4.0%)	27 (4.0%)
	Positive	Negative	3 (2.4%)	5 (4.3%)	2 (3.4%)	1 (1.7%)	2 (3.2%)	5 (7.7%)	0	2 (3.0%)	0	17 (3.1%)	20 (3.0%)
		Trace	8 (6.3%)	10 (8.6%)	4 (6.8%)	6 (10.3%)	3 (4.8%)	2 (3.1%)	4 (6.7%)	5 (7.5%)	1 (1.6%)	35 (6.4%)	43 (6.4%)
		Positive	6 (4.8%)	16 (13.8%)	6 (10.2%)	8 (13.8%)	7 (11.3%)	4 (6.2%)	9 (15.0%)	9 (13.4%)	7 (11.3%)	66 (12.0%)	72 (10.7%)
LOCF Endpoint	m		134	127	64	64	64	65	63	70	63	580	714
	Negative	Negative	48 (35.8%)	19 (15.0%)	22 (34.4%)	18 (28.1%)	18 (28.1%)	13 (20.0%)	16 (25.4%)	20 (28.6%)	32 (50.8%)	158 (27.2%)	206 (28.9%)
		Trace	11 (8.2%)	13 (10.2%)	7 (10.9%)	4 (6.3%)	5 (7.8%)	7 (10.8%)	9 (14.3%)	5 (7.1%)	3 (4.8%)	53 (9.1%)	64 (9.0%)
		Positive	4 (3.0%)	4 (3.1%)	0	1 (1.6%)	0	1 (1.5%)	1 (1.6%)	3 (4.3%)	0	10 (1.7%)	14 (2.0%)
	Trace	Negative	26 (19.4%)	22 (17.3%)	7 (10.9%)	11 (17.2%)	14 (21.9%)	14 (21.5%)	10 (15.9%)	8 (11.4%)	11 (17.5%)	97 (16.7%)	123 (17.2%)
		Trace	20 (14.9%)	26 (20.5%)	14 (21.9%)	11 (17.2%)	14 (21.9%)	13 (20.0%)	10 (15.9%)	14 (20.0%)	9 (14.3%)	111 (19.1%)	131 (18.3%)
		Positive	6 (4.5%)	10 (7.9%)	1 (1.6%)	1 (1.6%)	1 (1.6%)	6 (9.2%)	2 (3.2%)	3 (4.3%)	0	24 (4.1%)	30 (4.2%)
	Positive	Negative	3 (2.2%)	5 (3.9%)	2 (3.1%)	3 (4.7%)	2 (3.1%)	5 (7.7%)	0	2 (2.9%)	0	19 (3.3%)	22 (3.1%)
		Trace	8 (6.0%)	11 (8.7%)	4 (6.3%)	6 (9.4%)	3 (4.7%)	2 (3.1%)	5 (7.9%)	5 (7.1%)	1 (1.6%)	37 (6.4%)	45 (6.3%)
		Positive	8 (6.0%)	17 (13.4%)	7 (10.9%)	9 (14.1%)	7 (10.9%)	4 (6.2%)	10 (15.9%)	10 (14.3%)	7 (11.1%)	71 (12.2%)	79 (11.1%)
Urobilinogen Week 4	m		134	127	64	64	64	65	63	70	63	580	714
	Normal	Normal	132 (98.5%)	120 (94.5%)	62 (96.9%)	64 (100.0%)	64 (100.0%)	64 (98.5%)	61 (96.8%)	67 (95.7%)	63 (100.0%)	565 (97.4%)	697 (97.6%)
		Abnormal	1 (0.7%)	1 (0.8%)	1 (1.6%)	0	0	0	0	1 (1.4%)	0	3 (0.5%)	4 (0.6%)
	Abnormal	Normal	1 (0.7%)	5 (3.9%)	1 (1.6%)	0	0	1 (1.5%)	1 (1.6%)	2 (2.9%)	0	10 (1.7%)	11 (1.5%)
		Abnormal	0	1 (0.8%)	0	0	0	0	1 (1.6%)	0	0	2 (0.3%)	2 (0.3%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
Week 8	m		132	126	63	64	64	65	62	69	63	576	708
	Normal	Normal	131 (99.2%)	117 (92.9%)	62 (98.4%)	63 (98.4%)	64 (100.0%)	64 (98.5%)	59 (95.2%)	66 (95.7%)	63 (100.0%)	558 (96.9%)	689 (97.3%)
		Abnormal	0	3 (2.4%)	0	1 (1.6%)	0	0	1 (1.6%)	1 (1.4%)	0	6 (1.0%)	6 (0.8%)
	Abnormal	Normal	1 (0.8%)	3 (2.4%)	0	0	0	1 (1.5%)	2 (3.2%)	2 (2.9%)	0	8 (1.4%)	9 (1.3%)
		Abnormal	0	3 (2.4%)	1 (1.6%)	0	0	0	0	0	0	4 (0.7%)	4 (0.6%)
Week 12	m		131	123	63	64	64	65	62	68	63	572	703
	Normal	Normal	129 (98.5%)	115 (93.5%)	62 (98.4%)	63 (98.4%)	64 (100.0%)	64 (98.5%)	60 (96.8%)	66 (97.1%)	63 (100.0%)	557 (97.4%)	686 (97.6%)
		Abnormal	1 (0.8%)	2 (1.6%)	0	1 (1.6%)	0	0	0	0	0	3 (0.5%)	4 (0.6%)
	Abnormal	Normal	1 (0.8%)	2 (1.6%)	1 (1.6%)	0	0	1 (1.5%)	2 (3.2%)	2 (2.9%)	0	8 (1.4%)	9 (1.3%)
		Abnormal	0	4 (3.3%)	0	0	0	0	0	0	0	4 (0.7%)	4 (0.6%)
Week 16	m		130	123	63	64	64	64	62	69	63	572	702
	Normal	Normal	126 (96.9%)	116 (94.3%)	62 (98.4%)	64 (100.0%)	64 (100.0%)	61 (95.3%)	60 (96.8%)	66 (95.7%)	63 (100.0%)	556 (97.2%)	682 (97.2%)
		Abnormal	3 (2.3%)	1 (0.8%)	0	0	0	2 (3.1%)	0	1 (1.4%)	0	4 (0.7%)	7 (1.0%)
	Abnormal	Normal	0	4 (3.3%)	1 (1.6%)	0	0	1 (1.6%)	2 (3.2%)	2 (2.9%)	0	10 (1.7%)	10 (1.4%)
		Abnormal	1 (0.8%)	2 (1.6%)	0	0	0	0	0	0	0	2 (0.3%)	3 (0.4%)
Week 20	m		130	123	62	63	64	65	61	69	63	570	700
	Normal	Normal	126 (96.9%)	117 (95.1%)	61 (98.4%)	61 (96.8%)	64 (100.0%)	64 (98.5%)	58 (95.1%)	65 (94.2%)	63 (100.0%)	553 (97.0%)	679 (97.0%)
		Abnormal	3 (2.3%)	0	0	2 (3.2%)	0	0	1 (1.6%)	2 (2.9%)	0	5 (0.9%)	8 (1.1%)
	Abnormal	Normal	1 (0.8%)	5 (4.1%)	1 (1.6%)	0	0	1 (1.5%)	2 (3.3%)	2 (2.9%)	0	11 (1.9%)	12 (1.7%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
		Abnormal	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
Week 24	m		130	122	62	63	64	65	61	69	63	569	699
	Normal	Normal	128 (98.5%)	114 (93.4%)	61 (98.4%)	61 (96.8%)	64 (100.0%)	63 (96.9%)	59 (96.7%)	67 (97.1%)	63 (100.0%)	552 (97.0%)	680 (97.3%)
		Abnormal	1 (0.8%)	2 (1.6%)	0	2 (3.2%)	0	1 (1.5%)	0	0	0	5 (0.9%)	6 (0.9%)
	Abnormal	Normal	1 (0.8%)	4 (3.3%)	0	0	0	1 (1.5%)	2 (3.3%)	2 (2.9%)	0	9 (1.6%)	10 (1.4%)
		Abnormal	0	2 (1.6%)	1 (1.6%)	0	0	0	0	0	0	3 (0.5%)	3 (0.4%)
Week 32	m		128	120	62	60	62	65	60	69	63	561	689
	Normal	Normal	125 (97.7%)	111 (92.5%)	61 (98.4%)	60 (100.0%)	62 (100.0%)	63 (96.9%)	58 (96.7%)	66 (95.7%)	63 (100.0%)	544 (97.0%)	669 (97.1%)
		Abnormal	2 (1.6%)	3 (2.5%)	0	0	0	1 (1.5%)	0	1 (1.4%)	0	5 (0.9%)	7 (1.0%)
	Abnormal	Normal	1 (0.8%)	4 (3.3%)	0	0	0	1 (1.5%)	2 (3.3%)	1 (1.4%)	0	8 (1.4%)	9 (1.3%)
		Abnormal	0	2 (1.7%)	1 (1.6%)	0	0	0	0	1 (1.4%)	0	4 (0.7%)	4 (0.6%)
Week 40	m		128	120	60	59	62	65	60	69	63	558	686
	Normal	Normal	125 (97.7%)	111 (92.5%)	59 (98.3%)	55 (93.2%)	60 (96.8%)	63 (96.9%)	58 (96.7%)	64 (92.8%)	61 (96.8%)	531 (95.2%)	656 (95.6%)
		Abnormal	2 (1.6%)	3 (2.5%)	0	4 (6.8%)	2 (3.2%)	1 (1.5%)	0	3 (4.3%)	2 (3.2%)	15 (2.7%)	17 (2.5%)
	Abnormal	Normal	1 (0.8%)	3 (2.5%)	0	0	0	0	1 (1.7%)	1 (1.4%)	0	5 (0.9%)	6 (0.9%)
		Abnormal	0	3 (2.5%)	1 (1.7%)	0	0	1 (1.5%)	1 (1.7%)	1 (1.4%)	0	7 (1.3%)	7 (1.0%)
Week 48	m		127	118	60	59	62	65	60	66	63	553	680
	Normal	Normal	123 (96.9%)	106 (89.8%)	59 (98.3%)	58 (98.3%)	62 (100.0%)	59 (90.8%)	56 (93.3%)	64 (97.0%)	61 (96.8%)	525 (94.9%)	648 (95.3%)
		Abnormal	3 (2.4%)	6 (5.1%)	0	1 (1.7%)	0	5 (7.7%)	2 (3.3%)	0	2 (3.2%)	16 (2.9%)	19 (2.8%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
	Abnormal	Normal	0	4 (3.4%)	1 (1.7%)	0	0	1 (1.5%)	1 (1.7%)	2 (3.0%)	0	9 (1.6%)	9 (1.3%)
		Abnormal	1 (0.8%)	2 (1.7%)	0	0	0	0	1 (1.7%)	0	0	3 (0.5%)	4 (0.6%)
Week 52	m		126	116	59	58	62	65	60	67	62	549	675
	Normal	Normal	124 (98.4%)	107 (92.2%)	57 (96.6%)	57 (98.3%)	62 (100.0%)	61 (93.8%)	57 (95.0%)	62 (92.5%)	62 (100.0%)	525 (95.6%)	649 (96.1%)
		Abnormal	1 (0.8%)	4 (3.4%)	1 (1.7%)	1 (1.7%)	0	3 (4.6%)	1 (1.7%)	3 (4.5%)	0	13 (2.4%)	14 (2.1%)
	Abnormal	Normal	1 (0.8%)	4 (3.4%)	1 (1.7%)	0	0	0	1 (1.7%)	2 (3.0%)	0	8 (1.5%)	9 (1.3%)
		Abnormal	0	1 (0.9%)	0	0	0	1 (1.5%)	1 (1.7%)	0	0	3 (0.5%)	3 (0.4%)
LOCF Endpoint	m		134	127	64	64	64	65	63	70	63	580	714
	Normal	Normal	131 (97.8%)	117 (92.1%)	62 (96.9%)	63 (98.4%)	64 (100.0%)	61 (93.8%)	60 (95.2%)	65 (92.9%)	63 (100.0%)	555 (95.7%)	686 (96.1%)
		Abnormal	2 (1.5%)	4 (3.1%)	1 (1.6%)	1 (1.6%)	0	3 (4.6%)	1 (1.6%)	3 (4.3%)	0	13 (2.2%)	15 (2.1%)
	Abnormal	Normal	1 (0.7%)	4 (3.1%)	1 (1.6%)	0	0	0	1 (1.6%)	2 (2.9%)	0	8 (1.4%)	9 (1.3%)
		Abnormal	0	2 (1.6%)	0	0	0	1 (1.5%)	1 (1.6%)	0	0	4 (0.7%)	4 (0.6%)

- Abbreviations: LOCF, Last Observation Carried Forward; SU, Sulphonylurea; GLIN, Glinide; BIG, Biguanide; AGI, Alpha glucosidase inhibitor; TZD, Thiazolidinedione; DPP4-I, Dipeptidyl peptidase-4 inhibitor; GLP1-RA, Glucagon-like peptide 1 receptor agonist; SGLT2-I, Sodium glucose cotransporter 2 inhibitor
- "Imeglimin" in this table means "Imeglimin 1000 mg twice daily".
- "Combination Total" is the sum of the subjects excluding monotherapy "Imeglimin".
- "Imeglimin Total" is the sum of all subjects in Imeglimin treatment groups.
- m in row headings is the total number of subjects with both baseline and the corresponding visit values available, and is used as the denominator to calculate percentages.

Control No:<<t-s-188-labot-019lt.sas, 2020-03-06T00:15:40>>

Table S-189 Shift of Laboratory Findings of Coagulation in 52-Week Long-term Period with Monotherapy and Combination Therapy (PXL008-019; Long-term Safety Population)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
Activated Partial Thromboplastin Time (sec)													
Week 24	m		129	117	62	61	60	65	61	68	63	557	686
	Low	Low	13 (10.1%)	16 (13.7%)	11 (17.7%)	9 (14.8%)	11 (18.3%)	6 (9.2%)	12 (19.7%)	9 (13.2%)	7 (11.1%)	81 (14.5%)	94 (13.7%)
		Normal	14 (10.9%)	15 (12.8%)	5 (8.1%)	3 (4.9%)	4 (6.7%)	6 (9.2%)	10 (16.4%)	7 (10.3%)	9 (14.3%)	59 (10.6%)	73 (10.6%)
	Normal	Low	11 (8.5%)	8 (6.8%)	6 (9.7%)	6 (9.8%)	2 (3.3%)	4 (6.2%)	2 (3.3%)	3 (4.4%)	3 (4.8%)	34 (6.1%)	45 (6.6%)
		Normal	89 (69.0%)	78 (66.7%)	39 (62.9%)	43 (70.5%)	43 (71.7%)	49 (75.4%)	36 (59.0%)	48 (70.6%)	44 (69.8%)	380 (68.2%)	469 (68.4%)
		High	2 (1.6%)	0	1 (1.6%)	0	0	0	0	1 (1.5%)	0	2 (0.4%)	4 (0.6%)
	High	Normal	0	0	0	0	0	0	1 (1.6%)	0	0	1 (0.2%)	1 (0.1%)
Week 52	m		122	113	57	57	60	64	60	64	60	535	657
	Low	Low	15 (12.3%)	19 (16.8%)	10 (17.5%)	6 (10.5%)	10 (16.7%)	8 (12.5%)	13 (21.7%)	9 (14.1%)	9 (15.0%)	84 (15.7%)	99 (15.1%)
		Normal	11 (9.0%)	11 (9.7%)	4 (7.0%)	5 (8.8%)	5 (8.3%)	4 (6.3%)	8 (13.3%)	6 (9.4%)	6 (10.0%)	49 (9.2%)	60 (9.1%)
	Normal	Low	14 (11.5%)	10 (8.8%)	4 (7.0%)	7 (12.3%)	5 (8.3%)	5 (7.8%)	3 (5.0%)	9 (14.1%)	4 (6.7%)	47 (8.8%)	61 (9.3%)
		Normal	81 (66.4%)	73 (64.6%)	39 (68.4%)	38 (66.7%)	40 (66.7%)	47 (73.4%)	35 (58.3%)	40 (62.5%)	41 (68.3%)	353 (66.0%)	434 (66.1%)
		High	1 (0.8%)	0	0	1 (1.8%)	0	0	0	0	0	1 (0.2%)	2 (0.3%)
	High	Normal	0	0	0	0	0	0	1 (1.7%)	0	0	1 (0.2%)	1 (0.2%)
LOCF Endpoint	m		130	121	62	61	62	65	61	68	63	563	693
	Low	Low	16 (12.3%)	21 (17.4%)	11 (17.7%)	6 (9.8%)	10 (16.1%)	8 (12.3%)	14 (23.0%)	9 (13.2%)	9 (14.3%)	88 (15.6%)	104 (15.0%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
		Normal	11 (8.5%)	11 (9.1%)	5 (8.1%)	6 (9.8%)	5 (8.1%)	4 (6.2%)	8 (13.1%)	7 (10.3%)	7 (11.1%)	53 (9.4%)	64 (9.2%)
	Normal	Low	14 (10.8%)	10 (8.3%)	4 (6.5%)	7 (11.5%)	5 (8.1%)	5 (7.7%)	3 (4.9%)	10 (14.7%)	4 (6.3%)	48 (8.5%)	62 (8.9%)
		Normal	88 (67.7%)	79 (65.3%)	42 (67.7%)	41 (67.2%)	42 (67.7%)	48 (73.8%)	35 (57.4%)	42 (61.8%)	43 (68.3%)	372 (66.1%)	460 (66.4%)
		High	1 (0.8%)	0	0	1 (1.6%)	0	0	0	0	0	1 (0.2%)	2 (0.3%)
	High	Normal	0	0	0	0	0	0	1 (1.6%)	0	0	1 (0.2%)	1 (0.1%)
Prothrombin Time (sec)													
Week 24	m		129	117	62	61	60	65	61	68	63	557	686
	Low	Low	2 (1.6%)	2 (1.7%)	4 (6.5%)	2 (3.3%)	1 (1.7%)	1 (1.5%)	0	2 (2.9%)	3 (4.8%)	15 (2.7%)	17 (2.5%)
		Normal	7 (5.4%)	8 (6.8%)	1 (1.6%)	3 (4.9%)	4 (6.7%)	0	2 (3.3%)	1 (1.5%)	5 (7.9%)	24 (4.3%)	31 (4.5%)
	Normal	Low	3 (2.3%)	4 (3.4%)	3 (4.8%)	3 (4.9%)	2 (3.3%)	1 (1.5%)	2 (3.3%)	3 (4.4%)	3 (4.8%)	21 (3.8%)	24 (3.5%)
		Normal	117 (90.7%)	102 (87.2%)	53 (85.5%)	53 (86.9%)	53 (88.3%)	63 (96.9%)	57 (93.4%)	61 (89.7%)	52 (82.5%)	494 (88.7%)	611 (89.1%)
		High	0	1 (0.9%)	0	0	0	0	0	1 (1.5%)	0	2 (0.4%)	2 (0.3%)
	High	High	0	0	1 (1.6%)	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
Week 52	m		122	113	57	57	60	64	60	64	60	535	657
	Low	Low	2 (1.6%)	1 (0.9%)	1 (1.8%)	3 (5.3%)	2 (3.3%)	0	0	2 (3.1%)	3 (5.0%)	12 (2.2%)	14 (2.1%)
		Normal	7 (5.7%)	8 (7.1%)	4 (7.0%)	2 (3.5%)	3 (5.0%)	1 (1.6%)	1 (1.7%)	1 (1.6%)	3 (5.0%)	23 (4.3%)	30 (4.6%)
	Normal	Low	7 (5.7%)	1 (0.9%)	1 (1.8%)	2 (3.5%)	0	1 (1.6%)	3 (5.0%)	2 (3.1%)	0	10 (1.9%)	17 (2.6%)
		Normal	105 (86.1%)	102 (90.3%)	50 (87.7%)	50 (87.7%)	55 (91.7%)	62 (96.9%)	56 (93.3%)	59 (92.2%)	54 (90.0%)	488 (91.2%)	593 (90.3%)
		High	1 (0.8%)	1 (0.9%)	0	0	0	0	0	0	0	1 (0.2%)	2 (0.3%)
	High	High	0	0	1 (1.8%)	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
LOCF Endpoint	m		130	121	62	61	62	65	61	68	63	563	693
	Low	Low	2 (1.5%)	1 (0.8%)	1 (1.6%)	3 (4.9%)	2 (3.2%)	0	0	2 (2.9%)	4 (6.3%)	13 (2.3%)	15 (2.2%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
		Normal	7 (5.4%)	9 (7.4%)	4 (6.5%)	2 (3.3%)	3 (4.8%)	1 (1.5%)	2 (3.3%)	1 (1.5%)	4 (6.3%)	26 (4.6%)	33 (4.8%)
	Normal	Low	7 (5.4%)	2 (1.7%)	1 (1.6%)	2 (3.3%)	0	1 (1.5%)	3 (4.9%)	2 (2.9%)	0	11 (2.0%)	18 (2.6%)
		Normal	113 (86.9%)	108 (89.3%)	55 (88.7%)	54 (88.5%)	57 (91.9%)	63 (96.9%)	56 (91.8%)	63 (92.6%)	55 (87.3%)	511 (90.8%)	624 (90.0%)
		High	1 (0.8%)	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	2 (0.3%)
	High	High	0	0	1 (1.6%)	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)

- Abbreviations: LOCF, Last Observation Carried Forward; SU, Sulphonylurea; GLIN, Glinide; BIG, Biguanide; AGI, Alpha glucosidase inhibitor; TZD, Thiazolidinedione; DPP4-I, Dipeptidyl peptidase-4 inhibitor; GLP1-RA, Glucagon-like peptide 1 receptor agonist; SGLT2-I, Sodium glucose cotransporter 2 inhibitor
- "Imeglimin" in this table means "Imeglimin 1000 mg twice daily".
- "Combination Total" is the sum of the subjects excluding monotherapy "Imeglimin".
- "Imeglimin Total" is the sum of all subjects in Imeglimin treatment groups.
- m in row headings is the total number of subjects with both baseline and the corresponding visit values available, and is used as the denominator to calculate percentages.

Control No:<<t-s-189-labot-019lt.sas, 2020-03-06T00:15:50>>

Table S-191 Shift of Laboratory Findings of UACR (Albuminuria) in 52-Week Long-term Period with Monotherapy and Combination Therapy (PXL008-019; Long-term Safety Population)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
Albumin/Creatinine (mg/g)													
Week 12	m		131	123	63	64	64	65	62	68	63	572	703
	Normal	Normal	92 (70.2%)	68 (55.3%)	44 (69.8%)	34 (53.1%)	41 (64.1%)	46 (70.8%)	40 (64.5%)	39 (57.4%)	29 (46.0%)	341 (59.6%)	433 (61.6%)
		Micro	5 (3.8%)	10 (8.1%)	2 (3.2%)	4 (6.3%)	2 (3.1%)	0	1 (1.6%)	5 (7.4%)	3 (4.8%)	27 (4.7%)	32 (4.6%)
	Micro	Normal	15 (11.5%)	11 (8.9%)	4 (6.3%)	10 (15.6%)	7 (10.9%)	3 (4.6%)	7 (11.3%)	3 (4.4%)	11 (17.5%)	56 (9.8%)	71 (10.1%)
		Micro	17 (13.0%)	25 (20.3%)	8 (12.7%)	9 (14.1%)	9 (14.1%)	14 (21.5%)	11 (17.7%)	15 (22.1%)	14 (22.2%)	105 (18.4%)	122 (17.4%)
		Macro	0	1 (0.8%)	0	0	0	0	0	0	1 (1.6%)	2 (0.3%)	2 (0.3%)
	Macro	Micro	1 (0.8%)	4 (3.3%)	0	2 (3.1%)	1 (1.6%)	2 (3.1%)	0	0	3 (4.8%)	12 (2.1%)	13 (1.8%)
		Macro	1 (0.8%)	4 (3.3%)	5 (7.9%)	5 (7.8%)	4 (6.3%)	0	3 (4.8%)	6 (8.8%)	2 (3.2%)	29 (5.1%)	30 (4.3%)
Week 24	m		130	122	62	61	63	65	61	69	63	566	696
	Normal	Normal	94 (72.3%)	69 (56.6%)	40 (64.5%)	35 (57.4%)	40 (63.5%)	42 (64.6%)	38 (62.3%)	40 (58.0%)	31 (49.2%)	335 (59.2%)	429 (61.6%)
		Micro	2 (1.5%)	9 (7.4%)	5 (8.1%)	2 (3.3%)	3 (4.8%)	4 (6.2%)	2 (3.3%)	5 (7.2%)	1 (1.6%)	31 (5.5%)	33 (4.7%)
	Micro	Normal	16 (12.3%)	4 (3.3%)	4 (6.5%)	11 (18.0%)	9 (14.3%)	4 (6.2%)	4 (6.6%)	5 (7.2%)	6 (9.5%)	47 (8.3%)	63 (9.1%)
		Micro	16 (12.3%)	30 (24.6%)	8 (12.9%)	6 (9.8%)	6 (9.5%)	12 (18.5%)	14 (23.0%)	12 (17.4%)	20 (31.7%)	108 (19.1%)	124 (17.8%)
		Macro	0	2 (1.6%)	0	0	0	1 (1.5%)	0	1 (1.4%)	0	4 (0.7%)	4 (0.6%)
	Macro	Normal	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
		Micro	1 (0.8%)	2 (1.6%)	0	1 (1.6%)	2 (3.2%)	1 (1.5%)	2 (3.3%)	1 (1.4%)	1 (1.6%)	10 (1.8%)	11 (1.6%)
		Macro	1 (0.8%)	5 (4.1%)	5 (8.1%)	6 (9.8%)	3 (4.8%)	1 (1.5%)	1 (1.6%)	5 (7.2%)	4 (6.3%)	30 (5.3%)	31 (4.5%)
Week 40	m		128	119	60	59	62	65	60	69	63	557	685

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
	Normal	Normal	89 (69.5%)	64 (53.8%)	44 (73.3%)	33 (55.9%)	40 (64.5%)	42 (64.6%)	33 (55.0%)	36 (52.2%)	28 (44.4%)	320 (57.5%)	409 (59.7%)
		Micro	6 (4.7%)	11 (9.2%)	1 (1.7%)	3 (5.1%)	2 (3.2%)	4 (6.2%)	7 (11.7%)	9 (13.0%)	4 (6.3%)	41 (7.4%)	47 (6.9%)
	Micro	Normal	11 (8.6%)	6 (5.0%)	2 (3.3%)	6 (10.2%)	6 (9.7%)	1 (1.5%)	3 (5.0%)	3 (4.3%)	6 (9.5%)	33 (5.9%)	44 (6.4%)
		Micro	19 (14.8%)	30 (25.2%)	8 (13.3%)	11 (18.6%)	9 (14.5%)	16 (24.6%)	13 (21.7%)	13 (18.8%)	19 (30.2%)	119 (21.4%)	138 (20.1%)
		Macro	1 (0.8%)	0	1 (1.7%)	0	0	0	1 (1.7%)	2 (2.9%)	1 (1.6%)	5 (0.9%)	6 (0.9%)
	Macro	Micro	1 (0.8%)	3 (2.5%)	0	1 (1.7%)	0	1 (1.5%)	1 (1.7%)	2 (2.9%)	2 (3.2%)	10 (1.8%)	11 (1.6%)
		Macro	1 (0.8%)	5 (4.2%)	4 (6.7%)	5 (8.5%)	5 (8.1%)	1 (1.5%)	2 (3.3%)	4 (5.8%)	3 (4.8%)	29 (5.2%)	30 (4.4%)
Week 52	m		126	116	59	58	62	65	60	65	61	546	672
	Normal	Normal	87 (69.0%)	59 (50.9%)	44 (74.6%)	31 (53.4%)	39 (62.9%)	45 (69.2%)	35 (58.3%)	37 (56.9%)	27 (44.3%)	317 (58.1%)	404 (60.1%)
		Micro	6 (4.8%)	15 (12.9%)	1 (1.7%)	5 (8.6%)	3 (4.8%)	1 (1.5%)	5 (8.3%)	5 (7.7%)	5 (8.2%)	40 (7.3%)	46 (6.8%)
	Micro	Normal	10 (7.9%)	4 (3.4%)	2 (3.4%)	3 (5.2%)	7 (11.3%)	1 (1.5%)	3 (5.0%)	6 (9.2%)	7 (11.5%)	33 (6.0%)	43 (6.4%)
		Micro	19 (15.1%)	30 (25.9%)	8 (13.6%)	12 (20.7%)	8 (12.9%)	15 (23.1%)	13 (21.7%)	11 (16.9%)	17 (27.9%)	114 (20.9%)	133 (19.8%)
		Macro	2 (1.6%)	0	0	1 (1.7%)	0	1 (1.5%)	1 (1.7%)	1 (1.5%)	1 (1.6%)	5 (0.9%)	7 (1.0%)
	Macro	Normal	0	0	0	0	0	1 (1.5%)	0	0	0	1 (0.2%)	1 (0.1%)
		Micro	1 (0.8%)	2 (1.7%)	0	0	1 (1.6%)	0	0	2 (3.1%)	2 (3.3%)	7 (1.3%)	8 (1.2%)
		Macro	1 (0.8%)	6 (5.2%)	4 (6.8%)	6 (10.3%)	4 (6.5%)	1 (1.5%)	3 (5.0%)	3 (4.6%)	2 (3.3%)	29 (5.3%)	30 (4.5%)
LOCF Endpoint	m		131	123	63	64	64	65	62	69	63	573	704
	Normal	Normal	91 (69.5%)	64 (52.0%)	45 (71.4%)	33 (51.6%)	40 (62.5%)	45 (69.2%)	36 (58.1%)	39 (56.5%)	27 (42.9%)	329 (57.4%)	420 (59.7%)
		Micro	6 (4.6%)	14 (11.4%)	1 (1.6%)	5 (7.8%)	3 (4.7%)	1 (1.5%)	5 (8.1%)	6 (8.7%)	5 (7.9%)	40 (7.0%)	46 (6.5%)
	Micro	Normal	10 (7.6%)	4 (3.3%)	3 (4.8%)	6 (9.4%)	8 (12.5%)	1 (1.5%)	3 (4.8%)	6 (8.7%)	7 (11.1%)	38 (6.6%)	48 (6.8%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
		Micro	20 (15.3%)	33 (26.8%)	8 (12.7%)	12 (18.8%)	8 (12.5%)	15 (23.1%)	14 (22.6%)	11 (15.9%)	18 (28.6%)	119 (20.8%)	139 (19.7%)
		Macro	2 (1.5%)	0	1 (1.6%)	1 (1.6%)	0	1 (1.5%)	1 (1.6%)	1 (1.4%)	1 (1.6%)	6 (1.0%)	8 (1.1%)
	Macro	Normal	0	0	0	0	0	1 (1.5%)	0	0	0	1 (0.2%)	1 (0.1%)
		Micro	1 (0.8%)	2 (1.6%)	0	0	1 (1.6%)	0	0	2 (2.9%)	3 (4.8%)	8 (1.4%)	9 (1.3%)
		Macro	1 (0.8%)	6 (4.9%)	5 (7.9%)	7 (10.9%)	4 (6.3%)	1 (1.5%)	3 (4.8%)	4 (5.8%)	2 (3.2%)	32 (5.6%)	33 (4.7%)

- Abbreviations: LOCF, Last Observation Carried Forward; SU, Sulphonylurea; GLIN, Glinide; BIG, Biguanide; AGI, Alpha glucosidase inhibitor; TZD, Thiazolidinedione; DPP4-I, Dipeptidyl peptidase-4 inhibitor; GLP1-RA, Glucagon-like peptide 1 receptor agonist; SGLT2-I, Sodium glucose cotransporter 2 inhibitor
- "Imeglimin" in this table means "Imeglimin 1000 mg twice daily".
- "Combination Total" is the sum of the subjects excluding monotherapy "Imeglimin".
- "Imeglimin Total" is the sum of all subjects in Imeglimin treatment groups.
- m in row headings is the total number of subjects with both baseline and the corresponding visit values available, and is used as the denominator to calculate percentages.

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Table S-192 Shift of Laboratory Findings of Lactate Concentration in 52-Week Long-term Period with Monotherapy and Combination Therapy (PXL008-019; Long-term Safety Population)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
Lactic Acid (mmol/L)													
Week 4	m		0	0	0	63	0	0	0	0	0	63	63
	Normal	Normal	.	.	.	56 (88.9%)	.	.	.	.	.	56 (88.9%)	56 (88.9%)
		High	.	.	.	2 (3.2%)	.	.	.	.	.	2 (3.2%)	2 (3.2%)
	High	Normal	.	.	.	3 (4.8%)	.	.	.	.	.	3 (4.8%)	3 (4.8%)
		High	.	.	.	2 (3.2%)	.	.	.	.	.	2 (3.2%)	2 (3.2%)
Week 8	m		0	0	0	64	0	0	0	0	0	64	64
	Normal	Normal	.	.	.	58 (90.6%)	.	.	.	.	.	58 (90.6%)	58 (90.6%)
		High	.	.	.	1 (1.6%)	.	.	.	.	.	1 (1.6%)	1 (1.6%)
	High	Normal	.	.	.	4 (6.3%)	.	.	.	.	.	4 (6.3%)	4 (6.3%)
		High	.	.	.	1 (1.6%)	.	.	.	.	.	1 (1.6%)	1 (1.6%)
Week 12	m		0	0	0	64	0	0	0	0	0	64	64
	Normal	Normal	.	.	.	54 (84.4%)	.	.	.	.	.	54 (84.4%)	54 (84.4%)
		High	.	.	.	5 (7.8%)	.	.	.	.	.	5 (7.8%)	5 (7.8%)
	High	Normal	.	.	.	3 (4.7%)	.	.	.	.	.	3 (4.7%)	3 (4.7%)
		High	.	.	.	2 (3.1%)	.	.	.	.	.	2 (3.1%)	2 (3.1%)
Week 16	m		0	0	0	63	0	0	0	0	0	63	63
	Normal	Normal	.	.	.	55 (87.3%)	.	.	.	.	.	55 (87.3%)	55 (87.3%)
		High	.	.	.	3 (4.8%)	.	.	.	.	.	3 (4.8%)	3 (4.8%)
	High	Normal	.	.	.	3 (4.8%)	.	.	.	.	.	3 (4.8%)	3 (4.8%)

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
		High	.	.	.	2 (3.2%)	.	.	.	.	.	2 (3.2%)	2 (3.2%)
Week 20	m		0	0	0	63	0	0	0	0	0	63	63
	Normal	Normal	.	.	.	55 (87.3%)	.	.	.	.	.	55 (87.3%)	55 (87.3%)
		High	.	.	.	3 (4.8%)	.	.	.	.	.	3 (4.8%)	3 (4.8%)
	High	Normal	.	.	.	2 (3.2%)	.	.	.	.	.	2 (3.2%)	2 (3.2%)
		High	.	.	.	3 (4.8%)	.	.	.	.	.	3 (4.8%)	3 (4.8%)
Week 24	m		128	122	62	61	63	65	58	69	62	562	690
	Normal	Normal	120 (93.8%)	109 (89.3%)	58 (93.5%)	54 (88.5%)	62 (98.4%)	61 (93.8%)	55 (94.8%)	63 (91.3%)	52 (83.9%)	514 (91.5%)	634 (91.9%)
		High	3 (2.3%)	5 (4.1%)	0	3 (4.9%)	1 (1.6%)	2 (3.1%)	1 (1.7%)	3 (4.3%)	3 (4.8%)	18 (3.2%)	21 (3.0%)
	High	Normal	3 (2.3%)	4 (3.3%)	2 (3.2%)	4 (6.6%)	0	1 (1.5%)	1 (1.7%)	1 (1.4%)	5 (8.1%)	18 (3.2%)	21 (3.0%)
		High	2 (1.6%)	4 (3.3%)	2 (3.2%)	0	0	1 (1.5%)	1 (1.7%)	2 (2.9%)	2 (3.2%)	12 (2.1%)	14 (2.0%)
Week 32	m		0	0	0	60	0	0	0	0	0	60	60
	Normal	Normal	.	.	.	54 (90.0%)	.	.	.	.	.	54 (90.0%)	54 (90.0%)
		High	.	.	.	2 (3.3%)	.	.	.	.	.	2 (3.3%)	2 (3.3%)
	High	Normal	.	.	.	4 (6.7%)	.	.	.	.	.	4 (6.7%)	4 (6.7%)
Week 40	m		0	0	0	59	0	0	0	0	0	59	59
	Normal	Normal	.	.	.	53 (89.8%)	.	.	.	.	.	53 (89.8%)	53 (89.8%)
		High	.	.	.	2 (3.4%)	.	.	.	.	.	2 (3.4%)	2 (3.4%)
	High	Normal	.	.	.	2 (3.4%)	.	.	.	.	.	2 (3.4%)	2 (3.4%)
		High	.	.	.	2 (3.4%)	.	.	.	.	.	2 (3.4%)	2 (3.4%)
Week 48	m		0	0	0	57	0	0	0	0	0	57	57

Parameter Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
	Normal	Normal	.	.	.	50 (87.7%)	.	.	.	.	.	50 (87.7%)	50 (87.7%)
		High	.	.	.	3 (5.3%)	.	.	.	.	.	3 (5.3%)	3 (5.3%)
	High	Normal	.	.	.	4 (7.0%)	.	.	.	.	.	4 (7.0%)	4 (7.0%)
Week 52	m		126	116	59	58	62	65	59	66	61	546	672
	Normal	Normal	118 (93.7%)	104 (89.7%)	54 (91.5%)	51 (87.9%)	59 (95.2%)	60 (92.3%)	54 (91.5%)	59 (89.4%)	54 (88.5%)	495 (90.7%)	613 (91.2%)
		High	3 (2.4%)	4 (3.4%)	1 (1.7%)	3 (5.2%)	3 (4.8%)	3 (4.6%)	3 (5.1%)	4 (6.1%)	1 (1.6%)	22 (4.0%)	25 (3.7%)
	High	Normal	3 (2.4%)	5 (4.3%)	3 (5.1%)	3 (5.2%)	0	2 (3.1%)	1 (1.7%)	1 (1.5%)	4 (6.6%)	19 (3.5%)	22 (3.3%)
		High	2 (1.6%)	3 (2.6%)	1 (1.7%)	1 (1.7%)	0	0	1 (1.7%)	2 (3.0%)	2 (3.3%)	10 (1.8%)	12 (1.8%)
LOCF Endpoint	m		130	122	62	64	63	65	60	69	63	568	698
	Normal	Normal	122 (93.8%)	110 (90.2%)	57 (91.9%)	56 (87.5%)	60 (95.2%)	60 (92.3%)	55 (91.7%)	62 (89.9%)	55 (87.3%)	515 (90.7%)	637 (91.3%)
		High	3 (2.3%)	4 (3.3%)	1 (1.6%)	3 (4.7%)	3 (4.8%)	3 (4.6%)	3 (5.0%)	4 (5.8%)	1 (1.6%)	22 (3.9%)	25 (3.6%)
	High	Normal	3 (2.3%)	6 (4.9%)	3 (4.8%)	3 (4.7%)	0	2 (3.1%)	1 (1.7%)	1 (1.4%)	4 (6.3%)	20 (3.5%)	23 (3.3%)
		High	2 (1.5%)	2 (1.6%)	1 (1.6%)	2 (3.1%)	0	0	1 (1.7%)	2 (2.9%)	3 (4.8%)	11 (1.9%)	13 (1.9%)

- Abbreviations: LOCF, Last Observation Carried Forward; SU, Sulphonylurea; GLIN, Glinide; BIG, Biguanide; AGI, Alpha glucosidase inhibitor; TZD, Thiazolidinedione; DPP4-I, Dipeptidyl peptidase-4 inhibitor; GLP1-RA, Glucagon-like peptide 1 receptor agonist; SGLT2-I, Sodium glucose cotransporter 2 inhibitor
- "Imeglimin" in this table means "Imeglimin 1000 mg twice daily".
- "Combination Total" is the sum of the subjects excluding monotherapy "Imeglimin".
- "Imeglimin Total" is the sum of all subjects in Imeglimin treatment groups.
- m in row headings is the total number of subjects with both baseline and the corresponding visit values available, and is used as the denominator to calculate percentages.

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Table S-193 Shift of ECG Findings in 52-Week Long-term Period with Monotherapy and Combination Therapy (PXL008-019; Long-term Safety Population)

Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
Interpretation													
Week 12	m		132	124	63	64	64	65	62	68	63	573	705
	Normal	Normal	95 (72.0%)	88 (71.0%)	50 (79.4%)	48 (75.0%)	44 (68.8%)	46 (70.8%)	49 (79.0%)	50 (73.5%)	51 (81.0%)	426 (74.3%)	521 (73.9%)
		Abnormal, not clinically significant	5 (3.8%)	5 (4.0%)	2 (3.2%)	2 (3.1%)	4 (6.3%)	6 (9.2%)	1 (1.6%)	3 (4.4%)	2 (3.2%)	25 (4.4%)	30 (4.3%)
		Abnormal, clinically significant	1 (0.8%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
	Abnormal, not clinically significant	Normal	9 (6.8%)	7 (5.6%)	2 (3.2%)	1 (1.6%)	4 (6.3%)	4 (6.2%)	4 (6.5%)	2 (2.9%)	0	24 (4.2%)	33 (4.7%)
		Abnormal, not clinically significant	21 (15.9%)	22 (17.7%)	9 (14.3%)	13 (20.3%)	12 (18.8%)	9 (13.8%)	8 (12.9%)	13 (19.1%)	9 (14.3%)	95 (16.6%)	116 (16.5%)
		Abnormal, clinically significant	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
	Abnormal, clinically significant	Abnormal, clinically significant	1 (0.8%)	1 (0.8%)	0	0	0	0	0	0	1 (1.6%)	2 (0.3%)	3 (0.4%)
Week 24	m		130	122	62	63	64	65	61	69	63	569	699
	Normal	Normal	96 (73.8%)	90 (73.8%)	48 (77.4%)	47 (74.6%)	43 (67.2%)	49 (75.4%)	45 (73.8%)	47 (68.1%)	52 (82.5%)	421 (74.0%)	517 (74.0%)
		Abnormal, not clinically significant	3 (2.3%)	2 (1.6%)	3 (4.8%)	2 (3.2%)	5 (7.8%)	3 (4.6%)	4 (6.6%)	7 (10.1%)	1 (1.6%)	27 (4.7%)	30 (4.3%)

Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
	Abnormal, not clinically significant	Normal	12 (9.2%)	7 (5.7%)	2 (3.2%)	2 (3.2%)	2 (3.1%)	4 (6.2%)	5 (8.2%)	2 (2.9%)	2 (3.2%)	26 (4.6%)	38 (5.4%)
		Abnormal, not clinically significant	18 (13.8%)	21 (17.2%)	9 (14.5%)	12 (19.0%)	14 (21.9%)	9 (13.8%)	7 (11.5%)	13 (18.8%)	7 (11.1%)	92 (16.2%)	110 (15.7%)
		Abnormal, clinically significant	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
	Abnormal, clinically significant	Abnormal, clinically significant	1 (0.8%)	1 (0.8%)	0	0	0	0	0	0	1 (1.6%)	2 (0.4%)	3 (0.4%)
Week 40	m		128	120	61	59	62	65	61	69	63	560	688
	Normal	Normal	90 (70.3%)	84 (70.0%)	48 (78.7%)	41 (69.5%)	41 (66.1%)	47 (72.3%)	46 (75.4%)	47 (68.1%)	49 (77.8%)	403 (72.0%)	493 (71.7%)
		Abnormal, not clinically significant	6 (4.7%)	5 (4.2%)	2 (3.3%)	5 (8.5%)	6 (9.7%)	5 (7.7%)	2 (3.3%)	6 (8.7%)	4 (6.3%)	35 (6.3%)	41 (6.0%)
		Abnormal, clinically significant	1 (0.8%)	1 (0.8%)	0	0	0	0	1 (1.6%)	1 (1.4%)	0	3 (0.5%)	4 (0.6%)
	Abnormal, not clinically significant	Normal	13 (10.2%)	10 (8.3%)	3 (4.9%)	1 (1.7%)	2 (3.2%)	2 (3.1%)	2 (3.3%)	5 (7.2%)	2 (3.2%)	27 (4.8%)	40 (5.8%)
		Abnormal, not clinically significant	17 (13.3%)	18 (15.0%)	8 (13.1%)	12 (20.3%)	13 (21.0%)	10 (15.4%)	10 (16.4%)	10 (14.5%)	7 (11.1%)	88 (15.7%)	105 (15.3%)
		Abnormal, clinically significant	0	1 (0.8%)	0	0	0	1 (1.5%)	0	0	0	2 (0.4%)	2 (0.3%)

Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
	Abnormal, clinically significant	Abnormal, clinically significant	1 (0.8%)	1 (0.8%)	0	0	0	0	0	0	1 (1.6%)	2 (0.4%)	3 (0.4%)
Week 52	m		126	116	59	58	62	65	60	67	63	550	676
	Normal	Normal	92 (73.0%)	82 (70.7%)	47 (79.7%)	40 (69.0%)	42 (67.7%)	46 (70.8%)	47 (78.3%)	50 (74.6%)	50 (79.4%)	404 (73.5%)	496 (73.4%)
		Abnormal, not clinically significant	4 (3.2%)	5 (4.3%)	2 (3.4%)	4 (6.9%)	5 (8.1%)	6 (9.2%)	1 (1.7%)	3 (4.5%)	3 (4.8%)	29 (5.3%)	33 (4.9%)
		Abnormal, clinically significant	0	0	0	1 (1.7%)	0	0	0	0	0	1 (0.2%)	1 (0.1%)
	Abnormal, not clinically significant	Normal	10 (7.9%)	7 (6.0%)	2 (3.4%)	1 (1.7%)	4 (6.5%)	2 (3.1%)	6 (10.0%)	4 (6.0%)	0	26 (4.7%)	36 (5.3%)
		Abnormal, not clinically significant	18 (14.3%)	20 (17.2%)	8 (13.6%)	12 (20.7%)	11 (17.7%)	10 (15.4%)	6 (10.0%)	10 (14.9%)	9 (14.3%)	86 (15.6%)	104 (15.4%)
		Abnormal, clinically significant	1 (0.8%)	1 (0.9%)	0	0	0	1 (1.5%)	0	0	0	2 (0.4%)	3 (0.4%)
	Abnormal, clinically significant	Abnormal, clinically significant	1 (0.8%)	1 (0.9%)	0	0	0	0	0	0	1 (1.6%)	2 (0.4%)	3 (0.4%)
LOCF Endpoint	m		132	124	63	64	64	65	62	69	63	574	706
	Normal	Normal	96 (72.7%)	86 (69.4%)	50 (79.4%)	45 (70.3%)	43 (67.2%)	46 (70.8%)	49 (79.0%)	51 (73.9%)	50 (79.4%)	420 (73.2%)	516 (73.1%)

Week	Baseline	Post-baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
		Abnormal, not clinically significant	5 (3.8%)	6 (4.8%)	2 (3.2%)	4 (6.3%)	5 (7.8%)	6 (9.2%)	1 (1.6%)	3 (4.3%)	3 (4.8%)	30 (5.2%)	35 (5.0%)
		Abnormal, clinically significant	0	1 (0.8%)	0	1 (1.6%)	0	0	0	0	0	2 (0.3%)	2 (0.3%)
	Abnormal, not clinically significant	Normal	11 (8.3%)	7 (5.6%)	2 (3.2%)	2 (3.1%)	4 (6.3%)	2 (3.1%)	6 (9.7%)	4 (5.8%)	0	27 (4.7%)	38 (5.4%)
		Abnormal, not clinically significant	18 (13.6%)	22 (17.7%)	9 (14.3%)	12 (18.8%)	12 (18.8%)	10 (15.4%)	6 (9.7%)	11 (15.9%)	9 (14.3%)	91 (15.9%)	109 (15.4%)
		Abnormal, clinically significant	1 (0.8%)	1 (0.8%)	0	0	0	1 (1.5%)	0	0	0	2 (0.3%)	3 (0.4%)
	Abnormal, clinically significant	Abnormal, clinically significant	1 (0.8%)	1 (0.8%)	0	0	0	0	0	0	1 (1.6%)	2 (0.3%)	3 (0.4%)

- Abbreviations: LOCF, Last Observation Carried Forward; SU, Sulphonylurea; GLIN, Glinide; BIG, Biguanide; AGI, Alpha glucosidase inhibitor; TZD, Thiazolidinedione; DPP4-I, Dipeptidyl peptidase-4 inhibitor; GLP1-RA, Glucagon-like peptide 1 receptor agonist; SGLT2-I, Sodium glucose cotransporter 2 inhibitor
- "Imeglimin" in this table means "Imeglimin 1000 mg twice daily".
- "Combination Total" is the sum of the subjects excluding monotherapy "Imeglimin".
- "Imeglimin Total" is the sum of all subjects in Imeglimin treatment groups.
- m in row headings is the total number of subjects with both baseline and the corresponding visit values available, and is used as the denominator to calculate percentages.

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Table S-194 Shift of Laboratory Findings of Hematology in 16-Week Double-blind Period in Combination with Insulin Therapy (PXL008-020; Safety Population)

Parameter Week	Baseline	Post-baseline	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
Basophils (10^9/L)				
Week 4	m		106	108
	Normal	Normal	106 (100.0%)	108 (100.0%)
Week 8	m		105	108
	Normal	Normal	105 (100.0%)	108 (100.0%)
Week 12	m		103	108
	Normal	Normal	103 (100.0%)	108 (100.0%)
Week 16	m		104	108
	Normal	Normal	104 (100.0%)	108 (100.0%)
LOCF Endpoint	m		106	108
	Normal	Normal	106 (100.0%)	108 (100.0%)
Basophils/Leukocytes (%)				
Week 4	m		106	108
	Normal	Normal	106 (100.0%)	107 (99.1%)
		High	0	1 (0.9%)
Week 8	m		105	108
	Normal	Normal	105 (100.0%)	108 (100.0%)
Week 12	m		103	108
	Normal	Normal	103 (100.0%)	108 (100.0%)
Week 16	m		104	108
	Normal	Normal	103 (99.0%)	108 (100.0%)
		High	1 (1.0%)	0
LOCF Endpoint	m		106	108
	Normal	Normal	105 (99.1%)	108 (100.0%)
		High	1 (0.9%)	0
Eosinophils (10^9/L)				
Week 4	m		106	108
	Normal	Normal	105 (99.1%)	108 (100.0%)
		High	1 (0.9%)	0
Week 8	m		105	108
	Normal	Normal	104 (99.0%)	108 (100.0%)
		High	1 (1.0%)	0
Week 12	m		103	108
	Normal	Normal	103 (100.0%)	108 (100.0%)

Parameter Week	Baseline	Post-baseline	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
Week 16	m		104	108
	Normal	Normal	104 (100.0%)	108 (100.0%)
LOCF Endpoint	m		106	108
	Normal	Normal	106 (100.0%)	108 (100.0%)
Eosinophils/Leukocytes (%)				
Week 4	m		106	108
	Normal	Normal	105 (99.1%)	105 (97.2%)
		High	0	1 (0.9%)
	High	Normal	0	2 (1.9%)
		High	1 (0.9%)	0
Week 8	m		105	108
	Normal	Normal	104 (99.0%)	105 (97.2%)
		High	0	1 (0.9%)
	High	Normal	0	2 (1.9%)
		High	1 (1.0%)	0
Week 12	m		103	108
	Normal	Normal	102 (99.0%)	105 (97.2%)
		High	0	1 (0.9%)
	High	Normal	1 (1.0%)	2 (1.9%)
Week 16	m		104	108
	Normal	Normal	102 (98.1%)	104 (96.3%)
		High	1 (1.0%)	2 (1.9%)
	High	Normal	1 (1.0%)	2 (1.9%)
LOCF Endpoint	m		106	108
	Normal	Normal	104 (98.1%)	104 (96.3%)
		High	1 (0.9%)	2 (1.9%)
	High	Normal	1 (0.9%)	2 (1.9%)
Ery. Mean Corpuscular Hemoglobin (pg)				
Week 4	m		106	108
	Low	Low	1 (0.9%)	1 (0.9%)
	Normal	Normal	104 (98.1%)	106 (98.1%)
		High	1 (0.9%)	1 (0.9%)
Week 8	m		105	108
	Low	Low	1 (1.0%)	1 (0.9%)
	Normal	Low	0	1 (0.9%)
		Normal	103 (98.1%)	105 (97.2%)
		High	1 (1.0%)	1 (0.9%)
Week 12	m		103	108
	Low	Low	1 (1.0%)	1 (0.9%)
	Normal	Low	0	1 (0.9%)

Parameter Week	Baseline	Post-baseline	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
		Normal	102 (99.0%)	103 (95.4%)
		High	0	3 (2.8%)
Week 16	m		104	108
	Low	Low	1 (1.0%)	1 (0.9%)
	Normal	Low	0	1 (0.9%)
		Normal	102 (98.1%)	104 (96.3%)
		High	1 (1.0%)	2 (1.9%)
LOCF Endpoint	m		106	108
	Low	Low	1 (0.9%)	1 (0.9%)
	Normal	Low	0	1 (0.9%)
		Normal	104 (98.1%)	104 (96.3%)
		High	1 (0.9%)	2 (1.9%)
Ery. Mean Corpuscular HGB Concentration (g/L)				
Week 4	m		106	108
	Low	Low	1 (0.9%)	0
		Normal	0	1 (0.9%)
	Normal	Normal	105 (99.1%)	107 (99.1%)
Week 8	m		105	108
	Low	Low	1 (1.0%)	0
		Normal	0	1 (0.9%)
	Normal	Low	2 (1.9%)	0
		Normal	102 (97.1%)	107 (99.1%)
Week 12	m		103	108
	Low	Low	1 (1.0%)	1 (0.9%)
	Normal	Low	0	1 (0.9%)
		Normal	102 (99.0%)	106 (98.1%)
Week 16	m		104	108
	Low	Low	1 (1.0%)	1 (0.9%)
	Normal	Low	0	1 (0.9%)
		Normal	103 (99.0%)	106 (98.1%)
LOCF Endpoint	m		106	108
	Low	Low	1 (0.9%)	1 (0.9%)
	Normal	Low	0	1 (0.9%)
		Normal	105 (99.1%)	106 (98.1%)
Ery. Mean Corpuscular Volume (fL)				
Week 4	m		106	108
	Low	Low	1 (0.9%)	1 (0.9%)
	Normal	Normal	101 (95.3%)	104 (96.3%)
		High	1 (0.9%)	2 (1.9%)
	High	High	3 (2.8%)	1 (0.9%)

Parameter Week	Baseline	Post-baseline	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
Week 8	m		105	108
	Low	Low	1 (1.0%)	1 (0.9%)
	Normal	Low	0	1 (0.9%)
		Normal	97 (92.4%)	99 (91.7%)
		High	4 (3.8%)	6 (5.6%)
	High	Normal	0	1 (0.9%)
		High	3 (2.9%)	0
Week 12	m		103	108
	Low	Low	1 (1.0%)	1 (0.9%)
	Normal	Low	0	1 (0.9%)
		Normal	96 (93.2%)	99 (91.7%)
		High	3 (2.9%)	6 (5.6%)
	High	High	3 (2.9%)	1 (0.9%)
Week 16	m		104	108
	Low	Low	1 (1.0%)	1 (0.9%)
	Normal	Low	0	1 (0.9%)
		Normal	98 (94.2%)	99 (91.7%)
		High	2 (1.9%)	6 (5.6%)
	High	High	3 (2.9%)	1 (0.9%)
LOCF Endpoint	m		106	108
	Low	Low	1 (0.9%)	1 (0.9%)
	Normal	Low	0	1 (0.9%)
		Normal	100 (94.3%)	99 (91.7%)
		High	2 (1.9%)	6 (5.6%)
	High	High	3 (2.8%)	1 (0.9%)
Erythrocytes (10^12/L)				
Week 4	m		106	108
	Low	Low	5 (4.7%)	6 (5.6%)
		Normal	5 (4.7%)	5 (4.6%)
	Normal	Low	2 (1.9%)	6 (5.6%)
		Normal	94 (88.7%)	90 (83.3%)
	High	High	0	1 (0.9%)
Week 8	m		105	108
	Low	Low	4 (3.8%)	6 (5.6%)
		Normal	6 (5.7%)	5 (4.6%)
	Normal	Low	2 (1.9%)	3 (2.8%)
		Normal	93 (88.6%)	93 (86.1%)
	High	High	0	1 (0.9%)
Week 12	m		103	108
	Low	Low	4 (3.9%)	3 (2.8%)
		Normal	6 (5.8%)	8 (7.4%)
	Normal	Low	1 (1.0%)	5 (4.6%)
		Normal	92 (89.3%)	91 (84.3%)

Parameter Week	Baseline	Post-baseline	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
	High	High	0	1 (0.9%)
Week 16	m		104	108
	Low	Low	3 (2.9%)	5 (4.6%)
		Normal	7 (6.7%)	6 (5.6%)
	Normal	Low	1 (1.0%)	4 (3.7%)
		Normal	92 (88.5%)	92 (85.2%)
		High	1 (1.0%)	0
	High	High	0	1 (0.9%)
LOCF Endpoint	m		106	108
	Low	Low	3 (2.8%)	5 (4.6%)
		Normal	7 (6.6%)	6 (5.6%)
	Normal	Low	1 (0.9%)	4 (3.7%)
		Normal	94 (88.7%)	92 (85.2%)
		High	1 (0.9%)	0
	High	High	0	1 (0.9%)
Hematocrit (fraction of 1)				
Week 4	m		106	108
	Low	Low	2 (1.9%)	1 (0.9%)
		Normal	0	3 (2.8%)
	Normal	Low	1 (0.9%)	0
		Normal	103 (97.2%)	104 (96.3%)
Week 8	m		105	108
	Low	Low	1 (1.0%)	1 (0.9%)
		Normal	1 (1.0%)	3 (2.8%)
	Normal	Low	0	1 (0.9%)
		Normal	103 (98.1%)	103 (95.4%)
Week 12	m		103	108
	Low	Low	1 (1.0%)	1 (0.9%)
		Normal	1 (1.0%)	3 (2.8%)
	Normal	Normal	101 (98.1%)	104 (96.3%)
Week 16	m		104	108
	Low	Low	0	1 (0.9%)
		Normal	2 (1.9%)	3 (2.8%)
	Normal	Normal	101 (97.1%)	104 (96.3%)
		High	1 (1.0%)	0
LOCF Endpoint	m		106	108
	Low	Low	0	1 (0.9%)
		Normal	2 (1.9%)	3 (2.8%)
	Normal	Normal	103 (97.2%)	104 (96.3%)
		High	1 (0.9%)	0
Hemoglobin (g/L)				
Week 4	m		106	108

Parameter Week	Baseline	Post-baseline	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
	Low	Low	3 (2.8%)	0
		Normal	0	3 (2.8%)
	Normal	Low	1 (0.9%)	2 (1.9%)
		Normal	101 (95.3%)	103 (95.4%)
	High	Normal	1 (0.9%)	0
Week 8	m		105	108
	Low	Low	1 (1.0%)	0
		Normal	2 (1.9%)	3 (2.8%)
	Normal	Normal	101 (96.2%)	105 (97.2%)
	High	Normal	1 (1.0%)	0
Week 12	m		103	108
	Low	Low	1 (1.0%)	0
		Normal	2 (1.9%)	3 (2.8%)
	Normal	Low	0	1 (0.9%)
		Normal	98 (95.1%)	104 (96.3%)
		High	1 (1.0%)	0
	High	Normal	1 (1.0%)	0
Week 16	m		104	108
	Low	Low	0	1 (0.9%)
		Normal	3 (2.9%)	2 (1.9%)
	Normal	Low	0	2 (1.9%)
		Normal	99 (95.2%)	103 (95.4%)
		High	1 (1.0%)	0
	High	High	1 (1.0%)	0
LOCF Endpoint	m		106	108
	Low	Low	0	1 (0.9%)
		Normal	3 (2.8%)	2 (1.9%)
	Normal	Low	0	2 (1.9%)
		Normal	101 (95.3%)	103 (95.4%)
		High	1 (0.9%)	0
	High	High	1 (0.9%)	0
Leukocytes (10^9/L)				
Week 4	m		106	108
	Low	Low	3 (2.8%)	4 (3.7%)
		Normal	2 (1.9%)	6 (5.6%)
	Normal	Low	3 (2.8%)	0
		Normal	97 (91.5%)	95 (88.0%)
		High	0	2 (1.9%)
	High	High	1 (0.9%)	1 (0.9%)
Week 8	m		105	108
	Low	Low	3 (2.9%)	2 (1.9%)
		Normal	2 (1.9%)	8 (7.4%)
	Normal	Low	3 (2.9%)	1 (0.9%)
		Normal	96 (91.4%)	96 (88.9%)

Parameter Week	Baseline	Post-baseline	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
	High	Normal	1 (1.0%)	1 (0.9%)
Week 12	m		103	108
	Low	Low	4 (3.9%)	3 (2.8%)
		Normal	1 (1.0%)	7 (6.5%)
	Normal	Low	2 (1.9%)	2 (1.9%)
		Normal	95 (92.2%)	93 (86.1%)
		High	0	2 (1.9%)
	High	Normal	1 (1.0%)	1 (0.9%)
Week 16	m		104	108
	Low	Low	3 (2.9%)	5 (4.6%)
		Normal	2 (1.9%)	5 (4.6%)
	Normal	Low	6 (5.8%)	0
		Normal	92 (88.5%)	95 (88.0%)
		High	0	2 (1.9%)
	High	Normal	1 (1.0%)	0
		High	0	1 (0.9%)
LOCF Endpoint	m		106	108
	Low	Low	3 (2.8%)	5 (4.6%)
		Normal	2 (1.9%)	5 (4.6%)
	Normal	Low	6 (5.7%)	0
		Normal	94 (88.7%)	95 (88.0%)
		High	0	2 (1.9%)
	High	Normal	1 (0.9%)	0
		High	0	1 (0.9%)
Lymphocytes (10^9/L)				
Week 4	m		106	108
	Low	Low	0	1 (0.9%)
		Normal	1 (0.9%)	1 (0.9%)
	Normal	Normal	102 (96.2%)	102 (94.4%)
		High	3 (2.8%)	2 (1.9%)
	High	Normal	0	1 (0.9%)
		High	0	1 (0.9%)
Week 8	m		105	108
	Low	Low	1 (1.0%)	1 (0.9%)
		Normal	0	1 (0.9%)
	Normal	Normal	103 (98.1%)	101 (93.5%)
		High	1 (1.0%)	3 (2.8%)
	High	Normal	0	2 (1.9%)
Week 12	m		103	108
	Low	Low	1 (1.0%)	2 (1.9%)
	Normal	Normal	101 (98.1%)	101 (93.5%)
		High	1 (1.0%)	3 (2.8%)
	High	Normal	0	1 (0.9%)
		High	0	1 (0.9%)

Parameter Week	Baseline	Post-baseline	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
Week 16	m		104	108
	Low	Low	1 (1.0%)	2 (1.9%)
	Normal	Low	0	1 (0.9%)
		Normal	103 (99.0%)	102 (94.4%)
		High	0	1 (0.9%)
	High	Normal	0	2 (1.9%)
LOCF Endpoint	m		106	108
	Low	Low	1 (0.9%)	2 (1.9%)
	Normal	Low	0	1 (0.9%)
		Normal	105 (99.1%)	102 (94.4%)
		High	0	1 (0.9%)
	High	Normal	0	2 (1.9%)
Lymphocytes/Leukocytes (%)				
Week 4	m		106	108
	Normal	Normal	100 (94.3%)	102 (94.4%)
		High	2 (1.9%)	0
	High	Normal	3 (2.8%)	4 (3.7%)
		High	1 (0.9%)	2 (1.9%)
Week 8	m		105	108
	Normal	Low	1 (1.0%)	1 (0.9%)
		Normal	98 (93.3%)	100 (92.6%)
		High	2 (1.9%)	1 (0.9%)
	High	Normal	2 (1.9%)	6 (5.6%)
		High	2 (1.9%)	0
Week 12	m		103	108
	Normal	Low	2 (1.9%)	0
		Normal	96 (93.2%)	102 (94.4%)
		High	1 (1.0%)	0
	High	Normal	2 (1.9%)	4 (3.7%)
		High	2 (1.9%)	2 (1.9%)
Week 16	m		104	108
	Normal	Low	2 (1.9%)	4 (3.7%)
		Normal	97 (93.3%)	96 (88.9%)
		High	1 (1.0%)	2 (1.9%)
	High	Normal	4 (3.8%)	5 (4.6%)
		High	0	1 (0.9%)
LOCF Endpoint	m		106	108
	Normal	Low	2 (1.9%)	4 (3.7%)
		Normal	99 (93.4%)	96 (88.9%)
		High	1 (0.9%)	2 (1.9%)
	High	Normal	4 (3.8%)	5 (4.6%)
		High	0	1 (0.9%)

Parameter Week	Baseline	Post-baseline	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
Monocytes (10^9/L)				
Week 4	m		106	108
	Normal	Low	0	1 (0.9%)
		Normal	106 (100.0%)	107 (99.1%)
Week 8	m		105	108
	Normal	Normal	105 (100.0%)	108 (100.0%)
Week 12	m		103	108
	Normal	Normal	103 (100.0%)	107 (99.1%)
		High	0	1 (0.9%)
Week 16	m		104	108
	Normal	Normal	104 (100.0%)	108 (100.0%)
LOCF Endpoint	m		106	108
	Normal	Normal	106 (100.0%)	108 (100.0%)
Monocytes/Leukocytes (%)				
Week 4	m		106	108
	Low	Normal	1 (0.9%)	0
	Normal	Low	1 (0.9%)	2 (1.9%)
		Normal	102 (96.2%)	105 (97.2%)
		High	0	1 (0.9%)
	High	Normal	1 (0.9%)	0
		High	1 (0.9%)	0
Week 8	m		105	108
	Low	Normal	1 (1.0%)	0
	Normal	Low	1 (1.0%)	0
		Normal	101 (96.2%)	108 (100.0%)
	High	Normal	2 (1.9%)	0
Week 12	m		103	108
	Low	Normal	1 (1.0%)	0
	Normal	Normal	100 (97.1%)	106 (98.1%)
		High	0	2 (1.9%)
	High	Normal	2 (1.9%)	0
Week 16	m		104	108
	Low	Normal	1 (1.0%)	0
	Normal	Normal	101 (97.1%)	108 (100.0%)
	High	Normal	2 (1.9%)	0
LOCF Endpoint	m		106	108
	Low	Normal	1 (0.9%)	0
	Normal	Normal	103 (97.2%)	108 (100.0%)
	High	Normal	2 (1.9%)	0
Neutrophils (10^9/L)				

Parameter Week	Baseline	Post-baseline	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
Week 4	m		106	108
	Low	Low	5 (4.7%)	6 (5.6%)
		Normal	4 (3.8%)	3 (2.8%)
	Normal	Low	1 (0.9%)	2 (1.9%)
		Normal	95 (89.6%)	94 (87.0%)
		High	0	2 (1.9%)
	High	Normal	0	1 (0.9%)
		High	1 (0.9%)	0
Week 8	m		105	108
	Low	Low	4 (3.8%)	1 (0.9%)
		Normal	5 (4.8%)	8 (7.4%)
	Normal	Low	4 (3.8%)	1 (0.9%)
		Normal	90 (85.7%)	96 (88.9%)
		High	1 (1.0%)	1 (0.9%)
	High	Normal	1 (1.0%)	1 (0.9%)
Week 12	m		103	108
	Low	Low	3 (2.9%)	3 (2.8%)
		Normal	6 (5.8%)	6 (5.6%)
	Normal	Low	3 (2.9%)	2 (1.9%)
		Normal	90 (87.4%)	94 (87.0%)
		High	0	2 (1.9%)
	High	Normal	0	1 (0.9%)
		High	1 (1.0%)	0
Week 16	m		104	108
	Low	Low	3 (2.9%)	4 (3.7%)
		Normal	6 (5.8%)	5 (4.6%)
	Normal	Low	3 (2.9%)	2 (1.9%)
		Normal	91 (87.5%)	93 (86.1%)
		High	0	3 (2.8%)
	High	Normal	1 (1.0%)	0
		High	0	1 (0.9%)
LOCF Endpoint	m		106	108
	Low	Low	3 (2.8%)	4 (3.7%)
		Normal	6 (5.7%)	5 (4.6%)
	Normal	Low	3 (2.8%)	2 (1.9%)
		Normal	93 (87.7%)	93 (86.1%)
		High	0	3 (2.8%)
	High	Normal	1 (0.9%)	0
		High	0	1 (0.9%)
Neutrophils/Leukocytes (%)				
Week 4	m		106	108
	Low	Low	0	1 (0.9%)
		Normal	1 (0.9%)	1 (0.9%)
	Normal	Low	1 (0.9%)	1 (0.9%)
		Normal	101 (95.3%)	104 (96.3%)

Parameter Week	Baseline	Post-baseline	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
		High	3 (2.8%)	1 (0.9%)
Week 8	m		105	108
	Low	Low	1 (1.0%)	0
		Normal	0	2 (1.9%)
	Normal	Low	2 (1.9%)	0
		Normal	99 (94.3%)	103 (95.4%)
		High	3 (2.9%)	3 (2.8%)
Week 12	m		103	108
	Low	Low	1 (1.0%)	1 (0.9%)
		Normal	0	1 (0.9%)
	Normal	Low	0	2 (1.9%)
		Normal	98 (95.1%)	101 (93.5%)
		High	4 (3.9%)	3 (2.8%)
Week 16	m		104	108
	Low	Normal	1 (1.0%)	2 (1.9%)
	Normal	Low	1 (1.0%)	2 (1.9%)
		Normal	95 (91.3%)	98 (90.7%)
		High	7 (6.7%)	6 (5.6%)
LOCF Endpoint	m		106	108
	Low	Normal	1 (0.9%)	2 (1.9%)
	Normal	Low	1 (0.9%)	2 (1.9%)
		Normal	97 (91.5%)	98 (90.7%)
		High	7 (6.6%)	6 (5.6%)
Platelets (10^9/L)				
Week 4	m		106	107
	Low	Low	2 (1.9%)	3 (2.8%)
	Normal	Low	1 (0.9%)	3 (2.8%)
		Normal	102 (96.2%)	101 (94.4%)
	High	Normal	1 (0.9%)	0
Week 8	m		105	107
	Low	Low	2 (1.9%)	2 (1.9%)
	Normal	Normal	102 (97.1%)	104 (97.2%)
		High	0	1 (0.9%)
	High	Normal	1 (1.0%)	0
Week 12	m		103	108
	Low	Low	1 (1.0%)	2 (1.9%)
		Normal	1 (1.0%)	1 (0.9%)
	Normal	Low	1 (1.0%)	1 (0.9%)
		Normal	99 (96.1%)	101 (93.5%)
		High	0	3 (2.8%)
	High	Normal	1 (1.0%)	0
Week 16	m		104	108

Parameter Week	Baseline	Post-baseline	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
	Low	Low	1 (1.0%)	2 (1.9%)
		Normal	1 (1.0%)	1 (0.9%)
	Normal	Low	1 (1.0%)	1 (0.9%)
		Normal	100 (96.2%)	103 (95.4%)
		High	0	1 (0.9%)
	High	Normal	1 (1.0%)	0
LOCF Endpoint	m		106	108
	Low	Low	1 (0.9%)	2 (1.9%)
		Normal	1 (0.9%)	1 (0.9%)
	Normal	Low	1 (0.9%)	1 (0.9%)
		Normal	102 (96.2%)	103 (95.4%)
		High	0	1 (0.9%)
	High	Normal	1 (0.9%)	0

- Abbreviations: LOCF, Last Observation Carried Forward; bid, Twice a day
- m in row headings is the total number of subjects with both baseline and the corresponding visit values available, and is used as the denominator to calculate percentages.

Control No:<<t-s-194-labot-020db.sas, 2020-03-06T00:16:43>>

Table S-195 Shift of Laboratory Findings of Biochemistry in 16-Week Double-blind Period in Combination with Insulin Therapy (PXL008-020; Safety Population)

Parameter Week	Baseline	Post-baseline	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
Alanine Aminotransferase (U/L)				
Week 4	m		106	108
	Normal	Normal	99 (93.4%)	99 (91.7%)
		High	0	2 (1.9%)
	High	Normal	2 (1.9%)	5 (4.6%)
		High	5 (4.7%)	2 (1.9%)
Week 8	m		105	108
	Normal	Low	1 (1.0%)	0
		Normal	95 (90.5%)	97 (89.8%)
		High	2 (1.9%)	4 (3.7%)
	High	Normal	2 (1.9%)	6 (5.6%)
		High	5 (4.8%)	1 (0.9%)
Week 12	m		104	108
	Normal	Normal	90 (86.5%)	99 (91.7%)
		High	7 (6.7%)	2 (1.9%)
	High	Normal	2 (1.9%)	4 (3.7%)
		High	5 (4.8%)	3 (2.8%)
Week 16	m		104	108
	Normal	Normal	94 (90.4%)	94 (87.0%)
		High	3 (2.9%)	7 (6.5%)
	High	Normal	3 (2.9%)	6 (5.6%)
		High	4 (3.8%)	1 (0.9%)
LOCF Endpoint	m		106	108
	Normal	Normal	96 (90.6%)	94 (87.0%)
		High	3 (2.8%)	7 (6.5%)
	High	Normal	3 (2.8%)	6 (5.6%)
		High	4 (3.8%)	1 (0.9%)
Albumin (g/L)				
Week 4	m		106	108
	Normal	Normal	103 (97.2%)	102 (94.4%)
		High	1 (0.9%)	4 (3.7%)
	High	Normal	1 (0.9%)	2 (1.9%)
		High	1 (0.9%)	0
Week 8	m		105	108
	Normal	Normal	102 (97.1%)	101 (93.5%)
		High	1 (1.0%)	5 (4.6%)
	High	Normal	1 (1.0%)	2 (1.9%)
		High	1 (1.0%)	0
Week 12	m		104	108

Parameter Week	Baseline	Post-baseline	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
	Normal	Normal	101 (97.1%)	102 (94.4%)
		High	1 (1.0%)	4 (3.7%)
	High	Normal	2 (1.9%)	2 (1.9%)
Week 16	m		104	108
	Normal	Normal	96 (92.3%)	93 (86.1%)
		High	6 (5.8%)	13 (12.0%)
	High	Normal	0	2 (1.9%)
		High	2 (1.9%)	0
LOCF Endpoint	m		106	108
	Normal	Normal	98 (92.5%)	93 (86.1%)
		High	6 (5.7%)	13 (12.0%)
	High	Normal	0	2 (1.9%)
		High	2 (1.9%)	0
Alkaline Phosphatase (U/L)				
Week 4	m		106	108
	Low	Normal	0	1 (0.9%)
	Normal	Low	0	3 (2.8%)
		Normal	104 (98.1%)	101 (93.5%)
		High	1 (0.9%)	0
	High	Normal	1 (0.9%)	1 (0.9%)
		High	0	2 (1.9%)
Week 8	m		105	108
	Low	Low	0	1 (0.9%)
	Normal	Low	0	2 (1.9%)
		Normal	103 (98.1%)	101 (93.5%)
		High	1 (1.0%)	1 (0.9%)
	High	Normal	1 (1.0%)	1 (0.9%)
		High	0	2 (1.9%)
Week 12	m		104	108
	Low	Low	0	1 (0.9%)
	Normal	Low	0	2 (1.9%)
		Normal	102 (98.1%)	101 (93.5%)
		High	1 (1.0%)	1 (0.9%)
	High	Normal	1 (1.0%)	1 (0.9%)
		High	0	2 (1.9%)
Week 16	m		104	108
	Low	Low	0	1 (0.9%)
	Normal	Low	0	2 (1.9%)
		Normal	103 (99.0%)	101 (93.5%)
		High	0	1 (0.9%)
	High	Normal	0	1 (0.9%)
		High	1 (1.0%)	2 (1.9%)
LOCF Endpoint	m		106	108

Parameter Week	Baseline	Post-baseline	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
	Low	Low	0	1 (0.9%)
	Normal	Low	0	2 (1.9%)
		Normal	105 (99.1%)	101 (93.5%)
		High	0	1 (0.9%)
	High	Normal	0	1 (0.9%)
		High	1 (0.9%)	2 (1.9%)
Amylase (U/L)				
Week 4	m		106	108
	Low	Low	3 (2.8%)	11 (10.2%)
		Normal	1 (0.9%)	1 (0.9%)
	Normal	Low	2 (1.9%)	3 (2.8%)
		Normal	94 (88.7%)	88 (81.5%)
		High	1 (0.9%)	3 (2.8%)
	High	Normal	4 (3.8%)	2 (1.9%)
		High	1 (0.9%)	0
Week 8	m		105	108
	Low	Low	3 (2.9%)	9 (8.3%)
		Normal	1 (1.0%)	3 (2.8%)
	Normal	Low	1 (1.0%)	2 (1.9%)
		Normal	95 (90.5%)	91 (84.3%)
		High	0	1 (0.9%)
	High	Normal	4 (3.8%)	1 (0.9%)
		High	1 (1.0%)	1 (0.9%)
Week 12	m		104	108
	Low	Low	2 (1.9%)	8 (7.4%)
		Normal	2 (1.9%)	4 (3.7%)
	Normal	Low	5 (4.8%)	4 (3.7%)
		Normal	89 (85.6%)	88 (81.5%)
		High	2 (1.9%)	2 (1.9%)
	High	Normal	3 (2.9%)	1 (0.9%)
		High	1 (1.0%)	1 (0.9%)
Week 16	m		104	108
	Low	Low	3 (2.9%)	9 (8.3%)
		Normal	1 (1.0%)	3 (2.8%)
	Normal	Low	4 (3.8%)	1 (0.9%)
		Normal	90 (86.5%)	91 (84.3%)
		High	2 (1.9%)	2 (1.9%)
	High	Normal	3 (2.9%)	1 (0.9%)
		High	1 (1.0%)	1 (0.9%)
LOCF Endpoint	m		106	108
	Low	Low	3 (2.8%)	9 (8.3%)
		Normal	1 (0.9%)	3 (2.8%)
	Normal	Low	4 (3.8%)	1 (0.9%)
		Normal	91 (85.8%)	91 (84.3%)
		High	2 (1.9%)	2 (1.9%)

Parameter Week	Baseline	Post-baseline	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
	High	Normal	4 (3.8%)	1 (0.9%)
		High	1 (0.9%)	1 (0.9%)
Aspartate Aminotransferase (U/L)				
Week 4	m		105	108
	Normal	Normal	98 (93.3%)	101 (93.5%)
		High	1 (1.0%)	1 (0.9%)
	High	Normal	2 (1.9%)	4 (3.7%)
		High	4 (3.8%)	2 (1.9%)
Week 8	m		105	108
	Normal	Normal	98 (93.3%)	102 (94.4%)
		High	1 (1.0%)	0
	High	Normal	1 (1.0%)	5 (4.6%)
		High	5 (4.8%)	1 (0.9%)
Week 12	m		104	108
	Normal	Normal	97 (93.3%)	99 (91.7%)
		High	1 (1.0%)	3 (2.8%)
	High	Normal	1 (1.0%)	5 (4.6%)
		High	5 (4.8%)	1 (0.9%)
Week 16	m		104	108
	Normal	Low	2 (1.9%)	0
		Normal	93 (89.4%)	98 (90.7%)
		High	3 (2.9%)	4 (3.7%)
	High	Normal	2 (1.9%)	5 (4.6%)
		High	4 (3.8%)	1 (0.9%)
LOCF Endpoint	m		106	108
	Normal	Low	2 (1.9%)	0
		Normal	95 (89.6%)	98 (90.7%)
		High	3 (2.8%)	4 (3.7%)
	High	Normal	2 (1.9%)	5 (4.6%)
		High	4 (3.8%)	1 (0.9%)
Bicarbonate (mmol/L)				
Week 4	m		106	108
	Normal	Normal	106 (100.0%)	108 (100.0%)
Week 8	m		105	108
	Normal	Low	1 (1.0%)	1 (0.9%)
		Normal	104 (99.0%)	107 (99.1%)
Week 12	m		104	108
	Normal	Normal	104 (100.0%)	108 (100.0%)
Week 16	m		104	108
	Normal	Normal	104 (100.0%)	108 (100.0%)

Parameter Week	Baseline	Post-baseline	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
LOCF Endpoint	m		106	108
	Normal	Normal	106 (100.0%)	108 (100.0%)
Bilirubin (umol/L)				
Week 4	m		106	108
	Normal	Normal	103 (97.2%)	104 (96.3%)
		High	0	2 (1.9%)
	High	Normal	3 (2.8%)	1 (0.9%)
		High	0	1 (0.9%)
Week 8	m		105	108
	Normal	Low	2 (1.9%)	0
		Normal	99 (94.3%)	104 (96.3%)
		High	1 (1.0%)	2 (1.9%)
	High	Normal	2 (1.9%)	2 (1.9%)
		High	1 (1.0%)	0
Week 12	m		104	108
	Normal	Normal	100 (96.2%)	104 (96.3%)
		High	1 (1.0%)	2 (1.9%)
	High	Normal	2 (1.9%)	2 (1.9%)
		High	1 (1.0%)	0
Week 16	m		104	108
	Normal	Low	3 (2.9%)	0
		Normal	96 (92.3%)	104 (96.3%)
		High	2 (1.9%)	2 (1.9%)
	High	Normal	1 (1.0%)	2 (1.9%)
		High	2 (1.9%)	0
LOCF Endpoint	m		106	108
	Normal	Low	3 (2.8%)	0
		Normal	97 (91.5%)	104 (96.3%)
		High	3 (2.8%)	2 (1.9%)
	High	Normal	1 (0.9%)	2 (1.9%)
		High	2 (1.9%)	0
Calcium (mmol/L)				
Week 4	m		106	108
	Low	Normal	0	1 (0.9%)
	Normal	Normal	106 (100.0%)	107 (99.1%)
Week 8	m		105	108
	Low	Normal	0	1 (0.9%)
	Normal	Normal	105 (100.0%)	107 (99.1%)
Week 12	m		104	108
	Low	Normal	0	1 (0.9%)
	Normal	Normal	104 (100.0%)	107 (99.1%)

Parameter Week	Baseline	Post-baseline	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
Week 16	m		104	108
	Low	Normal	0	1 (0.9%)
	Normal	Normal	104 (100.0%)	107 (99.1%)
LOCF Endpoint	m		106	108
	Low	Normal	0	1 (0.9%)
	Normal	Normal	106 (100.0%)	107 (99.1%)
Chloride (mmol/L)				
Week 4	m		106	108
	Normal	Low	1 (0.9%)	1 (0.9%)
		Normal	105 (99.1%)	107 (99.1%)
Week 8	m		105	108
	Normal	Normal	105 (100.0%)	108 (100.0%)
Week 12	m		104	108
	Normal	Low	0	1 (0.9%)
		Normal	104 (100.0%)	107 (99.1%)
Week 16	m		104	108
	Normal	Low	1 (1.0%)	0
		Normal	103 (99.0%)	108 (100.0%)
LOCF Endpoint	m		106	108
	Normal	Low	1 (0.9%)	0
		Normal	105 (99.1%)	108 (100.0%)
Creatine Kinase (U/L)				
Week 4	m		106	108
	Normal	Normal	99 (93.4%)	98 (90.7%)
		High	2 (1.9%)	4 (3.7%)
	High	Normal	5 (4.7%)	6 (5.6%)
Week 8	m		105	108
	Normal	Normal	97 (92.4%)	100 (92.6%)
		High	3 (2.9%)	2 (1.9%)
	High	Normal	3 (2.9%)	4 (3.7%)
		High	2 (1.9%)	2 (1.9%)
Week 12	m		104	108
	Normal	Normal	97 (93.3%)	98 (90.7%)
		High	2 (1.9%)	4 (3.7%)
	High	Normal	5 (4.8%)	4 (3.7%)
		High	0	2 (1.9%)
Week 16	m		104	108
	Normal	Normal	96 (92.3%)	99 (91.7%)
		High	3 (2.9%)	3 (2.8%)

Parameter Week	Baseline	Post-baseline	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
	High	Normal	4 (3.8%)	4 (3.7%)
		High	1 (1.0%)	2 (1.9%)
LOCF Endpoint	m		106	108
	Normal	Normal	98 (92.5%)	99 (91.7%)
		High	3 (2.8%)	3 (2.8%)
	High	Normal	4 (3.8%)	4 (3.7%)
		High	1 (0.9%)	2 (1.9%)
Creatinine (umol/L)				
Week 4	m		106	108
	Normal	Normal	106 (100.0%)	108 (100.0%)
Week 8	m		105	108
	Normal	Normal	105 (100.0%)	108 (100.0%)
Week 12	m		104	108
	Normal	Normal	104 (100.0%)	108 (100.0%)
Week 16	m		104	108
	Normal	Normal	104 (100.0%)	108 (100.0%)
LOCF Endpoint	m		106	108
	Normal	Normal	106 (100.0%)	108 (100.0%)
Gamma Glutamyl Transferase (U/L)				
Week 4	m		106	108
	Normal	Low	0	1 (0.9%)
		Normal	92 (86.8%)	92 (85.2%)
		High	4 (3.8%)	1 (0.9%)
	High	Normal	2 (1.9%)	1 (0.9%)
		High	8 (7.5%)	13 (12.0%)
Week 8	m		105	108
	Normal	Low	0	2 (1.9%)
		Normal	92 (87.6%)	91 (84.3%)
		High	3 (2.9%)	1 (0.9%)
	High	Normal	1 (1.0%)	1 (0.9%)
		High	9 (8.6%)	13 (12.0%)
Week 12	m		104	108
	Normal	Low	0	1 (0.9%)
		Normal	92 (88.5%)	93 (86.1%)
		High	2 (1.9%)	0
	High	Normal	2 (1.9%)	0
		High	8 (7.7%)	14 (13.0%)
Week 16	m		104	108
	Normal	Low	0	1 (0.9%)

Parameter Week	Baseline	Post-baseline	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
		Normal	90 (86.5%)	90 (83.3%)
		High	4 (3.8%)	3 (2.8%)
	High	Normal	1 (1.0%)	2 (1.9%)
		High	9 (8.7%)	12 (11.1%)
LOCF Endpoint	m		106	108
	Normal	Low	0	1 (0.9%)
		Normal	92 (86.8%)	90 (83.3%)
		High	4 (3.8%)	3 (2.8%)
	High	Normal	1 (0.9%)	2 (1.9%)
		High	9 (8.5%)	12 (11.1%)
Lipase (U/L)				
Week 4	m		106	108
	Normal	Normal	103 (97.2%)	107 (99.1%)
		High	1 (0.9%)	0
	High	Normal	1 (0.9%)	1 (0.9%)
		High	1 (0.9%)	0
Week 8	m		105	108
	Normal	Normal	102 (97.1%)	107 (99.1%)
		High	1 (1.0%)	0
	High	Normal	1 (1.0%)	1 (0.9%)
		High	1 (1.0%)	0
Week 12	m		104	108
	Normal	Normal	100 (96.2%)	107 (99.1%)
		High	2 (1.9%)	0
	High	Normal	2 (1.9%)	1 (0.9%)
Week 16	m		104	108
	Normal	Normal	101 (97.1%)	106 (98.1%)
		High	1 (1.0%)	1 (0.9%)
	High	Normal	2 (1.9%)	1 (0.9%)
LOCF Endpoint	m		106	108
	Normal	Normal	103 (97.2%)	106 (98.1%)
		High	1 (0.9%)	1 (0.9%)
	High	Normal	2 (1.9%)	1 (0.9%)
Phosphate (mmol/L)				
Week 4	m		106	108
	Normal	Low	0	1 (0.9%)
		Normal	106 (100.0%)	106 (98.1%)
	High	Normal	0	1 (0.9%)
Week 8	m		105	108
	Normal	Normal	105 (100.0%)	107 (99.1%)
	High	Normal	0	1 (0.9%)

Parameter Week	Baseline	Post-baseline	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
Week 12	m		104	108
	Normal	Normal	104 (100.0%)	106 (98.1%)
		High	0	1 (0.9%)
	High	Normal	0	1 (0.9%)
Week 16	m		104	108
	Normal	Normal	104 (100.0%)	107 (99.1%)
	High	Normal	0	1 (0.9%)
LOCF Endpoint	m		106	108
	Normal	Normal	106 (100.0%)	107 (99.1%)
	High	Normal	0	1 (0.9%)
Potassium (mmol/L)				
Week 4	m		106	108
	Low	Normal	0	1 (0.9%)
	Normal	Normal	105 (99.1%)	106 (98.1%)
		High	1 (0.9%)	1 (0.9%)
Week 8	m		105	108
	Low	Normal	0	1 (0.9%)
	Normal	Normal	105 (100.0%)	106 (98.1%)
		High	0	1 (0.9%)
Week 12	m		104	108
	Low	Normal	0	1 (0.9%)
	Normal	Normal	103 (99.0%)	107 (99.1%)
		High	1 (1.0%)	0
Week 16	m		104	108
	Low	Normal	0	1 (0.9%)
	Normal	Normal	103 (99.0%)	106 (98.1%)
		High	1 (1.0%)	1 (0.9%)
LOCF Endpoint	m		106	108
	Low	Normal	0	1 (0.9%)
	Normal	Normal	105 (99.1%)	106 (98.1%)
		High	1 (0.9%)	1 (0.9%)
Protein (g/L)				
Week 4	m		106	108
	Low	Normal	0	3 (2.8%)
	Normal	Low	0	1 (0.9%)
		Normal	104 (98.1%)	103 (95.4%)
	High	Normal	2 (1.9%)	1 (0.9%)
Week 8	m		105	108
	Low	Normal	0	3 (2.8%)
	Normal	Normal	103 (98.1%)	104 (96.3%)
	High	Normal	2 (1.9%)	1 (0.9%)

Parameter Week	Baseline	Post-baseline	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
Week 12	m		104	108
	Low	Normal	0	3 (2.8%)
	Normal	Normal	100 (96.2%)	104 (96.3%)
		High	2 (1.9%)	0
	High	Normal	2 (1.9%)	1 (0.9%)
Week 16	m		104	108
	Low	Low	0	1 (0.9%)
		Normal	0	2 (1.9%)
	Normal	Normal	100 (96.2%)	104 (96.3%)
		High	2 (1.9%)	0
	High	Normal	1 (1.0%)	1 (0.9%)
		High	1 (1.0%)	0
LOCF Endpoint	m		106	108
	Low	Low	0	1 (0.9%)
		Normal	0	2 (1.9%)
	Normal	Normal	102 (96.2%)	104 (96.3%)
		High	2 (1.9%)	0
	High	Normal	1 (0.9%)	1 (0.9%)
		High	1 (0.9%)	0
Sodium (mmol/L)				
Week 4	m		106	108
	Low	Normal	0	1 (0.9%)
	Normal	Normal	106 (100.0%)	106 (98.1%)
	High	Normal	0	1 (0.9%)
Week 8	m		105	108
	Low	Low	0	1 (0.9%)
	Normal	Normal	105 (100.0%)	106 (98.1%)
	High	Normal	0	1 (0.9%)
Week 12	m		104	108
	Low	Normal	0	1 (0.9%)
	Normal	Normal	104 (100.0%)	106 (98.1%)
	High	Normal	0	1 (0.9%)
Week 16	m		104	108
	Low	Low	0	1 (0.9%)
	Normal	Low	1 (1.0%)	0
		Normal	103 (99.0%)	106 (98.1%)
	High	Normal	0	1 (0.9%)
LOCF Endpoint	m		106	108
	Low	Low	0	1 (0.9%)
	Normal	Low	1 (0.9%)	0
		Normal	105 (99.1%)	106 (98.1%)
	High	Normal	0	1 (0.9%)

Parameter Week	Baseline	Post-baseline	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
Urate (umol/L)				
Week 4	m		106	108
	Low	Low	1 (0.9%)	1 (0.9%)
		Normal	1 (0.9%)	2 (1.9%)
	Normal	Low	0	1 (0.9%)
		Normal	104 (98.1%)	103 (95.4%)
	High	Normal	0	1 (0.9%)
Week 8	m		105	108
	Low	Low	1 (1.0%)	2 (1.9%)
		Normal	1 (1.0%)	1 (0.9%)
	Normal	Normal	103 (98.1%)	104 (96.3%)
	High	Normal	0	1 (0.9%)
Week 12	m		104	108
	Low	Low	1 (1.0%)	2 (1.9%)
		Normal	1 (1.0%)	1 (0.9%)
	Normal	Low	0	1 (0.9%)
		Normal	101 (97.1%)	103 (95.4%)
		High	1 (1.0%)	0
	High	Normal	0	1 (0.9%)
Week 16	m		104	108
	Low	Low	2 (1.9%)	0
		Normal	0	3 (2.8%)
	Normal	Low	0	1 (0.9%)
		Normal	102 (98.1%)	103 (95.4%)
	High	Normal	0	1 (0.9%)
LOCF Endpoint	m		106	108
	Low	Low	2 (1.9%)	0
		Normal	0	3 (2.8%)
	Normal	Low	0	1 (0.9%)
		Normal	104 (98.1%)	103 (95.4%)
	High	Normal	0	1 (0.9%)
Urea Nitrogen (mmol/L)				
Week 4	m		106	108
	Normal	Normal	105 (99.1%)	104 (96.3%)
		High	0	2 (1.9%)
	High	Normal	0	2 (1.9%)
		High	1 (0.9%)	0
Week 8	m		105	108
	Normal	Normal	103 (98.1%)	104 (96.3%)
		High	1 (1.0%)	2 (1.9%)
	High	Normal	0	1 (0.9%)
		High	1 (1.0%)	1 (0.9%)

Parameter Week	Baseline	Post-baseline	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
Week 12	m		104	108
	Normal	Normal	103 (99.0%)	105 (97.2%)
		High	0	1 (0.9%)
	High	Normal	0	2 (1.9%)
		High	1 (1.0%)	0
Week 16	m		104	108
	Normal	Normal	102 (98.1%)	105 (97.2%)
		High	1 (1.0%)	1 (0.9%)
	High	Normal	1 (1.0%)	2 (1.9%)
LOCF Endpoint	m		106	108
	Normal	Normal	104 (98.1%)	105 (97.2%)
		High	1 (0.9%)	1 (0.9%)
	High	Normal	1 (0.9%)	2 (1.9%)

- Abbreviations: LOCF, Last Observation Carried Forward; bid, Twice a day
- m in row headings is the total number of subjects with both baseline and the corresponding visit values available, and is used as the denominator to calculate percentages.

Control No:<<t-s-195-labot-020db.sas, 2020-03-06T00:18:30>>

Table S-196 Shift of Laboratory Findings of Urinalysis in 16-Week Double-blind Period in Combination with Insulin Therapy (PXL008-020; Safety Population)

Parameter Week	Baseline	Post-baseline	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
Ketones				
Week 4	m		106	108
	Negative	Negative	94 (88.7%)	94 (87.0%)
		Trace	1 (0.9%)	4 (3.7%)
		Positive	4 (3.8%)	2 (1.9%)
	Trace	Negative	2 (1.9%)	7 (6.5%)
	Positive	Negative	5 (4.7%)	1 (0.9%)
Week 8	m		105	108
	Negative	Negative	97 (92.4%)	96 (88.9%)
		Trace	1 (1.0%)	2 (1.9%)
		Positive	0	2 (1.9%)
	Trace	Negative	1 (1.0%)	7 (6.5%)
		Positive	1 (1.0%)	0
	Positive	Negative	3 (2.9%)	0
		Trace	2 (1.9%)	0
		Positive	0	1 (0.9%)
Week 12	m		104	108
	Negative	Negative	90 (86.5%)	93 (86.1%)
		Trace	4 (3.8%)	2 (1.9%)
		Positive	4 (3.8%)	5 (4.6%)
	Trace	Negative	2 (1.9%)	4 (3.7%)
		Trace	0	1 (0.9%)
		Positive	0	2 (1.9%)
	Positive	Negative	2 (1.9%)	0
		Trace	0	1 (0.9%)
		Positive	2 (1.9%)	0
Week 16	m		104	108
	Negative	Negative	90 (86.5%)	93 (86.1%)
		Trace	4 (3.8%)	4 (3.7%)
		Positive	4 (3.8%)	3 (2.8%)
	Trace	Negative	0	5 (4.6%)
		Trace	0	1 (0.9%)
		Positive	2 (1.9%)	1 (0.9%)
	Positive	Negative	2 (1.9%)	1 (0.9%)
		Positive	2 (1.9%)	0
LOCF Endpoint	m		106	108
	Negative	Negative	91 (85.8%)	93 (86.1%)
		Trace	4 (3.8%)	4 (3.7%)
		Positive	4 (3.8%)	3 (2.8%)
	Trace	Negative	0	5 (4.6%)
		Trace	0	1 (0.9%)
		Positive	2 (1.9%)	1 (0.9%)
	Positive	Negative	2 (1.9%)	1 (0.9%)

Parameter Week	Baseline	Post-baseline	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
		Trace	1 (0.9%)	0
		Positive	2 (1.9%)	0
Leukocyte Esterase				
Week 4	m		106	108
	Negative	Negative	83 (78.3%)	87 (80.6%)
		Trace	1 (0.9%)	1 (0.9%)
		Positive	6 (5.7%)	8 (7.4%)
	Trace	Negative	2 (1.9%)	0
		Trace	1 (0.9%)	0
		Positive	1 (0.9%)	1 (0.9%)
	Positive	Negative	4 (3.8%)	3 (2.8%)
		Trace	2 (1.9%)	2 (1.9%)
		Positive	6 (5.7%)	6 (5.6%)
Week 8	m		105	108
	Negative	Negative	83 (79.0%)	94 (87.0%)
		Trace	2 (1.9%)	1 (0.9%)
		Positive	4 (3.8%)	1 (0.9%)
	Trace	Negative	2 (1.9%)	0
		Positive	2 (1.9%)	1 (0.9%)
	Positive	Negative	3 (2.9%)	0
		Trace	3 (2.9%)	3 (2.8%)
		Positive	6 (5.7%)	8 (7.4%)
Week 12	m		104	108
	Negative	Negative	86 (82.7%)	94 (87.0%)
		Trace	1 (1.0%)	2 (1.9%)
		Positive	1 (1.0%)	0
	Trace	Negative	1 (1.0%)	1 (0.9%)
		Positive	3 (2.9%)	0
	Positive	Negative	1 (1.0%)	2 (1.9%)
		Trace	3 (2.9%)	0
		Positive	8 (7.7%)	9 (8.3%)
Week 16	m		104	108
	Negative	Negative	84 (80.8%)	91 (84.3%)
		Trace	2 (1.9%)	3 (2.8%)
		Positive	2 (1.9%)	2 (1.9%)
	Trace	Negative	1 (1.0%)	1 (0.9%)
		Trace	2 (1.9%)	0
		Positive	1 (1.0%)	0
	Positive	Negative	3 (2.9%)	5 (4.6%)
		Trace	2 (1.9%)	0
		Positive	7 (6.7%)	6 (5.6%)
LOCF Endpoint	m		106	108
	Negative	Negative	86 (81.1%)	91 (84.3%)
		Trace	2 (1.9%)	3 (2.8%)
		Positive	2 (1.9%)	2 (1.9%)

Parameter Week	Baseline	Post-baseline	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
	Trace	Negative	1 (0.9%)	1 (0.9%)
		Trace	2 (1.9%)	0
		Positive	1 (0.9%)	0
	Positive	Negative	3 (2.8%)	5 (4.6%)
		Trace	2 (1.9%)	0
		Positive	7 (6.6%)	6 (5.6%)
Nitrite				
Week 4	m		106	108
	Negative	Negative	102 (96.2%)	103 (95.4%)
		Positive	1 (0.9%)	2 (1.9%)
	Positive	Negative	2 (1.9%)	0
		Positive	1 (0.9%)	3 (2.8%)
Week 8	m		105	108
	Negative	Negative	100 (95.2%)	104 (96.3%)
		Positive	2 (1.9%)	1 (0.9%)
	Positive	Negative	2 (1.9%)	0
		Positive	1 (1.0%)	3 (2.8%)
Week 12	m		104	108
	Negative	Negative	99 (95.2%)	103 (95.4%)
		Positive	2 (1.9%)	2 (1.9%)
	Positive	Negative	2 (1.9%)	0
		Positive	1 (1.0%)	3 (2.8%)
Week 16	m		104	108
	Negative	Negative	100 (96.2%)	102 (94.4%)
		Positive	1 (1.0%)	3 (2.8%)
	Positive	Negative	0	1 (0.9%)
		Positive	3 (2.9%)	2 (1.9%)
LOCF Endpoint	m		106	108
	Negative	Negative	102 (96.2%)	102 (94.4%)
		Positive	1 (0.9%)	3 (2.8%)
	Positive	Negative	0	1 (0.9%)
		Positive	3 (2.8%)	2 (1.9%)
Occult Blood				
Week 4	m		106	108
	Negative	Negative	102 (96.2%)	100 (92.6%)
		Trace	2 (1.9%)	2 (1.9%)
		Positive	0	2 (1.9%)
	Trace	Positive	0	1 (0.9%)
	Positive	Negative	1 (0.9%)	1 (0.9%)
		Trace	0	1 (0.9%)
		Positive	1 (0.9%)	1 (0.9%)
Week 8	m		105	108
	Negative	Negative	98 (93.3%)	101 (93.5%)

Parameter Week	Baseline	Post-baseline	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
		Trace	4 (3.8%)	2 (1.9%)
		Positive	1 (1.0%)	1 (0.9%)
	Trace	Positive	0	1 (0.9%)
	Positive	Negative	1 (1.0%)	0
		Trace	0	1 (0.9%)
		Positive	1 (1.0%)	2 (1.9%)
Week 12	m		104	108
	Negative	Negative	100 (96.2%)	100 (92.6%)
		Trace	0	1 (0.9%)
		Positive	2 (1.9%)	3 (2.8%)
	Trace	Trace	0	1 (0.9%)
	Positive	Negative	1 (1.0%)	1 (0.9%)
		Trace	0	2 (1.9%)
		Positive	1 (1.0%)	0
Week 16	m		104	108
	Negative	Negative	97 (93.3%)	101 (93.5%)
		Trace	2 (1.9%)	1 (0.9%)
		Positive	3 (2.9%)	2 (1.9%)
	Trace	Positive	0	1 (0.9%)
	Positive	Negative	1 (1.0%)	0
		Positive	1 (1.0%)	3 (2.8%)
LOCF Endpoint	m		106	108
	Negative	Negative	99 (93.4%)	101 (93.5%)
		Trace	2 (1.9%)	1 (0.9%)
		Positive	3 (2.8%)	2 (1.9%)
	Trace	Positive	0	1 (0.9%)
	Positive	Negative	1 (0.9%)	0
		Positive	1 (0.9%)	3 (2.8%)
pH				
Week 4	m		106	108
	5.5	5.5	7 (6.6%)	6 (5.6%)
		6	7 (6.6%)	5 (4.6%)
		6.5	2 (1.9%)	2 (1.9%)
		7.5	0	1 (0.9%)
	6	5.5	8 (7.5%)	3 (2.8%)
		6	24 (22.6%)	21 (19.4%)
		6.5	10 (9.4%)	8 (7.4%)
		7	2 (1.9%)	3 (2.8%)
	6.5	5.5	2 (1.9%)	0
		6	8 (7.5%)	20 (18.5%)
		6.5	9 (8.5%)	5 (4.6%)
		7	1 (0.9%)	3 (2.8%)
		7.5	1 (0.9%)	0
		8	1 (0.9%)	1 (0.9%)
	7	5.5	1 (0.9%)	0
		6	4 (3.8%)	3 (2.8%)

Parameter Week	Baseline	Post-baseline	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
		6.5	5 (4.7%)	5 (4.6%)
		7	3 (2.8%)	4 (3.7%)
		7.5	1 (0.9%)	1 (0.9%)
		8	1 (0.9%)	0
	7.5	5.5	0	2 (1.9%)
		6	3 (2.8%)	6 (5.6%)
		6.5	3 (2.8%)	2 (1.9%)
		7	3 (2.8%)	3 (2.8%)
		7.5	0	2 (1.9%)
		8	0	1 (0.9%)
	8	7	0	1 (0.9%)
Week 8	m		105	108
	5.5	5.5	6 (5.7%)	6 (5.6%)
		6	6 (5.7%)	3 (2.8%)
		6.5	3 (2.9%)	2 (1.9%)
		7	1 (1.0%)	2 (1.9%)
		7.5	0	1 (0.9%)
	6	5.5	2 (1.9%)	3 (2.8%)
		6	21 (20.0%)	19 (17.6%)
		6.5	13 (12.4%)	7 (6.5%)
		7	5 (4.8%)	3 (2.8%)
		7.5	3 (2.9%)	3 (2.8%)
	6.5	5.5	3 (2.9%)	0
		6	9 (8.6%)	10 (9.3%)
		6.5	7 (6.7%)	8 (7.4%)
		7	2 (1.9%)	7 (6.5%)
		7.5	1 (1.0%)	4 (3.7%)
	7	5.5	1 (1.0%)	0
		6	7 (6.7%)	5 (4.6%)
		6.5	1 (1.0%)	2 (1.9%)
		7	4 (3.8%)	3 (2.8%)
		7.5	1 (1.0%)	2 (1.9%)
		8	0	1 (0.9%)
	7.5	5.5	0	2 (1.9%)
		6	3 (2.9%)	5 (4.6%)
		6.5	1 (1.0%)	3 (2.8%)
		7	2 (1.9%)	1 (0.9%)
		7.5	3 (2.9%)	5 (4.6%)
	8	8	0	1 (0.9%)
Week 12	m		104	108
	5.5	5.5	8 (7.7%)	6 (5.6%)
		6	5 (4.8%)	4 (3.7%)
		6.5	1 (1.0%)	2 (1.9%)
		7	1 (1.0%)	2 (1.9%)
	6	5.5	7 (6.7%)	2 (1.9%)
		6	24 (23.1%)	16 (14.8%)
		6.5	8 (7.7%)	11 (10.2%)
		7	3 (2.9%)	2 (1.9%)

Parameter Week	Baseline	Post-baseline	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
		7.5	0	3 (2.8%)
		8	2 (1.9%)	1 (0.9%)
	6.5	5.5	2 (1.9%)	1 (0.9%)
		6	7 (6.7%)	5 (4.6%)
		6.5	9 (8.7%)	15 (13.9%)
		7	4 (3.8%)	6 (5.6%)
		7.5	0	2 (1.9%)
	7	6	2 (1.9%)	5 (4.6%)
		6.5	7 (6.7%)	2 (1.9%)
		7	1 (1.0%)	3 (2.8%)
		7.5	4 (3.8%)	3 (2.8%)
	7.5	6	4 (3.8%)	4 (3.7%)
		6.5	1 (1.0%)	4 (3.7%)
		7	1 (1.0%)	3 (2.8%)
		7.5	3 (2.9%)	3 (2.8%)
		8	0	2 (1.9%)
	8	8	0	1 (0.9%)
Week 16	m		104	108
	5.5	5.5	5 (4.8%)	4 (3.7%)
		6	6 (5.8%)	5 (4.6%)
		6.5	1 (1.0%)	3 (2.8%)
		7	3 (2.9%)	1 (0.9%)
		7.5	0	1 (0.9%)
	6	5.5	7 (6.7%)	6 (5.6%)
		6	20 (19.2%)	13 (12.0%)
		6.5	10 (9.6%)	7 (6.5%)
		7	4 (3.8%)	7 (6.5%)
		7.5	3 (2.9%)	1 (0.9%)
		8	0	1 (0.9%)
	6.5	5.5	2 (1.9%)	3 (2.8%)
		6	5 (4.8%)	8 (7.4%)
		6.5	11 (10.6%)	6 (5.6%)
		7	2 (1.9%)	11 (10.2%)
		7.5	1 (1.0%)	1 (0.9%)
		8	1 (1.0%)	0
	7	6	2 (1.9%)	3 (2.8%)
		6.5	4 (3.8%)	3 (2.8%)
		7	5 (4.8%)	5 (4.6%)
		7.5	3 (2.9%)	0
		8	0	2 (1.9%)
	7.5	5.5	1 (1.0%)	1 (0.9%)
		6	2 (1.9%)	2 (1.9%)
		6.5	1 (1.0%)	4 (3.7%)
		7	2 (1.9%)	5 (4.6%)
		7.5	3 (2.9%)	2 (1.9%)
		8	0	2 (1.9%)
	8	8	0	1 (0.9%)
LOCF Endpoint	m		106	108

Parameter Week	Baseline	Post-baseline	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
	5.5	5.5	5 (4.7%)	4 (3.7%)
		6	7 (6.6%)	5 (4.6%)
		6.5	1 (0.9%)	3 (2.8%)
		7	3 (2.8%)	1 (0.9%)
		7.5	0	1 (0.9%)
	6	5.5	7 (6.6%)	6 (5.6%)
		6	20 (18.9%)	13 (12.0%)
		6.5	10 (9.4%)	7 (6.5%)
		7	4 (3.8%)	7 (6.5%)
		7.5	3 (2.8%)	1 (0.9%)
		8	0	1 (0.9%)
	6.5	5.5	2 (1.9%)	3 (2.8%)
		6	5 (4.7%)	8 (7.4%)
		6.5	11 (10.4%)	6 (5.6%)
		7	2 (1.9%)	11 (10.2%)
		7.5	1 (0.9%)	1 (0.9%)
		8	1 (0.9%)	0
	7	5.5	1 (0.9%)	0
		6	2 (1.9%)	3 (2.8%)
		6.5	4 (3.8%)	3 (2.8%)
		7	5 (4.7%)	5 (4.6%)
		7.5	3 (2.8%)	0
		8	0	2 (1.9%)
	7.5	5.5	1 (0.9%)	1 (0.9%)
		6	2 (1.9%)	2 (1.9%)
		6.5	1 (0.9%)	4 (3.7%)
		7	2 (1.9%)	5 (4.6%)
		7.5	3 (2.8%)	2 (1.9%)
		8	0	2 (1.9%)
	8	8	0	1 (0.9%)
Specific Gravity				
Week 4	m		106	108
	Low	Low	1 (0.9%)	1 (0.9%)
		Normal	0	3 (2.8%)
	Normal	Low	2 (1.9%)	1 (0.9%)
		Normal	102 (96.2%)	103 (95.4%)
		High	1 (0.9%)	0
Week 8	m		105	108
	Low	Low	0	2 (1.9%)
		Normal	1 (1.0%)	2 (1.9%)
	Normal	Low	2 (1.9%)	1 (0.9%)
		Normal	102 (97.1%)	103 (95.4%)
Week 12	m		104	108
	Low	Low	0	2 (1.9%)
		Normal	1 (1.0%)	2 (1.9%)
	Normal	Low	2 (1.9%)	2 (1.9%)
		Normal	100 (96.2%)	102 (94.4%)

Parameter Week	Baseline	Post-baseline	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
		High	1 (1.0%)	0
Week 16	m		104	108
	Low	Low	1 (1.0%)	2 (1.9%)
		Normal	0	2 (1.9%)
	Normal	Low	2 (1.9%)	2 (1.9%)
		Normal	100 (96.2%)	101 (93.5%)
		High	1 (1.0%)	1 (0.9%)
LOCF Endpoint	m		106	108
	Low	Low	1 (0.9%)	2 (1.9%)
		Normal	0	2 (1.9%)
	Normal	Low	2 (1.9%)	2 (1.9%)
		Normal	102 (96.2%)	101 (93.5%)
		High	1 (0.9%)	1 (0.9%)
Urine Glucose				
Week 4	m		106	108
	Negative	Negative	40 (37.7%)	65 (60.2%)
		Trace	9 (8.5%)	5 (4.6%)
		Positive	9 (8.5%)	3 (2.8%)
	Trace	Negative	4 (3.8%)	7 (6.5%)
		Trace	3 (2.8%)	4 (3.7%)
		Positive	3 (2.8%)	1 (0.9%)
	Positive	Negative	8 (7.5%)	12 (11.1%)
		Trace	6 (5.7%)	1 (0.9%)
		Positive	24 (22.6%)	10 (9.3%)
Week 8	m		105	108
	Negative	Negative	43 (41.0%)	65 (60.2%)
		Trace	6 (5.7%)	4 (3.7%)
		Positive	9 (8.6%)	4 (3.7%)
	Trace	Negative	4 (3.8%)	6 (5.6%)
		Trace	2 (1.9%)	2 (1.9%)
		Positive	4 (3.8%)	4 (3.7%)
	Positive	Negative	11 (10.5%)	13 (12.0%)
		Trace	3 (2.9%)	3 (2.8%)
		Positive	23 (21.9%)	7 (6.5%)
Week 12	m		104	108
	Negative	Negative	46 (44.2%)	65 (60.2%)
		Trace	4 (3.8%)	4 (3.7%)
		Positive	8 (7.7%)	4 (3.7%)
	Trace	Negative	5 (4.8%)	6 (5.6%)
		Trace	2 (1.9%)	3 (2.8%)
		Positive	2 (1.9%)	3 (2.8%)
	Positive	Negative	10 (9.6%)	13 (12.0%)
		Trace	2 (1.9%)	1 (0.9%)
		Positive	25 (24.0%)	9 (8.3%)

Parameter Week	Baseline	Post-baseline	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
Week 16	m		104	108
	Negative	Negative	45 (43.3%)	63 (58.3%)
		Trace	3 (2.9%)	4 (3.7%)
		Positive	10 (9.6%)	6 (5.6%)
	Trace	Negative	5 (4.8%)	7 (6.5%)
		Trace	2 (1.9%)	2 (1.9%)
		Positive	2 (1.9%)	3 (2.8%)
	Positive	Negative	9 (8.7%)	10 (9.3%)
		Trace	4 (3.8%)	4 (3.7%)
		Positive	24 (23.1%)	9 (8.3%)
LOCF Endpoint	m		106	108
	Negative	Negative	45 (42.5%)	63 (58.3%)
		Trace	3 (2.8%)	4 (3.7%)
		Positive	10 (9.4%)	6 (5.6%)
	Trace	Negative	6 (5.7%)	7 (6.5%)
		Trace	2 (1.9%)	2 (1.9%)
		Positive	2 (1.9%)	3 (2.8%)
	Positive	Negative	10 (9.4%)	10 (9.3%)
		Trace	4 (3.8%)	4 (3.7%)
		Positive	24 (22.6%)	9 (8.3%)
Urine Protein				
Week 4	m		106	108
	Negative	Negative	20 (18.9%)	35 (32.4%)
		Trace	11 (10.4%)	8 (7.4%)
		Positive	2 (1.9%)	2 (1.9%)
	Trace	Negative	13 (12.3%)	16 (14.8%)
		Trace	19 (17.9%)	21 (19.4%)
		Positive	11 (10.4%)	5 (4.6%)
	Positive	Negative	2 (1.9%)	0
		Trace	13 (12.3%)	10 (9.3%)
		Positive	15 (14.2%)	11 (10.2%)
Week 8	m		105	108
	Negative	Negative	22 (21.0%)	33 (30.6%)
		Trace	11 (10.5%)	10 (9.3%)
		Positive	0	2 (1.9%)
	Trace	Negative	12 (11.4%)	16 (14.8%)
		Trace	21 (20.0%)	21 (19.4%)
		Positive	10 (9.5%)	5 (4.6%)
	Positive	Negative	1 (1.0%)	1 (0.9%)
		Trace	9 (8.6%)	10 (9.3%)
		Positive	19 (18.1%)	10 (9.3%)
Week 12	m		104	108
	Negative	Negative	20 (19.2%)	33 (30.6%)
		Trace	12 (11.5%)	9 (8.3%)
		Positive	1 (1.0%)	3 (2.8%)
	Trace	Negative	17 (16.3%)	15 (13.9%)

Parameter Week	Baseline	Post-baseline	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
		Trace	19 (18.3%)	21 (19.4%)
		Positive	7 (6.7%)	6 (5.6%)
	Positive	Negative	2 (1.9%)	1 (0.9%)
		Trace	8 (7.7%)	10 (9.3%)
		Positive	18 (17.3%)	10 (9.3%)
Week 16	m		104	108
	Negative	Negative	19 (18.3%)	34 (31.5%)
		Trace	10 (9.6%)	8 (7.4%)
		Positive	4 (3.8%)	3 (2.8%)
	Trace	Negative	18 (17.3%)	14 (13.0%)
		Trace	17 (16.3%)	22 (20.4%)
		Positive	8 (7.7%)	6 (5.6%)
	Positive	Negative	1 (1.0%)	3 (2.8%)
		Trace	9 (8.7%)	9 (8.3%)
		Positive	18 (17.3%)	9 (8.3%)
LOCF Endpoint	m		106	108
	Negative	Negative	19 (17.9%)	34 (31.5%)
		Trace	10 (9.4%)	8 (7.4%)
		Positive	4 (3.8%)	3 (2.8%)
	Trace	Negative	18 (17.0%)	14 (13.0%)
		Trace	17 (16.0%)	22 (20.4%)
		Positive	8 (7.5%)	6 (5.6%)
	Positive	Negative	2 (1.9%)	3 (2.8%)
		Trace	10 (9.4%)	9 (8.3%)
		Positive	18 (17.0%)	9 (8.3%)
Urobilinogen				
Week 4	m		106	108
	Normal	Normal	102 (96.2%)	107 (99.1%)
		Abnormal	3 (2.8%)	0
	Abnormal	Normal	0	1 (0.9%)
		Abnormal	1 (0.9%)	0
Week 8	m		105	108
	Normal	Normal	103 (98.1%)	106 (98.1%)
		Abnormal	1 (1.0%)	1 (0.9%)
	Abnormal	Normal	1 (1.0%)	0
		Abnormal	0	1 (0.9%)
Week 12	m		104	108
	Normal	Normal	101 (97.1%)	105 (97.2%)
		Abnormal	2 (1.9%)	2 (1.9%)
	Abnormal	Normal	0	1 (0.9%)
		Abnormal	1 (1.0%)	0
Week 16	m		104	108
	Normal	Normal	100 (96.2%)	106 (98.1%)
		Abnormal	3 (2.9%)	1 (0.9%)

Parameter Week	Baseline	Post-baseline	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
	Abnormal	Normal	1 (1.0%)	1 (0.9%)
LOCF Endpoint	m		106	108
	Normal	Normal	102 (96.2%)	106 (98.1%)
		Abnormal	3 (2.8%)	1 (0.9%)
	Abnormal	Normal	1 (0.9%)	1 (0.9%)

- Abbreviations: LOCF, Last Observation Carried Forward; bid, Twice a day
- m in row headings is the total number of subjects with both baseline and the corresponding visit values available, and is used as the denominator to calculate percentages.

Control No:<<t-s-196-labot-020db.sas, 2020-03-06T00:18:30>>

Table S-197 Shift of Laboratory Findings of Coagulation in 16-Week Double-blind Period in Combination with Insulin Therapy (PXL008-020; Safety Population)

Parameter Week	Baseline	Post-baseline	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
Activated Partial Thromboplastin Time (sec)				
Week 16	m		101	105
	Low	Low	16 (15.8%)	15 (14.3%)
		Normal	6 (5.9%)	6 (5.7%)
	Normal	Low	4 (4.0%)	11 (10.5%)
		Normal	74 (73.3%)	73 (69.5%)
	High	High	1 (1.0%)	0
LOCF Endpoint	m		101	105
	Low	Low	16 (15.8%)	15 (14.3%)
		Normal	6 (5.9%)	6 (5.7%)
	Normal	Low	4 (4.0%)	11 (10.5%)
		Normal	74 (73.3%)	73 (69.5%)
	High	High	1 (1.0%)	0
Prothrombin Time (sec)				
Week 16	m		101	105
	Low	Low	8 (7.9%)	3 (2.9%)
		Normal	7 (6.9%)	10 (9.5%)
	Normal	Low	5 (5.0%)	3 (2.9%)
		Normal	81 (80.2%)	89 (84.8%)
LOCF Endpoint	m		101	105
	Low	Low	8 (7.9%)	3 (2.9%)
		Normal	7 (6.9%)	10 (9.5%)
	Normal	Low	5 (5.0%)	3 (2.9%)
		Normal	81 (80.2%)	89 (84.8%)

- Abbreviations: LOCF, Last Observation Carried Forward; bid, Twice a day
- m in row headings is the total number of subjects with both baseline and the corresponding visit values available, and is used as the denominator to calculate percentages.

Control No:<<t-s-197-labot-020db.sas, 2020-03-06T00:18:29>>

Table S-199 Shift of Laboratory Findings of UACR (Albuminuria) in 16-Week Double-blind Period in Combination with Insulin Therapy (PXL008-020; Safety Population)

Parameter Week	Baseline	Post-baseline	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
Albumin/Creatinine (mg/g)				
Week 16	m		104	108
	Normal	Normal	54 (51.9%)	63 (58.3%)
		Micro	13 (12.5%)	8 (7.4%)
	Micro	Normal	4 (3.8%)	6 (5.6%)
		Micro	23 (22.1%)	24 (22.2%)
		Macro	1 (1.0%)	3 (2.8%)
	Macro	Micro	1 (1.0%)	0
		Macro	8 (7.7%)	4 (3.7%)
LOCF Endpoint	m		104	108
	Normal	Normal	54 (51.9%)	63 (58.3%)
		Micro	13 (12.5%)	8 (7.4%)
	Micro	Normal	4 (3.8%)	6 (5.6%)
		Micro	23 (22.1%)	24 (22.2%)
		Macro	1 (1.0%)	3 (2.8%)
	Macro	Micro	1 (1.0%)	0
		Macro	8 (7.7%)	4 (3.7%)

- Abbreviations: LOCF, Last Observation Carried Forward; bid, Twice a day
- m in row headings is the total number of subjects with both baseline and the corresponding visit values available, and is used as the denominator to calculate percentages.

Control No:<<t-s-199-labot-020db.sas, 2020-03-06T00:19:36>>

Table S-200 Shift of Laboratory Findings of Lactate Concentration in 16-Week Double-blind Period in Combination with Insulin Therapy (PXL008-020; Safety Population)

Parameter Week	Baseline	Post-baseline	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
Lactic Acid (mmol/L)				
Week 16	m		104	108
	Normal	Low	1 (1.0%)	0
		Normal	99 (95.2%)	101 (93.5%)
		High	1 (1.0%)	3 (2.8%)
	High	Normal	3 (2.9%)	0
		High	0	4 (3.7%)
LOCF Endpoint	m		104	108
	Normal	Low	1 (1.0%)	0
		Normal	99 (95.2%)	101 (93.5%)
		High	1 (1.0%)	3 (2.8%)
	High	Normal	3 (2.9%)	0
		High	0	4 (3.7%)

- Abbreviations: LOCF, Last Observation Carried Forward; bid, Twice a day
- m in row headings is the total number of subjects with both baseline and the corresponding visit values available, and is used as the denominator to calculate percentages.

Control No:<<t-s-200-labot-020db.sas, 2020-03-06T00:15:34>>

Table S-201 Shift of ECG Findings in 16-Week Double-blind Period in Combination with Insulin Therapy (PXL008-020; Safety Population)

Week	Baseline	Post-baseline	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
Interpretation				
Week 16	m		104	108
	Normal	Normal	81 (77.9%)	86 (79.6%)
		Abnormal, not clinically significant	3 (2.9%)	1 (0.9%)
	Abnormal, not clinically significant	Normal	4 (3.8%)	4 (3.7%)
		Abnormal, not clinically significant	15 (14.4%)	17 (15.7%)
		Abnormal, clinically significant	1 (1.0%)	0
LOCF Endpoint	m		104	108
	Normal	Normal	81 (77.9%)	86 (79.6%)
		Abnormal, not clinically significant	3 (2.9%)	1 (0.9%)
	Abnormal, not clinically significant	Normal	4 (3.8%)	4 (3.7%)
		Abnormal, not clinically significant	15 (14.4%)	17 (15.7%)
		Abnormal, clinically significant	1 (1.0%)	0

- Abbreviations: LOCF, Last Observation Carried Forward; bid, Twice a day
- m in row headings is the total number of subjects with both baseline and the corresponding visit values available, and is used as the denominator to calculate percentages.

Control No:<<t-s-201-ecgqt-020db.sas, 2020-03-06T00:15:51>>

Table S-202 Shift of Laboratory Findings of Hematology in Long-term Period (PXL008-020; Long-term Safety Population)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
Basophils (10^9/L)					
Week 4	m		100	108	208
	Normal	Normal	100 (100.0%)	108 (100.0%)	208 (100.0%)
Week 8	m		101	108	209
	Normal	Normal	101 (100.0%)	108 (100.0%)	209 (100.0%)
Week 12	m		100	108	208
	Normal	Normal	100 (100.0%)	108 (100.0%)	208 (100.0%)
Week 16	m		99	108	207
	Normal	Normal	99 (100.0%)	108 (100.0%)	207 (100.0%)
Week 20	m		99	107	206
	Normal	Normal	99 (100.0%)	107 (100.0%)	206 (100.0%)
Week 24	m		99	108	207
	Normal	Normal	99 (100.0%)	108 (100.0%)	207 (100.0%)
Week 32	m		98	108	206
	Normal	Normal	98 (100.0%)	108 (100.0%)	206 (100.0%)
Week 36	m		98	108	206
	Normal	Normal	98 (100.0%)	108 (100.0%)	206 (100.0%)
Week 40	m		0	107	107
	Normal	Normal	.	107 (100.0%)	107 (100.0%)
Week 44	m		0	107	107
	Normal	Normal	.	107 (100.0%)	107 (100.0%)
Week 48	m		0	107	107
	Normal	Normal	.	107 (100.0%)	107 (100.0%)
Week 52	m		0	107	107
	Normal	Normal	.	107 (100.0%)	107 (100.0%)
LOCF Endpoint	m		101	108	209
	Normal	Normal	101 (100.0%)	108 (100.0%)	209 (100.0%)
Basophils/Leukocytes (%)					
Week 4	m		100	108	208
	Normal	Normal	99 (99.0%)	107 (99.1%)	206 (99.0%)
		High	0	1 (0.9%)	1 (0.5%)
	High	Normal	1 (1.0%)	0	1 (0.5%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
Week 8	m		101	108	209
	Normal	Normal	99 (98.0%)	108 (100.0%)	207 (99.0%)
		High	1 (1.0%)	0	1 (0.5%)
	High	Normal	1 (1.0%)	0	1 (0.5%)
Week 12	m		100	108	208
	Normal	Normal	99 (99.0%)	108 (100.0%)	207 (99.5%)
	High	Normal	1 (1.0%)	0	1 (0.5%)
Week 16	m		99	108	207
	Normal	Normal	97 (98.0%)	108 (100.0%)	205 (99.0%)
		High	1 (1.0%)	0	1 (0.5%)
	High	Normal	1 (1.0%)	0	1 (0.5%)
Week 20	m		99	107	206
	Normal	Normal	97 (98.0%)	106 (99.1%)	203 (98.5%)
		High	1 (1.0%)	1 (0.9%)	2 (1.0%)
	High	Normal	1 (1.0%)	0	1 (0.5%)
Week 24	m		99	108	207
	Normal	Normal	96 (97.0%)	106 (98.1%)	202 (97.6%)
		High	2 (2.0%)	2 (1.9%)	4 (1.9%)
	High	Normal	1 (1.0%)	0	1 (0.5%)
Week 32	m		98	108	206
	Normal	Normal	96 (98.0%)	108 (100.0%)	204 (99.0%)
		High	1 (1.0%)	0	1 (0.5%)
	High	Normal	1 (1.0%)	0	1 (0.5%)
Week 36	m		98	108	206
	Normal	Normal	97 (99.0%)	108 (100.0%)	205 (99.5%)
	High	Normal	1 (1.0%)	0	1 (0.5%)
Week 40	m		0	107	107
	Normal	Normal	.	107 (100.0%)	107 (100.0%)
Week 44	m		0	107	107
	Normal	Normal	.	107 (100.0%)	107 (100.0%)
Week 48	m		0	107	107
	Normal	Normal	.	107 (100.0%)	107 (100.0%)
Week 52	m		0	107	107
	Normal	Normal	.	107 (100.0%)	107 (100.0%)
LOCF Endpoint	m		101	108	209
	Normal	Normal	100 (99.0%)	108 (100.0%)	208 (99.5%)
	High	Normal	1 (1.0%)	0	1 (0.5%)

Eosinophils (10^9/L)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
Week 4	m		100	108	208
	Normal	Normal	100 (100.0%)	108 (100.0%)	208 (100.0%)
Week 8	m		101	108	209
	Normal	Normal	100 (99.0%)	108 (100.0%)	208 (99.5%)
		High	1 (1.0%)	0	1 (0.5%)
Week 12	m		100	108	208
	Normal	Normal	100 (100.0%)	108 (100.0%)	208 (100.0%)
Week 16	m		99	108	207
	Normal	Normal	99 (100.0%)	108 (100.0%)	207 (100.0%)
Week 20	m		99	107	206
	Normal	Normal	99 (100.0%)	106 (99.1%)	205 (99.5%)
		High	0	1 (0.9%)	1 (0.5%)
Week 24	m		99	108	207
	Normal	Normal	99 (100.0%)	106 (98.1%)	205 (99.0%)
		High	0	2 (1.9%)	2 (1.0%)
Week 32	m		98	108	206
	Normal	Normal	97 (99.0%)	107 (99.1%)	204 (99.0%)
		High	1 (1.0%)	1 (0.9%)	2 (1.0%)
Week 36	m		98	108	206
	Normal	Normal	98 (100.0%)	107 (99.1%)	205 (99.5%)
		High	0	1 (0.9%)	1 (0.5%)
Week 40	m		0	107	107
	Normal	Normal	.	106 (99.1%)	106 (99.1%)
		High	.	1 (0.9%)	1 (0.9%)
Week 44	m		0	107	107
	Normal	Normal	.	107 (100.0%)	107 (100.0%)
Week 48	m		0	107	107
	Normal	Normal	.	106 (99.1%)	106 (99.1%)
		High	.	1 (0.9%)	1 (0.9%)
Week 52	m		0	107	107
	Normal	Normal	.	107 (100.0%)	107 (100.0%)
LOCF Endpoint	m		101	108	209
	Normal	Normal	101 (100.0%)	108 (100.0%)	209 (100.0%)
Eosinophils/Leukocytes (%)					
Week 4	m		100	108	208
	Normal	Normal	97 (97.0%)	105 (97.2%)	202 (97.1%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
		High	2 (2.0%)	1 (0.9%)	3 (1.4%)
	High	Normal	0	2 (1.9%)	2 (1.0%)
		High	1 (1.0%)	0	1 (0.5%)
Week 8	m		101	108	209
	Normal	Normal	97 (96.0%)	105 (97.2%)	202 (96.7%)
		High	3 (3.0%)	1 (0.9%)	4 (1.9%)
	High	Normal	1 (1.0%)	2 (1.9%)	3 (1.4%)
Week 12	m		100	108	208
	Normal	Normal	99 (99.0%)	105 (97.2%)	204 (98.1%)
		High	0	1 (0.9%)	1 (0.5%)
	High	Normal	1 (1.0%)	2 (1.9%)	3 (1.4%)
Week 16	m		99	108	207
	Normal	Normal	96 (97.0%)	104 (96.3%)	200 (96.6%)
		High	2 (2.0%)	2 (1.9%)	4 (1.9%)
	High	Normal	1 (1.0%)	2 (1.9%)	3 (1.4%)
Week 20	m		99	107	206
	Normal	Normal	96 (97.0%)	103 (96.3%)	199 (96.6%)
		High	2 (2.0%)	2 (1.9%)	4 (1.9%)
	High	Normal	1 (1.0%)	2 (1.9%)	3 (1.5%)
Week 24	m		99	108	207
	Normal	Normal	96 (97.0%)	103 (95.4%)	199 (96.1%)
		High	2 (2.0%)	3 (2.8%)	5 (2.4%)
	High	Normal	1 (1.0%)	1 (0.9%)	2 (1.0%)
		High	0	1 (0.9%)	1 (0.5%)
Week 32	m		98	108	206
	Normal	Normal	96 (98.0%)	104 (96.3%)	200 (97.1%)
		High	1 (1.0%)	2 (1.9%)	3 (1.5%)
	High	Normal	1 (1.0%)	2 (1.9%)	3 (1.5%)
Week 36	m		98	108	206
	Normal	Normal	97 (99.0%)	103 (95.4%)	200 (97.1%)
		High	0	3 (2.8%)	3 (1.5%)
	High	Normal	1 (1.0%)	2 (1.9%)	3 (1.5%)
Week 40	m		0	107	107
	Normal	Normal	.	103 (96.3%)	103 (96.3%)
		High	.	2 (1.9%)	2 (1.9%)
	High	Normal	.	2 (1.9%)	2 (1.9%)
Week 44	m		0	107	107
	Normal	Normal	.	104 (97.2%)	104 (97.2%)
		High	.	1 (0.9%)	1 (0.9%)
	High	Normal	.	2 (1.9%)	2 (1.9%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
Week 48	m		0	107	107
	Normal	Normal	.	103 (96.3%)	103 (96.3%)
		High	.	2 (1.9%)	2 (1.9%)
	High	Normal	.	2 (1.9%)	2 (1.9%)
Week 52	m		0	107	107
	Normal	Normal	.	104 (97.2%)	104 (97.2%)
		High	.	1 (0.9%)	1 (0.9%)
	High	Normal	.	1 (0.9%)	1 (0.9%)
		High	.	1 (0.9%)	1 (0.9%)
LOCF Endpoint	m		101	108	209
	Normal	Normal	100 (99.0%)	105 (97.2%)	205 (98.1%)
		High	0	1 (0.9%)	1 (0.5%)
	High	Normal	1 (1.0%)	1 (0.9%)	2 (1.0%)
		High	0	1 (0.9%)	1 (0.5%)
Ery. Mean Corpuscular Hemoglobin (pg)					
Week 4	m		100	108	208
	Low	Low	1 (1.0%)	1 (0.9%)	2 (1.0%)
	Normal	Normal	98 (98.0%)	106 (98.1%)	204 (98.1%)
		High	0	1 (0.9%)	1 (0.5%)
	High	Normal	1 (1.0%)	0	1 (0.5%)
Week 8	m		101	108	209
	Low	Low	1 (1.0%)	1 (0.9%)	2 (1.0%)
	Normal	Low	0	1 (0.9%)	1 (0.5%)
		Normal	98 (97.0%)	105 (97.2%)	203 (97.1%)
		High	1 (1.0%)	1 (0.9%)	2 (1.0%)
	High	High	1 (1.0%)	0	1 (0.5%)
Week 12	m		100	108	208
	Low	Low	1 (1.0%)	1 (0.9%)	2 (1.0%)
	Normal	Low	0	1 (0.9%)	1 (0.5%)
		Normal	97 (97.0%)	103 (95.4%)	200 (96.2%)
		High	1 (1.0%)	3 (2.8%)	4 (1.9%)
	High	Normal	1 (1.0%)	0	1 (0.5%)
Week 16	m		99	108	207
	Low	Low	1 (1.0%)	1 (0.9%)	2 (1.0%)
	Normal	Low	0	1 (0.9%)	1 (0.5%)
		Normal	95 (96.0%)	104 (96.3%)	199 (96.1%)
		High	2 (2.0%)	2 (1.9%)	4 (1.9%)
	High	High	1 (1.0%)	0	1 (0.5%)
Week 20	m		99	107	206
	Low	Low	1 (1.0%)	1 (0.9%)	2 (1.0%)
	Normal	Low	0	1 (0.9%)	1 (0.5%)
		Normal	96 (97.0%)	102 (95.3%)	198 (96.1%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
		High	1 (1.0%)	3 (2.8%)	4 (1.9%)
	High	Normal	1 (1.0%)	0	1 (0.5%)
Week 24	m		99	108	207
	Low	Low	1 (1.0%)	1 (0.9%)	2 (1.0%)
	Normal	Low	0	1 (0.9%)	1 (0.5%)
		Normal	97 (98.0%)	105 (97.2%)	202 (97.6%)
		High	0	1 (0.9%)	1 (0.5%)
	High	Normal	1 (1.0%)	0	1 (0.5%)
Week 32	m		98	108	206
	Low	Low	1 (1.0%)	1 (0.9%)	2 (1.0%)
	Normal	Normal	94 (95.9%)	105 (97.2%)	199 (96.6%)
		High	2 (2.0%)	2 (1.9%)	4 (1.9%)
	High	Normal	1 (1.0%)	0	1 (0.5%)
Week 36	m		98	108	206
	Low	Low	0	1 (0.9%)	1 (0.5%)
		Normal	1 (1.0%)	0	1 (0.5%)
	Normal	Normal	96 (98.0%)	105 (97.2%)	201 (97.6%)
		High	0	2 (1.9%)	2 (1.0%)
	High	High	1 (1.0%)	0	1 (0.5%)
Week 40	m		0	107	107
	Low	Low	.	1 (0.9%)	1 (0.9%)
	Normal	Low	.	1 (0.9%)	1 (0.9%)
		Normal	.	104 (97.2%)	104 (97.2%)
		High	.	1 (0.9%)	1 (0.9%)
Week 44	m		0	107	107
	Low	Low	.	1 (0.9%)	1 (0.9%)
	Normal	Low	.	1 (0.9%)	1 (0.9%)
		Normal	.	104 (97.2%)	104 (97.2%)
		High	.	1 (0.9%)	1 (0.9%)
Week 48	m		0	107	107
	Low	Low	.	1 (0.9%)	1 (0.9%)
	Normal	Low	.	1 (0.9%)	1 (0.9%)
		Normal	.	105 (98.1%)	105 (98.1%)
Week 52	m		0	107	107
	Low	Low	.	1 (0.9%)	1 (0.9%)
	Normal	Low	.	1 (0.9%)	1 (0.9%)
		Normal	.	102 (95.3%)	102 (95.3%)
		High	.	3 (2.8%)	3 (2.8%)
LOCF Endpoint	m		101	108	209
	Low	Low	0	1 (0.9%)	1 (0.5%)
		Normal	1 (1.0%)	0	1 (0.5%)
	Normal	Low	0	1 (0.9%)	1 (0.5%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
		Normal	99 (98.0%)	103 (95.4%)	202 (96.7%)
		High	0	3 (2.8%)	3 (1.4%)
	High	High	1 (1.0%)	0	1 (0.5%)
Ery. Mean Corpuscular HGB Concentration (g/L)					
Week 4	m		100	108	208
	Low	Low	1 (1.0%)	0	1 (0.5%)
		Normal	0	1 (0.9%)	1 (0.5%)
	Normal	Low	2 (2.0%)	0	2 (1.0%)
		Normal	97 (97.0%)	107 (99.1%)	204 (98.1%)
Week 8	m		101	108	209
	Low	Low	1 (1.0%)	0	1 (0.5%)
		Normal	0	1 (0.9%)	1 (0.5%)
	Normal	Normal	100 (99.0%)	107 (99.1%)	207 (99.0%)
Week 12	m		100	108	208
	Low	Low	1 (1.0%)	1 (0.9%)	2 (1.0%)
	Normal	Low	1 (1.0%)	1 (0.9%)	2 (1.0%)
		Normal	98 (98.0%)	106 (98.1%)	204 (98.1%)
Week 16	m		99	108	207
	Low	Low	1 (1.0%)	1 (0.9%)	2 (1.0%)
	Normal	Low	0	1 (0.9%)	1 (0.5%)
		Normal	98 (99.0%)	106 (98.1%)	204 (98.6%)
Week 20	m		99	107	206
	Low	Low	1 (1.0%)	1 (0.9%)	2 (1.0%)
	Normal	Low	4 (4.0%)	0	4 (1.9%)
		Normal	94 (94.9%)	106 (99.1%)	200 (97.1%)
Week 24	m		99	108	207
	Low	Low	1 (1.0%)	1 (0.9%)	2 (1.0%)
	Normal	Normal	98 (99.0%)	107 (99.1%)	205 (99.0%)
Week 32	m		98	108	206
	Low	Low	1 (1.0%)	0	1 (0.5%)
		Normal	0	1 (0.9%)	1 (0.5%)
	Normal	Low	1 (1.0%)	1 (0.9%)	2 (1.0%)
		Normal	96 (98.0%)	106 (98.1%)	202 (98.1%)
Week 36	m		98	108	206
	Low	Normal	1 (1.0%)	1 (0.9%)	2 (1.0%)
	Normal	Low	0	1 (0.9%)	1 (0.5%)
		Normal	97 (99.0%)	106 (98.1%)	203 (98.5%)
Week 40	m		0	106	106
	Low	Normal	.	1 (0.9%)	1 (0.9%)
	Normal	Low	.	2 (1.9%)	2 (1.9%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
		Normal	.	103 (97.2%)	103 (97.2%)
Week 44	m		0	107	107
	Low	Normal	.	1 (0.9%)	1 (0.9%)
	Normal	Low	.	2 (1.9%)	2 (1.9%)
		Normal	.	104 (97.2%)	104 (97.2%)
Week 48	m		0	107	107
	Low	Normal	.	1 (0.9%)	1 (0.9%)
	Normal	Low	.	3 (2.8%)	3 (2.8%)
		Normal	.	103 (96.3%)	103 (96.3%)
Week 52	m		0	107	107
	Low	Normal	.	1 (0.9%)	1 (0.9%)
	Normal	Low	.	1 (0.9%)	1 (0.9%)
		Normal	.	105 (98.1%)	105 (98.1%)
LOCF Endpoint	m		101	108	209
	Low	Normal	1 (1.0%)	1 (0.9%)	2 (1.0%)
	Normal	Low	0	1 (0.9%)	1 (0.5%)
		Normal	100 (99.0%)	106 (98.1%)	206 (98.6%)
Ery. Mean Corpuscular Volume (fL)					
Week 4	m		100	108	208
	Low	Low	1 (1.0%)	1 (0.9%)	2 (1.0%)
	Normal	Normal	92 (92.0%)	104 (96.3%)	196 (94.2%)
		High	2 (2.0%)	2 (1.9%)	4 (1.9%)
	High	High	5 (5.0%)	1 (0.9%)	6 (2.9%)
Week 8	m		101	108	209
	Low	Low	1 (1.0%)	1 (0.9%)	2 (1.0%)
	Normal	Low	0	1 (0.9%)	1 (0.5%)
		Normal	92 (91.1%)	99 (91.7%)	191 (91.4%)
		High	3 (3.0%)	6 (5.6%)	9 (4.3%)
	High	Normal	0	1 (0.9%)	1 (0.5%)
		High	5 (5.0%)	0	5 (2.4%)
Week 12	m		100	108	208
	Low	Low	1 (1.0%)	1 (0.9%)	2 (1.0%)
	Normal	Low	0	1 (0.9%)	1 (0.5%)
		Normal	90 (90.0%)	99 (91.7%)	189 (90.9%)
		High	4 (4.0%)	6 (5.6%)	10 (4.8%)
	High	Normal	1 (1.0%)	0	1 (0.5%)
		High	4 (4.0%)	1 (0.9%)	5 (2.4%)
Week 16	m		99	108	207
	Low	Low	1 (1.0%)	1 (0.9%)	2 (1.0%)
	Normal	Low	0	1 (0.9%)	1 (0.5%)
		Normal	92 (92.9%)	99 (91.7%)	191 (92.3%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
		High	1 (1.0%)	6 (5.6%)	7 (3.4%)
	High	Normal	1 (1.0%)	0	1 (0.5%)
		High	4 (4.0%)	1 (0.9%)	5 (2.4%)
Week 20	m		99	107	206
	Low	Low	1 (1.0%)	1 (0.9%)	2 (1.0%)
	Normal	Low	0	1 (0.9%)	1 (0.5%)
		Normal	88 (88.9%)	94 (87.9%)	182 (88.3%)
		High	5 (5.1%)	10 (9.3%)	15 (7.3%)
	High	High	5 (5.1%)	1 (0.9%)	6 (2.9%)
Week 24	m		99	108	207
	Low	Low	1 (1.0%)	1 (0.9%)	2 (1.0%)
	Normal	Normal	91 (91.9%)	95 (88.0%)	186 (89.9%)
		High	2 (2.0%)	11 (10.2%)	13 (6.3%)
	High	High	5 (5.1%)	1 (0.9%)	6 (2.9%)
Week 32	m		98	108	206
	Low	Low	0	1 (0.9%)	1 (0.5%)
		Normal	1 (1.0%)	0	1 (0.5%)
	Normal	Normal	90 (91.8%)	99 (91.7%)	189 (91.7%)
		High	2 (2.0%)	7 (6.5%)	9 (4.4%)
	High	Normal	1 (1.0%)	0	1 (0.5%)
		High	4 (4.1%)	1 (0.9%)	5 (2.4%)
Week 36	m		98	108	206
	Low	Low	0	1 (0.9%)	1 (0.5%)
		Normal	1 (1.0%)	0	1 (0.5%)
	Normal	Normal	88 (89.8%)	102 (94.4%)	190 (92.2%)
		High	4 (4.1%)	4 (3.7%)	8 (3.9%)
	High	Normal	1 (1.0%)	0	1 (0.5%)
		High	4 (4.1%)	1 (0.9%)	5 (2.4%)
Week 40	m		0	106	106
	Low	Low	.	1 (0.9%)	1 (0.9%)
	Normal	Normal	.	99 (93.4%)	99 (93.4%)
		High	.	5 (4.7%)	5 (4.7%)
	High	High	.	1 (0.9%)	1 (0.9%)
Week 44	m		0	107	107
	Low	Low	.	1 (0.9%)	1 (0.9%)
	Normal	Normal	.	100 (93.5%)	100 (93.5%)
		High	.	5 (4.7%)	5 (4.7%)
	High	High	.	1 (0.9%)	1 (0.9%)
Week 48	m		0	107	107
	Low	Low	.	1 (0.9%)	1 (0.9%)
	Normal	Normal	.	98 (91.6%)	98 (91.6%)
		High	.	7 (6.5%)	7 (6.5%)
	High	High	.	1 (0.9%)	1 (0.9%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
Week 52	m		0	107	107
	Low	Low	.	1 (0.9%)	1 (0.9%)
	Normal	Normal	.	100 (93.5%)	100 (93.5%)
		High	.	5 (4.7%)	5 (4.7%)
	High	High	.	1 (0.9%)	1 (0.9%)
LOCF Endpoint	m		101	108	209
	Low	Low	0	1 (0.9%)	1 (0.5%)
		Normal	1 (1.0%)	0	1 (0.5%)
	Normal	Normal	91 (90.1%)	101 (93.5%)	192 (91.9%)
		High	4 (4.0%)	5 (4.6%)	9 (4.3%)
	High	Normal	1 (1.0%)	0	1 (0.5%)
		High	4 (4.0%)	1 (0.9%)	5 (2.4%)
Erythrocytes (10^12/L)					
Week 4	m		100	108	208
	Low	Low	3 (3.0%)	6 (5.6%)	9 (4.3%)
		Normal	1 (1.0%)	5 (4.6%)	6 (2.9%)
	Normal	Low	2 (2.0%)	6 (5.6%)	8 (3.8%)
		Normal	93 (93.0%)	90 (83.3%)	183 (88.0%)
	High	Normal	1 (1.0%)	0	1 (0.5%)
		High	0	1 (0.9%)	1 (0.5%)
Week 8	m		101	108	209
	Low	Low	2 (2.0%)	6 (5.6%)	8 (3.8%)
		Normal	2 (2.0%)	5 (4.6%)	7 (3.3%)
	Normal	Low	2 (2.0%)	3 (2.8%)	5 (2.4%)
		Normal	94 (93.1%)	93 (86.1%)	187 (89.5%)
	High	Normal	1 (1.0%)	0	1 (0.5%)
		High	0	1 (0.9%)	1 (0.5%)
Week 12	m		100	108	208
	Low	Low	2 (2.0%)	3 (2.8%)	5 (2.4%)
		Normal	2 (2.0%)	8 (7.4%)	10 (4.8%)
	Normal	Low	2 (2.0%)	5 (4.6%)	7 (3.4%)
		Normal	93 (93.0%)	91 (84.3%)	184 (88.5%)
	High	Normal	1 (1.0%)	0	1 (0.5%)
		High	0	1 (0.9%)	1 (0.5%)
Week 16	m		99	108	207
	Low	Low	4 (4.0%)	5 (4.6%)	9 (4.3%)
		Normal	0	6 (5.6%)	6 (2.9%)
	Normal	Low	2 (2.0%)	4 (3.7%)	6 (2.9%)
		Normal	92 (92.9%)	92 (85.2%)	184 (88.9%)
	High	Normal	1 (1.0%)	0	1 (0.5%)
		High	0	1 (0.9%)	1 (0.5%)
Week 20	m		99	107	206
	Low	Low	3 (3.0%)	5 (4.7%)	8 (3.9%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
		Normal	1 (1.0%)	6 (5.6%)	7 (3.4%)
	Normal	Low	5 (5.1%)	4 (3.7%)	9 (4.4%)
		Normal	89 (89.9%)	91 (85.0%)	180 (87.4%)
	High	Normal	1 (1.0%)	0	1 (0.5%)
		High	0	1 (0.9%)	1 (0.5%)
Week 24	m		99	108	207
	Low	Low	2 (2.0%)	6 (5.6%)	8 (3.9%)
		Normal	2 (2.0%)	5 (4.6%)	7 (3.4%)
	Normal	Low	4 (4.0%)	3 (2.8%)	7 (3.4%)
		Normal	90 (90.9%)	93 (86.1%)	183 (88.4%)
	High	Normal	1 (1.0%)	0	1 (0.5%)
		High	0	1 (0.9%)	1 (0.5%)
Week 32	m		98	108	206
	Low	Low	3 (3.1%)	6 (5.6%)	9 (4.4%)
		Normal	1 (1.0%)	5 (4.6%)	6 (2.9%)
	Normal	Low	7 (7.1%)	1 (0.9%)	8 (3.9%)
		Normal	86 (87.8%)	95 (88.0%)	181 (87.9%)
	High	High	1 (1.0%)	1 (0.9%)	2 (1.0%)
Week 36	m		98	108	206
	Low	Low	3 (3.1%)	5 (4.6%)	8 (3.9%)
		Normal	1 (1.0%)	6 (5.6%)	7 (3.4%)
	Normal	Low	6 (6.1%)	2 (1.9%)	8 (3.9%)
		Normal	87 (88.8%)	94 (87.0%)	181 (87.9%)
	High	High	1 (1.0%)	1 (0.9%)	2 (1.0%)
Week 40	m		0	107	107
	Low	Low	.	7 (6.5%)	7 (6.5%)
		Normal	.	4 (3.7%)	4 (3.7%)
	Normal	Low	.	5 (4.7%)	5 (4.7%)
		Normal	.	90 (84.1%)	90 (84.1%)
	High	Normal	.	1 (0.9%)	1 (0.9%)
Week 44	m		0	107	107
	Low	Low	.	6 (5.6%)	6 (5.6%)
		Normal	.	5 (4.7%)	5 (4.7%)
	Normal	Low	.	5 (4.7%)	5 (4.7%)
		Normal	.	89 (83.2%)	89 (83.2%)
		High	.	1 (0.9%)	1 (0.9%)
	High	High	.	1 (0.9%)	1 (0.9%)
Week 48	m		0	107	107
	Low	Low	.	6 (5.6%)	6 (5.6%)
		Normal	.	5 (4.7%)	5 (4.7%)
	Normal	Low	.	4 (3.7%)	4 (3.7%)
		Normal	.	91 (85.0%)	91 (85.0%)
	High	Normal	.	1 (0.9%)	1 (0.9%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
Week 52	m		0	107	107
	Low	Low	.	8 (7.5%)	8 (7.5%)
		Normal	.	3 (2.8%)	3 (2.8%)
	Normal	Low	.	6 (5.6%)	6 (5.6%)
		Normal	.	88 (82.2%)	88 (82.2%)
		High	.	1 (0.9%)	1 (0.9%)
	High	Normal	.	1 (0.9%)	1 (0.9%)
LOCF Endpoint	m		101	108	209
	Low	Low	3 (3.0%)	8 (7.4%)	11 (5.3%)
		Normal	1 (1.0%)	3 (2.8%)	4 (1.9%)
	Normal	Low	6 (5.9%)	6 (5.6%)	12 (5.7%)
		Normal	90 (89.1%)	89 (82.4%)	179 (85.6%)
		High	0	1 (0.9%)	1 (0.5%)
	High	Normal	0	1 (0.9%)	1 (0.5%)
		High	1 (1.0%)	0	1 (0.5%)
Hematocrit (fraction of 1)					
Week 4	m		100	108	208
	Low	Low	0	1 (0.9%)	1 (0.5%)
		Normal	0	3 (2.8%)	3 (1.4%)
	Normal	Normal	99 (99.0%)	104 (96.3%)	203 (97.6%)
	High	High	1 (1.0%)	0	1 (0.5%)
Week 8	m		101	108	209
	Low	Low	0	1 (0.9%)	1 (0.5%)
		Normal	0	3 (2.8%)	3 (1.4%)
	Normal	Low	0	1 (0.9%)	1 (0.5%)
		Normal	99 (98.0%)	103 (95.4%)	202 (96.7%)
		High	1 (1.0%)	0	1 (0.5%)
	High	Normal	1 (1.0%)	0	1 (0.5%)
Week 12	m		100	108	208
	Low	Low	0	1 (0.9%)	1 (0.5%)
		Normal	0	3 (2.8%)	3 (1.4%)
	Normal	Normal	99 (99.0%)	104 (96.3%)	203 (97.6%)
	High	Normal	1 (1.0%)	0	1 (0.5%)
Week 16	m		99	108	207
	Low	Low	0	1 (0.9%)	1 (0.5%)
		Normal	0	3 (2.8%)	3 (1.4%)
	Normal	Normal	97 (98.0%)	104 (96.3%)	201 (97.1%)
		High	1 (1.0%)	0	1 (0.5%)
	High	Normal	1 (1.0%)	0	1 (0.5%)
Week 20	m		99	107	206
	Low	Normal	0	4 (3.7%)	4 (1.9%)
	Normal	Low	2 (2.0%)	0	2 (1.0%)
		Normal	95 (96.0%)	103 (96.3%)	198 (96.1%)
		High	1 (1.0%)	0	1 (0.5%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
	High	Normal	1 (1.0%)	0	1 (0.5%)
Week 24	m		99	108	207
	Low	Normal	0	4 (3.7%)	4 (1.9%)
	Normal	Normal	98 (99.0%)	104 (96.3%)	202 (97.6%)
	High	Normal	1 (1.0%)	0	1 (0.5%)
Week 32	m		98	108	206
	Low	Normal	0	4 (3.7%)	4 (1.9%)
	Normal	Low	1 (1.0%)	0	1 (0.5%)
		Normal	96 (98.0%)	104 (96.3%)	200 (97.1%)
	High	Normal	1 (1.0%)	0	1 (0.5%)
Week 36	m		98	108	206
	Low	Normal	0	4 (3.7%)	4 (1.9%)
	Normal	Low	0	1 (0.9%)	1 (0.5%)
		Normal	96 (98.0%)	103 (95.4%)	199 (96.6%)
		High	1 (1.0%)	0	1 (0.5%)
	High	Normal	1 (1.0%)	0	1 (0.5%)
Week 40	m		0	106	106
	Low	Normal	.	4 (3.8%)	4 (3.8%)
	Normal	Normal	.	101 (95.3%)	101 (95.3%)
		High	.	1 (0.9%)	1 (0.9%)
Week 44	m		0	107	107
	Low	Low	.	1 (0.9%)	1 (0.9%)
		Normal	.	3 (2.8%)	3 (2.8%)
	Normal	Low	.	2 (1.9%)	2 (1.9%)
		Normal	.	100 (93.5%)	100 (93.5%)
		High	.	1 (0.9%)	1 (0.9%)
Week 48	m		0	107	107
	Low	Normal	.	4 (3.7%)	4 (3.7%)
	Normal	Low	.	1 (0.9%)	1 (0.9%)
		Normal	.	102 (95.3%)	102 (95.3%)
Week 52	m		0	107	107
	Low	Low	.	1 (0.9%)	1 (0.9%)
		Normal	.	3 (2.8%)	3 (2.8%)
	Normal	Low	.	1 (0.9%)	1 (0.9%)
		Normal	.	102 (95.3%)	102 (95.3%)
LOCF Endpoint	m		101	108	209
	Low	Low	0	1 (0.9%)	1 (0.5%)
		Normal	0	3 (2.8%)	3 (1.4%)
	Normal	Low	0	1 (0.9%)	1 (0.5%)
		Normal	99 (98.0%)	103 (95.4%)	202 (96.7%)
		High	1 (1.0%)	0	1 (0.5%)
	High	Normal	1 (1.0%)	0	1 (0.5%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
Hemoglobin (g/L)					
Week 4	m		100	108	208
	Low	Normal	0	3 (2.8%)	3 (1.4%)
	Normal	Low	1 (1.0%)	2 (1.9%)	3 (1.4%)
		Normal	96 (96.0%)	103 (95.4%)	199 (95.7%)
		High	1 (1.0%)	0	1 (0.5%)
	High	Normal	2 (2.0%)	0	2 (1.0%)
Week 8	m		101	108	209
	Low	Normal	0	3 (2.8%)	3 (1.4%)
	Normal	Low	1 (1.0%)	0	1 (0.5%)
		Normal	96 (95.0%)	105 (97.2%)	201 (96.2%)
		High	2 (2.0%)	0	2 (1.0%)
	High	Normal	2 (2.0%)	0	2 (1.0%)
Week 12	m		100	108	208
	Low	Normal	0	3 (2.8%)	3 (1.4%)
	Normal	Low	2 (2.0%)	1 (0.9%)	3 (1.4%)
		Normal	96 (96.0%)	104 (96.3%)	200 (96.2%)
	High	Normal	2 (2.0%)	0	2 (1.0%)
Week 16	m		99	108	207
	Low	Low	0	1 (0.9%)	1 (0.5%)
		Normal	0	2 (1.9%)	2 (1.0%)
	Normal	Low	2 (2.0%)	2 (1.9%)	4 (1.9%)
		Normal	95 (96.0%)	103 (95.4%)	198 (95.7%)
	High	Normal	2 (2.0%)	0	2 (1.0%)
Week 20	m		99	107	206
	Low	Low	0	1 (0.9%)	1 (0.5%)
		Normal	0	2 (1.9%)	2 (1.0%)
	Normal	Low	2 (2.0%)	1 (0.9%)	3 (1.5%)
		Normal	95 (96.0%)	103 (96.3%)	198 (96.1%)
	High	Normal	2 (2.0%)	0	2 (1.0%)
Week 24	m		99	108	207
	Low	Low	0	1 (0.9%)	1 (0.5%)
		Normal	0	2 (1.9%)	2 (1.0%)
	Normal	Low	1 (1.0%)	1 (0.9%)	2 (1.0%)
		Normal	96 (97.0%)	104 (96.3%)	200 (96.6%)
	High	Normal	2 (2.0%)	0	2 (1.0%)
Week 32	m		98	108	206
	Low	Low	0	1 (0.9%)	1 (0.5%)
		Normal	0	2 (1.9%)	2 (1.0%)
	Normal	Low	2 (2.0%)	1 (0.9%)	3 (1.5%)
		Normal	95 (96.9%)	104 (96.3%)	199 (96.6%)
	High	Normal	1 (1.0%)	0	1 (0.5%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
Week 36	m		98	108	206
	Low	Low	0	1 (0.9%)	1 (0.5%)
		Normal	0	2 (1.9%)	2 (1.0%)
	Normal	Low	1 (1.0%)	3 (2.8%)	4 (1.9%)
		Normal	96 (98.0%)	102 (94.4%)	198 (96.1%)
	High	Normal	1 (1.0%)	0	1 (0.5%)
Week 40	m		0	107	107
	Low	Low	.	1 (0.9%)	1 (0.9%)
		Normal	.	2 (1.9%)	2 (1.9%)
	Normal	Low	.	3 (2.8%)	3 (2.8%)
		Normal	.	101 (94.4%)	101 (94.4%)
Week 44	m		0	107	107
	Low	Low	.	1 (0.9%)	1 (0.9%)
		Normal	.	2 (1.9%)	2 (1.9%)
	Normal	Low	.	1 (0.9%)	1 (0.9%)
		Normal	.	103 (96.3%)	103 (96.3%)
Week 48	m		0	107	107
	Low	Low	.	1 (0.9%)	1 (0.9%)
		Normal	.	2 (1.9%)	2 (1.9%)
	Normal	Low	.	3 (2.8%)	3 (2.8%)
		Normal	.	101 (94.4%)	101 (94.4%)
Week 52	m		0	107	107
	Low	Low	.	1 (0.9%)	1 (0.9%)
		Normal	.	2 (1.9%)	2 (1.9%)
	Normal	Low	.	4 (3.7%)	4 (3.7%)
		Normal	.	100 (93.5%)	100 (93.5%)
LOCF Endpoint	m		101	108	209
	Low	Low	0	1 (0.9%)	1 (0.5%)
		Normal	0	2 (1.9%)	2 (1.0%)
	Normal	Low	1 (1.0%)	4 (3.7%)	5 (2.4%)
		Normal	98 (97.0%)	101 (93.5%)	199 (95.2%)
	High	Normal	2 (2.0%)	0	2 (1.0%)
Leukocytes (10^9/L)					
Week 4	m		100	108	208
	Low	Low	5 (5.0%)	4 (3.7%)	9 (4.3%)
		Normal	4 (4.0%)	6 (5.6%)	10 (4.8%)
	Normal	Low	1 (1.0%)	0	1 (0.5%)
		Normal	90 (90.0%)	95 (88.0%)	185 (88.9%)
		High	0	2 (1.9%)	2 (1.0%)
	High	High	0	1 (0.9%)	1 (0.5%)
Week 8	m		101	108	209
	Low	Low	3 (3.0%)	2 (1.9%)	5 (2.4%)
		Normal	6 (5.9%)	8 (7.4%)	14 (6.7%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
	Normal	Low	2 (2.0%)	1 (0.9%)	3 (1.4%)
		Normal	89 (88.1%)	96 (88.9%)	185 (88.5%)
		High	1 (1.0%)	0	1 (0.5%)
	High	Normal	0	1 (0.9%)	1 (0.5%)
Week 12	m		100	108	208
	Low	Low	3 (3.0%)	3 (2.8%)	6 (2.9%)
		Normal	6 (6.0%)	7 (6.5%)	13 (6.3%)
	Normal	Low	2 (2.0%)	2 (1.9%)	4 (1.9%)
		Normal	89 (89.0%)	93 (86.1%)	182 (87.5%)
		High	0	2 (1.9%)	2 (1.0%)
	High	Normal	0	1 (0.9%)	1 (0.5%)
Week 16	m		99	108	207
	Low	Low	4 (4.0%)	5 (4.6%)	9 (4.3%)
		Normal	5 (5.1%)	5 (4.6%)	10 (4.8%)
	Normal	Low	2 (2.0%)	0	2 (1.0%)
		Normal	88 (88.9%)	95 (88.0%)	183 (88.4%)
		High	0	2 (1.9%)	2 (1.0%)
	High	High	0	1 (0.9%)	1 (0.5%)
Week 20	m		99	107	206
	Low	Low	4 (4.0%)	2 (1.9%)	6 (2.9%)
		Normal	5 (5.1%)	8 (7.5%)	13 (6.3%)
	Normal	Low	1 (1.0%)	2 (1.9%)	3 (1.5%)
		Normal	88 (88.9%)	92 (86.0%)	180 (87.4%)
		High	1 (1.0%)	2 (1.9%)	3 (1.5%)
	High	Normal	0	1 (0.9%)	1 (0.5%)
Week 24	m		99	108	207
	Low	Low	3 (3.0%)	2 (1.9%)	5 (2.4%)
		Normal	6 (6.1%)	8 (7.4%)	14 (6.8%)
	Normal	Low	1 (1.0%)	1 (0.9%)	2 (1.0%)
		Normal	85 (85.9%)	96 (88.9%)	181 (87.4%)
		High	4 (4.0%)	0	4 (1.9%)
	High	Normal	0	1 (0.9%)	1 (0.5%)
Week 32	m		98	108	206
	Low	Low	3 (3.1%)	2 (1.9%)	5 (2.4%)
		Normal	5 (5.1%)	8 (7.4%)	13 (6.3%)
	Normal	Low	2 (2.0%)	2 (1.9%)	4 (1.9%)
		Normal	88 (89.8%)	94 (87.0%)	182 (88.3%)
		High	0	1 (0.9%)	1 (0.5%)
	High	High	0	1 (0.9%)	1 (0.5%)
Week 36	m		98	108	206
	Low	Low	6 (6.1%)	5 (4.6%)	11 (5.3%)
		Normal	2 (2.0%)	5 (4.6%)	7 (3.4%)
	Normal	Low	1 (1.0%)	2 (1.9%)	3 (1.5%)
		Normal	88 (89.8%)	92 (85.2%)	180 (87.4%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
		High	1 (1.0%)	3 (2.8%)	4 (1.9%)
	High	High	0	1 (0.9%)	1 (0.5%)
Week 40	m		0	107	107
	Low	Low	.	6 (5.6%)	6 (5.6%)
		Normal	.	3 (2.8%)	3 (2.8%)
	Normal	Low	.	1 (0.9%)	1 (0.9%)
		Normal	.	94 (87.9%)	94 (87.9%)
		High	.	2 (1.9%)	2 (1.9%)
	High	Normal	.	1 (0.9%)	1 (0.9%)
Week 44	m		0	107	107
	Low	Low	.	4 (3.7%)	4 (3.7%)
		Normal	.	5 (4.7%)	5 (4.7%)
	Normal	Low	.	2 (1.9%)	2 (1.9%)
		Normal	.	94 (87.9%)	94 (87.9%)
		High	.	1 (0.9%)	1 (0.9%)
	High	Normal	.	1 (0.9%)	1 (0.9%)
Week 48	m		0	107	107
	Low	Low	.	4 (3.7%)	4 (3.7%)
		Normal	.	5 (4.7%)	5 (4.7%)
	Normal	Low	.	1 (0.9%)	1 (0.9%)
		Normal	.	92 (86.0%)	92 (86.0%)
		High	.	4 (3.7%)	4 (3.7%)
	High	Normal	.	1 (0.9%)	1 (0.9%)
Week 52	m		0	107	107
	Low	Low	.	6 (5.6%)	6 (5.6%)
		Normal	.	3 (2.8%)	3 (2.8%)
	Normal	Low	.	2 (1.9%)	2 (1.9%)
		Normal	.	93 (86.9%)	93 (86.9%)
		High	.	2 (1.9%)	2 (1.9%)
	High	Normal	.	1 (0.9%)	1 (0.9%)
LOCF Endpoint	m		101	108	209
	Low	Low	6 (5.9%)	6 (5.6%)	12 (5.7%)
		Normal	3 (3.0%)	4 (3.7%)	7 (3.3%)
	Normal	Low	1 (1.0%)	2 (1.9%)	3 (1.4%)
		Normal	90 (89.1%)	93 (86.1%)	183 (87.6%)
		High	1 (1.0%)	2 (1.9%)	3 (1.4%)
	High	Normal	0	1 (0.9%)	1 (0.5%)
Lymphocytes (10^9/L)					
Week 4	m		100	108	208
	Low	Low	0	1 (0.9%)	1 (0.5%)
		Normal	1 (1.0%)	1 (0.9%)	2 (1.0%)
	Normal	Low	1 (1.0%)	0	1 (0.5%)
		Normal	95 (95.0%)	102 (94.4%)	197 (94.7%)
		High	3 (3.0%)	2 (1.9%)	5 (2.4%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
	High	Normal	0	1 (0.9%)	1 (0.5%)
		High	0	1 (0.9%)	1 (0.5%)
Week 8	m		101	108	209
	Low	Low	1 (1.0%)	1 (0.9%)	2 (1.0%)
		Normal	0	1 (0.9%)	1 (0.5%)
	Normal	Low	1 (1.0%)	0	1 (0.5%)
		Normal	97 (96.0%)	101 (93.5%)	198 (94.7%)
		High	2 (2.0%)	3 (2.8%)	5 (2.4%)
	High	Normal	0	2 (1.9%)	2 (1.0%)
Week 12	m		100	108	208
	Low	Low	0	2 (1.9%)	2 (1.0%)
		Normal	1 (1.0%)	0	1 (0.5%)
	Normal	Normal	97 (97.0%)	101 (93.5%)	198 (95.2%)
		High	2 (2.0%)	3 (2.8%)	5 (2.4%)
	High	Normal	0	1 (0.9%)	1 (0.5%)
		High	0	1 (0.9%)	1 (0.5%)
Week 16	m		99	108	207
	Low	Low	0	2 (1.9%)	2 (1.0%)
		Normal	1 (1.0%)	0	1 (0.5%)
	Normal	Low	1 (1.0%)	1 (0.9%)	2 (1.0%)
		Normal	95 (96.0%)	102 (94.4%)	197 (95.2%)
		High	2 (2.0%)	1 (0.9%)	3 (1.4%)
	High	Normal	0	2 (1.9%)	2 (1.0%)
Week 20	m		99	107	206
	Low	Low	1 (1.0%)	2 (1.9%)	3 (1.5%)
	Normal	Low	0	1 (0.9%)	1 (0.5%)
		Normal	98 (99.0%)	101 (94.4%)	199 (96.6%)
		High	0	1 (0.9%)	1 (0.5%)
	High	Normal	0	2 (1.9%)	2 (1.0%)
Week 24	m		99	108	207
	Low	Low	0	1 (0.9%)	1 (0.5%)
		Normal	1 (1.0%)	1 (0.9%)	2 (1.0%)
	Normal	Normal	96 (97.0%)	103 (95.4%)	199 (96.1%)
		High	2 (2.0%)	1 (0.9%)	3 (1.4%)
	High	Normal	0	1 (0.9%)	1 (0.5%)
		High	0	1 (0.9%)	1 (0.5%)
Week 32	m		98	108	206
	Low	Low	0	1 (0.9%)	1 (0.5%)
		Normal	1 (1.0%)	1 (0.9%)	2 (1.0%)
	Normal	Normal	96 (98.0%)	98 (90.7%)	194 (94.2%)
		High	1 (1.0%)	6 (5.6%)	7 (3.4%)
	High	Normal	0	2 (1.9%)	2 (1.0%)
Week 36	m		98	108	206

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
	Low	Low	1 (1.0%)	2 (1.9%)	3 (1.5%)
	Normal	Low	0	1 (0.9%)	1 (0.5%)
		Normal	97 (99.0%)	101 (93.5%)	198 (96.1%)
		High	0	2 (1.9%)	2 (1.0%)
	High	Normal	0	2 (1.9%)	2 (1.0%)
Week 40	m		0	107	107
	Low	Low	.	2 (1.9%)	2 (1.9%)
	Normal	Low	.	1 (0.9%)	1 (0.9%)
		Normal	.	100 (93.5%)	100 (93.5%)
		High	.	2 (1.9%)	2 (1.9%)
	High	Normal	.	2 (1.9%)	2 (1.9%)
Week 44	m		0	107	107
	Low	Low	.	1 (0.9%)	1 (0.9%)
		Normal	.	1 (0.9%)	1 (0.9%)
	Normal	Normal	.	101 (94.4%)	101 (94.4%)
		High	.	2 (1.9%)	2 (1.9%)
	High	Normal	.	1 (0.9%)	1 (0.9%)
		High	.	1 (0.9%)	1 (0.9%)
Week 48	m		0	107	107
	Low	Low	.	1 (0.9%)	1 (0.9%)
		Normal	.	1 (0.9%)	1 (0.9%)
	Normal	Normal	.	102 (95.3%)	102 (95.3%)
		High	.	1 (0.9%)	1 (0.9%)
	High	Normal	.	2 (1.9%)	2 (1.9%)
Week 52	m		0	107	107
	Low	Low	.	2 (1.9%)	2 (1.9%)
	Normal	Low	.	1 (0.9%)	1 (0.9%)
		Normal	.	102 (95.3%)	102 (95.3%)
	High	Normal	.	2 (1.9%)	2 (1.9%)
LOCF Endpoint	m		101	108	209
	Low	Low	1 (1.0%)	2 (1.9%)	3 (1.4%)
	Normal	Low	0	1 (0.9%)	1 (0.5%)
		Normal	100 (99.0%)	103 (95.4%)	203 (97.1%)
	High	Normal	0	2 (1.9%)	2 (1.0%)
Lymphocytes/Leukocytes (%)					
Week 4	m		100	108	208
	Low	Normal	1 (1.0%)	0	1 (0.5%)
	Normal	Low	1 (1.0%)	0	1 (0.5%)
		Normal	93 (93.0%)	102 (94.4%)	195 (93.8%)
		High	4 (4.0%)	0	4 (1.9%)
	High	Normal	1 (1.0%)	4 (3.7%)	5 (2.4%)
		High	0	2 (1.9%)	2 (1.0%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
Week 8	m		101	108	209
	Low	Low	1 (1.0%)	0	1 (0.5%)
	Normal	Low	1 (1.0%)	1 (0.9%)	2 (1.0%)
		Normal	95 (94.1%)	100 (92.6%)	195 (93.3%)
		High	3 (3.0%)	1 (0.9%)	4 (1.9%)
	High	Normal	1 (1.0%)	6 (5.6%)	7 (3.3%)
Week 12	m		100	108	208
	Low	Low	1 (1.0%)	0	1 (0.5%)
	Normal	Low	2 (2.0%)	0	2 (1.0%)
		Normal	95 (95.0%)	102 (94.4%)	197 (94.7%)
		High	1 (1.0%)	0	1 (0.5%)
	High	Normal	1 (1.0%)	4 (3.7%)	5 (2.4%)
		High	0	2 (1.9%)	2 (1.0%)
Week 16	m		99	108	207
	Low	Low	1 (1.0%)	0	1 (0.5%)
	Normal	Low	3 (3.0%)	4 (3.7%)	7 (3.4%)
		Normal	93 (93.9%)	96 (88.9%)	189 (91.3%)
		High	1 (1.0%)	2 (1.9%)	3 (1.4%)
	High	Normal	1 (1.0%)	5 (4.6%)	6 (2.9%)
		High	0	1 (0.9%)	1 (0.5%)
Week 20	m		99	107	206
	Low	Low	1 (1.0%)	0	1 (0.5%)
	Normal	Low	1 (1.0%)	0	1 (0.5%)
		Normal	95 (96.0%)	100 (93.5%)	195 (94.7%)
		High	1 (1.0%)	1 (0.9%)	2 (1.0%)
	High	Normal	1 (1.0%)	6 (5.6%)	7 (3.4%)
Week 24	m		99	108	207
	Low	Normal	1 (1.0%)	0	1 (0.5%)
	Normal	Normal	96 (97.0%)	101 (93.5%)	197 (95.2%)
		High	1 (1.0%)	1 (0.9%)	2 (1.0%)
	High	Normal	1 (1.0%)	4 (3.7%)	5 (2.4%)
		High	0	2 (1.9%)	2 (1.0%)
Week 32	m		98	108	206
	Low	Normal	1 (1.0%)	0	1 (0.5%)
	Normal	Low	0	1 (0.9%)	1 (0.5%)
		Normal	93 (94.9%)	99 (91.7%)	192 (93.2%)
		High	3 (3.1%)	2 (1.9%)	5 (2.4%)
	High	Normal	1 (1.0%)	5 (4.6%)	6 (2.9%)
		High	0	1 (0.9%)	1 (0.5%)
Week 36	m		98	108	206
	Low	Low	1 (1.0%)	0	1 (0.5%)
	Normal	Low	2 (2.0%)	0	2 (1.0%)
		Normal	93 (94.9%)	101 (93.5%)	194 (94.2%)
		High	1 (1.0%)	1 (0.9%)	2 (1.0%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
	High	Normal	1 (1.0%)	6 (5.6%)	7 (3.4%)
Week 40	m		0	107	107
	Normal	Normal	.	99 (92.5%)	99 (92.5%)
		High	.	2 (1.9%)	2 (1.9%)
	High	Normal	.	5 (4.7%)	5 (4.7%)
		High	.	1 (0.9%)	1 (0.9%)
Week 44	m		0	107	107
	Normal	Normal	.	100 (93.5%)	100 (93.5%)
		High	.	1 (0.9%)	1 (0.9%)
	High	Normal	.	6 (5.6%)	6 (5.6%)
Week 48	m		0	107	107
	Normal	Normal	.	99 (92.5%)	99 (92.5%)
		High	.	2 (1.9%)	2 (1.9%)
	High	Normal	.	6 (5.6%)	6 (5.6%)
Week 52	m		0	107	107
	Normal	Low	.	2 (1.9%)	2 (1.9%)
		Normal	.	97 (90.7%)	97 (90.7%)
		High	.	2 (1.9%)	2 (1.9%)
	High	Normal	.	5 (4.7%)	5 (4.7%)
		High	.	1 (0.9%)	1 (0.9%)
LOCF Endpoint	m		101	108	209
	Low	Low	1 (1.0%)	0	1 (0.5%)
	Normal	Low	2 (2.0%)	2 (1.9%)	4 (1.9%)
		Normal	96 (95.0%)	98 (90.7%)	194 (92.8%)
		High	1 (1.0%)	2 (1.9%)	3 (1.4%)
	High	Normal	1 (1.0%)	5 (4.6%)	6 (2.9%)
		High	0	1 (0.9%)	1 (0.5%)
Monocytes (10^9/L)					
Week 4	m		100	108	208
	Normal	Low	0	1 (0.9%)	1 (0.5%)
		Normal	100 (100.0%)	107 (99.1%)	207 (99.5%)
Week 8	m		101	108	209
	Normal	Normal	101 (100.0%)	108 (100.0%)	209 (100.0%)
Week 12	m		100	108	208
	Normal	Normal	100 (100.0%)	107 (99.1%)	207 (99.5%)
		High	0	1 (0.9%)	1 (0.5%)
Week 16	m		99	108	207
	Normal	Normal	99 (100.0%)	108 (100.0%)	207 (100.0%)
Week 20	m		99	107	206
	Normal	Normal	99 (100.0%)	107 (100.0%)	206 (100.0%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
Week 24	m		99	108	207
	Normal	Normal	99 (100.0%)	108 (100.0%)	207 (100.0%)
Week 32	m		98	108	206
	Normal	Normal	98 (100.0%)	108 (100.0%)	206 (100.0%)
Week 36	m		98	108	206
	Normal	Low	1 (1.0%)	0	1 (0.5%)
		Normal	97 (99.0%)	108 (100.0%)	205 (99.5%)
Week 40	m		0	107	107
	Normal	Normal	.	107 (100.0%)	107 (100.0%)
Week 44	m		0	107	107
	Normal	Normal	.	107 (100.0%)	107 (100.0%)
Week 48	m		0	107	107
	Normal	Normal	.	107 (100.0%)	107 (100.0%)
Week 52	m		0	107	107
	Normal	Low	.	1 (0.9%)	1 (0.9%)
		Normal	.	106 (99.1%)	106 (99.1%)
LOCF Endpoint	m		101	108	209
	Normal	Low	1 (1.0%)	1 (0.9%)	2 (1.0%)
		Normal	100 (99.0%)	107 (99.1%)	207 (99.0%)
Monocytes/Leukocytes (%)					
Week 4	m		100	108	208
	Normal	Low	1 (1.0%)	2 (1.9%)	3 (1.4%)
		Normal	99 (99.0%)	105 (97.2%)	204 (98.1%)
		High	0	1 (0.9%)	1 (0.5%)
Week 8	m		101	108	209
	Normal	Normal	101 (100.0%)	108 (100.0%)	209 (100.0%)
Week 12	m		100	108	208
	Normal	Normal	100 (100.0%)	106 (98.1%)	206 (99.0%)
		High	0	2 (1.9%)	2 (1.0%)
Week 16	m		99	108	207
	Normal	Normal	99 (100.0%)	108 (100.0%)	207 (100.0%)
Week 20	m		99	107	206
	Normal	Normal	99 (100.0%)	107 (100.0%)	206 (100.0%)
Week 24	m		99	108	207
	Normal	Normal	99 (100.0%)	108 (100.0%)	207 (100.0%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
Week 32	m		98	108	206
	Normal	Normal	98 (100.0%)	107 (99.1%)	205 (99.5%)
		High	0	1 (0.9%)	1 (0.5%)
Week 36	m		98	108	206
	Normal	Normal	98 (100.0%)	108 (100.0%)	206 (100.0%)
Week 40	m		0	107	107
	Normal	Normal	.	107 (100.0%)	107 (100.0%)
Week 44	m		0	107	107
	Normal	Normal	.	107 (100.0%)	107 (100.0%)
Week 48	m		0	107	107
	Normal	Normal	.	107 (100.0%)	107 (100.0%)
Week 52	m		0	107	107
	Normal	Normal	.	107 (100.0%)	107 (100.0%)
LOCF Endpoint	m		101	108	209
	Normal	Normal	101 (100.0%)	108 (100.0%)	209 (100.0%)
Neutrophils (10^9/L)					
Week 4	m		100	108	208
	Low	Low	2 (2.0%)	6 (5.6%)	8 (3.8%)
		Normal	4 (4.0%)	3 (2.8%)	7 (3.4%)
	Normal	Low	3 (3.0%)	2 (1.9%)	5 (2.4%)
		Normal	91 (91.0%)	94 (87.0%)	185 (88.9%)
		High	0	2 (1.9%)	2 (1.0%)
	High	Normal	0	1 (0.9%)	1 (0.5%)
Week 8	m		101	108	209
	Low	Low	3 (3.0%)	1 (0.9%)	4 (1.9%)
		Normal	3 (3.0%)	8 (7.4%)	11 (5.3%)
	Normal	Low	2 (2.0%)	1 (0.9%)	3 (1.4%)
		Normal	91 (90.1%)	96 (88.9%)	187 (89.5%)
		High	2 (2.0%)	1 (0.9%)	3 (1.4%)
	High	Normal	0	1 (0.9%)	1 (0.5%)
Week 12	m		100	108	208
	Low	Low	2 (2.0%)	3 (2.8%)	5 (2.4%)
		Normal	4 (4.0%)	6 (5.6%)	10 (4.8%)
	Normal	Low	3 (3.0%)	2 (1.9%)	5 (2.4%)
		Normal	89 (89.0%)	94 (87.0%)	183 (88.0%)
		High	2 (2.0%)	2 (1.9%)	4 (1.9%)
	High	Normal	0	1 (0.9%)	1 (0.5%)
Week 16	m		99	108	207
	Low	Low	3 (3.0%)	4 (3.7%)	7 (3.4%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
		Normal	3 (3.0%)	5 (4.6%)	8 (3.9%)
	Normal	Low	4 (4.0%)	2 (1.9%)	6 (2.9%)
		Normal	88 (88.9%)	93 (86.1%)	181 (87.4%)
		High	1 (1.0%)	3 (2.8%)	4 (1.9%)
	High	High	0	1 (0.9%)	1 (0.5%)
Week 20	m		99	107	206
	Low	Low	3 (3.0%)	3 (2.8%)	6 (2.9%)
		Normal	3 (3.0%)	6 (5.6%)	9 (4.4%)
	Normal	Low	3 (3.0%)	2 (1.9%)	5 (2.4%)
		Normal	88 (88.9%)	94 (87.9%)	182 (88.3%)
		High	2 (2.0%)	1 (0.9%)	3 (1.5%)
	High	Normal	0	1 (0.9%)	1 (0.5%)
Week 24	m		99	108	207
	Low	Low	3 (3.0%)	2 (1.9%)	5 (2.4%)
		Normal	3 (3.0%)	7 (6.5%)	10 (4.8%)
	Normal	Low	4 (4.0%)	2 (1.9%)	6 (2.9%)
		Normal	85 (85.9%)	96 (88.9%)	181 (87.4%)
		High	4 (4.0%)	0	4 (1.9%)
	High	Normal	0	1 (0.9%)	1 (0.5%)
Week 32	m		98	108	206
	Low	Low	3 (3.1%)	2 (1.9%)	5 (2.4%)
		Normal	3 (3.1%)	7 (6.5%)	10 (4.9%)
	Normal	Low	2 (2.0%)	3 (2.8%)	5 (2.4%)
		Normal	90 (91.8%)	94 (87.0%)	184 (89.3%)
		High	0	1 (0.9%)	1 (0.5%)
	High	Normal	0	1 (0.9%)	1 (0.5%)
Week 36	m		98	108	206
	Low	Low	4 (4.1%)	4 (3.7%)	8 (3.9%)
		Normal	2 (2.0%)	5 (4.6%)	7 (3.4%)
	Normal	Low	2 (2.0%)	2 (1.9%)	4 (1.9%)
		Normal	89 (90.8%)	92 (85.2%)	181 (87.9%)
		High	1 (1.0%)	4 (3.7%)	5 (2.4%)
	High	Normal	0	1 (0.9%)	1 (0.5%)
Week 40	m		0	107	107
	Low	Low	.	5 (4.7%)	5 (4.7%)
		Normal	.	4 (3.7%)	4 (3.7%)
	Normal	Low	.	2 (1.9%)	2 (1.9%)
		Normal	.	93 (86.9%)	93 (86.9%)
		High	.	2 (1.9%)	2 (1.9%)
	High	Normal	.	1 (0.9%)	1 (0.9%)
Week 44	m		0	107	107
	Low	Low	.	3 (2.8%)	3 (2.8%)
		Normal	.	6 (5.6%)	6 (5.6%)
	Normal	Low	.	2 (1.9%)	2 (1.9%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
		Normal	.	94 (87.9%)	94 (87.9%)
		High	.	1 (0.9%)	1 (0.9%)
	High	Normal	.	1 (0.9%)	1 (0.9%)
Week 48	m		0	107	107
	Low	Low	.	2 (1.9%)	2 (1.9%)
		Normal	.	7 (6.5%)	7 (6.5%)
	Normal	Low	.	5 (4.7%)	5 (4.7%)
		Normal	.	87 (81.3%)	87 (81.3%)
		High	.	5 (4.7%)	5 (4.7%)
	High	Normal	.	1 (0.9%)	1 (0.9%)
Week 52	m		0	107	107
	Low	Low	.	5 (4.7%)	5 (4.7%)
		Normal	.	4 (3.7%)	4 (3.7%)
	Normal	Low	.	3 (2.8%)	3 (2.8%)
		Normal	.	90 (84.1%)	90 (84.1%)
		High	.	4 (3.7%)	4 (3.7%)
	High	Normal	.	1 (0.9%)	1 (0.9%)
LOCF Endpoint	m		101	108	209
	Low	Low	4 (4.0%)	5 (4.6%)	9 (4.3%)
		Normal	2 (2.0%)	4 (3.7%)	6 (2.9%)
	Normal	Low	2 (2.0%)	3 (2.8%)	5 (2.4%)
		Normal	92 (91.1%)	91 (84.3%)	183 (87.6%)
		High	1 (1.0%)	4 (3.7%)	5 (2.4%)
	High	Normal	0	1 (0.9%)	1 (0.5%)
Neutrophils/Leukocytes (%)					
Week 4	m		100	108	208
	Low	Low	0	1 (0.9%)	1 (0.5%)
		Normal	1 (1.0%)	1 (0.9%)	2 (1.0%)
	Normal	Low	3 (3.0%)	1 (0.9%)	4 (1.9%)
		Normal	87 (87.0%)	104 (96.3%)	191 (91.8%)
		High	3 (3.0%)	1 (0.9%)	4 (1.9%)
	High	Normal	5 (5.0%)	0	5 (2.4%)
		High	1 (1.0%)	0	1 (0.5%)
Week 8	m		101	108	209
	Low	Normal	1 (1.0%)	2 (1.9%)	3 (1.4%)
	Normal	Low	2 (2.0%)	0	2 (1.0%)
		Normal	91 (90.1%)	103 (95.4%)	194 (92.8%)
		High	1 (1.0%)	3 (2.8%)	4 (1.9%)
	High	Normal	5 (5.0%)	0	5 (2.4%)
		High	1 (1.0%)	0	1 (0.5%)
Week 12	m		100	108	208
	Low	Low	0	1 (0.9%)	1 (0.5%)
		Normal	1 (1.0%)	1 (0.9%)	2 (1.0%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
	Normal	Low	1 (1.0%)	2 (1.9%)	3 (1.4%)
		Normal	90 (90.0%)	101 (93.5%)	191 (91.8%)
		High	2 (2.0%)	3 (2.8%)	5 (2.4%)
	High	Normal	6 (6.0%)	0	6 (2.9%)
Week 16	m		99	108	207
	Low	Normal	1 (1.0%)	2 (1.9%)	3 (1.4%)
	Normal	Low	0	2 (1.9%)	2 (1.0%)
		Normal	89 (89.9%)	98 (90.7%)	187 (90.3%)
		High	3 (3.0%)	6 (5.6%)	9 (4.3%)
	High	Normal	5 (5.1%)	0	5 (2.4%)
		High	1 (1.0%)	0	1 (0.5%)
Week 20	m		99	107	206
	Low	Normal	1 (1.0%)	2 (1.9%)	3 (1.5%)
	Normal	Low	0	1 (0.9%)	1 (0.5%)
		Normal	90 (90.9%)	102 (95.3%)	192 (93.2%)
		High	2 (2.0%)	2 (1.9%)	4 (1.9%)
	High	Normal	4 (4.0%)	0	4 (1.9%)
		High	2 (2.0%)	0	2 (1.0%)
Week 24	m		99	108	207
	Low	Normal	1 (1.0%)	2 (1.9%)	3 (1.4%)
	Normal	Low	2 (2.0%)	1 (0.9%)	3 (1.4%)
		Normal	90 (90.9%)	105 (97.2%)	195 (94.2%)
	High	Normal	4 (4.0%)	0	4 (1.9%)
		High	2 (2.0%)	0	2 (1.0%)
Week 32	m		98	108	206
	Low	Normal	1 (1.0%)	2 (1.9%)	3 (1.5%)
	Normal	Low	1 (1.0%)	0	1 (0.5%)
		Normal	90 (91.8%)	104 (96.3%)	194 (94.2%)
		High	0	2 (1.9%)	2 (1.0%)
	High	Normal	4 (4.1%)	0	4 (1.9%)
		High	2 (2.0%)	0	2 (1.0%)
Week 36	m		98	108	206
	Low	Normal	1 (1.0%)	2 (1.9%)	3 (1.5%)
	Normal	Low	1 (1.0%)	0	1 (0.5%)
		Normal	87 (88.8%)	105 (97.2%)	192 (93.2%)
		High	3 (3.1%)	1 (0.9%)	4 (1.9%)
	High	Normal	4 (4.1%)	0	4 (1.9%)
		High	2 (2.0%)	0	2 (1.0%)
Week 40	m		0	107	107
	Low	Normal	.	2 (1.9%)	2 (1.9%)
	Normal	Normal	.	105 (98.1%)	105 (98.1%)
Week 44	m		0	107	107
	Low	Normal	.	2 (1.9%)	2 (1.9%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
	Normal	Low	.	1 (0.9%)	1 (0.9%)
		Normal	.	104 (97.2%)	104 (97.2%)
Week 48	m		0	107	107
	Low	Normal	.	2 (1.9%)	2 (1.9%)
	Normal	Low	.	2 (1.9%)	2 (1.9%)
		Normal	.	103 (96.3%)	103 (96.3%)
Week 52	m		0	107	107
	Low	Normal	.	2 (1.9%)	2 (1.9%)
	Normal	Normal	.	101 (94.4%)	101 (94.4%)
		High	.	4 (3.7%)	4 (3.7%)
LOCF Endpoint	m		101	108	209
	Low	Normal	1 (1.0%)	2 (1.9%)	3 (1.4%)
	Normal	Low	1 (1.0%)	0	1 (0.5%)
		Normal	90 (89.1%)	102 (94.4%)	192 (91.9%)
		High	3 (3.0%)	4 (3.7%)	7 (3.3%)
	High	Normal	4 (4.0%)	0	4 (1.9%)
		High	2 (2.0%)	0	2 (1.0%)
Platelets (10^9/L)					
Week 4	m		100	107	207
	Low	Low	0	3 (2.8%)	3 (1.4%)
		Normal	2 (2.0%)	0	2 (1.0%)
	Normal	Low	1 (1.0%)	3 (2.8%)	4 (1.9%)
		Normal	97 (97.0%)	101 (94.4%)	198 (95.7%)
Week 8	m		101	107	208
	Low	Low	0	2 (1.9%)	2 (1.0%)
		Normal	2 (2.0%)	0	2 (1.0%)
	Normal	Normal	98 (97.0%)	104 (97.2%)	202 (97.1%)
		High	1 (1.0%)	1 (0.9%)	2 (1.0%)
Week 12	m		100	108	208
	Low	Low	0	2 (1.9%)	2 (1.0%)
		Normal	2 (2.0%)	1 (0.9%)	3 (1.4%)
	Normal	Low	0	1 (0.9%)	1 (0.5%)
		Normal	98 (98.0%)	101 (93.5%)	199 (95.7%)
		High	0	3 (2.8%)	3 (1.4%)
Week 16	m		99	108	207
	Low	Low	1 (1.0%)	2 (1.9%)	3 (1.4%)
		Normal	1 (1.0%)	1 (0.9%)	2 (1.0%)
	Normal	Low	0	1 (0.9%)	1 (0.5%)
		Normal	97 (98.0%)	103 (95.4%)	200 (96.6%)
		High	0	1 (0.9%)	1 (0.5%)
Week 20	m		99	107	206
	Low	Low	0	1 (0.9%)	1 (0.5%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
		Normal	2 (2.0%)	2 (1.9%)	4 (1.9%)
	Normal	Normal	97 (98.0%)	99 (92.5%)	196 (95.1%)
		High	0	5 (4.7%)	5 (2.4%)
Week 24	m		99	108	207
	Low	Low	0	1 (0.9%)	1 (0.5%)
		Normal	2 (2.0%)	2 (1.9%)	4 (1.9%)
	Normal	Normal	97 (98.0%)	102 (94.4%)	199 (96.1%)
		High	0	3 (2.8%)	3 (1.4%)
Week 32	m		98	108	206
	Low	Low	0	1 (0.9%)	1 (0.5%)
		Normal	2 (2.0%)	2 (1.9%)	4 (1.9%)
	Normal	Low	2 (2.0%)	0	2 (1.0%)
		Normal	94 (95.9%)	101 (93.5%)	195 (94.7%)
		High	0	4 (3.7%)	4 (1.9%)
Week 36	m		98	108	206
	Low	Low	0	2 (1.9%)	2 (1.0%)
		Normal	2 (2.0%)	1 (0.9%)	3 (1.5%)
	Normal	Low	2 (2.0%)	0	2 (1.0%)
		Normal	94 (95.9%)	99 (91.7%)	193 (93.7%)
		High	0	6 (5.6%)	6 (2.9%)
Week 40	m		0	106	106
	Low	Low	.	1 (0.9%)	1 (0.9%)
		Normal	.	1 (0.9%)	1 (0.9%)
	Normal	Normal	.	98 (92.5%)	98 (92.5%)
		High	.	6 (5.7%)	6 (5.7%)
Week 44	m		0	107	107
	Low	Low	.	1 (0.9%)	1 (0.9%)
		Normal	.	2 (1.9%)	2 (1.9%)
	Normal	Normal	.	100 (93.5%)	100 (93.5%)
		High	.	4 (3.7%)	4 (3.7%)
Week 48	m		0	107	107
	Low	Low	.	2 (1.9%)	2 (1.9%)
		Normal	.	1 (0.9%)	1 (0.9%)
	Normal	Low	.	1 (0.9%)	1 (0.9%)
		Normal	.	100 (93.5%)	100 (93.5%)
		High	.	3 (2.8%)	3 (2.8%)
Week 52	m		0	106	106
	Low	Low	.	2 (1.9%)	2 (1.9%)
	Normal	Normal	.	102 (96.2%)	102 (96.2%)
		High	.	2 (1.9%)	2 (1.9%)
LOCF Endpoint	m		101	108	209
	Low	Low	0	2 (1.9%)	2 (1.0%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
		Normal	2 (2.0%)	1 (0.9%)	3 (1.4%)
	Normal	Low	2 (2.0%)	0	2 (1.0%)
		Normal	97 (96.0%)	103 (95.4%)	200 (95.7%)
		High	0	2 (1.9%)	2 (1.0%)

- Abbreviations: LOCF, Last Observation Carried Forward
- "Imeglimin" in this table means "Imeglimin 1000 mg twice daily".
- The Long-term Safety Population excludes data during administration of placebo in the double-blind period.
- "Imeglimin + Insulin Total" is the sum of subjects in the placebo group in the open-label period and Imeglimin group in the double-blind and open-label periods.
- m in row headings is the total number of subjects with both baseline and the corresponding visit values available, and is used as the denominator to calculate percentages.
- For "Placebo/Imeglimin + Insulin" group, baseline was defined as last visit with non-missing value prior to or at the day of first dose of Investigational Medicinal Product (IMP) in open-label treatment period. For "Imeglimin/Imeglimin + Insulin" group, baseline was the same as for the double-blind treatment period.

Control No:<<t-s-202-labot-020lt.sas, 2020-03-06T00:19:06>>

Table S-203 Shift of Laboratory Findings of Biochemistry in Long-term Period (PXL008-020; Long-term Safety Population)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
Alanine Aminotransferase (U/L)					
Week 4	m		100	108	208
	Normal	Normal	89 (89.0%)	99 (91.7%)	188 (90.4%)
		High	4 (4.0%)	2 (1.9%)	6 (2.9%)
	High	Normal	1 (1.0%)	5 (4.6%)	6 (2.9%)
		High	6 (6.0%)	2 (1.9%)	8 (3.8%)
Week 8	m		100	108	208
	Normal	Normal	90 (90.0%)	97 (89.8%)	187 (89.9%)
		High	4 (4.0%)	4 (3.7%)	8 (3.8%)
	High	Normal	2 (2.0%)	6 (5.6%)	8 (3.8%)
		High	4 (4.0%)	1 (0.9%)	5 (2.4%)
Week 12	m		101	108	209
	Normal	Normal	91 (90.1%)	99 (91.7%)	190 (90.9%)
		High	3 (3.0%)	2 (1.9%)	5 (2.4%)
	High	Normal	3 (3.0%)	4 (3.7%)	7 (3.3%)
		High	4 (4.0%)	3 (2.8%)	7 (3.3%)
Week 16	m		99	108	207
	Normal	Normal	88 (88.9%)	94 (87.0%)	182 (87.9%)
		High	4 (4.0%)	7 (6.5%)	11 (5.3%)
	High	Normal	3 (3.0%)	6 (5.6%)	9 (4.3%)
		High	4 (4.0%)	1 (0.9%)	5 (2.4%)
Week 20	m		99	108	207
	Normal	Normal	89 (89.9%)	97 (89.8%)	186 (89.9%)
		High	3 (3.0%)	4 (3.7%)	7 (3.4%)
	High	Normal	3 (3.0%)	5 (4.6%)	8 (3.9%)
		High	4 (4.0%)	2 (1.9%)	6 (2.9%)
Week 24	m		99	108	207
	Normal	Normal	86 (86.9%)	97 (89.8%)	183 (88.4%)
		High	6 (6.1%)	4 (3.7%)	10 (4.8%)
	High	Normal	3 (3.0%)	5 (4.6%)	8 (3.9%)
		High	4 (4.0%)	2 (1.9%)	6 (2.9%)
Week 32	m		98	108	206
	Normal	Normal	87 (88.8%)	97 (89.8%)	184 (89.3%)
		High	4 (4.1%)	4 (3.7%)	8 (3.9%)
	High	Normal	3 (3.1%)	4 (3.7%)	7 (3.4%)
		High	4 (4.1%)	3 (2.8%)	7 (3.4%)
Week 36	m		98	108	206
	Normal	Normal	90 (91.8%)	97 (89.8%)	187 (90.8%)
		High	1 (1.0%)	4 (3.7%)	5 (2.4%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
	High	Normal	3 (3.1%)	5 (4.6%)	8 (3.9%)
		High	4 (4.1%)	2 (1.9%)	6 (2.9%)
Week 40	m		0	107	107
	Normal	Normal	.	92 (86.0%)	92 (86.0%)
		High	.	8 (7.5%)	8 (7.5%)
	High	Normal	.	4 (3.7%)	4 (3.7%)
		High	.	3 (2.8%)	3 (2.8%)
Week 44	m		0	107	107
	Normal	Normal	.	96 (89.7%)	96 (89.7%)
		High	.	4 (3.7%)	4 (3.7%)
	High	Normal	.	6 (5.6%)	6 (5.6%)
		High	.	1 (0.9%)	1 (0.9%)
Week 48	m		0	107	107
	Normal	Normal	.	94 (87.9%)	94 (87.9%)
		High	.	6 (5.6%)	6 (5.6%)
	High	Normal	.	6 (5.6%)	6 (5.6%)
		High	.	1 (0.9%)	1 (0.9%)
Week 52	m		0	107	107
	Normal	Normal	.	96 (89.7%)	96 (89.7%)
		High	.	4 (3.7%)	4 (3.7%)
	High	Normal	.	5 (4.7%)	5 (4.7%)
		High	.	2 (1.9%)	2 (1.9%)
LOCF Endpoint	m		101	108	209
	Normal	Normal	93 (92.1%)	97 (89.8%)	190 (90.9%)
		High	1 (1.0%)	4 (3.7%)	5 (2.4%)
	High	Normal	3 (3.0%)	5 (4.6%)	8 (3.8%)
		High	4 (4.0%)	2 (1.9%)	6 (2.9%)
Albumin (g/L)					
Week 4	m		100	108	208
	Normal	Normal	90 (90.0%)	102 (94.4%)	192 (92.3%)
		High	2 (2.0%)	4 (3.7%)	6 (2.9%)
	High	Normal	4 (4.0%)	2 (1.9%)	6 (2.9%)
		High	4 (4.0%)	0	4 (1.9%)
Week 8	m		101	108	209
	Normal	Normal	90 (89.1%)	101 (93.5%)	191 (91.4%)
		High	3 (3.0%)	5 (4.6%)	8 (3.8%)
	High	Normal	7 (6.9%)	2 (1.9%)	9 (4.3%)
		High	1 (1.0%)	0	1 (0.5%)
Week 12	m		101	108	209
	Normal	Normal	92 (91.1%)	102 (94.4%)	194 (92.8%)
		High	1 (1.0%)	4 (3.7%)	5 (2.4%)
	High	Normal	5 (5.0%)	2 (1.9%)	7 (3.3%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
		High	3 (3.0%)	0	3 (1.4%)
Week 16	m		99	108	207
	Normal	Normal	89 (89.9%)	93 (86.1%)	182 (87.9%)
		High	2 (2.0%)	13 (12.0%)	15 (7.2%)
	High	Normal	7 (7.1%)	2 (1.9%)	9 (4.3%)
		High	1 (1.0%)	0	1 (0.5%)
Week 20	m		99	108	207
	Normal	Normal	90 (90.9%)	99 (91.7%)	189 (91.3%)
		High	1 (1.0%)	7 (6.5%)	8 (3.9%)
	High	Normal	5 (5.1%)	1 (0.9%)	6 (2.9%)
		High	3 (3.0%)	1 (0.9%)	4 (1.9%)
Week 24	m		99	108	207
	Normal	Normal	89 (89.9%)	98 (90.7%)	187 (90.3%)
		High	2 (2.0%)	8 (7.4%)	10 (4.8%)
	High	Normal	6 (6.1%)	2 (1.9%)	8 (3.9%)
		High	2 (2.0%)	0	2 (1.0%)
Week 32	m		98	108	206
	Normal	Normal	89 (90.8%)	99 (91.7%)	188 (91.3%)
		High	1 (1.0%)	7 (6.5%)	8 (3.9%)
	High	Normal	7 (7.1%)	2 (1.9%)	9 (4.4%)
		High	1 (1.0%)	0	1 (0.5%)
Week 36	m		98	108	206
	Normal	Low	0	1 (0.9%)	1 (0.5%)
		Normal	89 (90.8%)	99 (91.7%)	188 (91.3%)
		High	1 (1.0%)	6 (5.6%)	7 (3.4%)
	High	Normal	6 (6.1%)	2 (1.9%)	8 (3.9%)
		High	2 (2.0%)	0	2 (1.0%)
Week 40	m		0	107	107
	Normal	Normal	.	100 (93.5%)	100 (93.5%)
		High	.	5 (4.7%)	5 (4.7%)
	High	Normal	.	2 (1.9%)	2 (1.9%)
Week 44	m		0	107	107
	Normal	Normal	.	102 (95.3%)	102 (95.3%)
		High	.	3 (2.8%)	3 (2.8%)
	High	Normal	.	1 (0.9%)	1 (0.9%)
		High	.	1 (0.9%)	1 (0.9%)
Week 48	m		0	107	107
	Normal	Normal	.	99 (92.5%)	99 (92.5%)
		High	.	6 (5.6%)	6 (5.6%)
	High	Normal	.	2 (1.9%)	2 (1.9%)
Week 52	m		0	107	107

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
	Normal	Normal	.	100 (93.5%)	100 (93.5%)
		High	.	5 (4.7%)	5 (4.7%)
	High	Normal	.	1 (0.9%)	1 (0.9%)
		High	.	1 (0.9%)	1 (0.9%)
LOCF Endpoint	m		101	108	209
	Normal	Normal	92 (91.1%)	101 (93.5%)	193 (92.3%)
		High	1 (1.0%)	5 (4.6%)	6 (2.9%)
	High	Normal	6 (5.9%)	1 (0.9%)	7 (3.3%)
		High	2 (2.0%)	1 (0.9%)	3 (1.4%)
Alkaline Phosphatase (U/L)					
Week 4	m		100	108	208
	Low	Normal	0	1 (0.9%)	1 (0.5%)
	Normal	Low	0	3 (2.8%)	3 (1.4%)
		Normal	99 (99.0%)	101 (93.5%)	200 (96.2%)
	High	Normal	1 (1.0%)	1 (0.9%)	2 (1.0%)
		High	0	2 (1.9%)	2 (1.0%)
Week 8	m		101	108	209
	Low	Low	0	1 (0.9%)	1 (0.5%)
	Normal	Low	0	2 (1.9%)	2 (1.0%)
		Normal	100 (99.0%)	101 (93.5%)	201 (96.2%)
		High	0	1 (0.9%)	1 (0.5%)
	High	Normal	1 (1.0%)	1 (0.9%)	2 (1.0%)
		High	0	2 (1.9%)	2 (1.0%)
Week 12	m		101	108	209
	Low	Low	0	1 (0.9%)	1 (0.5%)
	Normal	Low	0	2 (1.9%)	2 (1.0%)
		Normal	100 (99.0%)	101 (93.5%)	201 (96.2%)
		High	0	1 (0.9%)	1 (0.5%)
	High	Normal	1 (1.0%)	1 (0.9%)	2 (1.0%)
		High	0	2 (1.9%)	2 (1.0%)
Week 16	m		99	108	207
	Low	Low	0	1 (0.9%)	1 (0.5%)
	Normal	Low	0	2 (1.9%)	2 (1.0%)
		Normal	98 (99.0%)	101 (93.5%)	199 (96.1%)
		High	0	1 (0.9%)	1 (0.5%)
	High	Normal	1 (1.0%)	1 (0.9%)	2 (1.0%)
		High	0	2 (1.9%)	2 (1.0%)
Week 20	m		99	108	207
	Low	Low	0	1 (0.9%)	1 (0.5%)
	Normal	Low	0	3 (2.8%)	3 (1.4%)
		Normal	98 (99.0%)	100 (92.6%)	198 (95.7%)
		High	0	1 (0.9%)	1 (0.5%)
	High	Normal	1 (1.0%)	1 (0.9%)	2 (1.0%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
		High	0	2 (1.9%)	2 (1.0%)
Week 24	m		99	108	207
	Low	Normal	0	1 (0.9%)	1 (0.5%)
	Normal	Low	0	2 (1.9%)	2 (1.0%)
		Normal	98 (99.0%)	102 (94.4%)	200 (96.6%)
	High	Normal	1 (1.0%)	1 (0.9%)	2 (1.0%)
		High	0	2 (1.9%)	2 (1.0%)
Week 32	m		98	108	206
	Low	Low	0	1 (0.9%)	1 (0.5%)
	Normal	Low	0	3 (2.8%)	3 (1.5%)
		Normal	97 (99.0%)	100 (92.6%)	197 (95.6%)
		High	0	1 (0.9%)	1 (0.5%)
	High	Normal	1 (1.0%)	1 (0.9%)	2 (1.0%)
		High	0	2 (1.9%)	2 (1.0%)
Week 36	m		98	108	206
	Low	Low	0	1 (0.9%)	1 (0.5%)
	Normal	Low	0	2 (1.9%)	2 (1.0%)
		Normal	97 (99.0%)	101 (93.5%)	198 (96.1%)
		High	0	1 (0.9%)	1 (0.5%)
	High	Normal	0	1 (0.9%)	1 (0.5%)
		High	1 (1.0%)	2 (1.9%)	3 (1.5%)
Week 40	m		0	107	107
	Low	Low	.	1 (0.9%)	1 (0.9%)
	Normal	Low	.	1 (0.9%)	1 (0.9%)
		Normal	.	101 (94.4%)	101 (94.4%)
		High	.	1 (0.9%)	1 (0.9%)
	High	Normal	.	1 (0.9%)	1 (0.9%)
		High	.	2 (1.9%)	2 (1.9%)
Week 44	m		0	107	107
	Low	Low	.	1 (0.9%)	1 (0.9%)
	Normal	Low	.	2 (1.9%)	2 (1.9%)
		Normal	.	101 (94.4%)	101 (94.4%)
	High	Normal	.	1 (0.9%)	1 (0.9%)
		High	.	2 (1.9%)	2 (1.9%)
Week 48	m		0	107	107
	Low	Low	.	1 (0.9%)	1 (0.9%)
	Normal	Low	.	4 (3.7%)	4 (3.7%)
		Normal	.	99 (92.5%)	99 (92.5%)
	High	Normal	.	1 (0.9%)	1 (0.9%)
		High	.	2 (1.9%)	2 (1.9%)
Week 52	m		0	107	107
	Low	Low	.	1 (0.9%)	1 (0.9%)
	Normal	Low	.	4 (3.7%)	4 (3.7%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
		Normal	.	99 (92.5%)	99 (92.5%)
	High	Normal	.	1 (0.9%)	1 (0.9%)
		High	.	2 (1.9%)	2 (1.9%)
LOCF Endpoint	m		101	108	209
	Low	Low	0	1 (0.9%)	1 (0.5%)
	Normal	Low	0	4 (3.7%)	4 (1.9%)
		Normal	100 (99.0%)	100 (92.6%)	200 (95.7%)
	High	Normal	0	1 (0.9%)	1 (0.5%)
		High	1 (1.0%)	2 (1.9%)	3 (1.4%)
Amylase (U/L)					
Week 4	m		100	108	208
	Low	Low	1 (1.0%)	11 (10.2%)	12 (5.8%)
		Normal	6 (6.0%)	1 (0.9%)	7 (3.4%)
	Normal	Low	0	3 (2.8%)	3 (1.4%)
		Normal	90 (90.0%)	88 (81.5%)	178 (85.6%)
		High	0	3 (2.8%)	3 (1.4%)
	High	Normal	2 (2.0%)	2 (1.9%)	4 (1.9%)
		High	1 (1.0%)	0	1 (0.5%)
Week 8	m		101	108	209
	Low	Low	2 (2.0%)	9 (8.3%)	11 (5.3%)
		Normal	5 (5.0%)	3 (2.8%)	8 (3.8%)
	Normal	Low	0	2 (1.9%)	2 (1.0%)
		Normal	90 (89.1%)	91 (84.3%)	181 (86.6%)
		High	1 (1.0%)	1 (0.9%)	2 (1.0%)
	High	Normal	2 (2.0%)	1 (0.9%)	3 (1.4%)
		High	1 (1.0%)	1 (0.9%)	2 (1.0%)
Week 12	m		101	108	209
	Low	Low	3 (3.0%)	8 (7.4%)	11 (5.3%)
		Normal	4 (4.0%)	4 (3.7%)	8 (3.8%)
	Normal	Low	1 (1.0%)	4 (3.7%)	5 (2.4%)
		Normal	87 (86.1%)	88 (81.5%)	175 (83.7%)
		High	3 (3.0%)	2 (1.9%)	5 (2.4%)
	High	Normal	2 (2.0%)	1 (0.9%)	3 (1.4%)
		High	1 (1.0%)	1 (0.9%)	2 (1.0%)
Week 16	m		99	108	207
	Low	Low	2 (2.0%)	9 (8.3%)	11 (5.3%)
		Normal	5 (5.1%)	3 (2.8%)	8 (3.9%)
	Normal	Low	0	1 (0.9%)	1 (0.5%)
		Normal	86 (86.9%)	91 (84.3%)	177 (85.5%)
		High	3 (3.0%)	2 (1.9%)	5 (2.4%)
	High	Normal	2 (2.0%)	1 (0.9%)	3 (1.4%)
		High	1 (1.0%)	1 (0.9%)	2 (1.0%)
Week 20	m		99	108	207
	Low	Low	4 (4.0%)	9 (8.3%)	13 (6.3%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
		Normal	3 (3.0%)	3 (2.8%)	6 (2.9%)
	Normal	Low	0	1 (0.9%)	1 (0.5%)
		Normal	87 (87.9%)	93 (86.1%)	180 (87.0%)
		High	2 (2.0%)	0	2 (1.0%)
	High	Normal	2 (2.0%)	2 (1.9%)	4 (1.9%)
		High	1 (1.0%)	0	1 (0.5%)
Week 24	m		99	108	207
	Low	Low	4 (4.0%)	8 (7.4%)	12 (5.8%)
		Normal	3 (3.0%)	4 (3.7%)	7 (3.4%)
	Normal	Low	2 (2.0%)	2 (1.9%)	4 (1.9%)
		Normal	85 (85.9%)	90 (83.3%)	175 (84.5%)
		High	2 (2.0%)	2 (1.9%)	4 (1.9%)
	High	Normal	2 (2.0%)	1 (0.9%)	3 (1.4%)
		High	1 (1.0%)	1 (0.9%)	2 (1.0%)
Week 32	m		98	108	206
	Low	Low	3 (3.1%)	8 (7.4%)	11 (5.3%)
		Normal	4 (4.1%)	4 (3.7%)	8 (3.9%)
	Normal	Low	1 (1.0%)	0	1 (0.5%)
		Normal	86 (87.8%)	91 (84.3%)	177 (85.9%)
		High	1 (1.0%)	3 (2.8%)	4 (1.9%)
	High	Normal	2 (2.0%)	1 (0.9%)	3 (1.5%)
		High	1 (1.0%)	1 (0.9%)	2 (1.0%)
Week 36	m		98	108	206
	Low	Low	3 (3.1%)	8 (7.4%)	11 (5.3%)
		Normal	4 (4.1%)	4 (3.7%)	8 (3.9%)
	Normal	Low	0	1 (0.9%)	1 (0.5%)
		Normal	85 (86.7%)	90 (83.3%)	175 (85.0%)
		High	3 (3.1%)	3 (2.8%)	6 (2.9%)
	High	Normal	1 (1.0%)	1 (0.9%)	2 (1.0%)
		High	2 (2.0%)	1 (0.9%)	3 (1.5%)
Week 40	m		0	107	107
	Low	Low	.	7 (6.5%)	7 (6.5%)
		Normal	.	5 (4.7%)	5 (4.7%)
	Normal	Low	.	2 (1.9%)	2 (1.9%)
		Normal	.	90 (84.1%)	90 (84.1%)
		High	.	1 (0.9%)	1 (0.9%)
	High	High	.	2 (1.9%)	2 (1.9%)
Week 44	m		0	107	107
	Low	Low	.	7 (6.5%)	7 (6.5%)
		Normal	.	4 (3.7%)	4 (3.7%)
		High	.	1 (0.9%)	1 (0.9%)
	Normal	Low	.	1 (0.9%)	1 (0.9%)
		Normal	.	91 (85.0%)	91 (85.0%)
		High	.	1 (0.9%)	1 (0.9%)
	High	Normal	.	1 (0.9%)	1 (0.9%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
		High	.	1 (0.9%)	1 (0.9%)
Week 48	m		0	107	107
	Low	Low	.	8 (7.5%)	8 (7.5%)
		Normal	.	4 (3.7%)	4 (3.7%)
	Normal	Low	.	3 (2.8%)	3 (2.8%)
		Normal	.	86 (80.4%)	86 (80.4%)
		High	.	4 (3.7%)	4 (3.7%)
	High	High	.	2 (1.9%)	2 (1.9%)
Week 52	m		0	107	107
	Low	Low	.	9 (8.4%)	9 (8.4%)
		Normal	.	3 (2.8%)	3 (2.8%)
	Normal	Low	.	1 (0.9%)	1 (0.9%)
		Normal	.	91 (85.0%)	91 (85.0%)
		High	.	1 (0.9%)	1 (0.9%)
	High	Normal	.	2 (1.9%)	2 (1.9%)
LOCF Endpoint	m		101	108	209
	Low	Low	3 (3.0%)	9 (8.3%)	12 (5.7%)
		Normal	4 (4.0%)	3 (2.8%)	7 (3.3%)
	Normal	Low	0	1 (0.9%)	1 (0.5%)
		Normal	88 (87.1%)	92 (85.2%)	180 (86.1%)
		High	3 (3.0%)	1 (0.9%)	4 (1.9%)
	High	Normal	1 (1.0%)	2 (1.9%)	3 (1.4%)
		High	2 (2.0%)	0	2 (1.0%)
Aspartate Aminotransferase (U/L)					
Week 4	m		100	108	208
	Low	Normal	2 (2.0%)	0	2 (1.0%)
	Normal	Normal	90 (90.0%)	101 (93.5%)	191 (91.8%)
		High	1 (1.0%)	1 (0.9%)	2 (1.0%)
	High	Normal	1 (1.0%)	4 (3.7%)	5 (2.4%)
		High	6 (6.0%)	2 (1.9%)	8 (3.8%)
Week 8	m		99	108	207
	Low	Normal	2 (2.0%)	0	2 (1.0%)
	Normal	Normal	88 (88.9%)	102 (94.4%)	190 (91.8%)
		High	3 (3.0%)	0	3 (1.4%)
	High	Normal	3 (3.0%)	5 (4.6%)	8 (3.9%)
		High	3 (3.0%)	1 (0.9%)	4 (1.9%)
Week 12	m		101	108	209
	Low	Normal	2 (2.0%)	0	2 (1.0%)
	Normal	Normal	91 (90.1%)	99 (91.7%)	190 (90.9%)
		High	1 (1.0%)	3 (2.8%)	4 (1.9%)
	High	Normal	4 (4.0%)	5 (4.6%)	9 (4.3%)
		High	3 (3.0%)	1 (0.9%)	4 (1.9%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
Week 16	m		98	108	206
	Low	Normal	2 (2.0%)	0	2 (1.0%)
	Normal	Normal	88 (89.8%)	98 (90.7%)	186 (90.3%)
		High	1 (1.0%)	4 (3.7%)	5 (2.4%)
	High	Normal	3 (3.1%)	5 (4.6%)	8 (3.9%)
		High	4 (4.1%)	1 (0.9%)	5 (2.4%)
Week 20	m		99	108	207
	Low	Normal	2 (2.0%)	0	2 (1.0%)
	Normal	Normal	89 (89.9%)	98 (90.7%)	187 (90.3%)
		High	1 (1.0%)	4 (3.7%)	5 (2.4%)
	High	Normal	3 (3.0%)	5 (4.6%)	8 (3.9%)
		High	4 (4.0%)	1 (0.9%)	5 (2.4%)
Week 24	m		98	107	205
	Low	Normal	2 (2.0%)	0	2 (1.0%)
	Normal	Normal	89 (90.8%)	98 (91.6%)	187 (91.2%)
		High	0	3 (2.8%)	3 (1.5%)
	High	Normal	3 (3.1%)	5 (4.7%)	8 (3.9%)
		High	4 (4.1%)	1 (0.9%)	5 (2.4%)
Week 32	m		98	108	206
	Low	Low	1 (1.0%)	0	1 (0.5%)
		Normal	1 (1.0%)	0	1 (0.5%)
	Normal	Normal	89 (90.8%)	100 (92.6%)	189 (91.7%)
		High	0	2 (1.9%)	2 (1.0%)
	High	Normal	4 (4.1%)	5 (4.6%)	9 (4.4%)
		High	3 (3.1%)	1 (0.9%)	4 (1.9%)
Week 36	m		98	108	206
	Low	Normal	2 (2.0%)	0	2 (1.0%)
	Normal	Normal	89 (90.8%)	101 (93.5%)	190 (92.2%)
		High	0	1 (0.9%)	1 (0.5%)
	High	Normal	4 (4.1%)	5 (4.6%)	9 (4.4%)
		High	3 (3.1%)	1 (0.9%)	4 (1.9%)
Week 40	m		0	106	106
	Normal	Normal	.	96 (90.6%)	96 (90.6%)
		High	.	5 (4.7%)	5 (4.7%)
	High	Normal	.	3 (2.8%)	3 (2.8%)
		High	.	2 (1.9%)	2 (1.9%)
Week 44	m		0	107	107
	Normal	Low	.	1 (0.9%)	1 (0.9%)
		Normal	.	96 (89.7%)	96 (89.7%)
		High	.	4 (3.7%)	4 (3.7%)
	High	Normal	.	5 (4.7%)	5 (4.7%)
		High	.	1 (0.9%)	1 (0.9%)
Week 48	m		0	106	106

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
	Normal	Normal	.	97 (91.5%)	97 (91.5%)
		High	.	3 (2.8%)	3 (2.8%)
	High	Normal	.	4 (3.8%)	4 (3.8%)
		High	.	2 (1.9%)	2 (1.9%)
Week 52	m		0	106	106
	Normal	Normal	.	98 (92.5%)	98 (92.5%)
		High	.	2 (1.9%)	2 (1.9%)
	High	Normal	.	4 (3.8%)	4 (3.8%)
		High	.	2 (1.9%)	2 (1.9%)
LOCF Endpoint	m		101	108	209
	Low	Normal	2 (2.0%)	0	2 (1.0%)
	Normal	Normal	92 (91.1%)	100 (92.6%)	192 (91.9%)
		High	0	2 (1.9%)	2 (1.0%)
	High	Normal	4 (4.0%)	4 (3.7%)	8 (3.8%)
		High	3 (3.0%)	2 (1.9%)	5 (2.4%)
Bicarbonate (mmol/L)					
Week 4	m		100	108	208
	Normal	Low	1 (1.0%)	0	1 (0.5%)
		Normal	99 (99.0%)	108 (100.0%)	207 (99.5%)
Week 8	m		101	108	209
	Normal	Low	0	1 (0.9%)	1 (0.5%)
		Normal	101 (100.0%)	107 (99.1%)	208 (99.5%)
Week 12	m		101	108	209
	Normal	Normal	101 (100.0%)	108 (100.0%)	209 (100.0%)
Week 16	m		99	108	207
	Normal	Normal	99 (100.0%)	108 (100.0%)	207 (100.0%)
Week 20	m		99	108	207
	Normal	Low	0	1 (0.9%)	1 (0.5%)
		Normal	99 (100.0%)	107 (99.1%)	206 (99.5%)
Week 24	m		99	108	207
	Normal	Low	0	1 (0.9%)	1 (0.5%)
		Normal	99 (100.0%)	107 (99.1%)	206 (99.5%)
Week 32	m		98	108	206
	Normal	Normal	98 (100.0%)	108 (100.0%)	206 (100.0%)
Week 36	m		98	108	206
	Normal	Low	2 (2.0%)	1 (0.9%)	3 (1.5%)
		Normal	96 (98.0%)	107 (99.1%)	203 (98.5%)
Week 40	m		0	107	107
	Normal	Normal	.	107 (100.0%)	107 (100.0%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
Week 44	m		0	107	107
	Normal	Normal	.	107 (100.0%)	107 (100.0%)
Week 48	m		0	107	107
	Normal	Low	.	1 (0.9%)	1 (0.9%)
		Normal	.	106 (99.1%)	106 (99.1%)
Week 52	m		0	107	107
	Normal	Normal	.	107 (100.0%)	107 (100.0%)
LOCF Endpoint	m		101	108	209
	Normal	Low	2 (2.0%)	0	2 (1.0%)
		Normal	99 (98.0%)	108 (100.0%)	207 (99.0%)
Bilirubin (umol/L)					
Week 4	m		100	108	208
	Low	Low	1 (1.0%)	0	1 (0.5%)
		Normal	2 (2.0%)	0	2 (1.0%)
	Normal	Normal	92 (92.0%)	104 (96.3%)	196 (94.2%)
		High	1 (1.0%)	2 (1.9%)	3 (1.4%)
	High	Normal	3 (3.0%)	1 (0.9%)	4 (1.9%)
		High	1 (1.0%)	1 (0.9%)	2 (1.0%)
Week 8	m		101	108	209
	Low	Normal	3 (3.0%)	0	3 (1.4%)
	Normal	Normal	94 (93.1%)	104 (96.3%)	198 (94.7%)
		High	0	2 (1.9%)	2 (1.0%)
	High	Normal	3 (3.0%)	2 (1.9%)	5 (2.4%)
		High	1 (1.0%)	0	1 (0.5%)
Week 12	m		101	108	209
	Low	Normal	3 (3.0%)	0	3 (1.4%)
	Normal	Normal	94 (93.1%)	104 (96.3%)	198 (94.7%)
		High	0	2 (1.9%)	2 (1.0%)
	High	Normal	4 (4.0%)	2 (1.9%)	6 (2.9%)
Week 16	m		99	108	207
	Low	Normal	2 (2.0%)	0	2 (1.0%)
	Normal	Normal	94 (94.9%)	104 (96.3%)	198 (95.7%)
		High	0	2 (1.9%)	2 (1.0%)
	High	Normal	3 (3.0%)	2 (1.9%)	5 (2.4%)
Week 20	m		99	108	207
	Low	Normal	2 (2.0%)	0	2 (1.0%)
	Normal	Low	0	2 (1.9%)	2 (1.0%)
		Normal	94 (94.9%)	103 (95.4%)	197 (95.2%)
		High	0	1 (0.9%)	1 (0.5%)
	High	Normal	3 (3.0%)	1 (0.9%)	4 (1.9%)
		High	0	1 (0.9%)	1 (0.5%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
Week 24	m		99	108	207
	Low	Normal	2 (2.0%)	0	2 (1.0%)
	Normal	Low	0	1 (0.9%)	1 (0.5%)
		Normal	94 (94.9%)	104 (96.3%)	198 (95.7%)
		High	0	1 (0.9%)	1 (0.5%)
	High	Normal	1 (1.0%)	2 (1.9%)	3 (1.4%)
		High	2 (2.0%)	0	2 (1.0%)
Week 32	m		98	108	206
	Low	Normal	2 (2.0%)	0	2 (1.0%)
	Normal	Low	1 (1.0%)	0	1 (0.5%)
		Normal	92 (93.9%)	106 (98.1%)	198 (96.1%)
	High	Normal	2 (2.0%)	2 (1.9%)	4 (1.9%)
		High	1 (1.0%)	0	1 (0.5%)
Week 36	m		98	108	206
	Low	Normal	2 (2.0%)	0	2 (1.0%)
	Normal	Low	2 (2.0%)	0	2 (1.0%)
		Normal	91 (92.9%)	105 (97.2%)	196 (95.1%)
		High	0	1 (0.9%)	1 (0.5%)
	High	Normal	2 (2.0%)	2 (1.9%)	4 (1.9%)
		High	1 (1.0%)	0	1 (0.5%)
Week 40	m		0	107	107
	Normal	Low	.	1 (0.9%)	1 (0.9%)
		Normal	.	104 (97.2%)	104 (97.2%)
	High	Normal	.	2 (1.9%)	2 (1.9%)
Week 44	m		0	107	107
	Normal	Normal	.	105 (98.1%)	105 (98.1%)
	High	Normal	.	2 (1.9%)	2 (1.9%)
Week 48	m		0	107	107
	Normal	Normal	.	105 (98.1%)	105 (98.1%)
	High	Normal	.	2 (1.9%)	2 (1.9%)
Week 52	m		0	107	107
	Normal	Low	.	3 (2.8%)	3 (2.8%)
		Normal	.	102 (95.3%)	102 (95.3%)
	High	Normal	.	1 (0.9%)	1 (0.9%)
		High	.	1 (0.9%)	1 (0.9%)
LOCF Endpoint	m		101	108	209
	Low	Normal	3 (3.0%)	0	3 (1.4%)
	Normal	Low	2 (2.0%)	3 (2.8%)	5 (2.4%)
		Normal	92 (91.1%)	103 (95.4%)	195 (93.3%)
	High	Normal	3 (3.0%)	1 (0.9%)	4 (1.9%)
		High	1 (1.0%)	1 (0.9%)	2 (1.0%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
Calcium (mmol/L)					
Week 4	m		100	108	208
	Low	Normal	0	1 (0.9%)	1 (0.5%)
	Normal	Normal	100 (100.0%)	107 (99.1%)	207 (99.5%)
Week 8	m		101	108	209
	Low	Normal	0	1 (0.9%)	1 (0.5%)
	Normal	Normal	101 (100.0%)	107 (99.1%)	208 (99.5%)
Week 12	m		101	108	209
	Low	Normal	0	1 (0.9%)	1 (0.5%)
	Normal	Normal	101 (100.0%)	107 (99.1%)	208 (99.5%)
Week 16	m		99	108	207
	Low	Normal	0	1 (0.9%)	1 (0.5%)
	Normal	Normal	99 (100.0%)	107 (99.1%)	206 (99.5%)
Week 20	m		99	108	207
	Low	Normal	0	1 (0.9%)	1 (0.5%)
	Normal	Low	1 (1.0%)	0	1 (0.5%)
		Normal	98 (99.0%)	106 (98.1%)	204 (98.6%)
		High	0	1 (0.9%)	1 (0.5%)
Week 24	m		99	108	207
	Low	Normal	0	1 (0.9%)	1 (0.5%)
	Normal	Normal	99 (100.0%)	106 (98.1%)	205 (99.0%)
		High	0	1 (0.9%)	1 (0.5%)
Week 32	m		98	108	206
	Low	Normal	0	1 (0.9%)	1 (0.5%)
	Normal	Normal	98 (100.0%)	107 (99.1%)	205 (99.5%)
Week 36	m		98	108	206
	Low	Normal	0	1 (0.9%)	1 (0.5%)
	Normal	Normal	98 (100.0%)	107 (99.1%)	205 (99.5%)
Week 40	m		0	107	107
	Low	Normal	.	1 (0.9%)	1 (0.9%)
	Normal	Normal	.	106 (99.1%)	106 (99.1%)
Week 44	m		0	107	107
	Low	Normal	.	1 (0.9%)	1 (0.9%)
	Normal	Low	.	1 (0.9%)	1 (0.9%)
		Normal	.	105 (98.1%)	105 (98.1%)
Week 48	m		0	107	107
	Low	Normal	.	1 (0.9%)	1 (0.9%)
	Normal	Low	.	1 (0.9%)	1 (0.9%)
		Normal	.	105 (98.1%)	105 (98.1%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
Week 52	m		0	107	107
	Low	Normal	.	1 (0.9%)	1 (0.9%)
	Normal	Normal	.	106 (99.1%)	106 (99.1%)
LOCF Endpoint	m		101	108	209
	Low	Normal	0	1 (0.9%)	1 (0.5%)
	Normal	Normal	101 (100.0%)	107 (99.1%)	208 (99.5%)
Chloride (mmol/L)					
Week 4	m		100	108	208
	Low	Normal	1 (1.0%)	0	1 (0.5%)
	Normal	Low	0	1 (0.9%)	1 (0.5%)
		Normal	99 (99.0%)	107 (99.1%)	206 (99.0%)
Week 8	m		101	108	209
	Low	Normal	1 (1.0%)	0	1 (0.5%)
	Normal	Low	1 (1.0%)	0	1 (0.5%)
		Normal	99 (98.0%)	108 (100.0%)	207 (99.0%)
Week 12	m		101	108	209
	Low	Low	1 (1.0%)	0	1 (0.5%)
	Normal	Low	0	1 (0.9%)	1 (0.5%)
		Normal	100 (99.0%)	107 (99.1%)	207 (99.0%)
Week 16	m		99	108	207
	Low	Low	1 (1.0%)	0	1 (0.5%)
	Normal	Normal	98 (99.0%)	108 (100.0%)	206 (99.5%)
Week 20	m		99	108	207
	Low	Normal	1 (1.0%)	0	1 (0.5%)
	Normal	Low	0	2 (1.9%)	2 (1.0%)
		Normal	98 (99.0%)	106 (98.1%)	204 (98.6%)
Week 24	m		99	108	207
	Low	Low	1 (1.0%)	0	1 (0.5%)
	Normal	Low	0	2 (1.9%)	2 (1.0%)
		Normal	98 (99.0%)	106 (98.1%)	204 (98.6%)
Week 32	m		98	108	206
	Low	Normal	1 (1.0%)	0	1 (0.5%)
	Normal	Normal	97 (99.0%)	108 (100.0%)	205 (99.5%)
Week 36	m		98	108	206
	Low	Low	1 (1.0%)	0	1 (0.5%)
	Normal	Normal	97 (99.0%)	108 (100.0%)	205 (99.5%)
Week 40	m		0	107	107
	Normal	Normal	.	107 (100.0%)	107 (100.0%)
Week 44	m		0	107	107

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
	Normal	Normal	.	107 (100.0%)	107 (100.0%)
Week 48	m		0	107	107
	Normal	Normal	.	107 (100.0%)	107 (100.0%)
Week 52	m		0	107	107
	Normal	Normal	.	107 (100.0%)	107 (100.0%)
LOCF Endpoint	m		101	108	209
	Low	Low	1 (1.0%)	0	1 (0.5%)
	Normal	Normal	100 (99.0%)	108 (100.0%)	208 (99.5%)
Creatine Kinase (U/L)					
Week 4	m		100	108	208
	Normal	Normal	91 (91.0%)	98 (90.7%)	189 (90.9%)
		High	5 (5.0%)	4 (3.7%)	9 (4.3%)
	High	Normal	3 (3.0%)	6 (5.6%)	9 (4.3%)
		High	1 (1.0%)	0	1 (0.5%)
Week 8	m		100	108	208
	Normal	Normal	96 (96.0%)	100 (92.6%)	196 (94.2%)
		High	0	2 (1.9%)	2 (1.0%)
	High	Normal	3 (3.0%)	4 (3.7%)	7 (3.4%)
		High	1 (1.0%)	2 (1.9%)	3 (1.4%)
Week 12	m		101	108	209
	Normal	Normal	95 (94.1%)	98 (90.7%)	193 (92.3%)
		High	2 (2.0%)	4 (3.7%)	6 (2.9%)
	High	Normal	3 (3.0%)	4 (3.7%)	7 (3.3%)
		High	1 (1.0%)	2 (1.9%)	3 (1.4%)
Week 16	m		99	108	207
	Normal	Normal	91 (91.9%)	99 (91.7%)	190 (91.8%)
		High	4 (4.0%)	3 (2.8%)	7 (3.4%)
	High	Normal	4 (4.0%)	4 (3.7%)	8 (3.9%)
		High	0	2 (1.9%)	2 (1.0%)
Week 20	m		99	108	207
	Normal	Normal	90 (90.9%)	98 (90.7%)	188 (90.8%)
		High	5 (5.1%)	4 (3.7%)	9 (4.3%)
	High	Normal	2 (2.0%)	4 (3.7%)	6 (2.9%)
		High	2 (2.0%)	2 (1.9%)	4 (1.9%)
Week 24	m		99	108	207
	Normal	Normal	92 (92.9%)	97 (89.8%)	189 (91.3%)
		High	3 (3.0%)	5 (4.6%)	8 (3.9%)
	High	Normal	3 (3.0%)	5 (4.6%)	8 (3.9%)
		High	1 (1.0%)	1 (0.9%)	2 (1.0%)
Week 32	m		98	108	206

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
	Normal	Normal	91 (92.9%)	96 (88.9%)	187 (90.8%)
		High	3 (3.1%)	6 (5.6%)	9 (4.4%)
	High	Normal	3 (3.1%)	3 (2.8%)	6 (2.9%)
		High	1 (1.0%)	3 (2.8%)	4 (1.9%)
Week 36	m		98	108	206
	Normal	Normal	92 (93.9%)	99 (91.7%)	191 (92.7%)
		High	2 (2.0%)	3 (2.8%)	5 (2.4%)
	High	Normal	3 (3.1%)	5 (4.6%)	8 (3.9%)
		High	1 (1.0%)	1 (0.9%)	2 (1.0%)
Week 40	m		0	107	107
	Normal	Normal	.	95 (88.8%)	95 (88.8%)
		High	.	6 (5.6%)	6 (5.6%)
	High	Normal	.	4 (3.7%)	4 (3.7%)
		High	.	2 (1.9%)	2 (1.9%)
Week 44	m		0	107	107
	Normal	Normal	.	99 (92.5%)	99 (92.5%)
		High	.	2 (1.9%)	2 (1.9%)
	High	Normal	.	3 (2.8%)	3 (2.8%)
		High	.	3 (2.8%)	3 (2.8%)
Week 48	m		0	107	107
	Normal	Normal	.	97 (90.7%)	97 (90.7%)
		High	.	4 (3.7%)	4 (3.7%)
	High	Normal	.	3 (2.8%)	3 (2.8%)
		High	.	3 (2.8%)	3 (2.8%)
Week 52	m		0	107	107
	Normal	Normal	.	98 (91.6%)	98 (91.6%)
		High	.	3 (2.8%)	3 (2.8%)
	High	Normal	.	4 (3.7%)	4 (3.7%)
		High	.	2 (1.9%)	2 (1.9%)
LOCF Endpoint	m		101	108	209
	Normal	Normal	95 (94.1%)	99 (91.7%)	194 (92.8%)
		High	2 (2.0%)	3 (2.8%)	5 (2.4%)
	High	Normal	3 (3.0%)	4 (3.7%)	7 (3.3%)
		High	1 (1.0%)	2 (1.9%)	3 (1.4%)
Creatinine (umol/L)					
Week 4	m		100	108	208
	Normal	Normal	100 (100.0%)	108 (100.0%)	208 (100.0%)
Week 8	m		101	108	209
	Normal	Normal	101 (100.0%)	108 (100.0%)	209 (100.0%)
Week 12	m		101	108	209
	Normal	Normal	101 (100.0%)	108 (100.0%)	209 (100.0%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
Week 16	m		99	108	207
	Normal	Normal	99 (100.0%)	108 (100.0%)	207 (100.0%)
Week 20	m		99	108	207
	Normal	Normal	99 (100.0%)	108 (100.0%)	207 (100.0%)
Week 24	m		99	108	207
	Normal	Normal	99 (100.0%)	108 (100.0%)	207 (100.0%)
Week 32	m		98	108	206
	Normal	Normal	98 (100.0%)	108 (100.0%)	206 (100.0%)
Week 36	m		98	108	206
	Normal	Normal	98 (100.0%)	108 (100.0%)	206 (100.0%)
Week 40	m		0	107	107
	Normal	Normal	.	107 (100.0%)	107 (100.0%)
Week 44	m		0	107	107
	Normal	Normal	.	107 (100.0%)	107 (100.0%)
Week 48	m		0	107	107
	Normal	Normal	.	107 (100.0%)	107 (100.0%)
Week 52	m		0	107	107
	Normal	Normal	.	107 (100.0%)	107 (100.0%)
LOCF Endpoint	m		101	108	209
	Normal	Normal	101 (100.0%)	108 (100.0%)	209 (100.0%)
Gamma Glutamyl Transferase (U/L)					
Week 4	m		100	108	208
	Normal	Low	0	1 (0.9%)	1 (0.5%)
		Normal	86 (86.0%)	92 (85.2%)	178 (85.6%)
		High	2 (2.0%)	1 (0.9%)	3 (1.4%)
	High	Normal	3 (3.0%)	1 (0.9%)	4 (1.9%)
		High	9 (9.0%)	13 (12.0%)	22 (10.6%)
Week 8	m		101	108	209
	Normal	Low	0	2 (1.9%)	2 (1.0%)
		Normal	86 (85.1%)	91 (84.3%)	177 (84.7%)
		High	2 (2.0%)	1 (0.9%)	3 (1.4%)
	High	Normal	5 (5.0%)	1 (0.9%)	6 (2.9%)
		High	8 (7.9%)	13 (12.0%)	21 (10.0%)
Week 12	m		101	108	209
	Normal	Low	0	1 (0.9%)	1 (0.5%)
		Normal	86 (85.1%)	93 (86.1%)	179 (85.6%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
		High	2 (2.0%)	0	2 (1.0%)
	High	Normal	5 (5.0%)	0	5 (2.4%)
		High	8 (7.9%)	14 (13.0%)	22 (10.5%)
Week 16	m		99	108	207
	Normal	Low	0	1 (0.9%)	1 (0.5%)
		Normal	83 (83.8%)	90 (83.3%)	173 (83.6%)
		High	3 (3.0%)	3 (2.8%)	6 (2.9%)
	High	Normal	6 (6.1%)	2 (1.9%)	8 (3.9%)
		High	7 (7.1%)	12 (11.1%)	19 (9.2%)
Week 20	m		99	108	207
	Normal	Low	0	2 (1.9%)	2 (1.0%)
		Normal	83 (83.8%)	91 (84.3%)	174 (84.1%)
		High	3 (3.0%)	1 (0.9%)	4 (1.9%)
	High	Normal	8 (8.1%)	2 (1.9%)	10 (4.8%)
		High	5 (5.1%)	12 (11.1%)	17 (8.2%)
Week 24	m		99	108	207
	Normal	Low	0	2 (1.9%)	2 (1.0%)
		Normal	84 (84.8%)	90 (83.3%)	174 (84.1%)
		High	2 (2.0%)	2 (1.9%)	4 (1.9%)
	High	Normal	7 (7.1%)	3 (2.8%)	10 (4.8%)
		High	6 (6.1%)	11 (10.2%)	17 (8.2%)
Week 32	m		98	108	206
	Normal	Low	0	1 (0.9%)	1 (0.5%)
		Normal	84 (85.7%)	88 (81.5%)	172 (83.5%)
		High	2 (2.0%)	5 (4.6%)	7 (3.4%)
	High	Normal	7 (7.1%)	4 (3.7%)	11 (5.3%)
		High	5 (5.1%)	10 (9.3%)	15 (7.3%)
Week 36	m		98	108	206
	Normal	Low	1 (1.0%)	0	1 (0.5%)
		Normal	81 (82.7%)	90 (83.3%)	171 (83.0%)
		High	4 (4.1%)	4 (3.7%)	8 (3.9%)
	High	Normal	5 (5.1%)	4 (3.7%)	9 (4.4%)
		High	7 (7.1%)	10 (9.3%)	17 (8.3%)
Week 40	m		0	107	107
	Normal	Low	.	3 (2.8%)	3 (2.8%)
		Normal	.	88 (82.2%)	88 (82.2%)
		High	.	2 (1.9%)	2 (1.9%)
	High	Normal	.	5 (4.7%)	5 (4.7%)
		High	.	9 (8.4%)	9 (8.4%)
Week 44	m		0	107	107
	Normal	Low	.	2 (1.9%)	2 (1.9%)
		Normal	.	88 (82.2%)	88 (82.2%)
		High	.	3 (2.8%)	3 (2.8%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
	High	Normal	.	6 (5.6%)	6 (5.6%)
		High	.	8 (7.5%)	8 (7.5%)
Week 48	m		0	107	107
	Normal	Low	.	1 (0.9%)	1 (0.9%)
		Normal	.	90 (84.1%)	90 (84.1%)
		High	.	2 (1.9%)	2 (1.9%)
	High	Normal	.	6 (5.6%)	6 (5.6%)
		High	.	8 (7.5%)	8 (7.5%)
Week 52	m		0	107	107
	Normal	Normal	.	90 (84.1%)	90 (84.1%)
		High	.	3 (2.8%)	3 (2.8%)
	High	Normal	.	5 (4.7%)	5 (4.7%)
		High	.	9 (8.4%)	9 (8.4%)
LOCF Endpoint	m		101	108	209
	Normal	Low	1 (1.0%)	0	1 (0.5%)
		Normal	82 (81.2%)	91 (84.3%)	173 (82.8%)
		High	5 (5.0%)	3 (2.8%)	8 (3.8%)
	High	Normal	6 (5.9%)	5 (4.6%)	11 (5.3%)
		High	7 (6.9%)	9 (8.3%)	16 (7.7%)
Lipase (U/L)					
Week 4	m		100	108	208
	Normal	Normal	99 (99.0%)	107 (99.1%)	206 (99.0%)
	High	Normal	1 (1.0%)	1 (0.9%)	2 (1.0%)
Week 8	m		101	108	209
	Normal	Normal	98 (97.0%)	107 (99.1%)	205 (98.1%)
		High	2 (2.0%)	0	2 (1.0%)
	High	Normal	1 (1.0%)	1 (0.9%)	2 (1.0%)
Week 12	m		101	108	209
	Normal	Normal	98 (97.0%)	107 (99.1%)	205 (98.1%)
		High	2 (2.0%)	0	2 (1.0%)
	High	Normal	1 (1.0%)	1 (0.9%)	2 (1.0%)
Week 16	m		99	108	207
	Normal	Normal	96 (97.0%)	106 (98.1%)	202 (97.6%)
		High	2 (2.0%)	1 (0.9%)	3 (1.4%)
	High	Normal	1 (1.0%)	1 (0.9%)	2 (1.0%)
Week 20	m		99	108	207
	Normal	Normal	98 (99.0%)	107 (99.1%)	205 (99.0%)
	High	Normal	1 (1.0%)	1 (0.9%)	2 (1.0%)
Week 24	m		99	108	207
	Normal	Normal	97 (98.0%)	106 (98.1%)	203 (98.1%)
		High	1 (1.0%)	1 (0.9%)	2 (1.0%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
	High	Normal	1 (1.0%)	1 (0.9%)	2 (1.0%)
Week 32	m		98	108	206
	Normal	Normal	97 (99.0%)	107 (99.1%)	204 (99.0%)
	High	Normal	1 (1.0%)	1 (0.9%)	2 (1.0%)
Week 36	m		98	108	206
	Normal	Normal	93 (94.9%)	107 (99.1%)	200 (97.1%)
		High	4 (4.1%)	0	4 (1.9%)
	High	Normal	1 (1.0%)	1 (0.9%)	2 (1.0%)
Week 40	m		0	107	107
	Normal	Normal	.	105 (98.1%)	105 (98.1%)
		High	.	1 (0.9%)	1 (0.9%)
	High	Normal	.	1 (0.9%)	1 (0.9%)
Week 44	m		0	107	107
	Normal	Normal	.	106 (99.1%)	106 (99.1%)
	High	Normal	.	1 (0.9%)	1 (0.9%)
Week 48	m		0	107	107
	Normal	Normal	.	106 (99.1%)	106 (99.1%)
	High	Normal	.	1 (0.9%)	1 (0.9%)
Week 52	m		0	107	107
	Normal	Normal	.	106 (99.1%)	106 (99.1%)
	High	Normal	.	1 (0.9%)	1 (0.9%)
LOCF Endpoint	m		101	108	209
	Normal	Normal	96 (95.0%)	107 (99.1%)	203 (97.1%)
		High	4 (4.0%)	0	4 (1.9%)
	High	Normal	1 (1.0%)	1 (0.9%)	2 (1.0%)
Phosphate (mmol/L)					
Week 4	m		100	108	208
	Normal	Low	0	1 (0.9%)	1 (0.5%)
		Normal	100 (100.0%)	106 (98.1%)	206 (99.0%)
	High	Normal	0	1 (0.9%)	1 (0.5%)
Week 8	m		101	108	209
	Normal	Normal	101 (100.0%)	107 (99.1%)	208 (99.5%)
	High	Normal	0	1 (0.9%)	1 (0.5%)
Week 12	m		101	108	209
	Normal	Normal	101 (100.0%)	106 (98.1%)	207 (99.0%)
		High	0	1 (0.9%)	1 (0.5%)
	High	Normal	0	1 (0.9%)	1 (0.5%)
Week 16	m		99	108	207
	Normal	Normal	99 (100.0%)	107 (99.1%)	206 (99.5%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
	High	Normal	0	1 (0.9%)	1 (0.5%)
Week 20	m		99	108	207
	Normal	Low	1 (1.0%)	1 (0.9%)	2 (1.0%)
		Normal	98 (99.0%)	106 (98.1%)	204 (98.6%)
	High	High	0	1 (0.9%)	1 (0.5%)
Week 24	m		99	108	207
	Normal	Normal	99 (100.0%)	107 (99.1%)	206 (99.5%)
	High	High	0	1 (0.9%)	1 (0.5%)
Week 32	m		98	108	206
	Normal	Normal	98 (100.0%)	107 (99.1%)	205 (99.5%)
	High	Normal	0	1 (0.9%)	1 (0.5%)
Week 36	m		98	108	206
	Normal	Normal	98 (100.0%)	107 (99.1%)	205 (99.5%)
	High	Normal	0	1 (0.9%)	1 (0.5%)
Week 40	m		0	107	107
	Normal	Normal	.	106 (99.1%)	106 (99.1%)
	High	Normal	.	1 (0.9%)	1 (0.9%)
Week 44	m		0	107	107
	Normal	Normal	.	106 (99.1%)	106 (99.1%)
	High	Normal	.	1 (0.9%)	1 (0.9%)
Week 48	m		0	107	107
	Normal	Low	.	1 (0.9%)	1 (0.9%)
		Normal	.	105 (98.1%)	105 (98.1%)
	High	Normal	.	1 (0.9%)	1 (0.9%)
Week 52	m		0	107	107
	Normal	Normal	.	106 (99.1%)	106 (99.1%)
	High	Normal	.	1 (0.9%)	1 (0.9%)
LOCF Endpoint	m		101	108	209
	Normal	Normal	101 (100.0%)	107 (99.1%)	208 (99.5%)
	High	Normal	0	1 (0.9%)	1 (0.5%)
Potassium (mmol/L)					
Week 4	m		100	108	208
	Low	Normal	0	1 (0.9%)	1 (0.5%)
	Normal	Normal	98 (98.0%)	106 (98.1%)	204 (98.1%)
		High	1 (1.0%)	1 (0.9%)	2 (1.0%)
	High	Normal	1 (1.0%)	0	1 (0.5%)
Week 8	m		100	108	208
	Low	Normal	0	1 (0.9%)	1 (0.5%)
	Normal	Normal	98 (98.0%)	106 (98.1%)	204 (98.1%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
		High	1 (1.0%)	1 (0.9%)	2 (1.0%)
	High	Normal	1 (1.0%)	0	1 (0.5%)
Week 12	m		101	108	209
	Low	Normal	0	1 (0.9%)	1 (0.5%)
	Normal	Normal	100 (99.0%)	107 (99.1%)	207 (99.0%)
	High	Normal	1 (1.0%)	0	1 (0.5%)
Week 16	m		99	108	207
	Low	Normal	0	1 (0.9%)	1 (0.5%)
	Normal	Normal	98 (99.0%)	106 (98.1%)	204 (98.6%)
		High	0	1 (0.9%)	1 (0.5%)
	High	Normal	1 (1.0%)	0	1 (0.5%)
Week 20	m		99	108	207
	Low	Low	0	1 (0.9%)	1 (0.5%)
	Normal	Normal	98 (99.0%)	106 (98.1%)	204 (98.6%)
		High	0	1 (0.9%)	1 (0.5%)
	High	Normal	1 (1.0%)	0	1 (0.5%)
Week 24	m		99	108	207
	Low	Normal	0	1 (0.9%)	1 (0.5%)
	Normal	Normal	98 (99.0%)	104 (96.3%)	202 (97.6%)
		High	0	3 (2.8%)	3 (1.4%)
	High	Normal	1 (1.0%)	0	1 (0.5%)
Week 32	m		98	108	206
	Low	Normal	0	1 (0.9%)	1 (0.5%)
	Normal	Low	1 (1.0%)	0	1 (0.5%)
		Normal	95 (96.9%)	105 (97.2%)	200 (97.1%)
		High	1 (1.0%)	2 (1.9%)	3 (1.5%)
	High	Normal	1 (1.0%)	0	1 (0.5%)
Week 36	m		98	108	206
	Low	Normal	0	1 (0.9%)	1 (0.5%)
	Normal	Normal	97 (99.0%)	105 (97.2%)	202 (98.1%)
		High	0	2 (1.9%)	2 (1.0%)
	High	Normal	1 (1.0%)	0	1 (0.5%)
Week 40	m		0	107	107
	Low	Normal	.	1 (0.9%)	1 (0.9%)
	Normal	Normal	.	105 (98.1%)	105 (98.1%)
		High	.	1 (0.9%)	1 (0.9%)
Week 44	m		0	107	107
	Low	Normal	.	1 (0.9%)	1 (0.9%)
	Normal	Normal	.	106 (99.1%)	106 (99.1%)
Week 48	m		0	107	107
	Low	Normal	.	1 (0.9%)	1 (0.9%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
	Normal	Normal	.	105 (98.1%)	105 (98.1%)
		High	.	1 (0.9%)	1 (0.9%)
Week 52	m		0	107	107
	Low	Low	.	1 (0.9%)	1 (0.9%)
	Normal	Normal	.	106 (99.1%)	106 (99.1%)
LOCF Endpoint	m		101	108	209
	Low	Low	0	1 (0.9%)	1 (0.5%)
	Normal	Normal	100 (99.0%)	107 (99.1%)	207 (99.0%)
	High	Normal	1 (1.0%)	0	1 (0.5%)
Protein (g/L)					
Week 4	m		100	108	208
	Low	Normal	0	3 (2.8%)	3 (1.4%)
	Normal	Low	0	1 (0.9%)	1 (0.5%)
		Normal	97 (97.0%)	103 (95.4%)	200 (96.2%)
	High	Normal	2 (2.0%)	1 (0.9%)	3 (1.4%)
		High	1 (1.0%)	0	1 (0.5%)
Week 8	m		101	108	209
	Low	Normal	0	3 (2.8%)	3 (1.4%)
	Normal	Normal	95 (94.1%)	104 (96.3%)	199 (95.2%)
		High	3 (3.0%)	0	3 (1.4%)
	High	Normal	2 (2.0%)	1 (0.9%)	3 (1.4%)
		High	1 (1.0%)	0	1 (0.5%)
Week 12	m		101	108	209
	Low	Normal	0	3 (2.8%)	3 (1.4%)
	Normal	Normal	98 (97.0%)	104 (96.3%)	202 (96.7%)
	High	Normal	3 (3.0%)	1 (0.9%)	4 (1.9%)
Week 16	m		99	108	207
	Low	Low	0	1 (0.9%)	1 (0.5%)
		Normal	0	2 (1.9%)	2 (1.0%)
	Normal	Normal	96 (97.0%)	104 (96.3%)	200 (96.6%)
	High	Normal	2 (2.0%)	1 (0.9%)	3 (1.4%)
		High	1 (1.0%)	0	1 (0.5%)
Week 20	m		99	108	207
	Low	Normal	0	3 (2.8%)	3 (1.4%)
	Normal	Low	0	1 (0.9%)	1 (0.5%)
		Normal	96 (97.0%)	102 (94.4%)	198 (95.7%)
		High	0	1 (0.9%)	1 (0.5%)
	High	Normal	2 (2.0%)	0	2 (1.0%)
		High	1 (1.0%)	1 (0.9%)	2 (1.0%)
Week 24	m		99	108	207
	Low	Normal	0	3 (2.8%)	3 (1.4%)
	Normal	Normal	96 (97.0%)	104 (96.3%)	200 (96.6%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
	High	Normal	3 (3.0%)	0	3 (1.4%)
		High	0	1 (0.9%)	1 (0.5%)
Week 32	m		98	108	206
	Low	Normal	0	3 (2.8%)	3 (1.5%)
	Normal	Normal	94 (95.9%)	104 (96.3%)	198 (96.1%)
		High	1 (1.0%)	0	1 (0.5%)
	High	Normal	3 (3.1%)	1 (0.9%)	4 (1.9%)
Week 36	m		98	108	206
	Low	Low	0	1 (0.9%)	1 (0.5%)
		Normal	0	2 (1.9%)	2 (1.0%)
	Normal	Normal	95 (96.9%)	103 (95.4%)	198 (96.1%)
		High	0	1 (0.9%)	1 (0.5%)
	High	Normal	3 (3.1%)	1 (0.9%)	4 (1.9%)
Week 40	m		0	107	107
	Low	Low	.	1 (0.9%)	1 (0.9%)
		Normal	.	2 (1.9%)	2 (1.9%)
	Normal	Low	.	1 (0.9%)	1 (0.9%)
		Normal	.	102 (95.3%)	102 (95.3%)
	High	Normal	.	1 (0.9%)	1 (0.9%)
Week 44	m		0	107	107
	Low	Normal	.	3 (2.8%)	3 (2.8%)
	Normal	Low	.	1 (0.9%)	1 (0.9%)
		Normal	.	101 (94.4%)	101 (94.4%)
		High	.	1 (0.9%)	1 (0.9%)
	High	Normal	.	1 (0.9%)	1 (0.9%)
Week 48	m		0	107	107
	Low	Normal	.	3 (2.8%)	3 (2.8%)
	Normal	Normal	.	101 (94.4%)	101 (94.4%)
		High	.	2 (1.9%)	2 (1.9%)
	High	Normal	.	1 (0.9%)	1 (0.9%)
Week 52	m		0	107	107
	Low	Low	.	1 (0.9%)	1 (0.9%)
		Normal	.	2 (1.9%)	2 (1.9%)
	Normal	Normal	.	102 (95.3%)	102 (95.3%)
		High	.	1 (0.9%)	1 (0.9%)
	High	Normal	.	1 (0.9%)	1 (0.9%)
LOCF Endpoint	m		101	108	209
	Low	Low	0	1 (0.9%)	1 (0.5%)
		Normal	0	2 (1.9%)	2 (1.0%)
	Normal	Normal	98 (97.0%)	103 (95.4%)	201 (96.2%)
		High	0	1 (0.9%)	1 (0.5%)
	High	Normal	3 (3.0%)	1 (0.9%)	4 (1.9%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
Sodium (mmol/L)					
Week 4	m		100	108	208
	Low	Low	1 (1.0%)	0	1 (0.5%)
		Normal	0	1 (0.9%)	1 (0.5%)
	Normal	Normal	98 (98.0%)	106 (98.1%)	204 (98.1%)
		High	1 (1.0%)	0	1 (0.5%)
	High	Normal	0	1 (0.9%)	1 (0.5%)
Week 8	m		101	108	209
	Low	Low	0	1 (0.9%)	1 (0.5%)
		Normal	1 (1.0%)	0	1 (0.5%)
	Normal	Normal	100 (99.0%)	106 (98.1%)	206 (98.6%)
	High	Normal	0	1 (0.9%)	1 (0.5%)
Week 12	m		101	108	209
	Low	Low	1 (1.0%)	0	1 (0.5%)
		Normal	0	1 (0.9%)	1 (0.5%)
	Normal	Normal	100 (99.0%)	106 (98.1%)	206 (98.6%)
	High	Normal	0	1 (0.9%)	1 (0.5%)
Week 16	m		99	108	207
	Low	Low	1 (1.0%)	1 (0.9%)	2 (1.0%)
	Normal	Normal	97 (98.0%)	106 (98.1%)	203 (98.1%)
		High	1 (1.0%)	0	1 (0.5%)
	High	Normal	0	1 (0.9%)	1 (0.5%)
Week 20	m		99	108	207
	Low	Low	0	1 (0.9%)	1 (0.5%)
		Normal	1 (1.0%)	0	1 (0.5%)
	Normal	Normal	98 (99.0%)	106 (98.1%)	204 (98.6%)
	High	Normal	0	1 (0.9%)	1 (0.5%)
Week 24	m		99	108	207
	Low	Low	1 (1.0%)	1 (0.9%)	2 (1.0%)
	Normal	Normal	98 (99.0%)	106 (98.1%)	204 (98.6%)
	High	Normal	0	1 (0.9%)	1 (0.5%)
Week 32	m		98	108	206
	Low	Normal	1 (1.0%)	1 (0.9%)	2 (1.0%)
	Normal	Low	0	1 (0.9%)	1 (0.5%)
		Normal	97 (99.0%)	104 (96.3%)	201 (97.6%)
		High	0	1 (0.9%)	1 (0.5%)
	High	Normal	0	1 (0.9%)	1 (0.5%)
Week 36	m		98	108	206
	Low	Low	1 (1.0%)	1 (0.9%)	2 (1.0%)
	Normal	Normal	97 (99.0%)	105 (97.2%)	202 (98.1%)
		High	0	1 (0.9%)	1 (0.5%)
	High	Normal	0	1 (0.9%)	1 (0.5%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
Week 40	m		0	107	107
	Low	Normal	.	1 (0.9%)	1 (0.9%)
	Normal	Normal	.	104 (97.2%)	104 (97.2%)
		High	.	1 (0.9%)	1 (0.9%)
	High	Normal	.	1 (0.9%)	1 (0.9%)
Week 44	m		0	107	107
	Low	Normal	.	1 (0.9%)	1 (0.9%)
	Normal	Normal	.	105 (98.1%)	105 (98.1%)
	High	Normal	.	1 (0.9%)	1 (0.9%)
Week 48	m		0	107	107
	Low	Low	.	1 (0.9%)	1 (0.9%)
	Normal	Normal	.	104 (97.2%)	104 (97.2%)
		High	.	1 (0.9%)	1 (0.9%)
	High	Normal	.	1 (0.9%)	1 (0.9%)
Week 52	m		0	107	107
	Low	Normal	.	1 (0.9%)	1 (0.9%)
	Normal	Normal	.	105 (98.1%)	105 (98.1%)
	High	Normal	.	1 (0.9%)	1 (0.9%)
LOCF Endpoint	m		101	108	209
	Low	Low	1 (1.0%)	0	1 (0.5%)
		Normal	0	1 (0.9%)	1 (0.5%)
	Normal	Normal	100 (99.0%)	106 (98.1%)	206 (98.6%)
	High	Normal	0	1 (0.9%)	1 (0.5%)
Urate (umol/L)					
Week 4	m		100	108	208
	Low	Low	1 (1.0%)	1 (0.9%)	2 (1.0%)
		Normal	1 (1.0%)	2 (1.9%)	3 (1.4%)
	Normal	Low	0	1 (0.9%)	1 (0.5%)
		Normal	98 (98.0%)	103 (95.4%)	201 (96.6%)
	High	Normal	0	1 (0.9%)	1 (0.5%)
Week 8	m		101	108	209
	Low	Low	1 (1.0%)	2 (1.9%)	3 (1.4%)
		Normal	1 (1.0%)	1 (0.9%)	2 (1.0%)
	Normal	Normal	99 (98.0%)	104 (96.3%)	203 (97.1%)
	High	Normal	0	1 (0.9%)	1 (0.5%)
Week 12	m		101	108	209
	Low	Low	1 (1.0%)	2 (1.9%)	3 (1.4%)
		Normal	1 (1.0%)	1 (0.9%)	2 (1.0%)
	Normal	Low	0	1 (0.9%)	1 (0.5%)
		Normal	99 (98.0%)	103 (95.4%)	202 (96.7%)
	High	Normal	0	1 (0.9%)	1 (0.5%)
Week 16	m		99	108	207

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
	Low	Low	1 (1.0%)	0	1 (0.5%)
		Normal	1 (1.0%)	3 (2.8%)	4 (1.9%)
	Normal	Low	1 (1.0%)	1 (0.9%)	2 (1.0%)
		Normal	96 (97.0%)	103 (95.4%)	199 (96.1%)
	High	Normal	0	1 (0.9%)	1 (0.5%)
Week 20	m		99	108	207
	Low	Low	1 (1.0%)	2 (1.9%)	3 (1.4%)
		Normal	1 (1.0%)	1 (0.9%)	2 (1.0%)
	Normal	Low	0	2 (1.9%)	2 (1.0%)
		Normal	96 (97.0%)	102 (94.4%)	198 (95.7%)
		High	1 (1.0%)	0	1 (0.5%)
	High	Normal	0	1 (0.9%)	1 (0.5%)
Week 24	m		99	108	207
	Low	Low	1 (1.0%)	2 (1.9%)	3 (1.4%)
		Normal	1 (1.0%)	1 (0.9%)	2 (1.0%)
	Normal	Low	1 (1.0%)	0	1 (0.5%)
		Normal	96 (97.0%)	104 (96.3%)	200 (96.6%)
	High	Normal	0	1 (0.9%)	1 (0.5%)
Week 32	m		98	108	206
	Low	Low	1 (1.0%)	1 (0.9%)	2 (1.0%)
		Normal	1 (1.0%)	2 (1.9%)	3 (1.5%)
	Normal	Low	1 (1.0%)	0	1 (0.5%)
		Normal	95 (96.9%)	104 (96.3%)	199 (96.6%)
	High	Normal	0	1 (0.9%)	1 (0.5%)
Week 36	m		98	108	206
	Low	Low	1 (1.0%)	2 (1.9%)	3 (1.5%)
		Normal	1 (1.0%)	1 (0.9%)	2 (1.0%)
	Normal	Normal	96 (98.0%)	104 (96.3%)	200 (97.1%)
	High	Normal	0	1 (0.9%)	1 (0.5%)
Week 40	m		0	107	107
	Low	Low	.	2 (1.9%)	2 (1.9%)
		Normal	.	1 (0.9%)	1 (0.9%)
	Normal	Normal	.	102 (95.3%)	102 (95.3%)
		High	.	1 (0.9%)	1 (0.9%)
	High	Normal	.	1 (0.9%)	1 (0.9%)
Week 44	m		0	107	107
	Low	Low	.	1 (0.9%)	1 (0.9%)
		Normal	.	2 (1.9%)	2 (1.9%)
	Normal	Low	.	1 (0.9%)	1 (0.9%)
		Normal	.	102 (95.3%)	102 (95.3%)
	High	Normal	.	1 (0.9%)	1 (0.9%)
Week 48	m		0	107	107
	Low	Low	.	1 (0.9%)	1 (0.9%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
		Normal	.	2 (1.9%)	2 (1.9%)
	Normal	Low	.	1 (0.9%)	1 (0.9%)
		Normal	.	101 (94.4%)	101 (94.4%)
		High	.	1 (0.9%)	1 (0.9%)
	High	Normal	.	1 (0.9%)	1 (0.9%)
Week 52	m		0	107	107
	Low	Low	.	2 (1.9%)	2 (1.9%)
		Normal	.	1 (0.9%)	1 (0.9%)
	Normal	Low	.	1 (0.9%)	1 (0.9%)
		Normal	.	102 (95.3%)	102 (95.3%)
	High	Normal	.	1 (0.9%)	1 (0.9%)
LOCF Endpoint	m		101	108	209
	Low	Low	1 (1.0%)	2 (1.9%)	3 (1.4%)
		Normal	1 (1.0%)	1 (0.9%)	2 (1.0%)
	Normal	Low	0	1 (0.9%)	1 (0.5%)
		Normal	99 (98.0%)	103 (95.4%)	202 (96.7%)
	High	Normal	0	1 (0.9%)	1 (0.5%)
Urea Nitrogen (mmol/L)					
Week 4	m		100	108	208
	Normal	Normal	99 (99.0%)	104 (96.3%)	203 (97.6%)
		High	0	2 (1.9%)	2 (1.0%)
	High	Normal	1 (1.0%)	2 (1.9%)	3 (1.4%)
Week 8	m		101	108	209
	Normal	Normal	100 (99.0%)	104 (96.3%)	204 (97.6%)
		High	0	2 (1.9%)	2 (1.0%)
	High	Normal	1 (1.0%)	1 (0.9%)	2 (1.0%)
		High	0	1 (0.9%)	1 (0.5%)
Week 12	m		101	108	209
	Normal	Normal	100 (99.0%)	105 (97.2%)	205 (98.1%)
		High	0	1 (0.9%)	1 (0.5%)
	High	Normal	1 (1.0%)	2 (1.9%)	3 (1.4%)
Week 16	m		99	108	207
	Normal	Normal	97 (98.0%)	105 (97.2%)	202 (97.6%)
		High	1 (1.0%)	1 (0.9%)	2 (1.0%)
	High	Normal	1 (1.0%)	2 (1.9%)	3 (1.4%)
Week 20	m		99	108	207
	Normal	Normal	98 (99.0%)	105 (97.2%)	203 (98.1%)
		High	0	1 (0.9%)	1 (0.5%)
	High	Normal	1 (1.0%)	2 (1.9%)	3 (1.4%)
Week 24	m		99	108	207
	Normal	Normal	98 (99.0%)	105 (97.2%)	203 (98.1%)
		High	0	1 (0.9%)	1 (0.5%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
	High	Normal	1 (1.0%)	2 (1.9%)	3 (1.4%)
Week 32	m		98	108	206
	Normal	Normal	96 (98.0%)	104 (96.3%)	200 (97.1%)
		High	1 (1.0%)	2 (1.9%)	3 (1.5%)
	High	Normal	1 (1.0%)	2 (1.9%)	3 (1.5%)
Week 36	m		98	108	206
	Normal	Normal	96 (98.0%)	106 (98.1%)	202 (98.1%)
		High	1 (1.0%)	0	1 (0.5%)
	High	Normal	1 (1.0%)	2 (1.9%)	3 (1.5%)
Week 40	m		0	107	107
	Normal	Normal	.	105 (98.1%)	105 (98.1%)
	High	Normal	.	2 (1.9%)	2 (1.9%)
Week 44	m		0	107	107
	Normal	Normal	.	105 (98.1%)	105 (98.1%)
	High	Normal	.	2 (1.9%)	2 (1.9%)
Week 48	m		0	107	107
	Normal	Normal	.	105 (98.1%)	105 (98.1%)
	High	Normal	.	2 (1.9%)	2 (1.9%)
Week 52	m		0	107	107
	Normal	Normal	.	105 (98.1%)	105 (98.1%)
	High	Normal	.	2 (1.9%)	2 (1.9%)
LOCF Endpoint	m		101	108	209
	Normal	Normal	99 (98.0%)	106 (98.1%)	205 (98.1%)
		High	1 (1.0%)	0	1 (0.5%)
	High	Normal	1 (1.0%)	2 (1.9%)	3 (1.4%)

- Abbreviations: LOCF, Last Observation Carried Forward
- "Imeglimin" in this table means "Imeglimin 1000 mg twice daily".
- The Long-term Safety Population excludes data during administration of placebo in the double-blind period.
- "Imeglimin + Insulin Total" is the sum of subjects in the placebo group in the open-label period and Imeglimin group in the double-blind and open-label periods.
- m in row headings is the total number of subjects with both baseline and the corresponding visit values available, and is used as the denominator to calculate percentages.
- For "Placebo/Imeglimin + Insulin" group, baseline was defined as last visit with non-missing value prior to or at the day of first dose of Investigational Medicinal Product (IMP) in open-label treatment period. For "Imeglimin/Imeglimin + Insulin" group, baseline was the same as for the double-blind treatment period.

Control No:<<t-s-203-labot-020lt.sas, 2020-03-06T00:19:29>>

Table S-204 Shift of Laboratory Findings of Urinalysis in Long-term Period (PXL008-020; Long-term Safety Population)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
Ketones					
Week 4	m		100	108	208
	Negative	Negative	83 (83.0%)	94 (87.0%)	177 (85.1%)
		Trace	4 (4.0%)	4 (3.7%)	8 (3.8%)
		Positive	1 (1.0%)	2 (1.9%)	3 (1.4%)
	Trace	Negative	4 (4.0%)	7 (6.5%)	11 (5.3%)
	Positive	Negative	6 (6.0%)	1 (0.9%)	7 (3.4%)
		Positive	2 (2.0%)	0	2 (1.0%)
Week 8	m		101	108	209
	Negative	Negative	84 (83.2%)	96 (88.9%)	180 (86.1%)
		Trace	1 (1.0%)	2 (1.9%)	3 (1.4%)
		Positive	4 (4.0%)	2 (1.9%)	6 (2.9%)
	Trace	Negative	4 (4.0%)	7 (6.5%)	11 (5.3%)
	Positive	Negative	5 (5.0%)	0	5 (2.4%)
		Trace	3 (3.0%)	0	3 (1.4%)
		Positive	0	1 (0.9%)	1 (0.5%)
Week 12	m		101	108	209
	Negative	Negative	86 (85.1%)	93 (86.1%)	179 (85.6%)
		Trace	3 (3.0%)	2 (1.9%)	5 (2.4%)
		Positive	0	5 (4.6%)	5 (2.4%)
	Trace	Negative	3 (3.0%)	4 (3.7%)	7 (3.3%)
		Trace	0	1 (0.9%)	1 (0.5%)
		Positive	1 (1.0%)	2 (1.9%)	3 (1.4%)
	Positive	Negative	4 (4.0%)	0	4 (1.9%)
		Trace	2 (2.0%)	1 (0.9%)	3 (1.4%)
		Positive	2 (2.0%)	0	2 (1.0%)
Week 16	m		99	108	207
	Negative	Negative	83 (83.8%)	93 (86.1%)	176 (85.0%)
		Trace	2 (2.0%)	4 (3.7%)	6 (2.9%)
		Positive	2 (2.0%)	3 (2.8%)	5 (2.4%)
	Trace	Negative	4 (4.0%)	5 (4.6%)	9 (4.3%)
		Trace	0	1 (0.9%)	1 (0.5%)
		Positive	0	1 (0.9%)	1 (0.5%)
	Positive	Negative	6 (6.1%)	1 (0.9%)	7 (3.4%)
		Trace	1 (1.0%)	0	1 (0.5%)
		Positive	1 (1.0%)	0	1 (0.5%)
Week 20	m		99	108	207
	Negative	Negative	84 (84.8%)	94 (87.0%)	178 (86.0%)
		Trace	1 (1.0%)	0	1 (0.5%)
		Positive	2 (2.0%)	6 (5.6%)	8 (3.9%)
	Trace	Negative	4 (4.0%)	6 (5.6%)	10 (4.8%)
		Positive	0	1 (0.9%)	1 (0.5%)
	Positive	Negative	7 (7.1%)	0	7 (3.4%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
		Positive	1 (1.0%)	1 (0.9%)	2 (1.0%)
Week 24	m		99	108	207
	Negative	Negative	83 (83.8%)	96 (88.9%)	179 (86.5%)
		Trace	1 (1.0%)	1 (0.9%)	2 (1.0%)
		Positive	3 (3.0%)	3 (2.8%)	6 (2.9%)
	Trace	Negative	3 (3.0%)	6 (5.6%)	9 (4.3%)
		Positive	1 (1.0%)	1 (0.9%)	2 (1.0%)
	Positive	Negative	7 (7.1%)	0	7 (3.4%)
		Positive	1 (1.0%)	1 (0.9%)	2 (1.0%)
Week 32	m		98	107	205
	Negative	Negative	80 (81.6%)	94 (87.9%)	174 (84.9%)
		Trace	4 (4.1%)	3 (2.8%)	7 (3.4%)
		Positive	2 (2.0%)	2 (1.9%)	4 (2.0%)
	Trace	Negative	4 (4.1%)	4 (3.7%)	8 (3.9%)
		Trace	0	2 (1.9%)	2 (1.0%)
		Positive	0	1 (0.9%)	1 (0.5%)
	Positive	Negative	5 (5.1%)	1 (0.9%)	6 (2.9%)
		Trace	1 (1.0%)	0	1 (0.5%)
		Positive	2 (2.0%)	0	2 (1.0%)
Week 36	m		98	108	206
	Negative	Negative	83 (84.7%)	99 (91.7%)	182 (88.3%)
		Trace	2 (2.0%)	0	2 (1.0%)
		Positive	1 (1.0%)	1 (0.9%)	2 (1.0%)
	Trace	Negative	4 (4.1%)	5 (4.6%)	9 (4.4%)
		Positive	0	2 (1.9%)	2 (1.0%)
	Positive	Negative	6 (6.1%)	0	6 (2.9%)
		Positive	2 (2.0%)	1 (0.9%)	3 (1.5%)
Week 40	m		0	107	107
	Negative	Negative	.	92 (86.0%)	92 (86.0%)
		Trace	.	3 (2.8%)	3 (2.8%)
		Positive	.	4 (3.7%)	4 (3.7%)
	Trace	Negative	.	4 (3.7%)	4 (3.7%)
		Trace	.	1 (0.9%)	1 (0.9%)
		Positive	.	2 (1.9%)	2 (1.9%)
	Positive	Negative	.	1 (0.9%)	1 (0.9%)
Week 44	m		0	107	107
	Negative	Negative	.	94 (87.9%)	94 (87.9%)
		Trace	.	2 (1.9%)	2 (1.9%)
		Positive	.	3 (2.8%)	3 (2.8%)
	Trace	Negative	.	6 (5.6%)	6 (5.6%)
		Positive	.	1 (0.9%)	1 (0.9%)
	Positive	Negative	.	1 (0.9%)	1 (0.9%)
Week 48	m		0	107	107
	Negative	Negative	.	91 (85.0%)	91 (85.0%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
		Trace	.	4 (3.7%)	4 (3.7%)
		Positive	.	4 (3.7%)	4 (3.7%)
	Trace	Negative	.	5 (4.7%)	5 (4.7%)
		Trace	.	1 (0.9%)	1 (0.9%)
		Positive	.	1 (0.9%)	1 (0.9%)
	Positive	Negative	.	1 (0.9%)	1 (0.9%)
Week 52	m		0	107	107
	Negative	Negative	.	96 (89.7%)	96 (89.7%)
		Trace	.	1 (0.9%)	1 (0.9%)
		Positive	.	2 (1.9%)	2 (1.9%)
	Trace	Negative	.	5 (4.7%)	5 (4.7%)
		Positive	.	2 (1.9%)	2 (1.9%)
	Positive	Negative	.	1 (0.9%)	1 (0.9%)
LOCF Endpoint	m		101	108	209
	Negative	Negative	86 (85.1%)	97 (89.8%)	183 (87.6%)
		Trace	2 (2.0%)	1 (0.9%)	3 (1.4%)
		Positive	1 (1.0%)	2 (1.9%)	3 (1.4%)
	Trace	Negative	4 (4.0%)	5 (4.6%)	9 (4.3%)
		Positive	0	2 (1.9%)	2 (1.0%)
	Positive	Negative	6 (5.9%)	1 (0.9%)	7 (3.3%)
		Positive	2 (2.0%)	0	2 (1.0%)
Leukocyte Esterase					
Week 4	m		100	108	208
	Negative	Negative	82 (82.0%)	87 (80.6%)	169 (81.3%)
		Trace	1 (1.0%)	1 (0.9%)	2 (1.0%)
		Positive	2 (2.0%)	8 (7.4%)	10 (4.8%)
	Trace	Negative	1 (1.0%)	0	1 (0.5%)
		Positive	4 (4.0%)	1 (0.9%)	5 (2.4%)
	Positive	Negative	5 (5.0%)	3 (2.8%)	8 (3.8%)
		Trace	0	2 (1.9%)	2 (1.0%)
		Positive	5 (5.0%)	6 (5.6%)	11 (5.3%)
Week 8	m		101	108	209
	Negative	Negative	82 (81.2%)	94 (87.0%)	176 (84.2%)
		Trace	0	1 (0.9%)	1 (0.5%)
		Positive	3 (3.0%)	1 (0.9%)	4 (1.9%)
	Trace	Negative	2 (2.0%)	0	2 (1.0%)
		Positive	4 (4.0%)	1 (0.9%)	5 (2.4%)
	Positive	Negative	3 (3.0%)	0	3 (1.4%)
		Trace	1 (1.0%)	3 (2.8%)	4 (1.9%)
		Positive	6 (5.9%)	8 (7.4%)	14 (6.7%)
Week 12	m		101	108	209
	Negative	Negative	81 (80.2%)	94 (87.0%)	175 (83.7%)
		Trace	2 (2.0%)	2 (1.9%)	4 (1.9%)
		Positive	2 (2.0%)	0	2 (1.0%)
	Trace	Negative	4 (4.0%)	1 (0.9%)	5 (2.4%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
		Positive	2 (2.0%)	0	2 (1.0%)
	Positive	Negative	5 (5.0%)	2 (1.9%)	7 (3.3%)
		Positive	5 (5.0%)	9 (8.3%)	14 (6.7%)
Week 16	m		99	108	207
	Negative	Negative	80 (80.8%)	91 (84.3%)	171 (82.6%)
		Trace	1 (1.0%)	3 (2.8%)	4 (1.9%)
		Positive	2 (2.0%)	2 (1.9%)	4 (1.9%)
	Trace	Negative	2 (2.0%)	1 (0.9%)	3 (1.4%)
		Trace	1 (1.0%)	0	1 (0.5%)
		Positive	3 (3.0%)	0	3 (1.4%)
	Positive	Negative	5 (5.1%)	5 (4.6%)	10 (4.8%)
		Trace	1 (1.0%)	0	1 (0.5%)
		Positive	4 (4.0%)	6 (5.6%)	10 (4.8%)
Week 20	m		99	108	207
	Negative	Negative	81 (81.8%)	92 (85.2%)	173 (83.6%)
		Trace	1 (1.0%)	1 (0.9%)	2 (1.0%)
		Positive	1 (1.0%)	3 (2.8%)	4 (1.9%)
	Trace	Negative	0	1 (0.9%)	1 (0.5%)
		Trace	2 (2.0%)	0	2 (1.0%)
		Positive	4 (4.0%)	0	4 (1.9%)
	Positive	Negative	3 (3.0%)	2 (1.9%)	5 (2.4%)
		Trace	2 (2.0%)	1 (0.9%)	3 (1.4%)
		Positive	5 (5.1%)	8 (7.4%)	13 (6.3%)
Week 24	m		99	108	207
	Negative	Negative	79 (79.8%)	91 (84.3%)	170 (82.1%)
		Trace	0	5 (4.6%)	5 (2.4%)
		Positive	4 (4.0%)	0	4 (1.9%)
	Trace	Negative	1 (1.0%)	0	1 (0.5%)
		Trace	2 (2.0%)	0	2 (1.0%)
		Positive	3 (3.0%)	1 (0.9%)	4 (1.9%)
	Positive	Negative	4 (4.0%)	5 (4.6%)	9 (4.3%)
		Trace	1 (1.0%)	1 (0.9%)	2 (1.0%)
		Positive	5 (5.1%)	5 (4.6%)	10 (4.8%)
Week 32	m		98	107	205
	Negative	Negative	78 (79.6%)	89 (83.2%)	167 (81.5%)
		Trace	2 (2.0%)	3 (2.8%)	5 (2.4%)
		Positive	2 (2.0%)	3 (2.8%)	5 (2.4%)
	Trace	Negative	2 (2.0%)	0	2 (1.0%)
		Trace	1 (1.0%)	0	1 (0.5%)
		Positive	3 (3.1%)	1 (0.9%)	4 (2.0%)
	Positive	Negative	3 (3.1%)	4 (3.7%)	7 (3.4%)
		Trace	1 (1.0%)	0	1 (0.5%)
		Positive	6 (6.1%)	7 (6.5%)	13 (6.3%)
Week 36	m		98	108	206
	Negative	Negative	77 (78.6%)	89 (82.4%)	166 (80.6%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
		Trace	2 (2.0%)	3 (2.8%)	5 (2.4%)
		Positive	3 (3.1%)	4 (3.7%)	7 (3.4%)
	Trace	Negative	3 (3.1%)	0	3 (1.5%)
		Positive	3 (3.1%)	1 (0.9%)	4 (1.9%)
	Positive	Negative	3 (3.1%)	4 (3.7%)	7 (3.4%)
		Trace	1 (1.0%)	0	1 (0.5%)
		Positive	6 (6.1%)	7 (6.5%)	13 (6.3%)
Week 40	m		0	107	107
	Negative	Negative	.	85 (79.4%)	85 (79.4%)
		Trace	.	2 (1.9%)	2 (1.9%)
		Positive	.	8 (7.5%)	8 (7.5%)
	Trace	Positive	.	1 (0.9%)	1 (0.9%)
	Positive	Negative	.	5 (4.7%)	5 (4.7%)
		Trace	.	1 (0.9%)	1 (0.9%)
		Positive	.	5 (4.7%)	5 (4.7%)
Week 44	m		0	107	107
	Negative	Negative	.	85 (79.4%)	85 (79.4%)
		Trace	.	2 (1.9%)	2 (1.9%)
		Positive	.	8 (7.5%)	8 (7.5%)
	Trace	Negative	.	1 (0.9%)	1 (0.9%)
	Positive	Negative	.	2 (1.9%)	2 (1.9%)
		Trace	.	1 (0.9%)	1 (0.9%)
		Positive	.	8 (7.5%)	8 (7.5%)
Week 48	m		0	107	107
	Negative	Negative	.	84 (78.5%)	84 (78.5%)
		Trace	.	2 (1.9%)	2 (1.9%)
		Positive	.	9 (8.4%)	9 (8.4%)
	Trace	Positive	.	1 (0.9%)	1 (0.9%)
	Positive	Negative	.	3 (2.8%)	3 (2.8%)
		Trace	.	1 (0.9%)	1 (0.9%)
		Positive	.	7 (6.5%)	7 (6.5%)
Week 52	m		0	107	107
	Negative	Negative	.	86 (80.4%)	86 (80.4%)
		Trace	.	4 (3.7%)	4 (3.7%)
		Positive	.	5 (4.7%)	5 (4.7%)
	Trace	Positive	.	1 (0.9%)	1 (0.9%)
	Positive	Negative	.	4 (3.7%)	4 (3.7%)
		Positive	.	7 (6.5%)	7 (6.5%)
LOCF Endpoint	m		101	108	209
	Negative	Negative	80 (79.2%)	87 (80.6%)	167 (79.9%)
		Trace	2 (2.0%)	4 (3.7%)	6 (2.9%)
		Positive	3 (3.0%)	5 (4.6%)	8 (3.8%)
	Trace	Negative	3 (3.0%)	0	3 (1.4%)
		Positive	3 (3.0%)	1 (0.9%)	4 (1.9%)
	Positive	Negative	3 (3.0%)	4 (3.7%)	7 (3.3%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
		Trace	1 (1.0%)	0	1 (0.5%)
		Positive	6 (5.9%)	7 (6.5%)	13 (6.2%)
Nitrite					
Week 4	m		100	108	208
	Negative	Negative	94 (94.0%)	103 (95.4%)	197 (94.7%)
		Positive	2 (2.0%)	2 (1.9%)	4 (1.9%)
	Positive	Negative	2 (2.0%)	0	2 (1.0%)
		Positive	2 (2.0%)	3 (2.8%)	5 (2.4%)
Week 8	m		101	108	209
	Negative	Negative	94 (93.1%)	104 (96.3%)	198 (94.7%)
		Positive	3 (3.0%)	1 (0.9%)	4 (1.9%)
	Positive	Negative	2 (2.0%)	0	2 (1.0%)
		Positive	2 (2.0%)	3 (2.8%)	5 (2.4%)
Week 12	m		101	108	209
	Negative	Negative	93 (92.1%)	103 (95.4%)	196 (93.8%)
		Positive	4 (4.0%)	2 (1.9%)	6 (2.9%)
	Positive	Negative	2 (2.0%)	0	2 (1.0%)
		Positive	2 (2.0%)	3 (2.8%)	5 (2.4%)
Week 16	m		99	108	207
	Negative	Negative	93 (93.9%)	102 (94.4%)	195 (94.2%)
		Positive	2 (2.0%)	3 (2.8%)	5 (2.4%)
	Positive	Negative	2 (2.0%)	1 (0.9%)	3 (1.4%)
		Positive	2 (2.0%)	2 (1.9%)	4 (1.9%)
Week 20	m		99	108	207
	Negative	Negative	94 (94.9%)	103 (95.4%)	197 (95.2%)
		Positive	1 (1.0%)	2 (1.9%)	3 (1.4%)
	Positive	Negative	1 (1.0%)	2 (1.9%)	3 (1.4%)
		Positive	3 (3.0%)	1 (0.9%)	4 (1.9%)
Week 24	m		99	108	207
	Negative	Negative	93 (93.9%)	104 (96.3%)	197 (95.2%)
		Positive	2 (2.0%)	1 (0.9%)	3 (1.4%)
	Positive	Negative	2 (2.0%)	1 (0.9%)	3 (1.4%)
		Positive	2 (2.0%)	2 (1.9%)	4 (1.9%)
Week 32	m		98	107	205
	Negative	Negative	92 (93.9%)	102 (95.3%)	194 (94.6%)
		Positive	2 (2.0%)	2 (1.9%)	4 (2.0%)
	Positive	Negative	2 (2.0%)	1 (0.9%)	3 (1.5%)
		Positive	2 (2.0%)	2 (1.9%)	4 (2.0%)
Week 36	m		98	108	206
	Negative	Negative	93 (94.9%)	102 (94.4%)	195 (94.7%)
		Positive	1 (1.0%)	3 (2.8%)	4 (1.9%)
	Positive	Negative	2 (2.0%)	1 (0.9%)	3 (1.5%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
		Positive	2 (2.0%)	2 (1.9%)	4 (1.9%)
Week 40	m		0	107	107
	Negative	Negative	.	101 (94.4%)	101 (94.4%)
		Positive	.	3 (2.8%)	3 (2.8%)
	Positive	Negative	.	1 (0.9%)	1 (0.9%)
		Positive	.	2 (1.9%)	2 (1.9%)
Week 44	m		0	107	107
	Negative	Negative	.	100 (93.5%)	100 (93.5%)
		Positive	.	4 (3.7%)	4 (3.7%)
	Positive	Negative	.	1 (0.9%)	1 (0.9%)
		Positive	.	2 (1.9%)	2 (1.9%)
Week 48	m		0	107	107
	Negative	Negative	.	100 (93.5%)	100 (93.5%)
		Positive	.	4 (3.7%)	4 (3.7%)
	Positive	Positive	.	3 (2.8%)	3 (2.8%)
Week 52	m		0	107	107
	Negative	Negative	.	100 (93.5%)	100 (93.5%)
		Positive	.	4 (3.7%)	4 (3.7%)
	Positive	Negative	.	1 (0.9%)	1 (0.9%)
		Positive	.	2 (1.9%)	2 (1.9%)
LOCF Endpoint	m		101	108	209
	Negative	Negative	95 (94.1%)	101 (93.5%)	196 (93.8%)
		Positive	2 (2.0%)	4 (3.7%)	6 (2.9%)
	Positive	Negative	2 (2.0%)	1 (0.9%)	3 (1.4%)
		Positive	2 (2.0%)	2 (1.9%)	4 (1.9%)
Occult Blood					
Week 4	m		100	108	208
	Negative	Negative	93 (93.0%)	100 (92.6%)	193 (92.8%)
		Trace	1 (1.0%)	2 (1.9%)	3 (1.4%)
		Positive	0	2 (1.9%)	2 (1.0%)
	Trace	Negative	1 (1.0%)	0	1 (0.5%)
		Trace	1 (1.0%)	0	1 (0.5%)
		Positive	0	1 (0.9%)	1 (0.5%)
	Positive	Negative	3 (3.0%)	1 (0.9%)	4 (1.9%)
		Trace	0	1 (0.9%)	1 (0.5%)
		Positive	1 (1.0%)	1 (0.9%)	2 (1.0%)
Week 8	m		101	108	209
	Negative	Negative	94 (93.1%)	101 (93.5%)	195 (93.3%)
		Trace	1 (1.0%)	2 (1.9%)	3 (1.4%)
		Positive	0	1 (0.9%)	1 (0.5%)
	Trace	Negative	1 (1.0%)	0	1 (0.5%)
		Trace	1 (1.0%)	0	1 (0.5%)
		Positive	0	1 (0.9%)	1 (0.5%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
	Positive	Negative	2 (2.0%)	0	2 (1.0%)
		Trace	0	1 (0.9%)	1 (0.5%)
		Positive	2 (2.0%)	2 (1.9%)	4 (1.9%)
Week 12	m		101	108	209
	Negative	Negative	93 (92.1%)	100 (92.6%)	193 (92.3%)
		Trace	2 (2.0%)	1 (0.9%)	3 (1.4%)
		Positive	0	3 (2.8%)	3 (1.4%)
	Trace	Negative	2 (2.0%)	0	2 (1.0%)
		Trace	0	1 (0.9%)	1 (0.5%)
	Positive	Negative	3 (3.0%)	1 (0.9%)	4 (1.9%)
		Trace	0	2 (1.9%)	2 (1.0%)
		Positive	1 (1.0%)	0	1 (0.5%)
Week 16	m		99	108	207
	Negative	Negative	91 (91.9%)	101 (93.5%)	192 (92.8%)
		Trace	1 (1.0%)	1 (0.9%)	2 (1.0%)
		Positive	1 (1.0%)	2 (1.9%)	3 (1.4%)
	Trace	Negative	2 (2.0%)	0	2 (1.0%)
		Positive	0	1 (0.9%)	1 (0.5%)
	Positive	Negative	2 (2.0%)	0	2 (1.0%)
		Trace	1 (1.0%)	0	1 (0.5%)
		Positive	1 (1.0%)	3 (2.8%)	4 (1.9%)
Week 20	m		99	108	207
	Negative	Negative	90 (90.9%)	101 (93.5%)	191 (92.3%)
		Trace	3 (3.0%)	0	3 (1.4%)
		Positive	0	3 (2.8%)	3 (1.4%)
	Trace	Negative	2 (2.0%)	0	2 (1.0%)
		Positive	0	1 (0.9%)	1 (0.5%)
	Positive	Negative	2 (2.0%)	1 (0.9%)	3 (1.4%)
		Trace	0	1 (0.9%)	1 (0.5%)
		Positive	2 (2.0%)	1 (0.9%)	3 (1.4%)
Week 24	m		99	108	207
	Negative	Negative	92 (92.9%)	98 (90.7%)	190 (91.8%)
		Trace	1 (1.0%)	4 (3.7%)	5 (2.4%)
		Positive	0	2 (1.9%)	2 (1.0%)
	Trace	Negative	2 (2.0%)	1 (0.9%)	3 (1.4%)
	Positive	Negative	2 (2.0%)	1 (0.9%)	3 (1.4%)
		Trace	1 (1.0%)	1 (0.9%)	2 (1.0%)
		Positive	1 (1.0%)	1 (0.9%)	2 (1.0%)
Week 32	m		98	107	205
	Negative	Negative	89 (90.8%)	100 (93.5%)	189 (92.2%)
		Trace	2 (2.0%)	1 (0.9%)	3 (1.5%)
		Positive	1 (1.0%)	2 (1.9%)	3 (1.5%)
	Trace	Negative	2 (2.0%)	0	2 (1.0%)
		Positive	0	1 (0.9%)	1 (0.5%)
	Positive	Negative	2 (2.0%)	1 (0.9%)	3 (1.5%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
		Trace	1 (1.0%)	1 (0.9%)	2 (1.0%)
		Positive	1 (1.0%)	1 (0.9%)	2 (1.0%)
Week 36	m		98	108	206
	Negative	Negative	91 (92.9%)	100 (92.6%)	191 (92.7%)
		Trace	1 (1.0%)	1 (0.9%)	2 (1.0%)
		Positive	0	3 (2.8%)	3 (1.5%)
	Trace	Negative	2 (2.0%)	0	2 (1.0%)
		Positive	0	1 (0.9%)	1 (0.5%)
	Positive	Negative	1 (1.0%)	2 (1.9%)	3 (1.5%)
		Trace	1 (1.0%)	0	1 (0.5%)
		Positive	2 (2.0%)	1 (0.9%)	3 (1.5%)
Week 40	m		0	107	107
	Negative	Negative	.	99 (92.5%)	99 (92.5%)
		Trace	.	2 (1.9%)	2 (1.9%)
		Positive	.	2 (1.9%)	2 (1.9%)
	Trace	Positive	.	1 (0.9%)	1 (0.9%)
	Positive	Negative	.	2 (1.9%)	2 (1.9%)
		Trace	.	1 (0.9%)	1 (0.9%)
Week 44	m		0	107	107
	Negative	Negative	.	99 (92.5%)	99 (92.5%)
		Trace	.	2 (1.9%)	2 (1.9%)
		Positive	.	2 (1.9%)	2 (1.9%)
	Trace	Positive	.	1 (0.9%)	1 (0.9%)
	Positive	Negative	.	2 (1.9%)	2 (1.9%)
		Positive	.	1 (0.9%)	1 (0.9%)
Week 48	m		0	107	107
	Negative	Negative	.	98 (91.6%)	98 (91.6%)
		Trace	.	3 (2.8%)	3 (2.8%)
		Positive	.	2 (1.9%)	2 (1.9%)
	Trace	Negative	.	1 (0.9%)	1 (0.9%)
	Positive	Negative	.	1 (0.9%)	1 (0.9%)
		Positive	.	2 (1.9%)	2 (1.9%)
Week 52	m		0	107	107
	Negative	Negative	.	100 (93.5%)	100 (93.5%)
		Trace	.	2 (1.9%)	2 (1.9%)
		Positive	.	1 (0.9%)	1 (0.9%)
	Trace	Positive	.	1 (0.9%)	1 (0.9%)
	Positive	Negative	.	2 (1.9%)	2 (1.9%)
		Trace	.	1 (0.9%)	1 (0.9%)
LOCF Endpoint	m		101	108	209
	Negative	Negative	94 (93.1%)	101 (93.5%)	195 (93.3%)
		Trace	1 (1.0%)	2 (1.9%)	3 (1.4%)
		Positive	0	1 (0.9%)	1 (0.5%)
	Trace	Negative	2 (2.0%)	0	2 (1.0%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
		Positive	0	1 (0.9%)	1 (0.5%)
	Positive	Negative	1 (1.0%)	2 (1.9%)	3 (1.4%)
		Trace	1 (1.0%)	1 (0.9%)	2 (1.0%)
		Positive	2 (2.0%)	0	2 (1.0%)
pH					
Week 4	m		100	108	208
	5.5	5.5	4 (4.0%)	6 (5.6%)	10 (4.8%)
		6	7 (7.0%)	5 (4.6%)	12 (5.8%)
		6.5	1 (1.0%)	2 (1.9%)	3 (1.4%)
		7	1 (1.0%)	0	1 (0.5%)
		7.5	0	1 (0.9%)	1 (0.5%)
		8	1 (1.0%)	0	1 (0.5%)
	6	5.5	4 (4.0%)	3 (2.8%)	7 (3.4%)
		6	14 (14.0%)	21 (19.4%)	35 (16.8%)
		6.5	11 (11.0%)	8 (7.4%)	19 (9.1%)
		7	2 (2.0%)	3 (2.8%)	5 (2.4%)
		7.5	1 (1.0%)	0	1 (0.5%)
	6.5	5.5	2 (2.0%)	0	2 (1.0%)
		6	13 (13.0%)	20 (18.5%)	33 (15.9%)
		6.5	7 (7.0%)	5 (4.6%)	12 (5.8%)
		7	4 (4.0%)	3 (2.8%)	7 (3.4%)
		7.5	1 (1.0%)	0	1 (0.5%)
		8	0	1 (0.9%)	1 (0.5%)
	7	6	2 (2.0%)	3 (2.8%)	5 (2.4%)
		6.5	6 (6.0%)	5 (4.6%)	11 (5.3%)
		7	5 (5.0%)	4 (3.7%)	9 (4.3%)
		7.5	1 (1.0%)	1 (0.9%)	2 (1.0%)
		8	2 (2.0%)	0	2 (1.0%)
	7.5	5.5	0	2 (1.9%)	2 (1.0%)
		6	0	6 (5.6%)	6 (2.9%)
		6.5	2 (2.0%)	2 (1.9%)	4 (1.9%)
		7	5 (5.0%)	3 (2.8%)	8 (3.8%)
		7.5	2 (2.0%)	2 (1.9%)	4 (1.9%)
		8	1 (1.0%)	1 (0.9%)	2 (1.0%)
	8	7	1 (1.0%)	1 (0.9%)	2 (1.0%)
Week 8	m		101	108	209
	5.5	5.5	5 (5.0%)	6 (5.6%)	11 (5.3%)
		6	5 (5.0%)	3 (2.8%)	8 (3.8%)
		6.5	2 (2.0%)	2 (1.9%)	4 (1.9%)
		7	1 (1.0%)	2 (1.9%)	3 (1.4%)
		7.5	1 (1.0%)	1 (0.9%)	2 (1.0%)
		8	1 (1.0%)	0	1 (0.5%)
	6	5.5	3 (3.0%)	3 (2.8%)	6 (2.9%)
		6	16 (15.8%)	19 (17.6%)	35 (16.7%)
		6.5	12 (11.9%)	7 (6.5%)	19 (9.1%)
		7	1 (1.0%)	3 (2.8%)	4 (1.9%)
		7.5	0	3 (2.8%)	3 (1.4%)
	6.5	6	10 (9.9%)	10 (9.3%)	20 (9.6%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
		6.5	11 (10.9%)	8 (7.4%)	19 (9.1%)
		7	3 (3.0%)	7 (6.5%)	10 (4.8%)
		7.5	3 (3.0%)	4 (3.7%)	7 (3.3%)
	7	6	4 (4.0%)	5 (4.6%)	9 (4.3%)
		6.5	5 (5.0%)	2 (1.9%)	7 (3.3%)
		7	4 (4.0%)	3 (2.8%)	7 (3.3%)
		7.5	2 (2.0%)	2 (1.9%)	4 (1.9%)
		8	1 (1.0%)	1 (0.9%)	2 (1.0%)
	7.5	5.5	0	2 (1.9%)	2 (1.0%)
		6	0	5 (4.6%)	5 (2.4%)
		6.5	0	3 (2.8%)	3 (1.4%)
		7	4 (4.0%)	1 (0.9%)	5 (2.4%)
		7.5	4 (4.0%)	5 (4.6%)	9 (4.3%)
		8	2 (2.0%)	0	2 (1.0%)
	8	7	1 (1.0%)	0	1 (0.5%)
		8	0	1 (0.9%)	1 (0.5%)
Week 12	m		101	108	209
	5.5	5.5	4 (4.0%)	6 (5.6%)	10 (4.8%)
		6	6 (5.9%)	4 (3.7%)	10 (4.8%)
		6.5	3 (3.0%)	2 (1.9%)	5 (2.4%)
		7	1 (1.0%)	2 (1.9%)	3 (1.4%)
		8	1 (1.0%)	0	1 (0.5%)
	6	5.5	2 (2.0%)	2 (1.9%)	4 (1.9%)
		6	20 (19.8%)	16 (14.8%)	36 (17.2%)
		6.5	8 (7.9%)	11 (10.2%)	19 (9.1%)
		7	0	2 (1.9%)	2 (1.0%)
		7.5	2 (2.0%)	3 (2.8%)	5 (2.4%)
		8	0	1 (0.9%)	1 (0.5%)
	6.5	5.5	1 (1.0%)	1 (0.9%)	2 (1.0%)
		6	9 (8.9%)	5 (4.6%)	14 (6.7%)
		6.5	9 (8.9%)	15 (13.9%)	24 (11.5%)
		7	6 (5.9%)	6 (5.6%)	12 (5.7%)
		7.5	2 (2.0%)	2 (1.9%)	4 (1.9%)
	7	6	1 (1.0%)	5 (4.6%)	6 (2.9%)
		6.5	6 (5.9%)	2 (1.9%)	8 (3.8%)
		7	6 (5.9%)	3 (2.8%)	9 (4.3%)
		7.5	1 (1.0%)	3 (2.8%)	4 (1.9%)
		8	2 (2.0%)	0	2 (1.0%)
	7.5	6	0	4 (3.7%)	4 (1.9%)
		6.5	4 (4.0%)	4 (3.7%)	8 (3.8%)
		7	2 (2.0%)	3 (2.8%)	5 (2.4%)
		7.5	4 (4.0%)	3 (2.8%)	7 (3.3%)
		8	0	2 (1.9%)	2 (1.0%)
	8	7	1 (1.0%)	0	1 (0.5%)
		8	0	1 (0.9%)	1 (0.5%)
Week 16	m		99	108	207
	5.5	5.5	5 (5.1%)	4 (3.7%)	9 (4.3%)
		6	5 (5.1%)	5 (4.6%)	10 (4.8%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
		6.5	1 (1.0%)	3 (2.8%)	4 (1.9%)
		7	2 (2.0%)	1 (0.9%)	3 (1.4%)
		7.5	0	1 (0.9%)	1 (0.5%)
		8	1 (1.0%)	0	1 (0.5%)
	6	5.5	0	6 (5.6%)	6 (2.9%)
		6	19 (19.2%)	13 (12.0%)	32 (15.5%)
		6.5	8 (8.1%)	7 (6.5%)	15 (7.2%)
		7	4 (4.0%)	7 (6.5%)	11 (5.3%)
		7.5	1 (1.0%)	1 (0.9%)	2 (1.0%)
		8	0	1 (0.9%)	1 (0.5%)
	6.5	5.5	2 (2.0%)	3 (2.8%)	5 (2.4%)
		6	11 (11.1%)	8 (7.4%)	19 (9.2%)
		6.5	8 (8.1%)	6 (5.6%)	14 (6.8%)
		7	6 (6.1%)	11 (10.2%)	17 (8.2%)
		7.5	0	1 (0.9%)	1 (0.5%)
	7	5.5	4 (4.0%)	0	4 (1.9%)
		6	1 (1.0%)	3 (2.8%)	4 (1.9%)
		6.5	4 (4.0%)	3 (2.8%)	7 (3.4%)
		7	6 (6.1%)	5 (4.6%)	11 (5.3%)
		8	0	2 (1.9%)	2 (1.0%)
	7.5	5.5	0	1 (0.9%)	1 (0.5%)
		6	2 (2.0%)	2 (1.9%)	4 (1.9%)
		6.5	1 (1.0%)	4 (3.7%)	5 (2.4%)
		7	4 (4.0%)	5 (4.6%)	9 (4.3%)
		7.5	2 (2.0%)	2 (1.9%)	4 (1.9%)
		8	1 (1.0%)	2 (1.9%)	3 (1.4%)
	8	7	1 (1.0%)	0	1 (0.5%)
		8	0	1 (0.9%)	1 (0.5%)
Week 20	m		99	108	207
	5.5	5.5	5 (5.1%)	5 (4.6%)	10 (4.8%)
		6	6 (6.1%)	5 (4.6%)	11 (5.3%)
		6.5	1 (1.0%)	2 (1.9%)	3 (1.4%)
		7	1 (1.0%)	1 (0.9%)	2 (1.0%)
		7.5	1 (1.0%)	1 (0.9%)	2 (1.0%)
	6	5.5	2 (2.0%)	2 (1.9%)	4 (1.9%)
		6	13 (13.1%)	16 (14.8%)	29 (14.0%)
		6.5	10 (10.1%)	9 (8.3%)	19 (9.2%)
		7	4 (4.0%)	6 (5.6%)	10 (4.8%)
		7.5	1 (1.0%)	1 (0.9%)	2 (1.0%)
		8	2 (2.0%)	0	2 (1.0%)
		8.5	0	1 (0.9%)	1 (0.5%)
	6.5	5.5	1 (1.0%)	0	1 (0.5%)
		6	12 (12.1%)	4 (3.7%)	16 (7.7%)
		6.5	12 (12.1%)	9 (8.3%)	21 (10.1%)
		7	2 (2.0%)	12 (11.1%)	14 (6.8%)
		7.5	0	2 (1.9%)	2 (1.0%)
		8	0	2 (1.9%)	2 (1.0%)
	7	5.5	0	1 (0.9%)	1 (0.5%)
		6	4 (4.0%)	2 (1.9%)	6 (2.9%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
		6.5	7 (7.1%)	7 (6.5%)	14 (6.8%)
		7	3 (3.0%)	0	3 (1.4%)
		7.5	0	3 (2.8%)	3 (1.4%)
		8	1 (1.0%)	0	1 (0.5%)
	7.5	5.5	0	1 (0.9%)	1 (0.5%)
		6	2 (2.0%)	4 (3.7%)	6 (2.9%)
		6.5	1 (1.0%)	4 (3.7%)	5 (2.4%)
		7	2 (2.0%)	3 (2.8%)	5 (2.4%)
		7.5	5 (5.1%)	3 (2.8%)	8 (3.9%)
		8	0	1 (0.9%)	1 (0.5%)
	8	7.5	1 (1.0%)	1 (0.9%)	2 (1.0%)
Week 24	m		99	108	207
	5.5	5.5	5 (5.1%)	5 (4.6%)	10 (4.8%)
		6	7 (7.1%)	5 (4.6%)	12 (5.8%)
		6.5	0	2 (1.9%)	2 (1.0%)
		7	1 (1.0%)	2 (1.9%)	3 (1.4%)
		7.5	1 (1.0%)	0	1 (0.5%)
	6	5.5	2 (2.0%)	7 (6.5%)	9 (4.3%)
		6	18 (18.2%)	14 (13.0%)	32 (15.5%)
		6.5	9 (9.1%)	4 (3.7%)	13 (6.3%)
		7	2 (2.0%)	6 (5.6%)	8 (3.9%)
		7.5	1 (1.0%)	4 (3.7%)	5 (2.4%)
	6.5	6	14 (14.1%)	10 (9.3%)	24 (11.6%)
		6.5	9 (9.1%)	9 (8.3%)	18 (8.7%)
		7	1 (1.0%)	6 (5.6%)	7 (3.4%)
		7.5	3 (3.0%)	3 (2.8%)	6 (2.9%)
		8.5	0	1 (0.9%)	1 (0.5%)
	7	5.5	1 (1.0%)	0	1 (0.5%)
		6	3 (3.0%)	2 (1.9%)	5 (2.4%)
		6.5	6 (6.1%)	3 (2.8%)	9 (4.3%)
		7	1 (1.0%)	3 (2.8%)	4 (1.9%)
		7.5	4 (4.0%)	3 (2.8%)	7 (3.4%)
		8	0	2 (1.9%)	2 (1.0%)
	7.5	5.5	0	1 (0.9%)	1 (0.5%)
		6	1 (1.0%)	2 (1.9%)	3 (1.4%)
		6.5	3 (3.0%)	7 (6.5%)	10 (4.8%)
		7	1 (1.0%)	1 (0.9%)	2 (1.0%)
		7.5	4 (4.0%)	3 (2.8%)	7 (3.4%)
		8	1 (1.0%)	1 (0.9%)	2 (1.0%)
		8.5	0	1 (0.9%)	1 (0.5%)
	8	6.5	1 (1.0%)	0	1 (0.5%)
		7	0	1 (0.9%)	1 (0.5%)
Week 32	m		98	107	205
	5.5	5.5	5 (5.1%)	5 (4.7%)	10 (4.9%)
		6	3 (3.1%)	6 (5.6%)	9 (4.4%)
		6.5	3 (3.1%)	2 (1.9%)	5 (2.4%)
		7	2 (2.0%)	0	2 (1.0%)
		8.5	1 (1.0%)	0	1 (0.5%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
	6	5.5	4 (4.1%)	5 (4.7%)	9 (4.4%)
		6	15 (15.3%)	14 (13.1%)	29 (14.1%)
		6.5	7 (7.1%)	8 (7.5%)	15 (7.3%)
		7	4 (4.1%)	4 (3.7%)	8 (3.9%)
		7.5	2 (2.0%)	3 (2.8%)	5 (2.4%)
		8	0	1 (0.9%)	1 (0.5%)
	6.5	5.5	2 (2.0%)	0	2 (1.0%)
		6	12 (12.2%)	7 (6.5%)	19 (9.3%)
		6.5	8 (8.2%)	12 (11.2%)	20 (9.8%)
		7	2 (2.0%)	6 (5.6%)	8 (3.9%)
		7.5	2 (2.0%)	4 (3.7%)	6 (2.9%)
		8	1 (1.0%)	0	1 (0.5%)
	7	6	3 (3.1%)	1 (0.9%)	4 (2.0%)
		6.5	4 (4.1%)	3 (2.8%)	7 (3.4%)
		7	6 (6.1%)	2 (1.9%)	8 (3.9%)
		7.5	2 (2.0%)	6 (5.6%)	8 (3.9%)
		8	0	1 (0.9%)	1 (0.5%)
	7.5	5.5	0	1 (0.9%)	1 (0.5%)
		6	1 (1.0%)	4 (3.7%)	5 (2.4%)
		6.5	3 (3.1%)	2 (1.9%)	5 (2.4%)
		7	3 (3.1%)	5 (4.7%)	8 (3.9%)
		7.5	1 (1.0%)	3 (2.8%)	4 (2.0%)
		8	1 (1.0%)	1 (0.9%)	2 (1.0%)
	8	7.5	0	1 (0.9%)	1 (0.5%)
		8	1 (1.0%)	0	1 (0.5%)
Week 36	m		98	108	206
	5.5	5.5	4 (4.1%)	4 (3.7%)	8 (3.9%)
		6	7 (7.1%)	4 (3.7%)	11 (5.3%)
		6.5	1 (1.0%)	2 (1.9%)	3 (1.5%)
		7	0	3 (2.8%)	3 (1.5%)
		7.5	1 (1.0%)	1 (0.9%)	2 (1.0%)
		8	1 (1.0%)	0	1 (0.5%)
	6	5.5	4 (4.1%)	5 (4.6%)	9 (4.4%)
		6	11 (11.2%)	15 (13.9%)	26 (12.6%)
		6.5	11 (11.2%)	8 (7.4%)	19 (9.2%)
		7	4 (4.1%)	5 (4.6%)	9 (4.4%)
		7.5	2 (2.0%)	2 (1.9%)	4 (1.9%)
	6.5	5.5	2 (2.0%)	0	2 (1.0%)
		6	11 (11.2%)	9 (8.3%)	20 (9.7%)
		6.5	8 (8.2%)	11 (10.2%)	19 (9.2%)
		7	6 (6.1%)	7 (6.5%)	13 (6.3%)
		7.5	0	2 (1.9%)	2 (1.0%)
	7	5.5	1 (1.0%)	0	1 (0.5%)
		6	4 (4.1%)	5 (4.6%)	9 (4.4%)
		6.5	5 (5.1%)	2 (1.9%)	7 (3.4%)
		7	5 (5.1%)	3 (2.8%)	8 (3.9%)
		7.5	0	2 (1.9%)	2 (1.0%)
		8	0	1 (0.9%)	1 (0.5%)
	7.5	6	3 (3.1%)	6 (5.6%)	9 (4.4%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
		6.5	2 (2.0%)	6 (5.6%)	8 (3.9%)
		7	1 (1.0%)	1 (0.9%)	2 (1.0%)
		7.5	2 (2.0%)	2 (1.9%)	4 (1.9%)
		8	1 (1.0%)	0	1 (0.5%)
		8.5	0	1 (0.9%)	1 (0.5%)
	8	6.5	1 (1.0%)	0	1 (0.5%)
		7	0	1 (0.9%)	1 (0.5%)
Week 40	m		0	107	107
	5.5	5.5	.	5 (4.7%)	5 (4.7%)
		6	.	6 (5.6%)	6 (5.6%)
		6.5	.	1 (0.9%)	1 (0.9%)
		7	.	1 (0.9%)	1 (0.9%)
		7.5	.	1 (0.9%)	1 (0.9%)
	6	5.5	.	1 (0.9%)	1 (0.9%)
		6	.	16 (15.0%)	16 (15.0%)
		6.5	.	12 (11.2%)	12 (11.2%)
		7	.	3 (2.8%)	3 (2.8%)
		7.5	.	2 (1.9%)	2 (1.9%)
		8	.	1 (0.9%)	1 (0.9%)
	6.5	6	.	7 (6.5%)	7 (6.5%)
		6.5	.	10 (9.3%)	10 (9.3%)
		7	.	9 (8.4%)	9 (8.4%)
		7.5	.	1 (0.9%)	1 (0.9%)
		8	.	1 (0.9%)	1 (0.9%)
	7	6	.	2 (1.9%)	2 (1.9%)
		6.5	.	4 (3.7%)	4 (3.7%)
		7	.	5 (4.7%)	5 (4.7%)
		7.5	.	1 (0.9%)	1 (0.9%)
		8	.	1 (0.9%)	1 (0.9%)
	7.5	5.5	.	1 (0.9%)	1 (0.9%)
		6	.	2 (1.9%)	2 (1.9%)
		6.5	.	7 (6.5%)	7 (6.5%)
		7	.	2 (1.9%)	2 (1.9%)
		7.5	.	4 (3.7%)	4 (3.7%)
	8	7.5	.	1 (0.9%)	1 (0.9%)
Week 44	m		0	107	107
	5.5	5.5	.	5 (4.7%)	5 (4.7%)
		6	.	4 (3.7%)	4 (3.7%)
		6.5	.	2 (1.9%)	2 (1.9%)
		7	.	3 (2.8%)	3 (2.8%)
	6	5.5	.	1 (0.9%)	1 (0.9%)
		6	.	16 (15.0%)	16 (15.0%)
		6.5	.	9 (8.4%)	9 (8.4%)
		7	.	8 (7.5%)	8 (7.5%)
		7.5	.	1 (0.9%)	1 (0.9%)
	6.5	6	.	8 (7.5%)	8 (7.5%)
		6.5	.	10 (9.3%)	10 (9.3%)
		7	.	3 (2.8%)	3 (2.8%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
		7.5	.	5 (4.7%)	5 (4.7%)
		8	.	2 (1.9%)	2 (1.9%)
	7	5.5	.	1 (0.9%)	1 (0.9%)
		6	.	1 (0.9%)	1 (0.9%)
		6.5	.	3 (2.8%)	3 (2.8%)
		7	.	4 (3.7%)	4 (3.7%)
		7.5	.	2 (1.9%)	2 (1.9%)
		8	.	2 (1.9%)	2 (1.9%)
	7.5	6	.	6 (5.6%)	6 (5.6%)
		6.5	.	4 (3.7%)	4 (3.7%)
		7	.	3 (2.8%)	3 (2.8%)
		7.5	.	1 (0.9%)	1 (0.9%)
		8	.	2 (1.9%)	2 (1.9%)
	8	7.5	.	1 (0.9%)	1 (0.9%)
Week 48	m		0	107	107
	5.5	5.5	.	3 (2.8%)	3 (2.8%)
		6	.	5 (4.7%)	5 (4.7%)
		6.5	.	5 (4.7%)	5 (4.7%)
		7.5	.	1 (0.9%)	1 (0.9%)
	6	5.5	.	3 (2.8%)	3 (2.8%)
		6	.	14 (13.1%)	14 (13.1%)
		6.5	.	9 (8.4%)	9 (8.4%)
		7	.	8 (7.5%)	8 (7.5%)
		7.5	.	1 (0.9%)	1 (0.9%)
	6.5	6	.	5 (4.7%)	5 (4.7%)
		6.5	.	14 (13.1%)	14 (13.1%)
		7	.	8 (7.5%)	8 (7.5%)
		7.5	.	1 (0.9%)	1 (0.9%)
	7	5.5	.	2 (1.9%)	2 (1.9%)
		6	.	1 (0.9%)	1 (0.9%)
		6.5	.	3 (2.8%)	3 (2.8%)
		7	.	3 (2.8%)	3 (2.8%)
		7.5	.	1 (0.9%)	1 (0.9%)
		8	.	3 (2.8%)	3 (2.8%)
	7.5	6	.	3 (2.8%)	3 (2.8%)
		6.5	.	5 (4.7%)	5 (4.7%)
		7	.	2 (1.9%)	2 (1.9%)
		7.5	.	3 (2.8%)	3 (2.8%)
		8	.	2 (1.9%)	2 (1.9%)
		8.5	.	1 (0.9%)	1 (0.9%)
	8	8	.	1 (0.9%)	1 (0.9%)
Week 52	m		0	107	107
	5.5	5.5	.	2 (1.9%)	2 (1.9%)
		6	.	7 (6.5%)	7 (6.5%)
		6.5	.	3 (2.8%)	3 (2.8%)
		7	.	1 (0.9%)	1 (0.9%)
		7.5	.	1 (0.9%)	1 (0.9%)
	6	5.5	.	4 (3.7%)	4 (3.7%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
		6	.	15 (14.0%)	15 (14.0%)
		6.5	.	7 (6.5%)	7 (6.5%)
		7	.	6 (5.6%)	6 (5.6%)
		7.5	.	1 (0.9%)	1 (0.9%)
		8	.	2 (1.9%)	2 (1.9%)
	6.5	5.5	.	2 (1.9%)	2 (1.9%)
		6	.	7 (6.5%)	7 (6.5%)
		6.5	.	10 (9.3%)	10 (9.3%)
		7	.	6 (5.6%)	6 (5.6%)
		7.5	.	3 (2.8%)	3 (2.8%)
	7	6	.	2 (1.9%)	2 (1.9%)
		6.5	.	5 (4.7%)	5 (4.7%)
		7	.	4 (3.7%)	4 (3.7%)
		7.5	.	2 (1.9%)	2 (1.9%)
	7.5	6	.	5 (4.7%)	5 (4.7%)
		6.5	.	5 (4.7%)	5 (4.7%)
		7	.	3 (2.8%)	3 (2.8%)
		7.5	.	2 (1.9%)	2 (1.9%)
		8	.	1 (0.9%)	1 (0.9%)
	8	8	.	1 (0.9%)	1 (0.9%)
LOCF Endpoint	m		101	108	209
	5.5	5.5	4 (4.0%)	2 (1.9%)	6 (2.9%)
		6	8 (7.9%)	7 (6.5%)	15 (7.2%)
		6.5	1 (1.0%)	3 (2.8%)	4 (1.9%)
		7	0	1 (0.9%)	1 (0.5%)
		7.5	1 (1.0%)	1 (0.9%)	2 (1.0%)
		8	1 (1.0%)	0	1 (0.5%)
	6	5.5	4 (4.0%)	4 (3.7%)	8 (3.8%)
		6	11 (10.9%)	15 (13.9%)	26 (12.4%)
		6.5	11 (10.9%)	7 (6.5%)	18 (8.6%)
		7	4 (4.0%)	6 (5.6%)	10 (4.8%)
		7.5	2 (2.0%)	1 (0.9%)	3 (1.4%)
		8	0	2 (1.9%)	2 (1.0%)
	6.5	5.5	2 (2.0%)	2 (1.9%)	4 (1.9%)
		6	11 (10.9%)	7 (6.5%)	18 (8.6%)
		6.5	8 (7.9%)	11 (10.2%)	19 (9.1%)
		7	6 (5.9%)	6 (5.6%)	12 (5.7%)
		7.5	0	3 (2.8%)	3 (1.4%)
	7	5.5	1 (1.0%)	0	1 (0.5%)
		6	4 (4.0%)	2 (1.9%)	6 (2.9%)
		6.5	5 (5.0%)	5 (4.6%)	10 (4.8%)
		7	5 (5.0%)	4 (3.7%)	9 (4.3%)
		7.5	1 (1.0%)	2 (1.9%)	3 (1.4%)
	7.5	6	3 (3.0%)	5 (4.6%)	8 (3.8%)
		6.5	2 (2.0%)	5 (4.6%)	7 (3.3%)
		7	1 (1.0%)	3 (2.8%)	4 (1.9%)
		7.5	3 (3.0%)	2 (1.9%)	5 (2.4%)
		8	1 (1.0%)	1 (0.9%)	2 (1.0%)
	8	6.5	1 (1.0%)	0	1 (0.5%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
		8	0	1 (0.9%)	1 (0.5%)
Specific Gravity					
Week 4	m		100	108	208
	Low	Low	3 (3.0%)	1 (0.9%)	4 (1.9%)
		Normal	0	3 (2.8%)	3 (1.4%)
	Normal	Low	0	1 (0.9%)	1 (0.5%)
		Normal	97 (97.0%)	103 (95.4%)	200 (96.2%)
Week 8	m		101	108	209
	Low	Low	0	2 (1.9%)	2 (1.0%)
		Normal	3 (3.0%)	2 (1.9%)	5 (2.4%)
	Normal	Low	2 (2.0%)	1 (0.9%)	3 (1.4%)
		Normal	96 (95.0%)	103 (95.4%)	199 (95.2%)
Week 12	m		101	108	209
	Low	Low	1 (1.0%)	2 (1.9%)	3 (1.4%)
		Normal	2 (2.0%)	2 (1.9%)	4 (1.9%)
	Normal	Low	1 (1.0%)	2 (1.9%)	3 (1.4%)
		Normal	97 (96.0%)	102 (94.4%)	199 (95.2%)
Week 16	m		99	108	207
	Low	Low	2 (2.0%)	2 (1.9%)	4 (1.9%)
		Normal	1 (1.0%)	2 (1.9%)	3 (1.4%)
	Normal	Low	0	2 (1.9%)	2 (1.0%)
		Normal	95 (96.0%)	101 (93.5%)	196 (94.7%)
		High	1 (1.0%)	1 (0.9%)	2 (1.0%)
Week 20	m		99	108	207
	Low	Low	0	1 (0.9%)	1 (0.5%)
		Normal	3 (3.0%)	3 (2.8%)	6 (2.9%)
	Normal	Low	0	2 (1.9%)	2 (1.0%)
		Normal	96 (97.0%)	101 (93.5%)	197 (95.2%)
		High	0	1 (0.9%)	1 (0.5%)
Week 24	m		99	108	207
	Low	Low	2 (2.0%)	1 (0.9%)	3 (1.4%)
		Normal	1 (1.0%)	3 (2.8%)	4 (1.9%)
	Normal	Low	3 (3.0%)	1 (0.9%)	4 (1.9%)
		Normal	93 (93.9%)	103 (95.4%)	196 (94.7%)
Week 32	m		98	107	205
	Low	Low	3 (3.1%)	1 (0.9%)	4 (2.0%)
		Normal	0	3 (2.8%)	3 (1.5%)
	Normal	Low	1 (1.0%)	4 (3.7%)	5 (2.4%)
		Normal	93 (94.9%)	99 (92.5%)	192 (93.7%)
		High	1 (1.0%)	0	1 (0.5%)
Week 36	m		98	108	206
	Low	Low	1 (1.0%)	1 (0.9%)	2 (1.0%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
		Normal	1 (1.0%)	3 (2.8%)	4 (1.9%)
		High	1 (1.0%)	0	1 (0.5%)
	Normal	Low	3 (3.1%)	2 (1.9%)	5 (2.4%)
		Normal	91 (92.9%)	102 (94.4%)	193 (93.7%)
		High	1 (1.0%)	0	1 (0.5%)
Week 40	m		0	107	107
	Low	Low	.	1 (0.9%)	1 (0.9%)
		Normal	.	3 (2.8%)	3 (2.8%)
	Normal	Low	.	3 (2.8%)	3 (2.8%)
		Normal	.	100 (93.5%)	100 (93.5%)
Week 44	m		0	107	107
	Low	Low	.	1 (0.9%)	1 (0.9%)
		Normal	.	3 (2.8%)	3 (2.8%)
	Normal	Normal	.	103 (96.3%)	103 (96.3%)
Week 48	m		0	107	107
	Low	Low	.	2 (1.9%)	2 (1.9%)
		Normal	.	2 (1.9%)	2 (1.9%)
	Normal	Low	.	3 (2.8%)	3 (2.8%)
		Normal	.	99 (92.5%)	99 (92.5%)
		High	.	1 (0.9%)	1 (0.9%)
Week 52	m		0	107	107
	Low	Low	.	1 (0.9%)	1 (0.9%)
		Normal	.	3 (2.8%)	3 (2.8%)
	Normal	Low	.	3 (2.8%)	3 (2.8%)
		Normal	.	99 (92.5%)	99 (92.5%)
		High	.	1 (0.9%)	1 (0.9%)
LOCF Endpoint	m		101	108	209
	Low	Low	1 (1.0%)	1 (0.9%)	2 (1.0%)
		Normal	1 (1.0%)	3 (2.8%)	4 (1.9%)
		High	1 (1.0%)	0	1 (0.5%)
	Normal	Low	3 (3.0%)	3 (2.8%)	6 (2.9%)
		Normal	94 (93.1%)	100 (92.6%)	194 (92.8%)
		High	1 (1.0%)	1 (0.9%)	2 (1.0%)
Urine Glucose					
Week 4	m		100	108	208
	Negative	Negative	52 (52.0%)	65 (60.2%)	117 (56.3%)
		Trace	1 (1.0%)	5 (4.6%)	6 (2.9%)
		Positive	5 (5.0%)	3 (2.8%)	8 (3.8%)
	Trace	Negative	5 (5.0%)	7 (6.5%)	12 (5.8%)
		Trace	2 (2.0%)	4 (3.7%)	6 (2.9%)
		Positive	2 (2.0%)	1 (0.9%)	3 (1.4%)
	Positive	Negative	9 (9.0%)	12 (11.1%)	21 (10.1%)
		Trace	3 (3.0%)	1 (0.9%)	4 (1.9%)
		Positive	21 (21.0%)	10 (9.3%)	31 (14.9%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
Week 8	m		101	108	209
	Negative	Negative	48 (47.5%)	65 (60.2%)	113 (54.1%)
		Trace	5 (5.0%)	4 (3.7%)	9 (4.3%)
		Positive	5 (5.0%)	4 (3.7%)	9 (4.3%)
	Trace	Negative	6 (5.9%)	6 (5.6%)	12 (5.7%)
		Trace	1 (1.0%)	2 (1.9%)	3 (1.4%)
		Positive	2 (2.0%)	4 (3.7%)	6 (2.9%)
	Positive	Negative	9 (8.9%)	13 (12.0%)	22 (10.5%)
		Trace	3 (3.0%)	3 (2.8%)	6 (2.9%)
		Positive	22 (21.8%)	7 (6.5%)	29 (13.9%)
Week 12	m		101	108	209
	Negative	Negative	48 (47.5%)	65 (60.2%)	113 (54.1%)
		Trace	4 (4.0%)	4 (3.7%)	8 (3.8%)
		Positive	6 (5.9%)	4 (3.7%)	10 (4.8%)
	Trace	Negative	5 (5.0%)	6 (5.6%)	11 (5.3%)
		Trace	1 (1.0%)	3 (2.8%)	4 (1.9%)
		Positive	3 (3.0%)	3 (2.8%)	6 (2.9%)
	Positive	Negative	10 (9.9%)	13 (12.0%)	23 (11.0%)
		Trace	3 (3.0%)	1 (0.9%)	4 (1.9%)
		Positive	21 (20.8%)	9 (8.3%)	30 (14.4%)
Week 16	m		99	108	207
	Negative	Negative	50 (50.5%)	63 (58.3%)	113 (54.6%)
		Trace	5 (5.1%)	4 (3.7%)	9 (4.3%)
		Positive	3 (3.0%)	6 (5.6%)	9 (4.3%)
	Trace	Negative	6 (6.1%)	7 (6.5%)	13 (6.3%)
		Trace	0	2 (1.9%)	2 (1.0%)
		Positive	3 (3.0%)	3 (2.8%)	6 (2.9%)
	Positive	Negative	7 (7.1%)	10 (9.3%)	17 (8.2%)
		Trace	3 (3.0%)	4 (3.7%)	7 (3.4%)
		Positive	22 (22.2%)	9 (8.3%)	31 (15.0%)
Week 20	m		99	108	207
	Negative	Negative	50 (50.5%)	66 (61.1%)	116 (56.0%)
		Trace	3 (3.0%)	4 (3.7%)	7 (3.4%)
		Positive	5 (5.1%)	3 (2.8%)	8 (3.9%)
	Trace	Negative	6 (6.1%)	7 (6.5%)	13 (6.3%)
		Trace	1 (1.0%)	2 (1.9%)	3 (1.4%)
		Positive	2 (2.0%)	3 (2.8%)	5 (2.4%)
	Positive	Negative	10 (10.1%)	12 (11.1%)	22 (10.6%)
		Trace	5 (5.1%)	4 (3.7%)	9 (4.3%)
		Positive	17 (17.2%)	7 (6.5%)	24 (11.6%)
Week 24	m		99	108	207
	Negative	Negative	51 (51.5%)	65 (60.2%)	116 (56.0%)
		Trace	1 (1.0%)	3 (2.8%)	4 (1.9%)
		Positive	6 (6.1%)	5 (4.6%)	11 (5.3%)
	Trace	Negative	4 (4.0%)	7 (6.5%)	11 (5.3%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
		Trace	2 (2.0%)	3 (2.8%)	5 (2.4%)
		Positive	3 (3.0%)	2 (1.9%)	5 (2.4%)
	Positive	Negative	14 (14.1%)	13 (12.0%)	27 (13.0%)
		Trace	4 (4.0%)	2 (1.9%)	6 (2.9%)
		Positive	14 (14.1%)	8 (7.4%)	22 (10.6%)
Week 32	m		98	107	205
	Negative	Negative	47 (48.0%)	66 (61.7%)	113 (55.1%)
		Trace	3 (3.1%)	1 (0.9%)	4 (2.0%)
		Positive	7 (7.1%)	5 (4.7%)	12 (5.9%)
	Trace	Negative	5 (5.1%)	6 (5.6%)	11 (5.4%)
		Trace	2 (2.0%)	2 (1.9%)	4 (2.0%)
		Positive	2 (2.0%)	4 (3.7%)	6 (2.9%)
	Positive	Negative	11 (11.2%)	11 (10.3%)	22 (10.7%)
		Trace	7 (7.1%)	3 (2.8%)	10 (4.9%)
		Positive	14 (14.3%)	9 (8.4%)	23 (11.2%)
Week 36	m		98	108	206
	Negative	Negative	47 (48.0%)	65 (60.2%)	112 (54.4%)
		Trace	2 (2.0%)	3 (2.8%)	5 (2.4%)
		Positive	8 (8.2%)	5 (4.6%)	13 (6.3%)
	Trace	Negative	4 (4.1%)	7 (6.5%)	11 (5.3%)
		Trace	1 (1.0%)	1 (0.9%)	2 (1.0%)
		Positive	4 (4.1%)	4 (3.7%)	8 (3.9%)
	Positive	Negative	12 (12.2%)	14 (13.0%)	26 (12.6%)
		Trace	3 (3.1%)	3 (2.8%)	6 (2.9%)
		Positive	17 (17.3%)	6 (5.6%)	23 (11.2%)
Week 40	m		0	107	107
	Negative	Negative	.	64 (59.8%)	64 (59.8%)
		Trace	.	3 (2.8%)	3 (2.8%)
		Positive	.	6 (5.6%)	6 (5.6%)
	Trace	Negative	.	6 (5.6%)	6 (5.6%)
		Trace	.	1 (0.9%)	1 (0.9%)
		Positive	.	4 (3.7%)	4 (3.7%)
	Positive	Negative	.	15 (14.0%)	15 (14.0%)
		Trace	.	2 (1.9%)	2 (1.9%)
		Positive	.	6 (5.6%)	6 (5.6%)
Week 44	m		0	107	107
	Negative	Negative	.	68 (63.6%)	68 (63.6%)
		Trace	.	2 (1.9%)	2 (1.9%)
		Positive	.	3 (2.8%)	3 (2.8%)
	Trace	Negative	.	9 (8.4%)	9 (8.4%)
		Positive	.	2 (1.9%)	2 (1.9%)
	Positive	Negative	.	14 (13.1%)	14 (13.1%)
		Trace	.	2 (1.9%)	2 (1.9%)
		Positive	.	7 (6.5%)	7 (6.5%)
Week 48	m		0	107	107

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
	Negative	Negative	.	65 (60.7%)	65 (60.7%)
		Trace	.	5 (4.7%)	5 (4.7%)
		Positive	.	3 (2.8%)	3 (2.8%)
	Trace	Negative	.	7 (6.5%)	7 (6.5%)
		Trace	.	2 (1.9%)	2 (1.9%)
		Positive	.	2 (1.9%)	2 (1.9%)
	Positive	Negative	.	14 (13.1%)	14 (13.1%)
		Trace	.	1 (0.9%)	1 (0.9%)
		Positive	.	8 (7.5%)	8 (7.5%)
Week 52	m		0	107	107
	Negative	Negative	.	64 (59.8%)	64 (59.8%)
		Trace	.	4 (3.7%)	4 (3.7%)
		Positive	.	5 (4.7%)	5 (4.7%)
	Trace	Negative	.	9 (8.4%)	9 (8.4%)
		Trace	.	1 (0.9%)	1 (0.9%)
		Positive	.	1 (0.9%)	1 (0.9%)
	Positive	Negative	.	12 (11.2%)	12 (11.2%)
		Trace	.	3 (2.8%)	3 (2.8%)
		Positive	.	8 (7.5%)	8 (7.5%)
LOCF Endpoint	m		101	108	209
	Negative	Negative	48 (47.5%)	64 (59.3%)	112 (53.6%)
		Trace	2 (2.0%)	4 (3.7%)	6 (2.9%)
		Positive	8 (7.9%)	5 (4.6%)	13 (6.2%)
	Trace	Negative	4 (4.0%)	9 (8.3%)	13 (6.2%)
		Trace	1 (1.0%)	1 (0.9%)	2 (1.0%)
		Positive	4 (4.0%)	2 (1.9%)	6 (2.9%)
	Positive	Negative	12 (11.9%)	12 (11.1%)	24 (11.5%)
		Trace	4 (4.0%)	3 (2.8%)	7 (3.3%)
		Positive	18 (17.8%)	8 (7.4%)	26 (12.4%)
Urine Protein					
Week 4	m		100	108	208
	Negative	Negative	29 (29.0%)	35 (32.4%)	64 (30.8%)
		Trace	7 (7.0%)	8 (7.4%)	15 (7.2%)
		Positive	1 (1.0%)	2 (1.9%)	3 (1.4%)
	Trace	Negative	12 (12.0%)	16 (14.8%)	28 (13.5%)
		Trace	18 (18.0%)	21 (19.4%)	39 (18.8%)
		Positive	4 (4.0%)	5 (4.6%)	9 (4.3%)
	Positive	Negative	4 (4.0%)	0	4 (1.9%)
		Trace	8 (8.0%)	10 (9.3%)	18 (8.7%)
		Positive	17 (17.0%)	11 (10.2%)	28 (13.5%)
Week 8	m		101	108	209
	Negative	Negative	24 (23.8%)	33 (30.6%)	57 (27.3%)
		Trace	8 (7.9%)	10 (9.3%)	18 (8.6%)
		Positive	5 (5.0%)	2 (1.9%)	7 (3.3%)
	Trace	Negative	13 (12.9%)	16 (14.8%)	29 (13.9%)
		Trace	15 (14.9%)	21 (19.4%)	36 (17.2%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
		Positive	7 (6.9%)	5 (4.6%)	12 (5.7%)
	Positive	Negative	5 (5.0%)	1 (0.9%)	6 (2.9%)
		Trace	10 (9.9%)	10 (9.3%)	20 (9.6%)
		Positive	14 (13.9%)	10 (9.3%)	24 (11.5%)
Week 12	m		101	108	209
	Negative	Negative	28 (27.7%)	33 (30.6%)	61 (29.2%)
		Trace	6 (5.9%)	9 (8.3%)	15 (7.2%)
		Positive	3 (3.0%)	3 (2.8%)	6 (2.9%)
	Trace	Negative	14 (13.9%)	15 (13.9%)	29 (13.9%)
		Trace	12 (11.9%)	21 (19.4%)	33 (15.8%)
		Positive	9 (8.9%)	6 (5.6%)	15 (7.2%)
	Positive	Negative	1 (1.0%)	1 (0.9%)	2 (1.0%)
		Trace	10 (9.9%)	10 (9.3%)	20 (9.6%)
		Positive	18 (17.8%)	10 (9.3%)	28 (13.4%)
Week 16	m		99	108	207
	Negative	Negative	28 (28.3%)	34 (31.5%)	62 (30.0%)
		Trace	9 (9.1%)	8 (7.4%)	17 (8.2%)
		Positive	0	3 (2.8%)	3 (1.4%)
	Trace	Negative	14 (14.1%)	14 (13.0%)	28 (13.5%)
		Trace	14 (14.1%)	22 (20.4%)	36 (17.4%)
		Positive	5 (5.1%)	6 (5.6%)	11 (5.3%)
	Positive	Negative	5 (5.1%)	3 (2.8%)	8 (3.9%)
		Trace	5 (5.1%)	9 (8.3%)	14 (6.8%)
		Positive	19 (19.2%)	9 (8.3%)	28 (13.5%)
Week 20	m		99	108	207
	Negative	Negative	30 (30.3%)	37 (34.3%)	67 (32.4%)
		Trace	6 (6.1%)	7 (6.5%)	13 (6.3%)
		Positive	1 (1.0%)	1 (0.9%)	2 (1.0%)
	Trace	Negative	10 (10.1%)	19 (17.6%)	29 (14.0%)
		Trace	20 (20.2%)	19 (17.6%)	39 (18.8%)
		Positive	3 (3.0%)	4 (3.7%)	7 (3.4%)
	Positive	Negative	4 (4.0%)	2 (1.9%)	6 (2.9%)
		Trace	9 (9.1%)	8 (7.4%)	17 (8.2%)
		Positive	16 (16.2%)	11 (10.2%)	27 (13.0%)
Week 24	m		99	108	207
	Negative	Negative	25 (25.3%)	35 (32.4%)	60 (29.0%)
		Trace	10 (10.1%)	6 (5.6%)	16 (7.7%)
		Positive	2 (2.0%)	4 (3.7%)	6 (2.9%)
	Trace	Negative	12 (12.1%)	21 (19.4%)	33 (15.9%)
		Trace	13 (13.1%)	14 (13.0%)	27 (13.0%)
		Positive	8 (8.1%)	7 (6.5%)	15 (7.2%)
	Positive	Negative	6 (6.1%)	1 (0.9%)	7 (3.4%)
		Trace	7 (7.1%)	8 (7.4%)	15 (7.2%)
		Positive	16 (16.2%)	12 (11.1%)	28 (13.5%)
Week 32	m		98	107	205

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
	Negative	Negative	22 (22.4%)	35 (32.7%)	57 (27.8%)
		Trace	11 (11.2%)	7 (6.5%)	18 (8.8%)
		Positive	3 (3.1%)	3 (2.8%)	6 (2.9%)
	Trace	Negative	10 (10.2%)	22 (20.6%)	32 (15.6%)
		Trace	19 (19.4%)	13 (12.1%)	32 (15.6%)
		Positive	4 (4.1%)	6 (5.6%)	10 (4.9%)
	Positive	Negative	2 (2.0%)	3 (2.8%)	5 (2.4%)
		Trace	7 (7.1%)	6 (5.6%)	13 (6.3%)
		Positive	20 (20.4%)	12 (11.2%)	32 (15.6%)
Week 36	m		98	108	206
	Negative	Negative	24 (24.5%)	31 (28.7%)	55 (26.7%)
		Trace	8 (8.2%)	11 (10.2%)	19 (9.2%)
		Positive	4 (4.1%)	3 (2.8%)	7 (3.4%)
	Trace	Negative	11 (11.2%)	26 (24.1%)	37 (18.0%)
		Trace	14 (14.3%)	12 (11.1%)	26 (12.6%)
		Positive	8 (8.2%)	4 (3.7%)	12 (5.8%)
	Positive	Negative	4 (4.1%)	2 (1.9%)	6 (2.9%)
		Trace	6 (6.1%)	12 (11.1%)	18 (8.7%)
		Positive	19 (19.4%)	7 (6.5%)	26 (12.6%)
Week 40	m		0	107	107
	Negative	Negative	.	37 (34.6%)	37 (34.6%)
		Trace	.	6 (5.6%)	6 (5.6%)
		Positive	.	2 (1.9%)	2 (1.9%)
	Trace	Negative	.	20 (18.7%)	20 (18.7%)
		Trace	.	19 (17.8%)	19 (17.8%)
		Positive	.	3 (2.8%)	3 (2.8%)
	Positive	Negative	.	3 (2.8%)	3 (2.8%)
		Trace	.	5 (4.7%)	5 (4.7%)
		Positive	.	12 (11.2%)	12 (11.2%)
Week 44	m		0	107	107
	Negative	Negative	.	34 (31.8%)	34 (31.8%)
		Trace	.	7 (6.5%)	7 (6.5%)
		Positive	.	4 (3.7%)	4 (3.7%)
	Trace	Negative	.	20 (18.7%)	20 (18.7%)
		Trace	.	16 (15.0%)	16 (15.0%)
		Positive	.	6 (5.6%)	6 (5.6%)
	Positive	Negative	.	2 (1.9%)	2 (1.9%)
		Trace	.	8 (7.5%)	8 (7.5%)
		Positive	.	10 (9.3%)	10 (9.3%)
Week 48	m		0	107	107
	Negative	Negative	.	34 (31.8%)	34 (31.8%)
		Trace	.	9 (8.4%)	9 (8.4%)
		Positive	.	2 (1.9%)	2 (1.9%)
	Trace	Negative	.	18 (16.8%)	18 (16.8%)
		Trace	.	15 (14.0%)	15 (14.0%)
		Positive	.	9 (8.4%)	9 (8.4%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
	Positive	Negative	.	3 (2.8%)	3 (2.8%)
		Trace	.	7 (6.5%)	7 (6.5%)
		Positive	.	10 (9.3%)	10 (9.3%)
Week 52	m		0	107	107
	Negative	Negative	.	31 (29.0%)	31 (29.0%)
		Trace	.	12 (11.2%)	12 (11.2%)
		Positive	.	2 (1.9%)	2 (1.9%)
	Trace	Negative	.	20 (18.7%)	20 (18.7%)
		Trace	.	17 (15.9%)	17 (15.9%)
		Positive	.	5 (4.7%)	5 (4.7%)
	Positive	Negative	.	2 (1.9%)	2 (1.9%)
		Trace	.	9 (8.4%)	9 (8.4%)
		Positive	.	9 (8.4%)	9 (8.4%)
LOCF Endpoint	m		101	108	209
	Negative	Negative	24 (23.8%)	31 (28.7%)	55 (26.3%)
		Trace	9 (8.9%)	12 (11.1%)	21 (10.0%)
		Positive	4 (4.0%)	2 (1.9%)	6 (2.9%)
	Trace	Negative	12 (11.9%)	20 (18.5%)	32 (15.3%)
		Trace	15 (14.9%)	17 (15.7%)	32 (15.3%)
		Positive	8 (7.9%)	5 (4.6%)	13 (6.2%)
	Positive	Negative	4 (4.0%)	2 (1.9%)	6 (2.9%)
		Trace	6 (5.9%)	10 (9.3%)	16 (7.7%)
		Positive	19 (18.8%)	9 (8.3%)	28 (13.4%)
Urobilinogen					
Week 4	m		100	108	208
	Normal	Normal	97 (97.0%)	107 (99.1%)	204 (98.1%)
	Abnormal	Normal	3 (3.0%)	1 (0.9%)	4 (1.9%)
Week 8	m		101	108	209
	Normal	Normal	96 (95.0%)	106 (98.1%)	202 (96.7%)
		Abnormal	2 (2.0%)	1 (0.9%)	3 (1.4%)
	Abnormal	Normal	3 (3.0%)	0	3 (1.4%)
		Abnormal	0	1 (0.9%)	1 (0.5%)
Week 12	m		101	108	209
	Normal	Normal	98 (97.0%)	105 (97.2%)	203 (97.1%)
		Abnormal	0	2 (1.9%)	2 (1.0%)
	Abnormal	Normal	2 (2.0%)	1 (0.9%)	3 (1.4%)
		Abnormal	1 (1.0%)	0	1 (0.5%)
Week 16	m		99	108	207
	Normal	Normal	94 (94.9%)	106 (98.1%)	200 (96.6%)
		Abnormal	2 (2.0%)	1 (0.9%)	3 (1.4%)
	Abnormal	Normal	3 (3.0%)	1 (0.9%)	4 (1.9%)
Week 20	m		99	108	207
	Normal	Normal	92 (92.9%)	107 (99.1%)	199 (96.1%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
		Abnormal	4 (4.0%)	0	4 (1.9%)
	Abnormal	Normal	3 (3.0%)	1 (0.9%)	4 (1.9%)
Week 24	m		99	108	207
	Normal	Normal	94 (94.9%)	106 (98.1%)	200 (96.6%)
		Abnormal	2 (2.0%)	1 (0.9%)	3 (1.4%)
	Abnormal	Normal	1 (1.0%)	1 (0.9%)	2 (1.0%)
		Abnormal	2 (2.0%)	0	2 (1.0%)
Week 32	m		98	107	205
	Normal	Normal	92 (93.9%)	105 (98.1%)	197 (96.1%)
		Abnormal	3 (3.1%)	1 (0.9%)	4 (2.0%)
	Abnormal	Normal	3 (3.1%)	1 (0.9%)	4 (2.0%)
Week 36	m		98	108	206
	Normal	Normal	94 (95.9%)	106 (98.1%)	200 (97.1%)
		Abnormal	1 (1.0%)	1 (0.9%)	2 (1.0%)
	Abnormal	Normal	3 (3.1%)	1 (0.9%)	4 (1.9%)
Week 40	m		0	107	107
	Normal	Normal	.	102 (95.3%)	102 (95.3%)
		Abnormal	.	4 (3.7%)	4 (3.7%)
	Abnormal	Normal	.	1 (0.9%)	1 (0.9%)
Week 44	m		0	107	107
	Normal	Normal	.	104 (97.2%)	104 (97.2%)
		Abnormal	.	2 (1.9%)	2 (1.9%)
	Abnormal	Abnormal	.	1 (0.9%)	1 (0.9%)
Week 48	m		0	107	107
	Normal	Normal	.	103 (96.3%)	103 (96.3%)
		Abnormal	.	3 (2.8%)	3 (2.8%)
	Abnormal	Abnormal	.	1 (0.9%)	1 (0.9%)
Week 52	m		0	107	107
	Normal	Normal	.	101 (94.4%)	101 (94.4%)
		Abnormal	.	5 (4.7%)	5 (4.7%)
	Abnormal	Normal	.	1 (0.9%)	1 (0.9%)
LOCF Endpoint	m		101	108	209
	Normal	Normal	97 (96.0%)	102 (94.4%)	199 (95.2%)
		Abnormal	1 (1.0%)	5 (4.6%)	6 (2.9%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
	Abnormal	Normal	3 (3.0%)	1 (0.9%)	4 (1.9%)

- Abbreviations: LOCF, Last Observation Carried Forward
- "Imeglimin" in this table means "Imeglimin 1000 mg twice daily".
- The Long-term Safety Population excludes data during administration of placebo in the double-blind period.
- "Imeglimin + Insulin Total" is the sum of subjects in the placebo group in the open-label period and Imeglimin group in the double-blind and open-label periods.
- m in row headings is the total number of subjects with both baseline and the corresponding visit values available, and is used as the denominator to calculate percentages.
- For "Placebo/Imeglimin + Insulin" group, baseline was defined as last visit with non-missing value prior to or at the day of first dose of Investigational Medicinal Product (IMP) in open-label treatment period. For "Imeglimin/Imeglimin + Insulin" group, baseline was the same as for the double-blind treatment period.

Control No:<<t-s-204-labot-020lt.sas, 2020-03-06T00:19:28>>

Table S-205 Shift of Laboratory Findings of Coagulation in Long-term Period (PXL008-020; Long-term Safety Population)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
Activated Partial Thromboplastin Time (sec)					
Week 16	m		0	107	107
	Low	Low	.	16 (15.0%)	16 (15.0%)
		Normal	.	6 (5.6%)	6 (5.6%)
	Normal	Low	.	12 (11.2%)	12 (11.2%)
		Normal	.	73 (68.2%)	73 (68.2%)
Week 20	m		97	0	97
	Low	Low	13 (13.4%)	.	13 (13.4%)
		Normal	6 (6.2%)	.	6 (6.2%)
	Normal	Low	13 (13.4%)	.	13 (13.4%)
		Normal	64 (66.0%)	.	64 (66.0%)
	High	High	1 (1.0%)	.	1 (1.0%)
Week 36	m		96	101	197
	Low	Low	13 (13.5%)	17 (16.8%)	30 (15.2%)
		Normal	6 (6.3%)	5 (5.0%)	11 (5.6%)
	Normal	Low	4 (4.2%)	8 (7.9%)	12 (6.1%)
		Normal	72 (75.0%)	71 (70.3%)	143 (72.6%)
	High	High	1 (1.0%)	0	1 (0.5%)
Week 52	m		0	99	99
	Low	Low	.	15 (15.2%)	15 (15.2%)
		Normal	.	7 (7.1%)	7 (7.1%)
	Normal	Low	.	11 (11.1%)	11 (11.1%)
		Normal	.	66 (66.7%)	66 (66.7%)
LOCF Endpoint	m		99	108	207
	Low	Low	13 (13.1%)	16 (14.8%)	29 (14.0%)
		Normal	6 (6.1%)	7 (6.5%)	13 (6.3%)
	Normal	Low	5 (5.1%)	12 (11.1%)	17 (8.2%)
		Normal	74 (74.7%)	73 (67.6%)	147 (71.0%)
	High	High	1 (1.0%)	0	1 (0.5%)
Prothrombin Time (sec)					
Week 16	m		0	107	107
	Low	Low	.	3 (2.8%)	3 (2.8%)
		Normal	.	10 (9.3%)	10 (9.3%)
	Normal	Low	.	3 (2.8%)	3 (2.8%)
		Normal	.	91 (85.0%)	91 (85.0%)
Week 20	m		97	0	97
	Low	Low	4 (4.1%)	.	4 (4.1%)
		Normal	7 (7.2%)	.	7 (7.2%)
	Normal	Low	5 (5.2%)	.	5 (5.2%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
		Normal	81 (83.5%)	.	81 (83.5%)
Week 36	m		96	101	197
	Low	Low	5 (5.2%)	4 (4.0%)	9 (4.6%)
		Normal	7 (7.3%)	8 (7.9%)	15 (7.6%)
	Normal	Low	4 (4.2%)	5 (5.0%)	9 (4.6%)
		Normal	80 (83.3%)	84 (83.2%)	164 (83.2%)
Week 52	m		0	99	99
	Low	Low	.	4 (4.0%)	4 (4.0%)
		Normal	.	9 (9.1%)	9 (9.1%)
	Normal	Low	.	1 (1.0%)	1 (1.0%)
		Normal	.	85 (85.9%)	85 (85.9%)
LOCF Endpoint	m		99	108	207
	Low	Low	5 (5.1%)	4 (3.7%)	9 (4.3%)
		Normal	7 (7.1%)	9 (8.3%)	16 (7.7%)
	Normal	Low	4 (4.0%)	1 (0.9%)	5 (2.4%)
		Normal	83 (83.8%)	94 (87.0%)	177 (85.5%)

- Abbreviations: LOCF, Last Observation Carried Forward
- "Imeglimin" in this table means "Imeglimin 1000 mg twice daily".
- The Long-term Safety Population excludes data during administration of placebo in the double-blind period.
- "Imeglimin + Insulin Total" is the sum of subjects in the placebo group in the open-label period and Imeglimin group in the double-blind and open-label periods.
- m in row headings is the total number of subjects with both baseline and the corresponding visit values available, and is used as the denominator to calculate percentages.
- For "Placebo/Imeglimin + Insulin" group, baseline was defined as last visit with non-missing value prior to or at the day of first dose of Investigational Medicinal Product (IMP) in open-label treatment period. For "Imeglimin/Imeglimin + Insulin" group, baseline was the same as for the double-blind treatment period.

Control No:<<t-s-205-labot-020lt.sas, 2020-03-06T00:19:27>>

Table S-207 Shift of Laboratory Findings of UACR (Albuminuria) in Long-term Period (PXL008-020; Long-term Safety Population)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
Albumin/Creatinine (mg/g)					
Week 16	m		0	108	108
	Normal	Normal	.	63 (58.3%)	63 (58.3%)
		Micro	.	8 (7.4%)	8 (7.4%)
	Micro	Normal	.	6 (5.6%)	6 (5.6%)
		Micro	.	24 (22.2%)	24 (22.2%)
		Macro	.	3 (2.8%)	3 (2.8%)
	Macro	Macro	.	4 (3.7%)	4 (3.7%)
Week 20	m		99	0	99
	Normal	Normal	48 (48.5%)	.	48 (48.5%)
		Micro	7 (7.1%)	.	7 (7.1%)
	Micro	Normal	5 (5.1%)	.	5 (5.1%)
		Micro	26 (26.3%)	.	26 (26.3%)
		Macro	4 (4.0%)	.	4 (4.0%)
	Macro	Micro	1 (1.0%)	.	1 (1.0%)
		Macro	8 (8.1%)	.	8 (8.1%)
Week 36	m		98	107	205
	Normal	Normal	48 (49.0%)	62 (57.9%)	110 (53.7%)
		Micro	6 (6.1%)	9 (8.4%)	15 (7.3%)
	Micro	Normal	9 (9.2%)	7 (6.5%)	16 (7.8%)
		Micro	25 (25.5%)	23 (21.5%)	48 (23.4%)
		Macro	1 (1.0%)	2 (1.9%)	3 (1.5%)
	Macro	Micro	2 (2.0%)	0	2 (1.0%)
		Macro	7 (7.1%)	4 (3.7%)	11 (5.4%)
Week 52	m		0	107	107
	Normal	Normal	.	63 (58.9%)	63 (58.9%)
		Micro	.	8 (7.5%)	8 (7.5%)
	Micro	Normal	.	8 (7.5%)	8 (7.5%)
		Micro	.	22 (20.6%)	22 (20.6%)
		Macro	.	2 (1.9%)	2 (1.9%)
	Macro	Macro	.	4 (3.7%)	4 (3.7%)
LOCF Endpoint	m		99	108	207
	Normal	Normal	49 (49.5%)	63 (58.3%)	112 (54.1%)
		Micro	6 (6.1%)	8 (7.4%)	14 (6.8%)
	Micro	Normal	9 (9.1%)	8 (7.4%)	17 (8.2%)
		Micro	25 (25.3%)	23 (21.3%)	48 (23.2%)
		Macro	1 (1.0%)	2 (1.9%)	3 (1.4%)
	Macro	Micro	2 (2.0%)	0	2 (1.0%)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
		Macro	7 (7.1%)	4 (3.7%)	11 (5.3%)

- Abbreviations: LOCF, Last Observation Carried Forward
- "Imeglimin" in this table means "Imeglimin 1000 mg twice daily".
- The Long-term Safety Population excludes data during administration of placebo in the double-blind period.
- "Imeglimin + Insulin Total" is the sum of subjects in the placebo group in the open-label period and Imeglimin group in the double-blind and open-label periods.
- m in row headings is the total number of subjects with both baseline and the corresponding visit values available, and is used as the denominator to calculate percentages.
- For "Placebo/Imeglimin + Insulin" group, baseline was defined as last visit with non-missing value prior to or at the day of first dose of Investigational Medicinal Product (IMP) in open-label treatment period. For "Imeglimin/Imeglimin + Insulin" group, baseline was the same as for the double-blind treatment period.

Control No:<<t-s-207-labot-020lt.sas, 2020-03-06T00:19:27>>

Table S-208 Shift of Laboratory Findings of Lactate Concentration in Long-term Period (PXL008-020; Long-term Safety Population)

Parameter Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
Lactic Acid (mmol/L)					
Week 16	m		0	108	108
	Normal	Normal	.	101 (93.5%)	101 (93.5%)
		High	.	3 (2.8%)	3 (2.8%)
	High	High	.	4 (3.7%)	4 (3.7%)
Week 20	m		99	0	99
	Low	Low	1 (1.0%)	.	1 (1.0%)
	Normal	Normal	97 (98.0%)	.	97 (98.0%)
	High	Normal	1 (1.0%)	.	1 (1.0%)
Week 36	m		98	107	205
	Low	Normal	1 (1.0%)	0	1 (0.5%)
	Normal	Normal	92 (93.9%)	95 (88.8%)	187 (91.2%)
		High	4 (4.1%)	8 (7.5%)	12 (5.9%)
	High	Normal	0	1 (0.9%)	1 (0.5%)
		High	1 (1.0%)	3 (2.8%)	4 (2.0%)
Week 52	m		0	107	107
	Normal	Normal	.	100 (93.5%)	100 (93.5%)
		High	.	3 (2.8%)	3 (2.8%)
	High	Normal	.	2 (1.9%)	2 (1.9%)
		High	.	2 (1.9%)	2 (1.9%)
LOCF Endpoint	m		99	108	207
	Low	Normal	1 (1.0%)	0	1 (0.5%)
	Normal	Normal	93 (93.9%)	101 (93.5%)	194 (93.7%)
		High	4 (4.0%)	3 (2.8%)	7 (3.4%)
	High	Normal	0	2 (1.9%)	2 (1.0%)
		High	1 (1.0%)	2 (1.9%)	3 (1.4%)

- Abbreviations: LOCF, Last Observation Carried Forward
- "Imeglimin" in this table means "Imeglimin 1000 mg twice daily".
- The Long-term Safety Population excludes data during administration of placebo in the double-blind period.
- "Imeglimin + Insulin Total" is the sum of subjects in the placebo group in the open-label period and Imeglimin group in the double-blind and open-label periods.
- m in row headings is the total number of subjects with both baseline and the corresponding visit values available, and is used as the denominator to calculate percentages.
- For "Placebo/Imeglimin + Insulin" group, baseline was defined as last visit with non-missing value prior to or at the day of first dose of Investigational Medicinal Product (IMP) in open-label treatment period. For "Imeglimin/Imeglimin + Insulin" group, baseline was the same as for the double-blind treatment period.

Control No:<<t-s-208-labot-020lt.sas, 2020-03-06T00:19:37>>

Table S-209 Shift of ECG Findings in 52-Week Long-term Period in Combination with Insulin Therapy (PXL008-020; Long-term Safety Population)

Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
Interpretation					
Week 16	m		0	108	108
	Normal	Normal	.	86 (79.6%)	86 (79.6%)
		Abnormal, not clinically significant	.	1 (0.9%)	1 (0.9%)
	Abnormal, not clinically significant	Normal	.	4 (3.7%)	4 (3.7%)
		Abnormal, not clinically significant	.	17 (15.7%)	17 (15.7%)
Week 20	m		100	0	100
	Normal	Normal	75 (75.0%)	.	75 (75.0%)
		Abnormal, not clinically significant	6 (6.0%)	.	6 (6.0%)
	Abnormal, not clinically significant	Normal	2 (2.0%)	.	2 (2.0%)
		Abnormal, not clinically significant	15 (15.0%)	.	15 (15.0%)
		Abnormal, clinically significant	1 (1.0%)	.	1 (1.0%)
	Abnormal, clinically significant	Abnormal, clinically significant	1 (1.0%)	.	1 (1.0%)
Week 36	m		98	108	206
	Normal	Normal	76 (77.6%)	84 (77.8%)	160 (77.7%)
		Abnormal, not clinically significant	3 (3.1%)	3 (2.8%)	6 (2.9%)
	Abnormal, not clinically significant	Normal	3 (3.1%)	4 (3.7%)	7 (3.4%)
		Abnormal, not clinically significant	14 (14.3%)	17 (15.7%)	31 (15.0%)
		Abnormal, clinically significant	1 (1.0%)	0	1 (0.5%)
	Abnormal, clinically significant	Abnormal, clinically significant	1 (1.0%)	0	1 (0.5%)
Week 52	m		0	107	107
	Normal	Normal	.	82 (76.6%)	82 (76.6%)

Week	Baseline	Post-baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
		Abnormal, not clinically significant	.	4 (3.7%)	4 (3.7%)
	Abnormal, not clinically significant	Normal	.	4 (3.7%)	4 (3.7%)
		Abnormal, not clinically significant	.	17 (15.9%)	17 (15.9%)
LOCF Endpoint	m		100	108	208
	Normal	Normal	78 (78.0%)	82 (75.9%)	160 (76.9%)
		Abnormal, not clinically significant	3 (3.0%)	5 (4.6%)	8 (3.8%)
	Abnormal, not clinically significant	Normal	3 (3.0%)	4 (3.7%)	7 (3.4%)
		Abnormal, not clinically significant	14 (14.0%)	17 (15.7%)	31 (14.9%)
		Abnormal, clinically significant	1 (1.0%)	0	1 (0.5%)
	Abnormal, clinically significant	Abnormal, clinically significant	1 (1.0%)	0	1 (0.5%)

- Abbreviations: LOCF, Last Observation Carried Forward
- "Imeglimin" in this table means "Imeglimin 1000 mg twice daily".
- The Long-term Safety Population excludes data during administration of placebo in the double-blind period.
- "Imeglimin + Insulin Total" is the sum of subjects in the placebo group in the open-label period and Imeglimin group in the double-blind and open-label periods.
- m in row headings is the total number of subjects with both baseline and the corresponding visit values available, and is used as the denominator to calculate percentages.
- For "Placebo/Imeglimin + Insulin" group, baseline was defined as last visit with non-missing value prior to or at the day of first dose of Investigational Medicinal Product (IMP) in open-label treatment period. For "Imeglimin/Imeglimin + Insulin" group, baseline was the same as for the double-blind treatment period.

Control No:<<t-s-209-ecgqt-020lt.sas, 2020-03-06T00:15:21>>

Table S-214 Summary of Analysis Population in 24-Week Double-blind Period with Monotherapy (PXL008-014, PXL008-018; Safety Population)

Study Population	Placebo	Imeglimin 500 mg bid	Imeglimin 1000 mg bid	Imeglimin 1500 mg bid	Imeglimin Total
Study 014					
Safety Population	75	75	74	75	224
Efficacy Population	75	75	73	73	221
Study 018					
Safety Population	107	0	106	0	106
Efficacy Population	106	0	106	0	106
Pooled (Studies 014+018)					
Safety Population	182	75	180	75	330
Efficacy Population	181	75	179	73	327

- Abbreviations: bid, Twice a day

Control No:<<t-s-214-dispo-24wdb.sas, 2020-03-06T00:15:38>>

Table S-215 Summary of Analysis Population in 52-Week Long-term Period with Monotherapy and Combination Therapy (PXL008-019; Long-term Safety Population)

Population	Imeglimin	Imeglimin + SU	Imeglimin + GLIN	Imeglimin + BIG	Imeglimin + AGI	Imeglimin + TZD	Imeglimin + DPP4-I	Imeglimin + GLP1-RA	Imeglimin + SGLT2-I	Combination Total	Imeglimin Total
Long-term Safety Population	134	127	64	64	64	65	63	70	63	580	714
Long-term Efficacy Population	134	127	64	64	64	65	63	70	63	580	714

- Abbreviations: SU, Sulphonylurea; GLIN, Glinide; BIG, Biguanide; AGI, Alpha glucosidase inhibitor; TZD, Thiazolidinedione; DPP4-I, Dipeptidyl peptidase-4 inhibitor; GLP1-RA, Glucagon-like peptide 1 receptor agonist; SGLT2-I, Sodium glucose cotransporter 2 inhibitor
- "Imeglimin" in this table means "Imeglimin 1000 mg twice daily".
- "Combination Total" is the sum of the subjects excluding monotherapy "Imeglimin".
- "Imeglimin Total" is the sum of all subjects in Imeglimin treatment groups.

Control No:<<t-s-215-dispo-019lt.sas, 2020-03-06T00:14:58>>

Table S-216 Summary of Analysis Population in 16-Week Double-blind Period in Combination with Insulin Therapy (PXL008-020; Safety Population)

Population	Placebo + Insulin	Imeglimin 1000 mg bid + Insulin
Safety Population	107	108
Efficacy Population	106	108

- Abbreviations: bid, Twice a day

Control No:<<t-s-216-dispo-020db.sas, 2020-03-06T00:15:37>>

Table S-217 Summary of Analysis Population in 52-Week Long-term Period in Combination with Insulin Therapy (PXL008-020; Long-term Safety Population)

Population	Placebo/Imeglimin + Insulin	Imeglimin/Imeglimin + Insulin	Imeglimin + Insulin Total
Long-term Safety Population	101	108	209
Long-term Efficacy Population	101	108	209

- "Imeglimin" in this table means "Imeglimin 1000 mg twice daily".
- "Imeglimin + Insulin Total" is the sum of subjects in the placebo group in the open-label period and Imeglimin group in the double-blind and open-label periods.

Control No:<<t-s-217-dispo-020lt.sas, 2020-03-06T00:14:33>>

Table S-218 Subgroup Analysis of Overall Frequency of Treatment Emergent Adverse Events by Age in All Patients Treated Imeglimin 1000 mg bid Monotherapy (PXL008-014, PXL008-018, PXL008-019; Safety Population, Long-term Safety Population)

TEAE Age	Study 014 N = 74	Study 018 N = 106	Study 019 N = 134	Pooled (Studies 014+018+019) N = 314
Number of patients				
< 65 years	43	54	86	183
>= 65 years	31	52	48	131
< 75 years	72	99	127	298
>= 75 years	2	7	7	16
Any TEAE				
< 65 years	28 (65.1%)	21 (38.9%)	58 (67.4%)	107 (58.5%)
>= 65 years	18 (58.1%)	26 (50.0%)	40 (83.3%)	84 (64.1%)
< 75 years	45 (62.5%)	41 (41.4%)	92 (72.4%)	178 (59.7%)
>= 75 years	1 (50.0%)	6 (85.7%)	6 (85.7%)	13 (81.3%)
Treatment-related TEAE				
< 65 years	2 (4.7%)	3 (5.6%)	7 (8.1%)	12 (6.6%)
>= 65 years	2 (6.5%)	2 (3.8%)	6 (12.5%)	10 (7.6%)
< 75 years	4 (5.6%)	5 (5.1%)	11 (8.7%)	20 (6.7%)
>= 75 years	0	0	2 (28.6%)	2 (12.5%)
Severe TEAE				
< 65 years	2 (4.7%)	1 (1.9%)	0	3 (1.6%)
>= 65 years	2 (6.5%)	1 (1.9%)	2 (4.2%)	5 (3.8%)
< 75 years	4 (5.6%)	1 (1.0%)	2 (1.6%)	7 (2.3%)
>= 75 years	0	1 (14.3%)	0	1 (6.3%)
TEAE leading to death				
< 65 years	0	0	0	0
>= 65 years	0	0	1 (2.1%)	1 (0.8%)
< 75 years	0	0	1 (0.8%)	1 (0.3%)
>= 75 years	0	0	0	0
Serious TEAE				
< 65 years	1 (2.3%)	2 (3.7%)	1 (1.2%)	4 (2.2%)
>= 65 years	3 (9.7%)	2 (3.8%)	3 (6.3%)	8 (6.1%)
< 75 years	4 (5.6%)	2 (2.0%)	4 (3.1%)	10 (3.4%)
>= 75 years	0	2 (28.6%)	0	2 (12.5%)
TEAE leading to treatment discontinuation				
< 65 years	1 (2.3%)	2 (3.7%)	2 (2.3%)	5 (2.7%)
>= 65 years	2 (6.5%)	1 (1.9%)	1 (2.1%)	4 (3.1%)
< 75 years	3 (4.2%)	2 (2.0%)	3 (2.4%)	8 (2.7%)
>= 75 years	0	1 (14.3%)	0	1 (6.3%)
Hypoglycemia				
< 65 years	2 (4.7%)	3 (5.6%)	3 (3.5%)	8 (4.4%)
>= 65 years	0	0	2 (4.2%)	2 (1.5%)
< 75 years	2 (2.8%)	3 (3.0%)	5 (3.9%)	10 (3.4%)
>= 75 years	0	0	0	0
Lactic acidosis related TEAEs				
< 65 years	0	0	0	0
>= 65 years	0	0	0	0
< 75 years	0	0	0	0
>= 75 years	0	0	0	0
Cardiovascular TEAEs				

TEAE Age	Study 014 N = 74	Study 018 N = 106	Study 019 N = 134	Pooled (Studies 014+018+019) N = 314
< 65 years	0	0	0	0
>= 65 years	0	0	0	0
< 75 years	0	0	0	0
>= 75 years	0	0	0	0
Digestive Symptoms				
< 65 years	8 (18.6%)	6 (11.1%)	17 (19.8%)	31 (16.9%)
>= 65 years	6 (19.4%)	6 (11.5%)	13 (27.1%)	25 (19.1%)
< 75 years	14 (19.4%)	11 (11.1%)	27 (21.3%)	52 (17.4%)
>= 75 years	0	1 (14.3%)	3 (42.9%)	4 (25.0%)
Renal TEAEs				
< 65 years	0	1 (1.9%)	0	1 (0.5%)
>= 65 years	1 (3.2%)	0	1 (2.1%)	2 (1.5%)
< 75 years	1 (1.4%)	1 (1.0%)	1 (0.8%)	3 (1.0%)
>= 75 years	0	0	0	0
Hepatic TEAEs				
< 65 years	1 (2.3%)	1 (1.9%)	0	2 (1.1%)
>= 65 years	0	0	0	0
< 75 years	1 (1.4%)	1 (1.0%)	0	2 (0.7%)
>= 75 years	0	0	0	0

- Abbreviations: bid, Twice a day; AE, Adverse event; TEAE, Treatment Emergent AE
- Percentages are based on "Number of patients".

Control No:<<t-s-218-subae-other.sas, 2020-01-21T00:35:38>>

Table S-219 Subgroup Analysis of Overall Frequency of Treatment Emergent Adverse Events by Renal Function at Baseline in All Patients Treated Imeglimin 1000 mg bid Monotherapy (PXL008-014, PXL008-018, PXL008-019; Safety Population, Long-term Safety Population)

TEAE Renal function	Study 014 N = 74	Study 018 N = 106	Study 019 N = 134	Pooled (Studies 014+018+019) N = 314
Number of patients				
CKD Stage 1	9	12	24	45
CKD Stage 2	58	73	91	222
CKD Stage 3a	7	21	19	47
Any TEAE				
CKD Stage 1	6 (66.7%)	4 (33.3%)	16 (66.7%)	26 (57.8%)
CKD Stage 2	35 (60.3%)	33 (45.2%)	68 (74.7%)	136 (61.3%)
CKD Stage 3a	5 (71.4%)	10 (47.6%)	14 (73.7%)	29 (61.7%)
Treatment-related TEAE				
CKD Stage 1	0	0	3 (12.5%)	3 (6.7%)
CKD Stage 2	4 (6.9%)	4 (5.5%)	9 (9.9%)	17 (7.7%)
CKD Stage 3a	0	1 (4.8%)	1 (5.3%)	2 (4.3%)
Severe TEAE				
CKD Stage 1	0	0	0	0
CKD Stage 2	4 (6.9%)	2 (2.7%)	1 (1.1%)	7 (3.2%)
CKD Stage 3a	0	0	1 (5.3%)	1 (2.1%)
TEAE leading to death				
CKD Stage 1	0	0	0	0
CKD Stage 2	0	0	1 (1.1%)	1 (0.5%)
CKD Stage 3a	0	0	0	0
Serious TEAE				
CKD Stage 1	0	0	1 (4.2%)	1 (2.2%)
CKD Stage 2	4 (6.9%)	4 (5.5%)	2 (2.2%)	10 (4.5%)
CKD Stage 3a	0	0	1 (5.3%)	1 (2.1%)
TEAE leading to treatment discontinuation				
CKD Stage 1	0	0	0	0
CKD Stage 2	3 (5.2%)	3 (4.1%)	3 (3.3%)	9 (4.1%)
CKD Stage 3a	0	0	0	0
Hypoglycemia				
CKD Stage 1	0	0	2 (8.3%)	2 (4.4%)
CKD Stage 2	2 (3.4%)	1 (1.4%)	2 (2.2%)	5 (2.3%)
CKD Stage 3a	0	2 (9.5%)	1 (5.3%)	3 (6.4%)
Lactic acidosis related TEAEs				
CKD Stage 1	0	0	0	0
CKD Stage 2	0	0	0	0
CKD Stage 3a	0	0	0	0
Cardiovascular TEAEs				
CKD Stage 1	0	0	0	0
CKD Stage 2	0	0	0	0
CKD Stage 3a	0	0	0	0
Digestive Symptoms				
CKD Stage 1	1 (11.1%)	3 (25.0%)	6 (25.0%)	10 (22.2%)
CKD Stage 2	11 (19.0%)	8 (11.0%)	18 (19.8%)	37 (16.7%)
CKD Stage 3a	2 (28.6%)	1 (4.8%)	6 (31.6%)	9 (19.1%)
Renal TEAEs				
CKD Stage 1	0	0	0	0

TEAE Renal function	Study 014 N = 74	Study 018 N = 106	Study 019 N = 134	Pooled (Studies 014+018+019) N = 314
CKD Stage 2	1 (1.7%)	1 (1.4%)	1 (1.1%)	3 (1.4%)
CKD Stage 3a	0	0	0	0
Hepatic TEAEs				
CKD Stage 1	0	0	0	0
CKD Stage 2	1 (1.7%)	1 (1.4%)	0	2 (0.9%)
CKD Stage 3a	0	0	0	0

- Abbreviations: bid, Twice a day; AE, Adverse event; TEAE, Treatment Emergent AE; eGFR, Estimated Glomerular Filtration Rate; CKD, Chronic Kidney Disease
- CKD Stage 1 includes subjects with eGFR >= 90 mL/min/1.73m2, CKD Stage 2 includes subjects with eGFR >= 60 to < 90 mL/min/1.73m2, CKD Stage 3a includes subjects with eGFR >= 45 to < 60 mL/min/1.73m2.
- Percentages are based on "Number of patients".

Control No:<<t-s-219-subae-other.sas, 2020-03-06T00:15:26>>

Table S-232 Summary of Change from Baseline in Plasma Lactate Concentration (mmol/L) at All Visits in 24-Week Double-blind Period with Monotherapy (PXL008-014, PXL008-018; Safety Population)

Parameter	Observed			Change from baseline	
Treatment Visit	n	Mean (SD)	Median [Min, Max]	Mean (SD)	Median [Min, Max]
Lactic Acid (mmol/L)					
Placebo (N = 182)					
Baseline	181	1.26 (0.539)	1.10 [0.4, 3.3]		
Week 2	74	1.17 (0.518)	1.10 [0.3, 3.3]	-0.04 (0.486)	0.00 [-1.8, 1.3]
Week 4	72	1.22 (0.470)	1.15 [0.4, 2.6]	0.03 (0.480)	0.10 [-2.4, 0.9]
Week 8	70	1.21 (0.516)	1.10 [0.3, 3.3]	0.02 (0.552)	0.05 [-1.9, 1.4]
Week 12	168	1.27 (0.510)	1.20 [0.5, 3.9]	0.00 (0.483)	0.00 [-2.2, 1.2]
Week 16	66	1.23 (0.485)	1.10 [0.5, 2.9]	0.04 (0.506)	0.10 [-1.6, 1.3]
Week 20	66	1.12 (0.485)	1.00 [0.5, 2.6]	-0.07 (0.540)	0.00 [-2.2, 0.8]
Week 24	167	1.26 (0.574)	1.10 [0.5, 3.7]	-0.01 (0.481)	0.00 [-1.4, 2.7]
LOCF Endpoint	176	1.25 (0.560)	1.10 [0.5, 3.7]	-0.02 (0.477)	0.00 [-1.4, 2.7]
Imeglimin 500 mg bid (N = 75)					
Baseline	75	1.21 (0.507)	1.10 [0.4, 2.6]		
Week 2	75	1.22 (0.631)	1.10 [0.5, 3.6]	0.02 (0.512)	0.00 [-1.4, 1.8]
Week 4	75	1.22 (0.544)	1.10 [0.4, 3.3]	0.02 (0.537)	0.00 [-1.4, 2.4]
Week 8	72	1.20 (0.480)	1.10 [0.5, 2.8]	0.01 (0.442)	0.10 [-1.0, 1.6]
Week 12	72	1.25 (0.524)	1.15 [0.5, 3.3]	0.06 (0.504)	0.00 [-1.2, 1.5]
Week 16	71	1.21 (0.538)	1.10 [0.5, 3.1]	0.01 (0.455)	0.00 [-1.2, 1.5]
Week 20	70	1.28 (0.454)	1.20 [0.5, 2.4]	0.10 (0.442)	0.10 [-0.9, 1.3]
Week 24	69	1.32 (0.616)	1.20 [0.5, 3.9]	0.13 (0.596)	0.00 [-1.0, 1.9]
LOCF Endpoint	75	1.33 (0.606)	1.20 [0.5, 3.9]	0.12 (0.580)	0.00 [-1.0, 1.9]
Imeglimin 1000 mg bid (N = 180)					
Baseline	179	1.27 (0.588)	1.10 [0.5, 5.5]		
Week 2	73	1.05 (0.414)	1.00 [0.3, 2.4]	-0.09 (0.384)	0.00 [-1.2, 1.1]
Week 4	71	1.02 (0.371)	0.90 [0.5, 2.3]	-0.12 (0.375)	-0.10 [-1.3, 1.0]
Week 8	69	1.12 (0.513)	1.00 [0.5, 3.4]	-0.01 (0.488)	0.00 [-0.8, 2.6]
Week 12	172	1.22 (0.523)	1.10 [0.4, 5.1]	-0.05 (0.400)	0.00 [-1.7, 0.8]
Week 16	67	1.15 (0.430)	1.10 [0.4, 2.3]	0.03 (0.420)	0.00 [-0.8, 1.3]
Week 20	66	1.13 (0.577)	1.00 [0.4, 4.0]	0.00 (0.543)	0.00 [-1.1, 2.7]
Week 24	169	1.24 (0.541)	1.10 [0.4, 4.2]	-0.03 (0.473)	0.00 [-1.5, 1.9]
LOCF Endpoint	178	1.25 (0.546)	1.10 [0.4, 4.2]	-0.02 (0.490)	0.00 [-1.5, 1.9]
Imeglimin 1500 mg bid (N = 75)					
Baseline	75	1.28 (0.453)	1.20 [0.6, 3.0]		
Week 2	71	1.22 (0.435)	1.10 [0.6, 2.8]	-0.07 (0.462)	-0.10 [-1.6, 2.0]
Week 4	68	1.25 (0.449)	1.20 [0.5, 2.8]	-0.04 (0.416)	-0.05 [-1.1, 1.6]
Week 8	68	1.23 (0.485)	1.10 [0.5, 2.8]	-0.07 (0.368)	-0.10 [-1.8, 1.0]
Week 12	67	1.31 (0.483)	1.20 [0.6, 2.7]	0.01 (0.313)	0.00 [-0.7, 0.8]
Week 16	68	1.31 (0.642)	1.20 [0.5, 5.1]	0.02 (0.467)	0.00 [-1.5, 2.3]
Week 20	67	1.29 (0.496)	1.20 [0.6, 3.0]	-0.02 (0.429)	-0.10 [-1.1, 1.6]
Week 24	67	1.34 (0.567)	1.20 [0.5, 3.3]	0.04 (0.469)	0.00 [-1.4, 1.8]
LOCF Endpoint	75	1.31 (0.556)	1.20 [0.5, 3.3]	0.03 (0.463)	0.00 [-1.4, 1.8]

- Abbreviations: bid, Twice a day; SD, standard deviation; LOCF, Last Observation Carried Forward

Control No:<<t-s-232-labot-24wdb.sas, 2020-03-06T00:17:57>>

Table S-530 Subgroup Analysis of Overall Frequency of Treatment Emergent Adverse Events by BMI in 24-Week Double-blind Period with Monotherapy (PXL008-014, PXL008-018; Safety Population)

TEAE BMI at baseline	Placebo N = 182	Imeglimin 500 mg bid N = 75	Imeglimin 1000 mg bid N = 180	Imeglimin 1500 mg bid N = 75	Imeglimin Total N = 330
Number of patients					
< 25 kg/m2	95	39	90	28	157
>= 25 kg/m2	87	36	90	47	173
>= 25 to < 30 kg/m2	64	22	66	33	121
>= 30 kg/m2	23	14	24	14	52
Any TEAE					
< 25 kg/m2	55 (57.9%)	25 (64.1%)	44 (48.9%)	19 (67.9%)	88 (56.1%)
>= 25 kg/m2	44 (50.6%)	26 (72.2%)	49 (54.4%)	36 (76.6%)	111 (64.2%)
>= 25 to < 30 kg/m2	31 (48.4%)	16 (72.7%)	36 (54.5%)	25 (75.8%)	77 (63.6%)
>= 30 kg/m2	13 (56.5%)	10 (71.4%)	13 (54.2%)	11 (78.6%)	34 (65.4%)
Treatment-related TEAE					
< 25 kg/m2	7 (7.4%)	2 (5.1%)	4 (4.4%)	8 (28.6%)	14 (8.9%)
>= 25 kg/m2	6 (6.9%)	2 (5.6%)	5 (5.6%)	10 (21.3%)	17 (9.8%)
>= 25 to < 30 kg/m2	4 (6.3%)	1 (4.5%)	4 (6.1%)	7 (21.2%)	12 (9.9%)
>= 30 kg/m2	2 (8.7%)	1 (7.1%)	1 (4.2%)	3 (21.4%)	5 (9.6%)
Severe TEAE					
< 25 kg/m2	1 (1.1%)	0	3 (3.3%)	1 (3.6%)	4 (2.5%)
>= 25 kg/m2	0	0	3 (3.3%)	0	3 (1.7%)
>= 25 to < 30 kg/m2	0	0	1 (1.5%)	0	1 (0.8%)
>= 30 kg/m2	0	0	2 (8.3%)	0	2 (3.8%)
TEAE leading to death					
< 25 kg/m2	0	0	0	1 (3.6%)	1 (0.6%)
>= 25 kg/m2	0	0	0	0	0
>= 25 to < 30 kg/m2	0	0	0	0	0
>= 30 kg/m2	0	0	0	0	0
Serious TEAE					
< 25 kg/m2	1 (1.1%)	0	4 (4.4%)	1 (3.6%)	5 (3.2%)
>= 25 kg/m2	1 (1.1%)	0	4 (4.4%)	0	4 (2.3%)
>= 25 to < 30 kg/m2	0	0	2 (3.0%)	0	2 (1.7%)
>= 30 kg/m2	1 (4.3%)	0	2 (8.3%)	0	2 (3.8%)
TEAE leading to treatment discontinuation					
< 25 kg/m2	11 (11.6%)	0	2 (2.2%)	3 (10.7%)	5 (3.2%)
>= 25 kg/m2	3 (3.4%)	2 (5.6%)	4 (4.4%)	2 (4.3%)	8 (4.6%)
>= 25 to < 30 kg/m2	1 (1.6%)	1 (4.5%)	2 (3.0%)	1 (3.0%)	4 (3.3%)
>= 30 kg/m2	2 (8.7%)	1 (7.1%)	2 (8.3%)	1 (7.1%)	4 (7.7%)
Hypoglycemia					
< 25 kg/m2	1 (1.1%)	2 (5.1%)	1 (1.1%)	1 (3.6%)	4 (2.5%)
>= 25 kg/m2	1 (1.1%)	3 (8.3%)	4 (4.4%)	3 (6.4%)	10 (5.8%)
>= 25 to < 30 kg/m2	1 (1.6%)	3 (13.6%)	4 (6.1%)	2 (6.1%)	9 (7.4%)
>= 30 kg/m2	0	0	0	1 (7.1%)	1 (1.9%)
Lactic acidosis related TEAEs					
< 25 kg/m2	0	0	0	0	0
>= 25 kg/m2	0	0	0	0	0
>= 25 to < 30 kg/m2	0	0	0	0	0
>= 30 kg/m2	0	0	0	0	0
Cardiovascular-related TEAEs					

TEAE BMI at baseline	Placebo N = 182	Imeglimin 500 mg bid N = 75	Imeglimin 1000 mg bid N = 180	Imeglimin 1500 mg bid N = 75	Imeglimin Total N = 330
< 25 kg/m2	4 (4.2%)	0	2 (2.2%)	2 (7.1%)	4 (2.5%)
>= 25 kg/m2	3 (3.4%)	2 (5.6%)	1 (1.1%)	4 (8.5%)	7 (4.0%)
>= 25 to < 30 kg/m2	1 (1.6%)	1 (4.5%)	0	3 (9.1%)	4 (3.3%)
>= 30 kg/m2	2 (8.7%)	1 (7.1%)	1 (4.2%)	1 (7.1%)	3 (5.8%)
Digestive Symptoms					
< 25 kg/m2	10 (10.5%)	5 (12.8%)	12 (13.3%)	10 (35.7%)	27 (17.2%)
>= 25 kg/m2	10 (11.5%)	6 (16.7%)	14 (15.6%)	14 (29.8%)	34 (19.7%)
>= 25 to < 30 kg/m2	7 (10.9%)	4 (18.2%)	8 (12.1%)	8 (24.2%)	20 (16.5%)
>= 30 kg/m2	3 (13.0%)	2 (14.3%)	6 (25.0%)	6 (42.9%)	14 (26.9%)
Renal TEAEs					
< 25 kg/m2	1 (1.1%)	0	0	0	0
>= 25 kg/m2	1 (1.1%)	1 (2.8%)	2 (2.2%)	0	3 (1.7%)
>= 25 to < 30 kg/m2	1 (1.6%)	0	2 (3.0%)	0	2 (1.7%)
>= 30 kg/m2	0	1 (7.1%)	0	0	1 (1.9%)
Hepatic TEAEs					
< 25 kg/m2	1 (1.1%)	1 (2.6%)	0	1 (3.6%)	2 (1.3%)
>= 25 kg/m2	3 (3.4%)	0	2 (2.2%)	2 (4.3%)	4 (2.3%)
>= 25 to < 30 kg/m2	2 (3.1%)	0	2 (3.0%)	0	2 (1.7%)
>= 30 kg/m2	1 (4.3%)	0	0	2 (14.3%)	2 (3.8%)

- Abbreviations: bid, Twice a day; AE, Adverse event; TEAE, Treatment Emergent AE; BMI, body mass index
- Percentages are based on "Number of patients".

Control No:<<t-s-530-subae-24wdb.sas, 2020-03-11T11:31:49>>

Table S-531 Subgroup Analysis of Overall Frequency of Treatment Emergent Adverse Events by HbA1c at baseline in 24-Week Double-blind Period with Monotherapy (PXL008-014, PXL008-018; Safety Population)

TEAE HbA1c at baseline	Placebo N = 182	Imeglimin 500 mg bid N = 75	Imeglimin 1000 mg bid N = 180	Imeglimin 1500 mg bid N = 75	Imeglimin Total N = 330
Number of patients					
< 8.0%	107	47	107	42	196
>= 8.0%	75	28	73	33	134
>= 8.0 to < 9.0%	59	20	50	30	100
>= 9.0%	16	8	23	3	34
Any TEAE					
< 8.0%	58 (54.2%)	33 (70.2%)	60 (56.1%)	35 (83.3%)	128 (65.3%)
>= 8.0%	41 (54.7%)	18 (64.3%)	33 (45.2%)	20 (60.6%)	71 (53.0%)
>= 8.0 to < 9.0%	27 (45.8%)	13 (65.0%)	22 (44.0%)	17 (56.7%)	52 (52.0%)
>= 9.0%	14 (87.5%)	5 (62.5%)	11 (47.8%)	3 (100.0%)	19 (55.9%)
Treatment-related TEAE					
< 8.0%	6 (5.6%)	3 (6.4%)	8 (7.5%)	12 (28.6%)	23 (11.7%)
>= 8.0%	7 (9.3%)	1 (3.6%)	1 (1.4%)	6 (18.2%)	8 (6.0%)
>= 8.0 to < 9.0%	4 (6.8%)	0	1 (2.0%)	6 (20.0%)	7 (7.0%)
>= 9.0%	3 (18.8%)	1 (12.5%)	0	0	1 (2.9%)
Severe TEAE					
< 8.0%	0	0	4 (3.7%)	0	4 (2.0%)
>= 8.0%	1 (1.3%)	0	2 (2.7%)	1 (3.0%)	3 (2.2%)
>= 8.0 to < 9.0%	0	0	2 (4.0%)	1 (3.3%)	3 (3.0%)
>= 9.0%	1 (6.3%)	0	0	0	0
TEAE leading to death					
< 8.0%	0	0	0	0	0
>= 8.0%	0	0	0	1 (3.0%)	1 (0.7%)
>= 8.0 to < 9.0%	0	0	0	1 (3.3%)	1 (1.0%)
>= 9.0%	0	0	0	0	0
Serious TEAE					
< 8.0%	1 (0.9%)	0	7 (6.5%)	0	7 (3.6%)
>= 8.0%	1 (1.3%)	0	1 (1.4%)	1 (3.0%)	2 (1.5%)
>= 8.0 to < 9.0%	0	0	1 (2.0%)	1 (3.3%)	2 (2.0%)
>= 9.0%	1 (6.3%)	0	0	0	0
TEAE leading to treatment discontinuation					
< 8.0%	2 (1.9%)	0	5 (4.7%)	2 (4.8%)	7 (3.6%)
>= 8.0%	12 (16.0%)	2 (7.1%)	1 (1.4%)	3 (9.1%)	6 (4.5%)
>= 8.0 to < 9.0%	6 (10.2%)	0	0	3 (10.0%)	3 (3.0%)
>= 9.0%	6 (37.5%)	2 (25.0%)	1 (4.3%)	0	3 (8.8%)
Hypoglycemia					
< 8.0%	2 (1.9%)	3 (6.4%)	5 (4.7%)	2 (4.8%)	10 (5.1%)
>= 8.0%	0	2 (7.1%)	0	2 (6.1%)	4 (3.0%)
>= 8.0 to < 9.0%	0	2 (10.0%)	0	2 (6.7%)	4 (4.0%)
>= 9.0%	0	0	0	0	0
Lactic acidosis related TEAEs					
< 8.0%	0	0	0	0	0
>= 8.0%	0	0	0	0	0
>= 8.0 to < 9.0%	0	0	0	0	0
>= 9.0%	0	0	0	0	0
Cardiovascular-related TEAEs					

TEAE HbA1c at baseline	Placebo N = 182	Imeglimin 500 mg bid N = 75	Imeglimin 1000 mg bid N = 180	Imeglimin 1500 mg bid N = 75	Imeglimin Total N = 330
< 8.0%	4 (3.7%)	2 (4.3%)	2 (1.9%)	4 (9.5%)	8 (4.1%)
>= 8.0%	3 (4.0%)	0	1 (1.4%)	2 (6.1%)	3 (2.2%)
>= 8.0 to < 9.0%	3 (5.1%)	0	1 (2.0%)	2 (6.7%)	3 (3.0%)
>= 9.0%	0	0	0	0	0
Digestive Symptoms					
< 8.0%	11 (10.3%)	10 (21.3%)	18 (16.8%)	15 (35.7%)	43 (21.9%)
>= 8.0%	9 (12.0%)	1 (3.6%)	8 (11.0%)	9 (27.3%)	18 (13.4%)
>= 8.0 to < 9.0%	6 (10.2%)	1 (5.0%)	3 (6.0%)	9 (30.0%)	13 (13.0%)
>= 9.0%	3 (18.8%)	0	5 (21.7%)	0	5 (14.7%)
Renal TEAEs					
< 8.0%	2 (1.9%)	0	2 (1.9%)	0	2 (1.0%)
>= 8.0%	0	1 (3.6%)	0	0	1 (0.7%)
>= 8.0 to < 9.0%	0	1 (5.0%)	0	0	1 (1.0%)
>= 9.0%	0	0	0	0	0
Hepatic TEAEs					
< 8.0%	3 (2.8%)	1 (2.1%)	1 (0.9%)	1 (2.4%)	3 (1.5%)
>= 8.0%	1 (1.3%)	0	1 (1.4%)	2 (6.1%)	3 (2.2%)
>= 8.0 to < 9.0%	1 (1.7%)	0	0	2 (6.7%)	2 (2.0%)
>= 9.0%	0	0	1 (4.3%)	0	1 (2.9%)

- Abbreviations: bid, Twice a day; AE, Adverse event; TEAE, Treatment Emergent AE; HbA1c, Glycosylated Hemoglobin (Hemoglobin A1c)
- Percentages are based on "Number of patients".

Control No:<<t-s-531-subae-24wdb.sas, 2020-03-11T11:31:58>>

Table S-532 Subgroup Analysis of Overall Frequency of Treatment Emergent Adverse Events by Duration of type 2 diabetes in 24-Week Double-blind Period with Monotherapy (PXL008-014, PXL008-018; Safety Population)

TEAE Duration of type 2 diabetes	Placebo N = 182	Imeglimin 500 mg bid N = 75	Imeglimin 1000 mg bid N = 180	Imeglimin 1500 mg bid N = 75	Imeglimin Total N = 330
Number of patients					
< 5 years	89	32	76	42	150
>= 5 years	93	43	104	33	180
Any TEAE					
< 5 years	46 (51.7%)	21 (65.6%)	42 (55.3%)	32 (76.2%)	95 (63.3%)
>= 5 years	53 (57.0%)	30 (69.8%)	51 (49.0%)	23 (69.7%)	104 (57.8%)
Treatment-related TEAE					
< 5 years	7 (7.9%)	3 (9.4%)	3 (3.9%)	11 (26.2%)	17 (11.3%)
>= 5 years	6 (6.5%)	1 (2.3%)	6 (5.8%)	7 (21.2%)	14 (7.8%)
Severe TEAE					
< 5 years	0	0	2 (2.6%)	0	2 (1.3%)
>= 5 years	1 (1.1%)	0	4 (3.8%)	1 (3.0%)	5 (2.8%)
TEAE leading to death					
< 5 years	0	0	0	0	0
>= 5 years	0	0	0	1 (3.0%)	1 (0.6%)
Serious TEAE					
< 5 years	1 (1.1%)	0	1 (1.3%)	0	1 (0.7%)
>= 5 years	1 (1.1%)	0	7 (6.7%)	1 (3.0%)	8 (4.4%)
TEAE leading to treatment discontinuation					
< 5 years	6 (6.7%)	1 (3.1%)	1 (1.3%)	3 (7.1%)	5 (3.3%)
>= 5 years	8 (8.6%)	1 (2.3%)	5 (4.8%)	2 (6.1%)	8 (4.4%)
Hypoglycemia					
< 5 years	1 (1.1%)	2 (6.3%)	2 (2.6%)	4 (9.5%)	8 (5.3%)
>= 5 years	1 (1.1%)	3 (7.0%)	3 (2.9%)	0	6 (3.3%)
Lactic acidosis related TEAEs					
< 5 years	0	0	0	0	0
>= 5 years	0	0	0	0	0
Cardiovascular-related TEAEs					
< 5 years	4 (4.5%)	1 (3.1%)	1 (1.3%)	2 (4.8%)	4 (2.7%)
>= 5 years	3 (3.2%)	1 (2.3%)	2 (1.9%)	4 (12.1%)	7 (3.9%)
Digestive Symptoms					
< 5 years	10 (11.2%)	7 (21.9%)	7 (9.2%)	11 (26.2%)	25 (16.7%)
>= 5 years	10 (10.8%)	4 (9.3%)	19 (18.3%)	13 (39.4%)	36 (20.0%)
Renal TEAEs					
< 5 years	1 (1.1%)	1 (3.1%)	1 (1.3%)	0	2 (1.3%)
>= 5 years	1 (1.1%)	0	1 (1.0%)	0	1 (0.6%)
Hepatic TEAEs					
< 5 years	4 (4.5%)	0	2 (2.6%)	2 (4.8%)	4 (2.7%)
>= 5 years	0	1 (2.3%)	0	1 (3.0%)	2 (1.1%)

- Abbreviations: bid, Twice a day; AE, Adverse event; TEAE, Treatment Emergent AE
- Percentages are based on "Number of patients".

Control No:<<t-s-532-subae-24wdb.sas, 2020-03-11T11:32:09>>

Table S-533 Subgroup Analysis of Overall Frequency of Treatment Emergent Adverse Events by Complication of diabetes in 24-Week Double-blind Period with Monotherapy (PXL008-014, PXL008-018; Safety Population)

TEAE Complication of diabetes	Placebo N = 182	Imeglimin 500 mg bid N = 75	Imeglimin 1000 mg bid N = 180	Imeglimin 1500 mg bid N = 75	Imeglimin Total N = 330
Number of patients					
Yes	31	17	31	15	63
No	151	58	149	60	267
Any TEAE					
Yes	17 (54.8%)	11 (64.7%)	18 (58.1%)	14 (93.3%)	43 (68.3%)
No	82 (54.3%)	40 (69.0%)	75 (50.3%)	41 (68.3%)	156 (58.4%)
Treatment-related TEAE					
Yes	4 (12.9%)	1 (5.9%)	4 (12.9%)	3 (20.0%)	8 (12.7%)
No	9 (6.0%)	3 (5.2%)	5 (3.4%)	15 (25.0%)	23 (8.6%)
Severe TEAE					
Yes	0	0	0	0	0
No	1 (0.7%)	0	6 (4.0%)	1 (1.7%)	7 (2.6%)
TEAE leading to death					
Yes	0	0	0	0	0
No	0	0	0	1 (1.7%)	1 (0.4%)
Serious TEAE					
Yes	0	0	1 (3.2%)	0	1 (1.6%)
No	2 (1.3%)	0	7 (4.7%)	1 (1.7%)	8 (3.0%)
TEAE leading to treatment discontinuation					
Yes	2 (6.5%)	1 (5.9%)	2 (6.5%)	0	3 (4.8%)
No	12 (7.9%)	1 (1.7%)	4 (2.7%)	5 (8.3%)	10 (3.7%)
Hypoglycemia					
Yes	0	0	2 (6.5%)	1 (6.7%)	3 (4.8%)
No	2 (1.3%)	5 (8.6%)	3 (2.0%)	3 (5.0%)	11 (4.1%)
Lactic acidosis related TEAEs					
Yes	0	0	0	0	0
No	0	0	0	0	0
Cardiovascular-related TEAEs					
Yes	1 (3.2%)	1 (5.9%)	1 (3.2%)	2 (13.3%)	4 (6.3%)
No	6 (4.0%)	1 (1.7%)	2 (1.3%)	4 (6.7%)	7 (2.6%)
Digestive Symptoms					
Yes	5 (16.1%)	3 (17.6%)	4 (12.9%)	4 (26.7%)	11 (17.5%)
No	15 (9.9%)	8 (13.8%)	22 (14.8%)	20 (33.3%)	50 (18.7%)
Renal TEAEs					
Yes	0	0	1 (3.2%)	0	1 (1.6%)
No	2 (1.3%)	1 (1.7%)	1 (0.7%)	0	2 (0.7%)
Hepatic TEAEs					
Yes	0	1 (5.9%)	0	2 (13.3%)	3 (4.8%)
No	4 (2.6%)	0	2 (1.3%)	1 (1.7%)	3 (1.1%)

- Abbreviations: bid, Twice a day; AE, Adverse event; TEAE, Treatment Emergent AE
- Complication of diabetes is defined as any MedDRA Preferred Term (PT) of medical history which are included in High-Level Group Term (HLGT) of diabetic complication.
- Percentages are based on "Number of patients".

Control No:<<t-s-533-subae-24wdb.sas, 2020-03-11T11:32:19>>

Table S-534 Subgroup Analysis of Overall Frequency of Treatment Emergent Adverse Events by Metabolic syndrome in 24-Week Double-blind Period with Monotherapy (PXL008-014, PXL008-018; Safety Population)

TEAE Metabolic syndrome at baseline	Placebo N = 182	Imeglimin 500 mg bid N = 75	Imeglimin 1000 mg bid N = 180	Imeglimin 1500 mg bid N = 75	Imeglimin Total N = 330
Number of patients					
Yes	85	35	78	45	158
No	97	40	102	30	172
Any TEAE					
Yes	41 (48.2%)	24 (68.6%)	41 (52.6%)	35 (77.8%)	100 (63.3%)
No	58 (59.8%)	27 (67.5%)	52 (51.0%)	20 (66.7%)	99 (57.6%)
Treatment-related TEAE					
Yes	6 (7.1%)	3 (8.6%)	2 (2.6%)	13 (28.9%)	18 (11.4%)
No	7 (7.2%)	1 (2.5%)	7 (6.9%)	5 (16.7%)	13 (7.6%)
Severe TEAE					
Yes	0	0	3 (3.8%)	0	3 (1.9%)
No	1 (1.0%)	0	3 (2.9%)	1 (3.3%)	4 (2.3%)
TEAE leading to death					
Yes	0	0	0	0	0
No	0	0	0	1 (3.3%)	1 (0.6%)
Serious TEAE					
Yes	1 (1.2%)	0	6 (7.7%)	0	6 (3.8%)
No	1 (1.0%)	0	2 (2.0%)	1 (3.3%)	3 (1.7%)
TEAE leading to treatment discontinuation					
Yes	6 (7.1%)	2 (5.7%)	4 (5.1%)	2 (4.4%)	8 (5.1%)
No	8 (8.2%)	0	2 (2.0%)	3 (10.0%)	5 (2.9%)
Hypoglycemia					
Yes	0	3 (8.6%)	3 (3.8%)	4 (8.9%)	10 (6.3%)
No	2 (2.1%)	2 (5.0%)	2 (2.0%)	0	4 (2.3%)
Lactic acidosis related TEAEs					
Yes	0	0	0	0	0
No	0	0	0	0	0
Cardiovascular-related TEAEs					
Yes	3 (3.5%)	2 (5.7%)	1 (1.3%)	3 (6.7%)	6 (3.8%)
No	4 (4.1%)	0	2 (2.0%)	3 (10.0%)	5 (2.9%)
Digestive Symptoms					
Yes	9 (10.6%)	6 (17.1%)	10 (12.8%)	15 (33.3%)	31 (19.6%)
No	11 (11.3%)	5 (12.5%)	16 (15.7%)	9 (30.0%)	30 (17.4%)
Renal TEAEs					
Yes	1 (1.2%)	0	1 (1.3%)	0	1 (0.6%)
No	1 (1.0%)	1 (2.5%)	1 (1.0%)	0	2 (1.2%)
Hepatic TEAEs					
Yes	2 (2.4%)	0	1 (1.3%)	2 (4.4%)	3 (1.9%)
No	2 (2.1%)	1 (2.5%)	1 (1.0%)	1 (3.3%)	3 (1.7%)

- Abbreviations: bid, Twice a day; AE, Adverse event; TEAE, Treatment Emergent AE
- Metabolic Syndrome is defined as an excessive waist circumference (>= 85 cm in men and >= 90 cm in women) as well as the presence of two or more of the following symptoms: (1) Hypertension: systolic blood pressure >= 130 mmHg, or diastolic blood pressure >= 85 mmHg; (2) Glucose intolerance: fasting glucose >= 110 mg/dL; (3) Dyslipidemia: triglyceride >= 150 mg/dL, or HDL cholesterol < 40 mg/dL.
- Percentages are based on "Number of patients".

Control No:<<t-s-534-subae-24wdb.sas, 2020-03-11T11:32:28>>

Table S-539 Subgroup Analysis of Overall Frequency of Treatment Emergent Adverse Events by Previous Treatment Status in 52-Week Long-term Period with Monotherapy and Combination Therapy (PXL008-019; Long-term Safety Population)

TEAE Previous treatment status	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
Number of patients											
Treatment naive	134	0	0	0	0	0	0	0	0	0	134
Previously treated	0	127	64	64	64	65	63	70	63	580	580
Any TEAE											
Treatment naive	98 (73.1%)	.	.	.	.	.	.	.	.	.	98 (73.1%)
Previously treated	.	102 (80.3%)	54 (84.4%)	48 (75.0%)	33 (51.6%)	50 (76.9%)	50 (79.4%)	56 (80.0%)	48 (76.2%)	441 (76.0%)	441 (76.0%)
Treatment-related TEAE											
Treatment naive	13 (9.7%)	.	.	.	.	.	.	.	.	.	13 (9.7%)
Previously treated	.	27 (21.3%)	10 (15.6%)	24 (37.5%)	6 (9.4%)	6 (9.2%)	14 (22.2%)	8 (11.4%)	7 (11.1%)	102 (17.6%)	102 (17.6%)
Severe TEAE											
Treatment naive	2 (1.5%)	.	.	.	.	.	.	.	.	.	2 (1.5%)
Previously treated	.	5 (3.9%)	0	4 (6.3%)	1 (1.6%)	1 (1.5%)	1 (1.6%)	2 (2.9%)	1 (1.6%)	15 (2.6%)	15 (2.6%)
TEAE leading to death											
Treatment naive	1 (0.7%)	.	.	.	.	.	.	.	.	.	1 (0.7%)
Previously treated	.	0	0	0	0	0	0	0	0	0	0
Serious TEAE											
Treatment naive	4 (3.0%)	.	.	.	.	.	.	.	.	.	4 (3.0%)
Previously treated	.	11 (8.7%)	1 (1.6%)	4 (6.3%)	4 (6.3%)	4 (6.2%)	3 (4.8%)	5 (7.1%)	4 (6.3%)	36 (6.2%)	36 (6.2%)
TEAE leading to treatment discontinuation											
Treatment naive	3 (2.2%)	.	.	.	.	.	.	.	.	.	3 (2.2%)
Previously treated	.	9 (7.1%)	1 (1.6%)	7 (10.9%)	2 (3.1%)	4 (6.2%)	5 (7.9%)	15 (21.4%)	1 (1.6%)	44 (7.6%)	44 (7.6%)
Hypoglycemia											
Treatment naive	5 (3.7%)	.	.	.	.	.	.	.	.	.	5 (3.7%)
Previously treated	.	21 (16.5%)	9 (14.1%)	6 (9.4%)	2 (3.1%)	2 (3.1%)	5 (7.9%)	2 (2.9%)	4 (6.3%)	51 (8.8%)	51 (8.8%)
Lactic acidosis related TEAEs											
Treatment naive	0	.	.	.	.	.	.	.	.	.	0

TEAE Previous treatment status	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
Previously treated	.	2 (1.6%)	0	0	0	0	0	0	0	2 (0.3%)	2 (0.3%)
Cardiovascular-related TEAEs											
Treatment naive	4 (3.0%)	.	.	.	.	.	.	.	.	.	4 (3.0%)
Previously treated	.	11 (8.7%)	3 (4.7%)	6 (9.4%)	6 (9.4%)	8 (12.3%)	3 (4.8%)	5 (7.1%)	4 (6.3%)	46 (7.9%)	46 (7.9%)
Digestive Symptoms											
Treatment naive	30 (22.4%)	.	.	.	.	.	.	.	.	.	30 (22.4%)
Previously treated	.	28 (22.0%)	12 (18.8%)	26 (40.6%)	5 (7.8%)	10 (15.4%)	21 (33.3%)	15 (21.4%)	15 (23.8%)	132 (22.8%)	132 (22.8%)
Renal TEAEs											
Treatment naive	1 (0.7%)	.	.	.	.	.	.	.	.	.	1 (0.7%)
Previously treated	.	2 (1.6%)	1 (1.6%)	1 (1.6%)	3 (4.7%)	3 (4.6%)	3 (4.8%)	4 (5.7%)	3 (4.8%)	20 (3.4%)	20 (3.4%)
Hepatic TEAEs											
Treatment naive	0	.	.	.	.	.	.	.	.	.	0
Previously treated	.	3 (2.4%)	1 (1.6%)	0	1 (1.6%)	3 (4.6%)	1 (1.6%)	2 (2.9%)	3 (4.8%)	14 (2.4%)	14 (2.4%)

- Abbreviations: AE, Adverse event; TEAE, Treatment Emergent AE; SU, Sulphonylurea; GLIN, Glinide; BIG, Biguanide; AGI, Alpha glucosidase inhibitor; TZD, Thiazolidinedione; DPP4-I, Dipeptidyl peptidase-4 inhibitor; GLP1-RA, Glucagon-like peptide 1 receptor agonist; SGLT2-I, Sodium glucose cotransporter 2 inhibitor
- "Imeglimin" in this table means "Imeglimin 1000 mg twice daily".
- "Combination Total" is the sum of the subjects excluding monotherapy "Imeglimin".
- "Imeglimin Total" is the sum of all subjects in Imeglimin treatment groups.
- Percentages are based on "Number of patients".

Control No:<<t-s-539-subae-019lt.sas, 2020-03-11T11:33:31>>

Table S-540 Subgroup Analysis of Overall Frequency of Treatment Emergent Adverse Events by BMI in 52-Week Long-term Period with Monotherapy and Combination Therapy (PXL008-019; Long-term Safety Population)

TEAE BMI at baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
Number of patients											
< 25 kg/m2	67	65	35	22	31	24	38	27	32	274	341
>= 25 kg/m2	67	62	29	42	33	41	25	43	31	306	373
>= 25 to < 30 kg/m2	51	43	18	29	26	25	23	31	24	219	270
>= 30 kg/m2	16	19	11	13	7	16	2	12	7	87	103
Any TEAE											
< 25 kg/m2	51 (76.1%)	50 (76.9%)	31 (88.6%)	18 (81.8%)	17 (54.8%)	20 (83.3%)	30 (78.9%)	22 (81.5%)	25 (78.1%)	213 (77.7%)	264 (77.4%)
>= 25 kg/m2	47 (70.1%)	52 (83.9%)	23 (79.3%)	30 (71.4%)	16 (48.5%)	30 (73.2%)	20 (80.0%)	34 (79.1%)	23 (74.2%)	228 (74.5%)	275 (73.7%)
>= 25 to < 30 kg/m2	37 (72.5%)	33 (76.7%)	16 (88.9%)	19 (65.5%)	12 (46.2%)	18 (72.0%)	19 (82.6%)	24 (77.4%)	17 (70.8%)	158 (72.1%)	195 (72.2%)
>= 30 kg/m2	10 (62.5%)	19 (100.0%)	7 (63.6%)	11 (84.6%)	4 (57.1%)	12 (75.0%)	1 (50.0%)	10 (83.3%)	6 (85.7%)	70 (80.5%)	80 (77.7%)
Treatment-related TEAE											
< 25 kg/m2	9 (13.4%)	17 (26.2%)	4 (11.4%)	11 (50.0%)	5 (16.1%)	2 (8.3%)	9 (23.7%)	5 (18.5%)	5 (15.6%)	58 (21.2%)	67 (19.6%)
>= 25 kg/m2	4 (6.0%)	10 (16.1%)	6 (20.7%)	13 (31.0%)	1 (3.0%)	4 (9.8%)	5 (20.0%)	3 (7.0%)	2 (6.5%)	44 (14.4%)	48 (12.9%)
>= 25 to < 30 kg/m2	3 (5.9%)	7 (16.3%)	5 (27.8%)	7 (24.1%)	1 (3.8%)	3 (12.0%)	5 (21.7%)	3 (9.7%)	2 (8.3%)	33 (15.1%)	36 (13.3%)
>= 30 kg/m2	1 (6.3%)	3 (15.8%)	1 (9.1%)	6 (46.2%)	0	1 (6.3%)	0	0	0	11 (12.6%)	12 (11.7%)
Severe TEAE											
< 25 kg/m2	2 (3.0%)	1 (1.5%)	0	2 (9.1%)	1 (3.2%)	1 (4.2%)	1 (2.6%)	2 (7.4%)	1 (3.1%)	9 (3.3%)	11 (3.2%)
>= 25 kg/m2	0	4 (6.5%)	0	2 (4.8%)	0	0	0	0	0	6 (2.0%)	6 (1.6%)
>= 25 to < 30 kg/m2	0	3 (7.0%)	0	2 (6.9%)	0	0	0	0	0	5 (2.3%)	5 (1.9%)
>= 30 kg/m2	0	1 (5.3%)	0	0	0	0	0	0	0	1 (1.1%)	1 (1.0%)
TEAE leading to death											
< 25 kg/m2	1 (1.5%)	0	0	0	0	0	0	0	0	0	1 (0.3%)
>= 25 kg/m2	0	0	0	0	0	0	0	0	0	0	0
>= 25 to < 30 kg/m2	0	0	0	0	0	0	0	0	0	0	0
>= 30 kg/m2	0	0	0	0	0	0	0	0	0	0	0
Serious TEAE											
< 25 kg/m2	4 (6.0%)	7 (10.8%)	1 (2.9%)	1 (4.5%)	1 (3.2%)	2 (8.3%)	2 (5.3%)	3 (11.1%)	3 (9.4%)	20 (7.3%)	24 (7.0%)

TEAE BMI at baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
>= 25 kg/m2	0	4 (6.5%)	0	3 (7.1%)	3 (9.1%)	2 (4.9%)	1 (4.0%)	2 (4.7%)	1 (3.2%)	16 (5.2%)	16 (4.3%)
>= 25 to < 30 kg/m2	0	3 (7.0%)	0	3 (10.3%)	2 (7.7%)	1 (4.0%)	1 (4.3%)	1 (3.2%)	1 (4.2%)	12 (5.5%)	12 (4.4%)
>= 30 kg/m2	0	1 (5.3%)	0	0	1 (14.3%)	1 (6.3%)	0	1 (8.3%)	0	4 (4.6%)	4 (3.9%)
TEAE leading to treatment discontinuation											
< 25 kg/m2	2 (3.0%)	2 (3.1%)	1 (2.9%)	5 (22.7%)	2 (6.5%)	2 (8.3%)	3 (7.9%)	4 (14.8%)	0	19 (6.9%)	21 (6.2%)
>= 25 kg/m2	1 (1.5%)	7 (11.3%)	0	2 (4.8%)	0	2 (4.9%)	2 (8.0%)	11 (25.6%)	1 (3.2%)	25 (8.2%)	26 (7.0%)
>= 25 to < 30 kg/m2	1 (2.0%)	1 (2.3%)	0	2 (6.9%)	0	1 (4.0%)	2 (8.7%)	7 (22.6%)	1 (4.2%)	14 (6.4%)	15 (5.6%)
>= 30 kg/m2	0	6 (31.6%)	0	0	0	1 (6.3%)	0	4 (33.3%)	0	11 (12.6%)	11 (10.7%)
Hypoglycemia											
< 25 kg/m2	2 (3.0%)	16 (24.6%)	7 (20.0%)	2 (9.1%)	1 (3.2%)	1 (4.2%)	2 (5.3%)	1 (3.7%)	2 (6.3%)	32 (11.7%)	34 (10.0%)
>= 25 kg/m2	3 (4.5%)	5 (8.1%)	2 (6.9%)	4 (9.5%)	1 (3.0%)	1 (2.4%)	3 (12.0%)	1 (2.3%)	2 (6.5%)	19 (6.2%)	22 (5.9%)
>= 25 to < 30 kg/m2	3 (5.9%)	5 (11.6%)	0	1 (3.4%)	1 (3.8%)	1 (4.0%)	3 (13.0%)	0	2 (8.3%)	13 (5.9%)	16 (5.9%)
>= 30 kg/m2	0	0	2 (18.2%)	3 (23.1%)	0	0	0	1 (8.3%)	0	6 (6.9%)	6 (5.8%)
Lactic acidosis related TEAEs											
< 25 kg/m2	0	2 (3.1%)	0	0	0	0	0	0	0	2 (0.7%)	2 (0.6%)
>= 25 kg/m2	0	0	0	0	0	0	0	0	0	0	0
>= 25 to < 30 kg/m2	0	0	0	0	0	0	0	0	0	0	0
>= 30 kg/m2	0	0	0	0	0	0	0	0	0	0	0
Cardiovascular-related TEAEs											
< 25 kg/m2	3 (4.5%)	6 (9.2%)	2 (5.7%)	1 (4.5%)	3 (9.7%)	5 (20.8%)	2 (5.3%)	4 (14.8%)	2 (6.3%)	25 (9.1%)	28 (8.2%)
>= 25 kg/m2	1 (1.5%)	5 (8.1%)	1 (3.4%)	5 (11.9%)	3 (9.1%)	3 (7.3%)	1 (4.0%)	1 (2.3%)	2 (6.5%)	21 (6.9%)	22 (5.9%)
>= 25 to < 30 kg/m2	1 (2.0%)	5 (11.6%)	1 (5.6%)	3 (10.3%)	3 (11.5%)	3 (12.0%)	1 (4.3%)	0	0	16 (7.3%)	17 (6.3%)
>= 30 kg/m2	0	0	0	2 (15.4%)	0	0	0	1 (8.3%)	2 (28.6%)	5 (5.7%)	5 (4.9%)
Digestive Symptoms											
< 25 kg/m2	16 (23.9%)	16 (24.6%)	7 (20.0%)	11 (50.0%)	4 (12.9%)	2 (8.3%)	14 (36.8%)	8 (29.6%)	9 (28.1%)	71 (25.9%)	87 (25.5%)
>= 25 kg/m2	14 (20.9%)	12 (19.4%)	5 (17.2%)	15 (35.7%)	1 (3.0%)	8 (19.5%)	7 (28.0%)	7 (16.3%)	6 (19.4%)	61 (19.9%)	75 (20.1%)
>= 25 to < 30 kg/m2	10 (19.6%)	8 (18.6%)	5 (27.8%)	9 (31.0%)	0	4 (16.0%)	6 (26.1%)	6 (19.4%)	4 (16.7%)	42 (19.2%)	52 (19.3%)
>= 30 kg/m2	4 (25.0%)	4 (21.1%)	0	6 (46.2%)	1 (14.3%)	4 (25.0%)	1 (50.0%)	1 (8.3%)	2 (28.6%)	19 (21.8%)	23 (22.3%)
Renal TEAEs											

TEAE BMI at baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
< 25 kg/m2	0	1 (1.5%)	0	0	2 (6.5%)	2 (8.3%)	2 (5.3%)	0	2 (6.3%)	9 (3.3%)	9 (2.6%)
>= 25 kg/m2	1 (1.5%)	1 (1.6%)	1 (3.4%)	1 (2.4%)	1 (3.0%)	1 (2.4%)	1 (4.0%)	4 (9.3%)	1 (3.2%)	11 (3.6%)	12 (3.2%)
>= 25 to < 30 kg/m2	1 (2.0%)	1 (2.3%)	0	1 (3.4%)	1 (3.8%)	1 (4.0%)	1 (4.3%)	3 (9.7%)	1 (4.2%)	9 (4.1%)	10 (3.7%)
>= 30 kg/m2	0	0	1 (9.1%)	0	0	0	0	1 (8.3%)	0	2 (2.3%)	2 (1.9%)
Hepatic TEAEs											
< 25 kg/m2	0	2 (3.1%)	1 (2.9%)	0	1 (3.2%)	2 (8.3%)	0	0	2 (6.3%)	8 (2.9%)	8 (2.3%)
>= 25 kg/m2	0	1 (1.6%)	0	0	0	1 (2.4%)	1 (4.0%)	2 (4.7%)	1 (3.2%)	6 (2.0%)	6 (1.6%)
>= 25 to < 30 kg/m2	0	1 (2.3%)	0	0	0	1 (4.0%)	1 (4.3%)	1 (3.2%)	1 (4.2%)	5 (2.3%)	5 (1.9%)
>= 30 kg/m2	0	0	0	0	0	0	0	1 (8.3%)	0	1 (1.1%)	1 (1.0%)

- Abbreviations: AE, Adverse event; TEAE, Treatment Emergent AE; SU, Sulphonylurea; GLIN, Glinide; BIG, Biguanide; AGI, Alpha glucosidase inhibitor; TZD, Thiazolidinedione; DPP4-I, Dipeptidyl peptidase-4 inhibitor; GLP1-RA, Glucagon-like peptide 1 receptor agonist; SGLT2-I, Sodium glucose cotransporter 2 inhibitor; BMI, body mass index
- "Imeglimin" in this table means "Imeglimin 1000 mg twice daily".
- "Combination Total" is the sum of the subjects excluding monotherapy "Imeglimin".
- "Imeglimin Total" is the sum of all subjects in Imeglimin treatment groups.
- Percentages are based on "Number of patients".

Control No:<<t-s-540-subae-019lt.sas, 2020-03-11T11:33:44>>

Table S-541 Subgroup Analysis of Overall Frequency of Treatment Emergent Adverse Events by HbA1c at baseline in 52-Week Long-term Period with Monotherapy and Combination Therapy (PXL008-019; Long-term Safety Population)

TEAE HbA1c at baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
Number of patients											
< 8.0%	89	33	23	26	20	16	24	17	16	175	264
>= 8.0%	45	94	41	38	44	49	39	53	47	405	450
>= 8.0 to < 9.0%	34	52	22	32	31	24	28	26	31	246	280
>= 9.0%	11	42	19	6	13	25	11	27	16	159	170
Any TEAE											
< 8.0%	67 (75.3%)	31 (93.9%)	19 (82.6%)	18 (69.2%)	15 (75.0%)	11 (68.8%)	18 (75.0%)	13 (76.5%)	14 (87.5%)	139 (79.4%)	206 (78.0%)
>= 8.0%	31 (68.9%)	71 (75.5%)	35 (85.4%)	30 (78.9%)	18 (40.9%)	39 (79.6%)	32 (82.1%)	43 (81.1%)	34 (72.3%)	302 (74.6%)	333 (74.0%)
>= 8.0 to < 9.0%	24 (70.6%)	40 (76.9%)	19 (86.4%)	25 (78.1%)	15 (48.4%)	19 (79.2%)	22 (78.6%)	20 (76.9%)	20 (64.5%)	180 (73.2%)	204 (72.9%)
>= 9.0%	7 (63.6%)	31 (73.8%)	16 (84.2%)	5 (83.3%)	3 (23.1%)	20 (80.0%)	10 (90.9%)	23 (85.2%)	14 (87.5%)	122 (76.7%)	129 (75.9%)
Treatment-related TEAE											
< 8.0%	6 (6.7%)	12 (36.4%)	2 (8.7%)	8 (30.8%)	2 (10.0%)	1 (6.3%)	7 (29.2%)	0	3 (18.8%)	35 (20.0%)	41 (15.5%)
>= 8.0%	7 (15.6%)	15 (16.0%)	8 (19.5%)	16 (42.1%)	4 (9.1%)	5 (10.2%)	7 (17.9%)	8 (15.1%)	4 (8.5%)	67 (16.5%)	74 (16.4%)
>= 8.0 to < 9.0%	6 (17.6%)	10 (19.2%)	6 (27.3%)	14 (43.8%)	4 (12.9%)	1 (4.2%)	3 (10.7%)	3 (11.5%)	3 (9.7%)	44 (17.9%)	50 (17.9%)
>= 9.0%	1 (9.1%)	5 (11.9%)	2 (10.5%)	2 (33.3%)	0	4 (16.0%)	4 (36.4%)	5 (18.5%)	1 (6.3%)	23 (14.5%)	24 (14.1%)
Severe TEAE											
< 8.0%	1 (1.1%)	2 (6.1%)	0	0	0	0	0	0	0	2 (1.1%)	3 (1.1%)
>= 8.0%	1 (2.2%)	3 (3.2%)	0	4 (10.5%)	1 (2.3%)	1 (2.0%)	1 (2.6%)	2 (3.8%)	1 (2.1%)	13 (3.2%)	14 (3.1%)
>= 8.0 to < 9.0%	1 (2.9%)	0	0	3 (9.4%)	1 (3.2%)	0	1 (3.6%)	1 (3.8%)	1 (3.2%)	7 (2.8%)	8 (2.9%)
>= 9.0%	0	3 (7.1%)	0	1 (16.7%)	0	1 (4.0%)	0	1 (3.7%)	0	6 (3.8%)	6 (3.5%)
TEAE leading to death											
< 8.0%	1 (1.1%)	0	0	0	0	0	0	0	0	0	1 (0.4%)
>= 8.0%	0	0	0	0	0	0	0	0	0	0	0
>= 8.0 to < 9.0%	0	0	0	0	0	0	0	0	0	0	0
>= 9.0%	0	0	0	0	0	0	0	0	0	0	0
Serious TEAE											
< 8.0%	2 (2.2%)	2 (6.1%)	1 (4.3%)	1 (3.8%)	2 (10.0%)	2 (12.5%)	0	2 (11.8%)	0	10 (5.7%)	12 (4.5%)

TEAE HbA1c at baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
>= 8.0%	2 (4.4%)	9 (9.6%)	0	3 (7.9%)	2 (4.5%)	2 (4.1%)	3 (7.7%)	3 (5.7%)	4 (8.5%)	26 (6.4%)	28 (6.2%)
>= 8.0 to < 9.0%	2 (5.9%)	4 (7.7%)	0	3 (9.4%)	2 (6.5%)	0	2 (7.1%)	1 (3.8%)	4 (12.9%)	16 (6.5%)	18 (6.4%)
>= 9.0%	0	5 (11.9%)	0	0	0	2 (8.0%)	1 (9.1%)	2 (7.4%)	0	10 (6.3%)	10 (5.9%)
TEAE leading to treatment discontinuation											
< 8.0%	0	1 (3.0%)	1 (4.3%)	3 (11.5%)	0	2 (12.5%)	2 (8.3%)	2 (11.8%)	0	11 (6.3%)	11 (4.2%)
>= 8.0%	3 (6.7%)	8 (8.5%)	0	4 (10.5%)	2 (4.5%)	2 (4.1%)	3 (7.7%)	13 (24.5%)	1 (2.1%)	33 (8.1%)	36 (8.0%)
>= 8.0 to < 9.0%	0	1 (1.9%)	0	3 (9.4%)	1 (3.2%)	0	2 (7.1%)	2 (7.7%)	0	9 (3.7%)	9 (3.2%)
>= 9.0%	3 (27.3%)	7 (16.7%)	0	1 (16.7%)	1 (7.7%)	2 (8.0%)	1 (9.1%)	11 (40.7%)	1 (6.3%)	24 (15.1%)	27 (15.9%)
Hypoglycemia											
< 8.0%	3 (3.4%)	8 (24.2%)	5 (21.7%)	3 (11.5%)	1 (5.0%)	1 (6.3%)	2 (8.3%)	1 (5.9%)	2 (12.5%)	23 (13.1%)	26 (9.8%)
>= 8.0%	2 (4.4%)	13 (13.8%)	4 (9.8%)	3 (7.9%)	1 (2.3%)	1 (2.0%)	3 (7.7%)	1 (1.9%)	2 (4.3%)	28 (6.9%)	30 (6.7%)
>= 8.0 to < 9.0%	2 (5.9%)	10 (19.2%)	3 (13.6%)	3 (9.4%)	1 (3.2%)	1 (4.2%)	1 (3.6%)	1 (3.8%)	2 (6.5%)	22 (8.9%)	24 (8.6%)
>= 9.0%	0	3 (7.1%)	1 (5.3%)	0	0	0	2 (18.2%)	0	0	6 (3.8%)	6 (3.5%)
Lactic acidosis related TEAEs											
< 8.0%	0	2 (6.1%)	0	0	0	0	0	0	0	2 (1.1%)	2 (0.8%)
>= 8.0%	0	0	0	0	0	0	0	0	0	0	0
>= 8.0 to < 9.0%	0	0	0	0	0	0	0	0	0	0	0
>= 9.0%	0	0	0	0	0	0	0	0	0	0	0
Cardiovascular-related TEAEs											
< 8.0%	2 (2.2%)	4 (12.1%)	1 (4.3%)	2 (7.7%)	4 (20.0%)	0	2 (8.3%)	0	2 (12.5%)	15 (8.6%)	17 (6.4%)
>= 8.0%	2 (4.4%)	7 (7.4%)	2 (4.9%)	4 (10.5%)	2 (4.5%)	8 (16.3%)	1 (2.6%)	5 (9.4%)	2 (4.3%)	31 (7.7%)	33 (7.3%)
>= 8.0 to < 9.0%	2 (5.9%)	3 (5.8%)	0	3 (9.4%)	2 (6.5%)	4 (16.7%)	0	4 (15.4%)	2 (6.5%)	18 (7.3%)	20 (7.1%)
>= 9.0%	0	4 (9.5%)	2 (10.5%)	1 (16.7%)	0	4 (16.0%)	1 (9.1%)	1 (3.7%)	0	13 (8.2%)	13 (7.6%)
Digestive Symptoms											
< 8.0%	19 (21.3%)	10 (30.3%)	6 (26.1%)	8 (30.8%)	2 (10.0%)	3 (18.8%)	8 (33.3%)	2 (11.8%)	5 (31.3%)	44 (25.1%)	63 (23.9%)
>= 8.0%	11 (24.4%)	18 (19.1%)	6 (14.6%)	18 (47.4%)	3 (6.8%)	7 (14.3%)	13 (33.3%)	13 (24.5%)	10 (21.3%)	88 (21.7%)	99 (22.0%)
>= 8.0 to < 9.0%	11 (32.4%)	11 (21.2%)	5 (22.7%)	15 (46.9%)	3 (9.7%)	2 (8.3%)	12 (42.9%)	4 (15.4%)	6 (19.4%)	58 (23.6%)	69 (24.6%)
>= 9.0%	0	7 (16.7%)	1 (5.3%)	3 (50.0%)	0	5 (20.0%)	1 (9.1%)	9 (33.3%)	4 (25.0%)	30 (18.9%)	30 (17.6%)
Renal TEAEs											

TEAE HbA1c at baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
< 8.0%	1 (1.1%)	0	1 (4.3%)	0	2 (10.0%)	0	0	1 (5.9%)	0	4 (2.3%)	5 (1.9%)
>= 8.0%	0	2 (2.1%)	0	1 (2.6%)	1 (2.3%)	3 (6.1%)	3 (7.7%)	3 (5.7%)	3 (6.4%)	16 (4.0%)	16 (3.6%)
>= 8.0 to < 9.0%	0	0	0	1 (3.1%)	1 (3.2%)	1 (4.2%)	1 (3.6%)	1 (3.8%)	3 (9.7%)	8 (3.3%)	8 (2.9%)
>= 9.0%	0	2 (4.8%)	0	0	0	2 (8.0%)	2 (18.2%)	2 (7.4%)	0	8 (5.0%)	8 (4.7%)
Hepatic TEAEs											
< 8.0%	0	1 (3.0%)	1 (4.3%)	0	0	0	0	0	1 (6.3%)	3 (1.7%)	3 (1.1%)
>= 8.0%	0	2 (2.1%)	0	0	1 (2.3%)	3 (6.1%)	1 (2.6%)	2 (3.8%)	2 (4.3%)	11 (2.7%)	11 (2.4%)
>= 8.0 to < 9.0%	0	1 (1.9%)	0	0	1 (3.2%)	2 (8.3%)	1 (3.6%)	1 (3.8%)	1 (3.2%)	7 (2.8%)	7 (2.5%)
>= 9.0%	0	1 (2.4%)	0	0	0	1 (4.0%)	0	1 (3.7%)	1 (6.3%)	4 (2.5%)	4 (2.4%)

- Abbreviations: AE, Adverse event; TEAE, Treatment Emergent AE; SU, Sulphonylurea; GLIN, Glinide; BIG, Biguanide; AGI, Alpha glucosidase inhibitor; TZD, Thiazolidinedione; DPP4-I, Dipeptidyl peptidase-4 inhibitor; GLP1-RA, Glucagon-like peptide 1 receptor agonist; SGLT2-I, Sodium glucose cotransporter 2 inhibitor; HbA1c, Glycosylated Hemoglobin (Hemoglobin A1c)
- "Imeglimin" in this table means "Imeglimin 1000 mg twice daily".
- "Combination Total" is the sum of the subjects excluding monotherapy "Imeglimin".
- "Imeglimin Total" is the sum of all subjects in Imeglimin treatment groups.
- Percentages are based on "Number of patients".

Control No:<<t-s-541-subae-019lt.sas, 2020-03-11T11:33:59>>

Table S-542 Subgroup Analysis of Overall Frequency of Treatment Emergent Adverse Events by Duration of type 2 diabetes in 52-Week Long-term Period with Monotherapy and Combination Therapy (PXL008-019; Long-term Safety Population)

TEAE Duration of type 2 diabetes	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
Number of patients											
< 5 years	72	23	18	22	26	20	20	15	12	156	228
>= 5 years	62	104	46	42	38	45	43	55	51	424	486
Any TEAE											
< 5 years	53 (73.6%)	19 (82.6%)	16 (88.9%)	16 (72.7%)	11 (42.3%)	16 (80.0%)	13 (65.0%)	11 (73.3%)	9 (75.0%)	111 (71.2%)	164 (71.9%)
>= 5 years	45 (72.6%)	83 (79.8%)	38 (82.6%)	32 (76.2%)	22 (57.9%)	34 (75.6%)	37 (86.0%)	45 (81.8%)	39 (76.5%)	330 (77.8%)	375 (77.2%)
Treatment-related TEAE											
< 5 years	7 (9.7%)	4 (17.4%)	5 (27.8%)	12 (54.5%)	1 (3.8%)	1 (5.0%)	4 (20.0%)	2 (13.3%)	1 (8.3%)	30 (19.2%)	37 (16.2%)
>= 5 years	6 (9.7%)	23 (22.1%)	5 (10.9%)	12 (28.6%)	5 (13.2%)	5 (11.1%)	10 (23.3%)	6 (10.9%)	6 (11.8%)	72 (17.0%)	78 (16.0%)
Severe TEAE											
< 5 years	0	1 (4.3%)	0	1 (4.5%)	0	0	0	0	0	2 (1.3%)	2 (0.9%)
>= 5 years	2 (3.2%)	4 (3.8%)	0	3 (7.1%)	1 (2.6%)	1 (2.2%)	1 (2.3%)	2 (3.6%)	1 (2.0%)	13 (3.1%)	15 (3.1%)
TEAE leading to death											
< 5 years	0	0	0	0	0	0	0	0	0	0	0
>= 5 years	1 (1.6%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
Serious TEAE											
< 5 years	2 (2.8%)	1 (4.3%)	0	1 (4.5%)	2 (7.7%)	1 (5.0%)	2 (10.0%)	1 (6.7%)	0	8 (5.1%)	10 (4.4%)
>= 5 years	2 (3.2%)	10 (9.6%)	1 (2.2%)	3 (7.1%)	2 (5.3%)	3 (6.7%)	1 (2.3%)	4 (7.3%)	4 (7.8%)	28 (6.6%)	30 (6.2%)
TEAE leading to treatment discontinuation											
< 5 years	1 (1.4%)	2 (8.7%)	0	3 (13.6%)	0	2 (10.0%)	1 (5.0%)	3 (20.0%)	0	11 (7.1%)	12 (5.3%)
>= 5 years	2 (3.2%)	7 (6.7%)	1 (2.2%)	4 (9.5%)	2 (5.3%)	2 (4.4%)	4 (9.3%)	12 (21.8%)	1 (2.0%)	33 (7.8%)	35 (7.2%)
Hypoglycemia											
< 5 years	2 (2.8%)	3 (13.0%)	2 (11.1%)	4 (18.2%)	1 (3.8%)	1 (5.0%)	2 (10.0%)	2 (13.3%)	1 (8.3%)	16 (10.3%)	18 (7.9%)
>= 5 years	3 (4.8%)	18 (17.3%)	7 (15.2%)	2 (4.8%)	1 (2.6%)	1 (2.2%)	3 (7.0%)	0	3 (5.9%)	35 (8.3%)	38 (7.8%)
Lactic acidosis related TEAEs											
< 5 years	0	0	0	0	0	0	0	0	0	0	0

TEAE Duration of type 2 diabetes	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
>= 5 years	0	2 (1.9%)	0	0	0	0	0	0	0	2 (0.5%)	2 (0.4%)
Cardiovascular-related TEAEs											
< 5 years	3 (4.2%)	0	2 (11.1%)	2 (9.1%)	2 (7.7%)	4 (20.0%)	1 (5.0%)	1 (6.7%)	2 (16.7%)	14 (9.0%)	17 (7.5%)
>= 5 years	1 (1.6%)	11 (10.6%)	1 (2.2%)	4 (9.5%)	4 (10.5%)	4 (8.9%)	2 (4.7%)	4 (7.3%)	2 (3.9%)	32 (7.5%)	33 (6.8%)
Digestive Symptoms											
< 5 years	18 (25.0%)	4 (17.4%)	4 (22.2%)	11 (50.0%)	0	1 (5.0%)	7 (35.0%)	3 (20.0%)	2 (16.7%)	32 (20.5%)	50 (21.9%)
>= 5 years	12 (19.4%)	24 (23.1%)	8 (17.4%)	15 (35.7%)	5 (13.2%)	9 (20.0%)	14 (32.6%)	12 (21.8%)	13 (25.5%)	100 (23.6%)	112 (23.0%)
Renal TEAEs											
< 5 years	0	0	1 (5.6%)	1 (4.5%)	1 (3.8%)	2 (10.0%)	1 (5.0%)	0	0	6 (3.8%)	6 (2.6%)
>= 5 years	1 (1.6%)	2 (1.9%)	0	0	2 (5.3%)	1 (2.2%)	2 (4.7%)	4 (7.3%)	3 (5.9%)	14 (3.3%)	15 (3.1%)
Hepatic TEAEs											
< 5 years	0	1 (4.3%)	1 (5.6%)	0	0	2 (10.0%)	0	0	0	4 (2.6%)	4 (1.8%)
>= 5 years	0	2 (1.9%)	0	0	1 (2.6%)	1 (2.2%)	1 (2.3%)	2 (3.6%)	3 (5.9%)	10 (2.4%)	10 (2.1%)

- Abbreviations: AE, Adverse event; TEAE, Treatment Emergent AE; SU, Sulphonylurea; GLIN, Glinide; BIG, Biguanide; AGI, Alpha glucosidase inhibitor; TZD, Thiazolidinedione; DPP4-I, Dipeptidyl peptidase-4 inhibitor; GLP1-RA, Glucagon-like peptide 1 receptor agonist; SGLT2-I, Sodium glucose cotransporter 2 inhibitor
- "Imeglimin" in this table means "Imeglimin 1000 mg twice daily".
- "Combination Total" is the sum of the subjects excluding monotherapy "Imeglimin".
- "Imeglimin Total" is the sum of all subjects in Imeglimin treatment groups.
- Percentages are based on "Number of patients".

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Table S-543 Subgroup Analysis of Overall Frequency of Treatment Emergent Adverse Events by Complication of diabetes in 52-Week Long-term Period with Monotherapy and Combination Therapy (PXL008-019; Long-term Safety Population)

TEAE Complication of diabetes	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
Number of patients											
Yes	23	46	24	24	16	10	22	32	16	190	213
No	111	81	40	40	48	55	41	38	47	390	501
Any TEAE											
Yes	17 (73.9%)	40 (87.0%)	23 (95.8%)	22 (91.7%)	6 (37.5%)	7 (70.0%)	18 (81.8%)	25 (78.1%)	11 (68.8%)	152 (80.0%)	169 (79.3%)
No	81 (73.0%)	62 (76.5%)	31 (77.5%)	26 (65.0%)	27 (56.3%)	43 (78.2%)	32 (78.0%)	31 (81.6%)	37 (78.7%)	289 (74.1%)	370 (73.9%)
Treatment-related TEAE											
Yes	3 (13.0%)	16 (34.8%)	3 (12.5%)	10 (41.7%)	1 (6.3%)	1 (10.0%)	3 (13.6%)	7 (21.9%)	3 (18.8%)	44 (23.2%)	47 (22.1%)
No	10 (9.0%)	11 (13.6%)	7 (17.5%)	14 (35.0%)	5 (10.4%)	5 (9.1%)	11 (26.8%)	1 (2.6%)	4 (8.5%)	58 (14.9%)	68 (13.6%)
Severe TEAE											
Yes	1 (4.3%)	0	0	1 (4.2%)	0	0	1 (4.5%)	0	0	2 (1.1%)	3 (1.4%)
No	1 (0.9%)	5 (6.2%)	0	3 (7.5%)	1 (2.1%)	1 (1.8%)	0	2 (5.3%)	1 (2.1%)	13 (3.3%)	14 (2.8%)
TEAE leading to death											
Yes	1 (4.3%)	0	0	0	0	0	0	0	0	0	1 (0.5%)
No	0	0	0	0	0	0	0	0	0	0	0
Serious TEAE											
Yes	2 (8.7%)	3 (6.5%)	0	2 (8.3%)	0	1 (10.0%)	3 (13.6%)	2 (6.3%)	0	11 (5.8%)	13 (6.1%)
No	2 (1.8%)	8 (9.9%)	1 (2.5%)	2 (5.0%)	4 (8.3%)	3 (5.5%)	0	3 (7.9%)	4 (8.5%)	25 (6.4%)	27 (5.4%)
TEAE leading to treatment discontinuation											
Yes	1 (4.3%)	1 (2.2%)	0	3 (12.5%)	1 (6.3%)	0	1 (4.5%)	10 (31.3%)	0	16 (8.4%)	17 (8.0%)
No	2 (1.8%)	8 (9.9%)	1 (2.5%)	4 (10.0%)	1 (2.1%)	4 (7.3%)	4 (9.8%)	5 (13.2%)	1 (2.1%)	28 (7.2%)	30 (6.0%)
Hypoglycemia											
Yes	1 (4.3%)	12 (26.1%)	3 (12.5%)	3 (12.5%)	0	0	1 (4.5%)	1 (3.1%)	1 (6.3%)	21 (11.1%)	22 (10.3%)
No	4 (3.6%)	9 (11.1%)	6 (15.0%)	3 (7.5%)	2 (4.2%)	2 (3.6%)	4 (9.8%)	1 (2.6%)	3 (6.4%)	30 (7.7%)	34 (6.8%)
Lactic acidosis related TEAEs											
Yes	0	1 (2.2%)	0	0	0	0	0	0	0	1 (0.5%)	1 (0.5%)

TEAE Complication of diabetes	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
No	0	1 (1.2%)	0	0	0	0	0	0	0	1 (0.3%)	1 (0.2%)
Cardiovascular-related TEAEs											
Yes	2 (8.7%)	7 (15.2%)	3 (12.5%)	3 (12.5%)	2 (12.5%)	1 (10.0%)	2 (9.1%)	0	1 (6.3%)	19 (10.0%)	21 (9.9%)
No	2 (1.8%)	4 (4.9%)	0	3 (7.5%)	4 (8.3%)	7 (12.7%)	1 (2.4%)	5 (13.2%)	3 (6.4%)	27 (6.9%)	29 (5.8%)
Digestive Symptoms											
Yes	7 (30.4%)	11 (23.9%)	5 (20.8%)	12 (50.0%)	1 (6.3%)	3 (30.0%)	10 (45.5%)	11 (34.4%)	4 (25.0%)	57 (30.0%)	64 (30.0%)
No	23 (20.7%)	17 (21.0%)	7 (17.5%)	14 (35.0%)	4 (8.3%)	7 (12.7%)	11 (26.8%)	4 (10.5%)	11 (23.4%)	75 (19.2%)	98 (19.6%)
Renal TEAEs											
Yes	0	1 (2.2%)	1 (4.2%)	0	0	0	1 (4.5%)	3 (9.4%)	1 (6.3%)	7 (3.7%)	7 (3.3%)
No	1 (0.9%)	1 (1.2%)	0	1 (2.5%)	3 (6.3%)	3 (5.5%)	2 (4.9%)	1 (2.6%)	2 (4.3%)	13 (3.3%)	14 (2.8%)
Hepatic TEAEs											
Yes	0	1 (2.2%)	0	0	0	0	1 (4.5%)	1 (3.1%)	0	3 (1.6%)	3 (1.4%)
No	0	2 (2.5%)	1 (2.5%)	0	1 (2.1%)	3 (5.5%)	0	1 (2.6%)	3 (6.4%)	11 (2.8%)	11 (2.2%)

- Abbreviations: AE, Adverse event; TEAE, Treatment Emergent AE; SU, Sulphonylurea; GLIN, Glinide; BIG, Biguanide; AGI, Alpha glucosidase inhibitor; TZD, Thiazolidinedione; DPP4-I, Dipeptidyl peptidase-4 inhibitor; GLP1-RA, Glucagon-like peptide 1 receptor agonist; SGLT2-I, Sodium glucose cotransporter 2 inhibitor
- Complication of diabetes is defined as any MedDRA Preferred Term (PT) of medical history which are included in High-Level Group Term (HLGT) of diabetic complication.
- "Imeglimin" in this table means "Imeglimin 1000 mg twice daily".
- "Combination Total" is the sum of the subjects excluding monotherapy "Imeglimin".
- "Imeglimin Total" is the sum of all subjects in Imeglimin treatment groups.
- Percentages are based on "Number of patients".

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Table S-544 Subgroup Analysis of Overall Frequency of Treatment Emergent Adverse Events by Metabolic syndrome in 52-Week Long-term Period with Monotherapy and Combination Therapy (PXL008-019; Long-term Safety Population)

TEAE Metabolic syndrome at baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
Number of patients											
Yes	62	64	28	36	32	32	25	39	31	287	349
No	72	63	36	28	32	33	38	31	32	293	365
Any TEAE											
Yes	42 (67.7%)	54 (84.4%)	24 (85.7%)	25 (69.4%)	15 (46.9%)	26 (81.3%)	18 (72.0%)	34 (87.2%)	22 (71.0%)	218 (76.0%)	260 (74.5%)
No	56 (77.8%)	48 (76.2%)	30 (83.3%)	23 (82.1%)	18 (56.3%)	24 (72.7%)	32 (84.2%)	22 (71.0%)	26 (81.3%)	223 (76.1%)	279 (76.4%)
Treatment-related TEAE											
Yes	5 (8.1%)	13 (20.3%)	5 (17.9%)	10 (27.8%)	1 (3.1%)	2 (6.3%)	2 (8.0%)	4 (10.3%)	3 (9.7%)	40 (13.9%)	45 (12.9%)
No	8 (11.1%)	14 (22.2%)	5 (13.9%)	14 (50.0%)	5 (15.6%)	4 (12.1%)	12 (31.6%)	4 (12.9%)	4 (12.5%)	62 (21.2%)	70 (19.2%)
Severe TEAE											
Yes	0	2 (3.1%)	0	1 (2.8%)	0	0	0	2 (5.1%)	0	5 (1.7%)	5 (1.4%)
No	2 (2.8%)	3 (4.8%)	0	3 (10.7%)	1 (3.1%)	1 (3.0%)	1 (2.6%)	0	1 (3.1%)	10 (3.4%)	12 (3.3%)
TEAE leading to death											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	1 (1.4%)	0	0	0	0	0	0	0	0	0	1 (0.3%)
Serious TEAE											
Yes	1 (1.6%)	5 (7.8%)	0	2 (5.6%)	2 (6.3%)	2 (6.3%)	1 (4.0%)	4 (10.3%)	1 (3.2%)	17 (5.9%)	18 (5.2%)
No	3 (4.2%)	6 (9.5%)	1 (2.8%)	2 (7.1%)	2 (6.3%)	2 (6.1%)	2 (5.3%)	1 (3.2%)	3 (9.4%)	19 (6.5%)	22 (6.0%)
TEAE leading to treatment discontinuation											
Yes	1 (1.6%)	7 (10.9%)	0	0	0	1 (3.1%)	0	9 (23.1%)	0	17 (5.9%)	18 (5.2%)
No	2 (2.8%)	2 (3.2%)	1 (2.8%)	7 (25.0%)	2 (6.3%)	3 (9.1%)	5 (13.2%)	6 (19.4%)	1 (3.1%)	27 (9.2%)	29 (7.9%)
Hypoglycemia											
Yes	2 (3.2%)	10 (15.6%)	4 (14.3%)	4 (11.1%)	1 (3.1%)	1 (3.1%)	3 (12.0%)	2 (5.1%)	1 (3.2%)	26 (9.1%)	28 (8.0%)
No	3 (4.2%)	11 (17.5%)	5 (13.9%)	2 (7.1%)	1 (3.1%)	1 (3.0%)	2 (5.3%)	0	3 (9.4%)	25 (8.5%)	28 (7.7%)
Lactic acidosis related TEAEs											
Yes	0	1 (1.6%)	0	0	0	0	0	0	0	1 (0.3%)	1 (0.3%)

TEAE Metabolic syndrome at baseline	Imeglimin N = 134	Imeglimin + SU N = 127	Imeglimin + GLIN N = 64	Imeglimin + BIG N = 64	Imeglimin + AGI N = 64	Imeglimin + TZD N = 65	Imeglimin + DPP4-I N = 63	Imeglimin + GLP1-RA N = 70	Imeglimin + SGLT2-I N = 63	Combination Total N = 580	Imeglimin Total N = 714
No	0	1 (1.6%)	0	0	0	0	0	0	0	1 (0.3%)	1 (0.3%)
Cardiovascular-related TEAEs											
Yes	1 (1.6%)	7 (10.9%)	1 (3.6%)	4 (11.1%)	5 (15.6%)	5 (15.6%)	1 (4.0%)	3 (7.7%)	2 (6.5%)	28 (9.8%)	29 (8.3%)
No	3 (4.2%)	4 (6.3%)	2 (5.6%)	2 (7.1%)	1 (3.1%)	3 (9.1%)	2 (5.3%)	2 (6.5%)	2 (6.3%)	18 (6.1%)	21 (5.8%)
Digestive Symptoms											
Yes	14 (22.6%)	16 (25.0%)	4 (14.3%)	12 (33.3%)	1 (3.1%)	5 (15.6%)	5 (20.0%)	9 (23.1%)	6 (19.4%)	58 (20.2%)	72 (20.6%)
No	16 (22.2%)	12 (19.0%)	8 (22.2%)	14 (50.0%)	4 (12.5%)	5 (15.2%)	16 (42.1%)	6 (19.4%)	9 (28.1%)	74 (25.3%)	90 (24.7%)
Renal TEAEs											
Yes	0	1 (1.6%)	1 (3.6%)	1 (2.8%)	2 (6.3%)	2 (6.3%)	1 (4.0%)	2 (5.1%)	2 (6.5%)	12 (4.2%)	12 (3.4%)
No	1 (1.4%)	1 (1.6%)	0	0	1 (3.1%)	1 (3.0%)	2 (5.3%)	2 (6.5%)	1 (3.1%)	8 (2.7%)	9 (2.5%)
Hepatic TEAEs											
Yes	0	0	0	0	0	2 (6.3%)	1 (4.0%)	0	1 (3.2%)	4 (1.4%)	4 (1.1%)
No	0	3 (4.8%)	1 (2.8%)	0	1 (3.1%)	1 (3.0%)	0	2 (6.5%)	2 (6.3%)	10 (3.4%)	10 (2.7%)

- Abbreviations: AE, Adverse event; TEAE, Treatment Emergent AE; SU, Sulphonylurea; GLIN, Glinide; BIG, Biguanide; AGI, Alpha glucosidase inhibitor; TZD, Thiazolidinedione; DPP4-I, Dipeptidyl peptidase-4 inhibitor; GLP1-RA, Glucagon-like peptide 1 receptor agonist; SGLT2-I, Sodium glucose cotransporter 2 inhibitor
- Metabolic Syndrome is defined as an excessive waist circumference (>= 85 cm in men and >= 90 cm in women) as well as the presence of two or more of the following symptoms: (1) Hypertension: systolic blood pressure >= 130 mmHg, or diastolic blood pressure >= 85 mmHg; (2) Glucose intolerance: fasting glucose >= 110 mg/dL; (3) Dyslipidemia: triglyceride >= 150 mg/dL, or HDL cholesterol < 40 mg/dL.
- "Imeglimin" in this table means "Imeglimin 1000 mg twice daily".
- "Combination Total" is the sum of the subjects excluding monotherapy "Imeglimin".
- "Imeglimin Total" is the sum of all subjects in Imeglimin treatment groups.
- Percentages are based on "Number of patients".

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Table S-550 Subgroup Analysis of Overall Frequency of Treatment Emergent Adverse Events by BMI in 16-Week Double-blind Period in Combination with Insulin Therapy (PXL008-020; Safety Population)

TEAE BMI at baseline	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
Number of patients		
< 25 kg/m2	60	56
>= 25 kg/m2	47	52
>= 25 to < 30 kg/m2	35	44
>= 30 kg/m2	12	8
Any TEAE		
< 25 kg/m2	27 (45.0%)	30 (53.6%)
>= 25 kg/m2	24 (51.1%)	27 (51.9%)
>= 25 to < 30 kg/m2	16 (45.7%)	24 (54.5%)
>= 30 kg/m2	8 (66.7%)	3 (37.5%)
Treatment-related TEAE		
< 25 kg/m2	7 (11.7%)	9 (16.1%)
>= 25 kg/m2	6 (12.8%)	7 (13.5%)
>= 25 to < 30 kg/m2	5 (14.3%)	7 (15.9%)
>= 30 kg/m2	1 (8.3%)	0
Severe TEAE		
< 25 kg/m2	1 (1.7%)	0
>= 25 kg/m2	1 (2.1%)	0
>= 25 to < 30 kg/m2	0	0
>= 30 kg/m2	1 (8.3%)	0
TEAE leading to death		
< 25 kg/m2	0	0
>= 25 kg/m2	0	0
>= 25 to < 30 kg/m2	0	0
>= 30 kg/m2	0	0
Serious TEAE		
< 25 kg/m2	2 (3.3%)	0
>= 25 kg/m2	1 (2.1%)	1 (1.9%)
>= 25 to < 30 kg/m2	0	1 (2.3%)
>= 30 kg/m2	1 (8.3%)	0
TEAE leading to treatment discontinuation		
< 25 kg/m2	0	1 (1.8%)
>= 25 kg/m2	4 (8.5%)	0
>= 25 to < 30 kg/m2	2 (5.7%)	0
>= 30 kg/m2	2 (16.7%)	0
Hypoglycemia		
< 25 kg/m2	14 (23.3%)	12 (21.4%)
>= 25 kg/m2	3 (6.4%)	11 (21.2%)
>= 25 to < 30 kg/m2	3 (8.6%)	11 (25.0%)
>= 30 kg/m2	0	0
Lactic acidosis related TEAEs		
< 25 kg/m2	0	0
>= 25 kg/m2	0	0
>= 25 to < 30 kg/m2	0	0
>= 30 kg/m2	0	0
Cardiovascular-related TEAEs		
< 25 kg/m2	1 (1.7%)	2 (3.6%)

TEAE BMI at baseline	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
>= 25 kg/m2	0	2 (3.8%)
>= 25 to < 30 kg/m2	0	2 (4.5%)
>= 30 kg/m2	0	0
Digestive Symptoms		
< 25 kg/m2	2 (3.3%)	6 (10.7%)
>= 25 kg/m2	5 (10.6%)	4 (7.7%)
>= 25 to < 30 kg/m2	2 (5.7%)	4 (9.1%)
>= 30 kg/m2	3 (25.0%)	0
Renal TEAEs		
< 25 kg/m2	0	0
>= 25 kg/m2	0	1 (1.9%)
>= 25 to < 30 kg/m2	0	1 (2.3%)
>= 30 kg/m2	0	0
Hepatic TEAEs		
< 25 kg/m2	0	0
>= 25 kg/m2	0	0
>= 25 to < 30 kg/m2	0	0
>= 30 kg/m2	0	0

- Abbreviations: bid, Twice a day; AE, Adverse event; TEAE, Treatment Emergent AE; BMI, body mass index
- Percentages are based on "Number of patients".

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Table S-551 Subgroup Analysis of Overall Frequency of Treatment Emergent Adverse Events by HbA1c at baseline in 16-Week Double-blind Period in Combination with Insulin Therapy (PXL008-020; Safety Population)

TEAE HbA1c at baseline	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
Number of patients		
< 8.0%	16	16
>= 8.0%	91	92
>= 8.0 to < 9.0%	44	53
>= 9.0%	47	39
Any TEAE		
< 8.0%	7 (43.8%)	11 (68.8%)
>= 8.0%	44 (48.4%)	46 (50.0%)
>= 8.0 to < 9.0%	18 (40.9%)	28 (52.8%)
>= 9.0%	26 (55.3%)	18 (46.2%)
Treatment-related TEAE		
< 8.0%	4 (25.0%)	4 (25.0%)
>= 8.0%	9 (9.9%)	12 (13.0%)
>= 8.0 to < 9.0%	5 (11.4%)	9 (17.0%)
>= 9.0%	4 (8.5%)	3 (7.7%)
Severe TEAE		
< 8.0%	0	0
>= 8.0%	2 (2.2%)	0
>= 8.0 to < 9.0%	0	0
>= 9.0%	2 (4.3%)	0
TEAE leading to death		
< 8.0%	0	0
>= 8.0%	0	0
>= 8.0 to < 9.0%	0	0
>= 9.0%	0	0
Serious TEAE		
< 8.0%	0	0
>= 8.0%	3 (3.3%)	1 (1.1%)
>= 8.0 to < 9.0%	1 (2.3%)	0
>= 9.0%	2 (4.3%)	1 (2.6%)
TEAE leading to treatment discontinuation		
< 8.0%	0	0
>= 8.0%	4 (4.4%)	1 (1.1%)
>= 8.0 to < 9.0%	0	1 (1.9%)
>= 9.0%	4 (8.5%)	0
Hypoglycemia		
< 8.0%	5 (31.3%)	3 (18.8%)
>= 8.0%	12 (13.2%)	20 (21.7%)
>= 8.0 to < 9.0%	8 (18.2%)	12 (22.6%)
>= 9.0%	4 (8.5%)	8 (20.5%)
Lactic acidosis related TEAEs		
< 8.0%	0	0
>= 8.0%	0	0
>= 8.0 to < 9.0%	0	0
>= 9.0%	0	0
Cardiovascular-related TEAEs		
< 8.0%	0	2 (12.5%)

TEAE HbA1c at baseline	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
>= 8.0%	1 (1.1%)	2 (2.2%)
>= 8.0 to < 9.0%	1 (2.3%)	1 (1.9%)
>= 9.0%	0	1 (2.6%)
Digestive Symptoms		
< 8.0%	1 (6.3%)	3 (18.8%)
>= 8.0%	6 (6.6%)	7 (7.6%)
>= 8.0 to < 9.0%	4 (9.1%)	4 (7.5%)
>= 9.0%	2 (4.3%)	3 (7.7%)
Renal TEAEs		
< 8.0%	0	1 (6.3%)
>= 8.0%	0	0
>= 8.0 to < 9.0%	0	0
>= 9.0%	0	0
Hepatic TEAEs		
< 8.0%	0	0
>= 8.0%	0	0
>= 8.0 to < 9.0%	0	0
>= 9.0%	0	0

- Abbreviations: bid, Twice a day; AE, Adverse event; TEAE, Treatment Emergent AE; HbA1c, Glycosylated Hemoglobin (Hemoglobin A1c)
- Percentages are based on "Number of patients".

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Table S-552 Subgroup Analysis of Overall Frequency of Treatment Emergent Adverse Events by Duration of type 2 diabetes in 16-Week Double-blind Period in Combination with Insulin Therapy (PXL008-020; Safety Population)

TEAE Duration of type 2 diabetes	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
Number of patients		
< 5 years	12	16
>= 5 years	95	92
Any TEAE		
< 5 years	7 (58.3%)	6 (37.5%)
>= 5 years	44 (46.3%)	51 (55.4%)
Treatment-related TEAE		
< 5 years	0	2 (12.5%)
>= 5 years	13 (13.7%)	14 (15.2%)
Severe TEAE		
< 5 years	0	0
>= 5 years	2 (2.1%)	0
TEAE leading to death		
< 5 years	0	0
>= 5 years	0	0
Serious TEAE		
< 5 years	0	1 (6.3%)
>= 5 years	3 (3.2%)	0
TEAE leading to treatment discontinuation		
< 5 years	2 (16.7%)	0
>= 5 years	2 (2.1%)	1 (1.1%)
Hypoglycemia		
< 5 years	1 (8.3%)	3 (18.8%)
>= 5 years	16 (16.8%)	20 (21.7%)
Lactic acidosis related TEAEs		
< 5 years	0	0
>= 5 years	0	0
Cardiovascular-related TEAEs		
< 5 years	0	2 (12.5%)
>= 5 years	1 (1.1%)	2 (2.2%)
Digestive Symptoms		
< 5 years	0	1 (6.3%)
>= 5 years	7 (7.4%)	9 (9.8%)
Renal TEAEs		
< 5 years	0	0
>= 5 years	0	1 (1.1%)
Hepatic TEAEs		
< 5 years	0	0
>= 5 years	0	0

- Abbreviations: bid, Twice a day; AE, Adverse event; TEAE, Treatment Emergent AE
- Percentages are based on "Number of patients".

Control No:<<t-s-552-subae-020db.sas, 2020-03-11T11:35:44>>

Table S-553 Subgroup Analysis of Overall Frequency of Treatment Emergent Adverse Events by Complication of diabetes in 16-Week Double-blind Period in Combination with Insulin Therapy (PXL008-020; Safety Population)

TEAE Complication of diabetes	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
Number of patients		
Yes	53	45
No	54	63
Any TEAE		
Yes	31 (58.5%)	24 (53.3%)
No	20 (37.0%)	33 (52.4%)
Treatment-related TEAE		
Yes	7 (13.2%)	9 (20.0%)
No	6 (11.1%)	7 (11.1%)
Severe TEAE		
Yes	2 (3.8%)	0
No	0	0
TEAE leading to death		
Yes	0	0
No	0	0
Serious TEAE		
Yes	3 (5.7%)	1 (2.2%)
No	0	0
TEAE leading to treatment discontinuation		
Yes	2 (3.8%)	0
No	2 (3.7%)	1 (1.6%)
Hypoglycemia		
Yes	10 (18.9%)	11 (24.4%)
No	7 (13.0%)	12 (19.0%)
Lactic acidosis related TEAEs		
Yes	0	0
No	0	0
Cardiovascular-related TEAEs		
Yes	0	2 (4.4%)
No	1 (1.9%)	2 (3.2%)
Digestive Symptoms		
Yes	6 (11.3%)	4 (8.9%)
No	1 (1.9%)	6 (9.5%)
Renal TEAEs		
Yes	0	0
No	0	1 (1.6%)
Hepatic TEAEs		
Yes	0	0
No	0	0

- Abbreviations: bid, Twice a day; AE, Adverse event; TEAE, Treatment Emergent AE
- Complication of diabetes is defined as any MedDRA Preferred Term (PT) of medical history which are included in High-Level Group Term (HLGT) of diabetic complication.
- Percentages are based on "Number of patients".

Control No:<<t-s-553-subae-020db.sas, 2020-03-11T11:35:52>>

Table S-554 Subgroup Analysis of Overall Frequency of Treatment Emergent Adverse Events by Metabolic syndrome in 16-Week Double-blind Period in Combination with Insulin Therapy (PXL008-020; Safety Population)

TEAE Metabolic syndrome at baseline	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
Number of patients		
Yes	50	39
No	57	69
Any TEAE		
Yes	23 (46.0%)	19 (48.7%)
No	28 (49.1%)	38 (55.1%)
Treatment-related TEAE		
Yes	2 (4.0%)	3 (7.7%)
No	11 (19.3%)	13 (18.8%)
Severe TEAE		
Yes	1 (2.0%)	0
No	1 (1.8%)	0
TEAE leading to death		
Yes	0	0
No	0	0
Serious TEAE		
Yes	1 (2.0%)	0
No	2 (3.5%)	1 (1.4%)
TEAE leading to treatment discontinuation		
Yes	4 (8.0%)	0
No	0	1 (1.4%)
Hypoglycemia		
Yes	2 (4.0%)	7 (17.9%)
No	15 (26.3%)	16 (23.2%)
Lactic acidosis related TEAEs		
Yes	0	0
No	0	0
Cardiovascular-related TEAEs		
Yes	0	1 (2.6%)
No	1 (1.8%)	3 (4.3%)
Digestive Symptoms		
Yes	5 (10.0%)	2 (5.1%)
No	2 (3.5%)	8 (11.6%)
Renal TEAEs		
Yes	0	1 (2.6%)
No	0	0
Hepatic TEAEs		
Yes	0	0
No	0	0

- Abbreviations: bid, Twice a day; AE, Adverse event; TEAE, Treatment Emergent AE
- Metabolic Syndrome is defined as an excessive waist circumference (>= 85 cm in men and >= 90 cm in women) as well as the presence of two or more of the following symptoms: (1) Hypertension: systolic blood pressure >= 130 mmHg, or diastolic blood pressure >= 85 mmHg; (2) Glucose intolerance: fasting glucose >= 110 mg/dL; (3) Dyslipidemia: triglyceride >= 150 mg/dL, or HDL cholesterol < 40 mg/dL.
- Percentages are based on "Number of patients".

Control No:<<t-s-554-subae-020db.sas, 2020-03-11T11:36:01>>

Table S-560 Subgroup Analysis of Overall Frequency of Treatment Emergent Adverse Events by BMI in 52-Week Long-term Period in Combination with Insulin Therapy (PXL008-020; Long-term Safety Population)

TEAE BMI at baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
Number of patients			
< 25 kg/m2	58	56	114
>= 25 kg/m2	43	52	95
>= 25 to < 30 kg/m2	33	44	77
>= 30 kg/m2	10	8	18
Any TEAE			
< 25 kg/m2	44 (75.9%)	49 (87.5%)	93 (81.6%)
>= 25 kg/m2	33 (76.7%)	43 (82.7%)	76 (80.0%)
>= 25 to < 30 kg/m2	25 (75.8%)	35 (79.5%)	60 (77.9%)
>= 30 kg/m2	8 (80.0%)	8 (100.0%)	16 (88.9%)
Treatment-related TEAE			
< 25 kg/m2	12 (20.7%)	15 (26.8%)	27 (23.7%)
>= 25 kg/m2	4 (9.3%)	13 (25.0%)	17 (17.9%)
>= 25 to < 30 kg/m2	4 (12.1%)	10 (22.7%)	14 (18.2%)
>= 30 kg/m2	0	3 (37.5%)	3 (16.7%)
Severe TEAE			
< 25 kg/m2	3 (5.2%)	0	3 (2.6%)
>= 25 kg/m2	0	1 (1.9%)	1 (1.1%)
>= 25 to < 30 kg/m2	0	1 (2.3%)	1 (1.3%)
>= 30 kg/m2	0	0	0
TEAE leading to death			
< 25 kg/m2	1 (1.7%)	0	1 (0.9%)
>= 25 kg/m2	0	0	0
>= 25 to < 30 kg/m2	0	0	0
>= 30 kg/m2	0	0	0
Serious TEAE			
< 25 kg/m2	4 (6.9%)	1 (1.8%)	5 (4.4%)
>= 25 kg/m2	2 (4.7%)	5 (9.6%)	7 (7.4%)
>= 25 to < 30 kg/m2	2 (6.1%)	5 (11.4%)	7 (9.1%)
>= 30 kg/m2	0	0	0
TEAE leading to treatment discontinuation			
< 25 kg/m2	2 (3.4%)	3 (5.4%)	5 (4.4%)
>= 25 kg/m2	1 (2.3%)	2 (3.8%)	3 (3.2%)
>= 25 to < 30 kg/m2	1 (3.0%)	0	1 (1.3%)
>= 30 kg/m2	0	2 (25.0%)	2 (11.1%)
Hypoglycemia			
< 25 kg/m2	25 (43.1%)	22 (39.3%)	47 (41.2%)
>= 25 kg/m2	11 (25.6%)	17 (32.7%)	28 (29.5%)
>= 25 to < 30 kg/m2	11 (33.3%)	16 (36.4%)	27 (35.1%)
>= 30 kg/m2	0	1 (12.5%)	1 (5.6%)
Lactic acidosis related TEAEs			
< 25 kg/m2	0	1 (1.8%)	1 (0.9%)
>= 25 kg/m2	0	0	0
>= 25 to < 30 kg/m2	0	0	0
>= 30 kg/m2	0	0	0
Cardiovascular-related TEAEs			
< 25 kg/m2	5 (8.6%)	4 (7.1%)	9 (7.9%)

TEAE BMI at baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
>= 25 kg/m2	2 (4.7%)	4 (7.7%)	6 (6.3%)
>= 25 to < 30 kg/m2	2 (6.1%)	4 (9.1%)	6 (7.8%)
>= 30 kg/m2	0	0	0
Digestive Symptoms			
< 25 kg/m2	6 (10.3%)	9 (16.1%)	15 (13.2%)
>= 25 kg/m2	4 (9.3%)	11 (21.2%)	15 (15.8%)
>= 25 to < 30 kg/m2	3 (9.1%)	9 (20.5%)	12 (15.6%)
>= 30 kg/m2	1 (10.0%)	2 (25.0%)	3 (16.7%)
Renal TEAEs			
< 25 kg/m2	0	0	0
>= 25 kg/m2	1 (2.3%)	1 (1.9%)	2 (2.1%)
>= 25 to < 30 kg/m2	1 (3.0%)	1 (2.3%)	2 (2.6%)
>= 30 kg/m2	0	0	0
Hepatic TEAEs			
< 25 kg/m2	2 (3.4%)	2 (3.6%)	4 (3.5%)
>= 25 kg/m2	0	1 (1.9%)	1 (1.1%)
>= 25 to < 30 kg/m2	0	1 (2.3%)	1 (1.3%)
>= 30 kg/m2	0	0	0

- Abbreviations: AE, Adverse event; TEAE, Treatment Emergent AE; BMI, body mass index
- "Imeglimin" in this table means "Imeglimin 1000 mg twice daily".
- The Long-term Safety Population excludes data during administration of placebo in the double-blind period.
- "Imeglimin + Insulin Total" is the sum of subjects in the placebo group in the open-label period and Imeglimin group in the double-blind and open-label periods.
- Percentages are based on "Number of patients".

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Table S-561 Subgroup Analysis of Overall Frequency of Treatment Emergent Adverse Events by HbA1c at baseline in 52-Week Long-term Period in Combination with Insulin Therapy (PXL008-020; Long-term Safety Population)

TEAE HbA1c at baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
Number of patients			
< 8.0%	16	16	32
>= 8.0%	85	92	177
>= 8.0 to < 9.0%	41	53	94
>= 9.0%	44	39	83
Any TEAE			
< 8.0%	14 (87.5%)	14 (87.5%)	28 (87.5%)
>= 8.0%	63 (74.1%)	78 (84.8%)	141 (79.7%)
>= 8.0 to < 9.0%	29 (70.7%)	46 (86.8%)	75 (79.8%)
>= 9.0%	34 (77.3%)	32 (82.1%)	66 (79.5%)
Treatment-related TEAE			
< 8.0%	6 (37.5%)	5 (31.3%)	11 (34.4%)
>= 8.0%	10 (11.8%)	23 (25.0%)	33 (18.6%)
>= 8.0 to < 9.0%	7 (17.1%)	16 (30.2%)	23 (24.5%)
>= 9.0%	3 (6.8%)	7 (17.9%)	10 (12.0%)
Severe TEAE			
< 8.0%	0	0	0
>= 8.0%	3 (3.5%)	1 (1.1%)	4 (2.3%)
>= 8.0 to < 9.0%	3 (7.3%)	1 (1.9%)	4 (4.3%)
>= 9.0%	0	0	0
TEAE leading to death			
< 8.0%	0	0	0
>= 8.0%	1 (1.2%)	0	1 (0.6%)
>= 8.0 to < 9.0%	1 (2.4%)	0	1 (1.1%)
>= 9.0%	0	0	0
Serious TEAE			
< 8.0%	0	1 (6.3%)	1 (3.1%)
>= 8.0%	6 (7.1%)	5 (5.4%)	11 (6.2%)
>= 8.0 to < 9.0%	3 (7.3%)	3 (5.7%)	6 (6.4%)
>= 9.0%	3 (6.8%)	2 (5.1%)	5 (6.0%)
TEAE leading to treatment discontinuation			
< 8.0%	0	0	0
>= 8.0%	3 (3.5%)	5 (5.4%)	8 (4.5%)
>= 8.0 to < 9.0%	1 (2.4%)	2 (3.8%)	3 (3.2%)
>= 9.0%	2 (4.5%)	3 (7.7%)	5 (6.0%)
Hypoglycemia			
< 8.0%	8 (50.0%)	5 (31.3%)	13 (40.6%)
>= 8.0%	28 (32.9%)	34 (37.0%)	62 (35.0%)
>= 8.0 to < 9.0%	12 (29.3%)	23 (43.4%)	35 (37.2%)
>= 9.0%	16 (36.4%)	11 (28.2%)	27 (32.5%)
Lactic acidosis related TEAEs			
< 8.0%	0	0	0
>= 8.0%	0	1 (1.1%)	1 (0.6%)
>= 8.0 to < 9.0%	0	1 (1.9%)	1 (1.1%)
>= 9.0%	0	0	0
Cardiovascular-related TEAEs			
< 8.0%	1 (6.3%)	2 (12.5%)	3 (9.4%)

TEAE HbA1c at baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
>= 8.0%	6 (7.1%)	6 (6.5%)	12 (6.8%)
>= 8.0 to < 9.0%	5 (12.2%)	4 (7.5%)	9 (9.6%)
>= 9.0%	1 (2.3%)	2 (5.1%)	3 (3.6%)
Digestive Symptoms			
< 8.0%	1 (6.3%)	7 (43.8%)	8 (25.0%)
>= 8.0%	9 (10.6%)	13 (14.1%)	22 (12.4%)
>= 8.0 to < 9.0%	4 (9.8%)	6 (11.3%)	10 (10.6%)
>= 9.0%	5 (11.4%)	7 (17.9%)	12 (14.5%)
Renal TEAEs			
< 8.0%	1 (6.3%)	1 (6.3%)	2 (6.3%)
>= 8.0%	0	0	0
>= 8.0 to < 9.0%	0	0	0
>= 9.0%	0	0	0
Hepatic TEAEs			
< 8.0%	0	0	0
>= 8.0%	2 (2.4%)	3 (3.3%)	5 (2.8%)
>= 8.0 to < 9.0%	2 (4.9%)	2 (3.8%)	4 (4.3%)
>= 9.0%	0	1 (2.6%)	1 (1.2%)

- Abbreviations: AE, Adverse event; TEAE, Treatment Emergent AE; HbA1c, Glycosylated Hemoglobin (Hemoglobin A1c)
- "Imeglimin" in this table means "Imeglimin 1000 mg twice daily".
- The Long-term Safety Population excludes data during administration of placebo in the double-blind period.
- "Imeglimin + Insulin Total" is the sum of subjects in the placebo group in the open-label period and Imeglimin group in the double-blind and open-label periods.
- Percentages are based on "Number of patients".

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Table S-562 Subgroup Analysis of Overall Frequency of Treatment Emergent Adverse Events by Duration of type 2 diabetes in 52-Week Long-term Period in Combination with Insulin Therapy (PXL008-020; Long-term Safety Population)

TEAE Duration of type 2 diabetes	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
Number of patients			
< 5 years	11	16	27
>= 5 years	90	92	182
Any TEAE			
< 5 years	6 (54.5%)	11 (68.8%)	17 (63.0%)
>= 5 years	71 (78.9%)	81 (88.0%)	152 (83.5%)
Treatment-related TEAE			
< 5 years	1 (9.1%)	3 (18.8%)	4 (14.8%)
>= 5 years	15 (16.7%)	25 (27.2%)	40 (22.0%)
Severe TEAE			
< 5 years	0	1 (6.3%)	1 (3.7%)
>= 5 years	3 (3.3%)	0	3 (1.6%)
TEAE leading to death			
< 5 years	0	0	0
>= 5 years	1 (1.1%)	0	1 (0.5%)
Serious TEAE			
< 5 years	0	2 (12.5%)	2 (7.4%)
>= 5 years	6 (6.7%)	4 (4.3%)	10 (5.5%)
TEAE leading to treatment discontinuation			
< 5 years	0	1 (6.3%)	1 (3.7%)
>= 5 years	3 (3.3%)	4 (4.3%)	7 (3.8%)
Hypoglycemia			
< 5 years	4 (36.4%)	4 (25.0%)	8 (29.6%)
>= 5 years	32 (35.6%)	35 (38.0%)	67 (36.8%)
Lactic acidosis related TEAEs			
< 5 years	0	0	0
>= 5 years	0	1 (1.1%)	1 (0.5%)
Cardiovascular-related TEAEs			
< 5 years	2 (18.2%)	3 (18.8%)	5 (18.5%)
>= 5 years	5 (5.6%)	5 (5.4%)	10 (5.5%)
Digestive Symptoms			
< 5 years	1 (9.1%)	5 (31.3%)	6 (22.2%)
>= 5 years	9 (10.0%)	15 (16.3%)	24 (13.2%)
Renal TEAEs			
< 5 years	0	0	0
>= 5 years	1 (1.1%)	1 (1.1%)	2 (1.1%)
Hepatic TEAEs			
< 5 years	0	0	0
>= 5 years	2 (2.2%)	3 (3.3%)	5 (2.7%)

- Abbreviations: AE, Adverse event; TEAE, Treatment Emergent AE
- "Imeglimin" in this table means "Imeglimin 1000 mg twice daily".
- The Long-term Safety Population excludes data during administration of placebo in the double-blind period.
- "Imeglimin + Insulin Total" is the sum of subjects in the placebo group in the open-label period and Imeglimin group in the double-blind and open-label periods.
- Percentages are based on "Number of patients".

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Table S-563 Subgroup Analysis of Overall Frequency of Treatment Emergent Adverse Events by Complication of diabetes in 52-Week Long-term Period in Combination with Insulin Therapy (PXL008-020; Long-term Safety Population)

TEAE Complication of diabetes	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
Number of patients			
Yes	48	45	93
No	53	63	116
Any TEAE			
Yes	42 (87.5%)	41 (91.1%)	83 (89.2%)
No	35 (66.0%)	51 (81.0%)	86 (74.1%)
Treatment-related TEAE			
Yes	8 (16.7%)	13 (28.9%)	21 (22.6%)
No	8 (15.1%)	15 (23.8%)	23 (19.8%)
Severe TEAE			
Yes	1 (2.1%)	1 (2.2%)	2 (2.2%)
No	2 (3.8%)	0	2 (1.7%)
TEAE leading to death			
Yes	0	0	0
No	1 (1.9%)	0	1 (0.9%)
Serious TEAE			
Yes	3 (6.3%)	4 (8.9%)	7 (7.5%)
No	3 (5.7%)	2 (3.2%)	5 (4.3%)
TEAE leading to treatment discontinuation			
Yes	2 (4.2%)	3 (6.7%)	5 (5.4%)
No	1 (1.9%)	2 (3.2%)	3 (2.6%)
Hypoglycemia			
Yes	18 (37.5%)	17 (37.8%)	35 (37.6%)
No	18 (34.0%)	22 (34.9%)	40 (34.5%)
Lactic acidosis related TEAEs			
Yes	0	0	0
No	0	1 (1.6%)	1 (0.9%)
Cardiovascular-related TEAEs			
Yes	5 (10.4%)	3 (6.7%)	8 (8.6%)
No	2 (3.8%)	5 (7.9%)	7 (6.0%)
Digestive Symptoms			
Yes	4 (8.3%)	7 (15.6%)	11 (11.8%)
No	6 (11.3%)	13 (20.6%)	19 (16.4%)
Renal TEAEs			
Yes	1 (2.1%)	0	1 (1.1%)
No	0	1 (1.6%)	1 (0.9%)
Hepatic TEAEs			
Yes	2 (4.2%)	2 (4.4%)	4 (4.3%)
No	0	1 (1.6%)	1 (0.9%)

- Abbreviations: AE, Adverse event; TEAE, Treatment Emergent AE
- Complication of diabetes is defined as any MedDRA Preferred Term (PT) of medical history which are included in High-Level Group Term (HLGT) of diabetic complication.
- "Imeglimin" in this table means "Imeglimin 1000 mg twice daily".
- The Long-term Safety Population excludes data during administration of placebo in the double-blind period.
- "Imeglimin + Insulin Total" is the sum of subjects in the placebo group in the open-label period and Imeglimin group in the double-blind and open-label periods.
- Percentages are based on "Number of patients".

Table S-564 Subgroup Analysis of Overall Frequency of Treatment Emergent Adverse Events by Metabolic syndrome in 52-Week Long-term Period in Combination with Insulin Therapy (PXL008-020; Long-term Safety Population)

TEAE Metabolic syndrome at baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
Number of patients			
Yes	46	39	85
No	55	69	124
Any TEAE			
Yes	33 (71.7%)	33 (84.6%)	66 (77.6%)
No	44 (80.0%)	59 (85.5%)	103 (83.1%)
Treatment-related TEAE			
Yes	4 (8.7%)	8 (20.5%)	12 (14.1%)
No	12 (21.8%)	20 (29.0%)	32 (25.8%)
Severe TEAE			
Yes	0	0	0
No	3 (5.5%)	1 (1.4%)	4 (3.2%)
TEAE leading to death			
Yes	0	0	0
No	1 (1.8%)	0	1 (0.8%)
Serious TEAE			
Yes	1 (2.2%)	3 (7.7%)	4 (4.7%)
No	5 (9.1%)	3 (4.3%)	8 (6.5%)
TEAE leading to treatment discontinuation			
Yes	1 (2.2%)	1 (2.6%)	2 (2.4%)
No	2 (3.6%)	4 (5.8%)	6 (4.8%)
Hypoglycemia			
Yes	12 (26.1%)	13 (33.3%)	25 (29.4%)
No	24 (43.6%)	26 (37.7%)	50 (40.3%)
Lactic acidosis related TEAEs			
Yes	0	0	0
No	0	1 (1.4%)	1 (0.8%)
Cardiovascular-related TEAEs			
Yes	1 (2.2%)	4 (10.3%)	5 (5.9%)
No	6 (10.9%)	4 (5.8%)	10 (8.1%)
Digestive Symptoms			
Yes	3 (6.5%)	6 (15.4%)	9 (10.6%)
No	7 (12.7%)	14 (20.3%)	21 (16.9%)
Renal TEAEs			
Yes	1 (2.2%)	1 (2.6%)	2 (2.4%)
No	0	0	0
Hepatic TEAEs			
Yes	0	1 (2.6%)	1 (1.2%)

TEAE Metabolic syndrome at baseline	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
No	2 (3.6%)	2 (2.9%)	4 (3.2%)

- Abbreviations: AE, Adverse event; TEAE, Treatment Emergent AE
- Metabolic Syndrome is defined as an excessive waist circumference (>= 85 cm in men and >= 90 cm in women) as well as the presence of two or more of the following symptoms: (1) Hypertension: systolic blood pressure >= 130 mmHg, or diastolic blood pressure >= 85 mmHg; (2) Glucose intolerance: fasting glucose >= 110 mg/dL; (3) Dyslipidemia: triglyceride >= 150 mg/dL, or HDL cholesterol < 40 mg/dL.
- "Imeglimin" in this table means "Imeglimin 1000 mg twice daily".
- The Long-term Safety Population excludes data during administration of placebo in the double-blind period.
- "Imeglimin + Insulin Total" is the sum of subjects in the placebo group in the open-label period and Imeglimin group in the double-blind and open-label periods.
- Percentages are based on "Number of patients".

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Table S-565 Summary of Change from Baseline in Vital Signs to Week 24 in 24-Week Double-blind Period with Monotherapy (PXL008-014, PXL008-018; Safety Population)

Parameter	Observed			Change from baseline	
Treatment Visit	n	Mean (SD)	Median [Min, Max]	Mean (SD)	Median [Min, Max]
Systolic Blood Pressure (mmHg)					
Placebo (N = 182)					
Baseline	182	128.103 (13.6711)	127.165 [90.67, 166.00]		
Week 24	167	129.894 (12.6763)	129.330 [95.00, 166.00]	1.786 (11.6142)	1.000 [-31.00, 36.00]
LOCF Endpoint	182	129.815 (12.5044)	129.165 [95.00, 166.00]	1.712 (11.4514)	1.000 [-31.00, 36.00]
Imeglimin 500 mg bid (N = 75)					
Baseline	75	125.053 (13.0103)	126.000 [104.00, 157.00]		
Week 24	70	127.371 (13.4123)	128.000 [99.00, 153.00]	3.200 (12.0730)	2.000 [-30.00, 31.00]
LOCF Endpoint	75	127.560 (13.2596)	128.000 [99.00, 153.00]	2.507 (12.1959)	2.000 [-30.00, 31.00]
Imeglimin 1000 mg bid (N = 180)					
Baseline	180	126.570 (14.9790)	127.000 [88.00, 175.00]		
Week 24	169	129.057 (13.7308)	128.330 [94.00, 177.00]	2.748 (12.8539)	3.000 [-37.00, 49.00]
LOCF Endpoint	180	129.124 (14.3871)	128.165 [94.00, 177.00]	2.554 (12.6985)	3.000 [-37.00, 49.00]
Imeglimin 1500 mg bid (N = 75)					
Baseline	75	129.147 (14.4780)	131.000 [100.00, 158.00]		
Week 24	67	126.970 (15.6146)	126.000 [93.00, 162.00]	-1.045 (13.4732)	0.000 [-38.00, 35.00]
LOCF Endpoint	75	128.200 (16.2547)	127.000 [93.00, 172.00]	-0.947 (13.2644)	0.000 [-38.00, 35.00]
Diastolic Blood Pressure (mmHg)					
Placebo (N = 182)					
Baseline	182	77.476 (9.4720)	78.000 [53.00, 98.00]		
Week 24	167	78.184 (9.2814)	79.000 [53.00, 98.00]	0.922 (7.5589)	0.340 [-18.67, 27.00]
LOCF Endpoint	182	78.434 (9.1853)	79.165 [53.00, 98.00]	0.958 (7.3221)	0.170 [-18.67, 27.00]
Imeglimin 500 mg bid (N = 75)					
Baseline	75	76.387 (8.5596)	76.000 [55.00, 99.00]		
Week 24	70	76.986 (8.7766)	77.500 [60.00, 96.00]	0.957 (8.3864)	2.000 [-24.00, 22.00]
LOCF Endpoint	75	77.027 (8.9442)	78.000 [60.00, 96.00]	0.640 (8.4175)	2.000 [-24.00, 22.00]
Imeglimin 1000 mg bid (N = 180)					

Parameter	Observed			Change from baseline	
Treatment Visit	n	Mean (SD)	Median [Min, Max]	Mean (SD)	Median [Min, Max]
Baseline	180	77.311 (9.7269)	77.000 [55.00, 98.00]		
Week 24	169	79.069 (9.1258)	78.670 [60.00, 108.00]	1.627 (8.7444)	1.000 [-20.00, 32.00]
LOCF Endpoint	180	78.711 (9.2973)	78.165 [59.00, 108.00]	1.400 (8.6607)	1.000 [-20.00, 32.00]
Imeglimin 1500 mg bid (N = 75)					
Baseline	75	79.333 (10.2249)	79.000 [52.00, 102.00]		
Week 24	67	77.000 (11.0316)	76.000 [47.00, 100.00]	-2.657 (9.2549)	-3.000 [-28.00, 22.00]
LOCF Endpoint	75	76.800 (10.9186)	76.000 [47.00, 100.00]	-2.533 (8.9734)	-3.000 [-28.00, 22.00]
Heart Rate (beats/min)					
Placebo (N = 182)					
Baseline	182	67.1 (10.37)	66.0 [41, 102]		
Week 24	167	67.2 (9.95)	66.0 [42, 107]	0.3 (7.57)	0.0 [-32, 27]
LOCF Endpoint	182	67.6 (9.97)	67.0 [42, 107]	0.5 (7.68)	0.0 [-32, 27]
Imeglimin 500 mg bid (N = 75)					
Baseline	75	65.5 (8.89)	64.0 [48, 90]		
Week 24	70	66.8 (10.84)	66.5 [46, 96]	1.8 (8.17)	1.0 [-16, 28]
LOCF Endpoint	75	67.1 (11.20)	67.0 [46, 96]	1.6 (8.18)	2.0 [-16, 28]
Imeglimin 1000 mg bid (N = 180)					
Baseline	180	68.7 (10.89)	67.5 [45, 107]		
Week 24	169	69.3 (11.11)	68.0 [42, 112]	0.4 (9.66)	0.0 [-47, 58]
LOCF Endpoint	180	69.0 (11.02)	68.0 [42, 112]	0.3 (9.39)	0.0 [-47, 58]
Imeglimin 1500 mg bid (N = 75)					
Baseline	75	67.2 (11.91)	65.0 [44, 112]		
Week 24	67	67.6 (11.00)	67.0 [41, 96]	0.0 (8.84)	0.0 [-44, 19]
LOCF Endpoint	75	67.4 (11.03)	67.0 [41, 96]	0.2 (8.52)	0.0 [-44, 19]

- Abbreviations: bid, Twice a day; SD, standard deviation; LOCF, Last Observation Carried Forward

Table S-566 Summary of Change from Baseline in Vital Signs at All Visits in 24-Week Double-blind Period with Monotherapy (PXL008-014, PXL008-018; Safety Population)

Parameter	Observed			Change from baseline	
Treatment Visit	n	Mean (SD)	Median [Min, Max]	Mean (SD)	Median [Min, Max]
Systolic Blood Pressure (mmHg)					
Placebo (N = 182)					
Baseline	182	128.103 (13.6711)	127.165 [90.67, 166.00]		
Week 2	74	128.770 (12.5114)	129.000 [99.00, 169.00]	-0.851 (9.6808)	-1.000 [-22.00, 30.00]
Week 4	180	127.391 (13.3520)	126.500 [94.00, 163.67]	-0.713 (9.6846)	-0.340 [-28.33, 26.67]
Week 8	176	127.413 (12.6041)	128.000 [95.00, 160.00]	-0.748 (10.1753)	0.000 [-33.00, 27.67]
Week 12	169	127.448 (13.5889)	127.000 [95.00, 174.00]	-0.598 (11.7871)	0.000 [-27.67, 36.00]
Week 16	168	128.600 (12.9067)	128.000 [98.33, 164.00]	0.593 (10.7101)	1.340 [-38.33, 36.00]
Week 20	168	128.534 (13.0854)	129.330 [97.00, 158.00]	0.528 (11.2947)	1.000 [-31.67, 34.66]
Week 24	167	129.894 (12.6763)	129.330 [95.00, 166.00]	1.786 (11.6142)	1.000 [-31.00, 36.00]
LOCF Endpoint	182	129.815 (12.5044)	129.165 [95.00, 166.00]	1.712 (11.4514)	1.000 [-31.00, 36.00]
Imeglimin 500 mg bid (N = 75)					
Baseline	75	125.053 (13.0103)	126.000 [104.00, 157.00]		
Week 2	75	124.320 (14.6030)	123.000 [96.00, 174.00]	-0.733 (10.7356)	0.000 [-31.00, 27.00]
Week 4	75	125.520 (12.4003)	125.000 [100.00, 156.00]	0.467 (10.5732)	0.000 [-28.00, 22.00]
Week 8	72	125.056 (12.9385)	124.000 [102.00, 159.00]	0.653 (11.5845)	1.000 [-26.00, 22.00]
Week 12	72	123.583 (14.5793)	122.500 [92.00, 162.00]	-0.819 (11.3216)	-1.500 [-33.00, 36.00]
Week 16	71	124.268 (13.5667)	124.000 [94.00, 159.00]	-0.085 (11.5000)	0.000 [-24.00, 33.00]
Week 20	70	126.457 (15.1128)	125.000 [100.00, 167.00]	2.286 (12.0171)	3.500 [-27.00, 27.00]
Week 24	70	127.371 (13.4123)	128.000 [99.00, 153.00]	3.200 (12.0730)	2.000 [-30.00, 31.00]
LOCF Endpoint	75	127.560 (13.2596)	128.000 [99.00, 153.00]	2.507 (12.1959)	2.000 [-30.00, 31.00]
Imeglimin 1000 mg bid (N = 180)					
Baseline	180	126.570 (14.9790)	127.000 [88.00, 175.00]		
Week 2	73	123.192 (12.3104)	123.000 [95.00, 156.00]	-2.329 (10.6498)	-1.000 [-36.00, 22.00]
Week 4	178	125.261 (13.6900)	124.500 [94.00, 170.67]	-1.153 (12.0248)	-1.670 [-44.00, 34.00]
Week 8	175	126.023 (13.5888)	126.000 [93.33, 158.00]	-0.535 (11.1771)	-1.000 [-29.67, 33.00]

Parameter	Observed			Change from baseline	
Treatment Visit	n	Mean (SD)	Median [Min, Max]	Mean (SD)	Median [Min, Max]
Week 12	172	125.946 (13.8166)	125.670 [90.00, 167.67]	-0.190 (12.0421)	0.000 [-40.67, 41.00]
Week 16	171	125.735 (14.1613)	126.670 [90.00, 165.00]	-0.474 (11.6022)	0.000 [-35.00, 44.00]
Week 20	169	126.095 (14.7166)	127.000 [91.33, 174.33]	-0.229 (11.4917)	1.000 [-41.33, 34.33]
Week 24	169	129.057 (13.7308)	128.330 [94.00, 177.00]	2.748 (12.8539)	3.000 [-37.00, 49.00]
LOCF Endpoint	180	129.124 (14.3871)	128.165 [94.00, 177.00]	2.554 (12.6985)	3.000 [-37.00, 49.00]
Imeglimin 1500 mg bid (N = 75)					
Baseline	75	129.147 (14.4780)	131.000 [100.00, 158.00]		
Week 2	71	129.901 (14.5839)	131.000 [97.00, 177.00]	0.887 (9.8453)	0.000 [-24.00, 28.00]
Week 4	70	129.186 (13.2471)	130.000 [104.00, 166.00]	0.414 (12.1076)	1.500 [-47.00, 21.00]
Week 8	68	127.897 (13.6493)	129.500 [102.00, 160.00]	-0.500 (10.6610)	-1.000 [-28.00, 24.00]
Week 12	68	128.515 (15.0407)	128.000 [105.00, 166.00]	0.118 (12.3621)	1.000 [-39.00, 27.00]
Week 16	68	128.206 (13.9183)	128.500 [103.00, 164.00]	-0.191 (12.6883)	-2.000 [-30.00, 29.00]
Week 20	67	129.343 (12.7024)	131.000 [98.00, 157.00]	1.328 (11.3797)	2.000 [-32.00, 22.00]
Week 24	67	126.970 (15.6146)	126.000 [93.00, 162.00]	-1.045 (13.4732)	0.000 [-38.00, 35.00]
LOCF Endpoint	75	128.200 (16.2547)	127.000 [93.00, 172.00]	-0.947 (13.2644)	0.000 [-38.00, 35.00]
Diastolic Blood Pressure (mmHg)					
Placebo (N = 182)					
Baseline	182	77.476 (9.4720)	78.000 [53.00, 98.00]		
Week 2	74	78.554 (9.4784)	78.000 [54.00, 106.00]	0.500 (5.9386)	0.000 [-18.00, 20.00]
Week 4	180	76.505 (9.5716)	77.165 [55.67, 98.33]	-0.943 (7.1010)	0.000 [-27.00, 18.00]
Week 8	176	76.858 (9.2727)	77.000 [52.00, 99.00]	-0.598 (6.8084)	-0.495 [-21.00, 20.00]
Week 12	169	76.738 (8.8174)	77.000 [52.00, 103.00]	-0.513 (6.9409)	-1.000 [-21.00, 24.33]
Week 16	168	76.849 (9.2425)	77.670 [53.67, 97.00]	-0.375 (6.9984)	-0.670 [-22.00, 17.67]
Week 20	168	77.867 (9.8137)	77.835 [54.00, 103.00]	0.643 (8.1807)	1.000 [-22.67, 22.66]
Week 24	167	78.184 (9.2814)	79.000 [53.00, 98.00]	0.922 (7.5589)	0.340 [-18.67, 27.00]
LOCF Endpoint	182	78.434 (9.1853)	79.165 [53.00, 98.00]	0.958 (7.3221)	0.170 [-18.67, 27.00]
Imeglimin 500 mg bid (N = 75)					

Parameter	Observed			Change from baseline	
Treatment Visit	n	Mean (SD)	Median [Min, Max]	Mean (SD)	Median [Min, Max]
Baseline	75	76.387 (8.5596)	76.000 [55.00, 99.00]		
Week 2	75	76.640 (9.4091)	76.000 [54.00, 106.00]	0.253 (8.2840)	0.000 [-28.00, 21.00]
Week 4	75	77.493 (8.8842)	78.000 [56.00, 96.00]	1.107 (8.1433)	0.000 [-20.00, 24.00]
Week 8	72	76.611 (8.8835)	76.000 [54.00, 102.00]	0.569 (8.9014)	0.000 [-21.00, 24.00]
Week 12	72	76.028 (8.5448)	76.000 [53.00, 96.00]	-0.014 (8.7121)	-1.500 [-28.00, 20.00]
Week 16	71	76.606 (8.5498)	78.000 [54.00, 98.00]	0.535 (8.3475)	2.000 [-22.00, 19.00]
Week 20	70	78.014 (8.1106)	78.500 [60.00, 97.00]	1.986 (8.3014)	2.000 [-17.00, 26.00]
Week 24	70	76.986 (8.7766)	77.500 [60.00, 96.00]	0.957 (8.3864)	2.000 [-24.00, 22.00]
LOCF Endpoint	75	77.027 (8.9442)	78.000 [60.00, 96.00]	0.640 (8.4175)	2.000 [-24.00, 22.00]
Imeglimin 1000 mg bid (N = 180)					
Baseline	180	77.311 (9.7269)	77.000 [55.00, 98.00]		
Week 2	73	76.027 (8.3898)	76.000 [59.00, 97.00]	-0.315 (7.3935)	0.000 [-15.00, 20.00]
Week 4	178	75.981 (8.6004)	76.000 [56.00, 96.00]	-1.384 (7.3862)	-0.170 [-24.00, 16.00]
Week 8	175	76.644 (9.2382)	76.670 [55.00, 98.00]	-0.876 (7.9348)	-0.340 [-24.67, 22.00]
Week 12	172	76.266 (9.0307)	76.000 [50.00, 105.00]	-1.012 (8.1065)	-1.000 [-33.00, 19.00]
Week 16	171	76.475 (10.1071)	77.000 [40.00, 107.33]	-0.862 (7.4796)	-1.000 [-20.00, 27.00]
Week 20	169	76.574 (9.9101)	76.000 [53.00, 101.00]	-0.692 (8.0765)	0.000 [-21.00, 24.00]
Week 24	169	79.069 (9.1258)	78.670 [60.00, 108.00]	1.627 (8.7444)	1.000 [-20.00, 32.00]
LOCF Endpoint	180	78.711 (9.2973)	78.165 [59.00, 108.00]	1.400 (8.6607)	1.000 [-20.00, 32.00]
Imeglimin 1500 mg bid (N = 75)					
Baseline	75	79.333 (10.2249)	79.000 [52.00, 102.00]		
Week 2	71	79.451 (9.5151)	78.000 [59.00, 98.00]	-0.099 (9.4388)	0.000 [-26.00, 24.00]
Week 4	70	78.343 (9.3326)	78.000 [58.00, 101.00]	-1.371 (7.3172)	-2.500 [-23.00, 18.00]
Week 8	68	78.382 (10.3823)	78.000 [59.00, 104.00]	-1.324 (8.0473)	-1.000 [-26.00, 18.00]
Week 12	68	79.353 (9.3693)	78.500 [60.00, 100.00]	-0.353 (8.0720)	-1.000 [-20.00, 22.00]
Week 16	68	77.971 (10.3289)	77.500 [60.00, 106.00]	-1.735 (9.0184)	-1.500 [-30.00, 19.00]
Week 20	67	79.687 (10.2369)	78.000 [60.00, 100.00]	0.030 (8.7559)	0.000 [-27.00, 26.00]

Parameter	Observed			Change from baseline	
Treatment Visit	n	Mean (SD)	Median [Min, Max]	Mean (SD)	Median [Min, Max]
Week 24	67	77.000 (11.0316)	76.000 [47.00, 100.00]	-2.657 (9.2549)	-3.000 [-28.00, 22.00]
LOCF Endpoint	75	76.800 (10.9186)	76.000 [47.00, 100.00]	-2.533 (8.9734)	-3.000 [-28.00, 22.00]
Heart Rate (beats/min)					
Placebo (N = 182)					
Baseline	182	67.1 (10.37)	66.0 [41, 102]		
Week 2	74	65.0 (8.81)	64.0 [50, 88]	-0.1 (5.85)	1.0 [-16, 12]
Week 4	180	67.5 (9.80)	67.0 [46, 90]	0.5 (6.58)	0.5 [-18, 20]
Week 8	176	67.7 (10.19)	69.0 [42, 100]	0.8 (7.52)	1.0 [-21, 26]
Week 12	169	67.6 (10.40)	68.0 [45, 99]	0.8 (7.36)	1.0 [-20, 23]
Week 16	168	67.7 (10.56)	68.0 [47, 105]	0.9 (7.59)	0.5 [-22, 26]
Week 20	168	67.7 (9.92)	67.0 [48, 100]	0.9 (8.10)	1.0 [-32, 24]
Week 24	167	67.2 (9.95)	66.0 [42, 107]	0.3 (7.57)	0.0 [-32, 27]
LOCF Endpoint	182	67.6 (9.97)	67.0 [42, 107]	0.5 (7.68)	0.0 [-32, 27]
Imeglimin 500 mg bid (N = 75)					
Baseline	75	65.5 (8.89)	64.0 [48, 90]		
Week 2	75	65.4 (9.62)	64.0 [47, 94]	-0.1 (6.92)	0.0 [-22, 23]
Week 4	75	65.7 (9.46)	65.0 [44, 92]	0.1 (7.19)	-1.0 [-14, 32]
Week 8	72	65.1 (9.17)	64.5 [48, 90]	0.4 (7.04)	0.0 [-17, 29]
Week 12	72	64.6 (8.97)	64.5 [46, 86]	-0.2 (6.10)	-0.5 [-13, 23]
Week 16	71	65.3 (9.50)	64.0 [47, 87]	0.4 (5.97)	0.0 [-14, 20]
Week 20	70	66.5 (10.96)	65.5 [44, 116]	1.4 (9.66)	1.0 [-18, 57]
Week 24	70	66.8 (10.84)	66.5 [46, 96]	1.8 (8.17)	1.0 [-16, 28]
LOCF Endpoint	75	67.1 (11.20)	67.0 [46, 96]	1.6 (8.18)	2.0 [-16, 28]
Imeglimin 1000 mg bid (N = 180)					
Baseline	180	68.7 (10.89)	67.5 [45, 107]		
Week 2	73	66.1 (10.11)	65.0 [42, 88]	-1.8 (7.73)	-1.0 [-34, 21]
Week 4	178	68.7 (10.06)	68.0 [45, 97]	-0.1 (7.93)	0.0 [-45, 23]
Week 8	175	68.0 (10.24)	68.0 [46, 100]	-0.8 (8.06)	0.0 [-44, 18]
Week 12	172	67.9 (9.96)	68.0 [46, 92]	-1.0 (8.33)	0.0 [-45, 19]
Week 16	171	69.1 (10.18)	68.0 [45, 99]	0.3 (7.93)	1.0 [-41, 18]
Week 20	169	68.5 (10.58)	68.0 [42, 98]	-0.2 (9.04)	0.0 [-50, 31]
Week 24	169	69.3 (11.11)	68.0 [42, 112]	0.4 (9.66)	0.0 [-47, 58]
LOCF Endpoint	180	69.0 (11.02)	68.0 [42, 112]	0.3 (9.39)	0.0 [-47, 58]
Imeglimin 1500 mg bid (N = 75)					
Baseline	75	67.2 (11.91)	65.0 [44, 112]		
Week 2	71	67.1 (9.84)	66.0 [46, 90]	-0.2 (7.89)	1.0 [-40, 15]
Week 4	69	67.4 (9.38)	66.0 [49, 88]	0.1 (8.38)	1.0 [-47, 15]
Week 8	68	67.5 (9.39)	68.0 [45, 92]	0.0 (9.09)	1.0 [-45, 19]
Week 12	68	66.8 (9.82)	65.0 [44, 88]	-0.7 (9.27)	0.0 [-44, 17]
Week 16	68	66.4 (9.53)	67.5 [42, 89]	-1.2 (9.49)	-0.5 [-44, 21]
Week 20	67	68.2 (10.90)	67.0 [46, 105]	0.5 (7.49)	2.0 [-24, 17]
Week 24	67	67.6 (11.00)	67.0 [41, 96]	0.0 (8.84)	0.0 [-44, 19]
LOCF Endpoint	75	67.4 (11.03)	67.0 [41, 96]	0.2 (8.52)	0.0 [-44, 19]

- Abbreviations: bid, Twice a day; SD, standard deviation; LOCF, Last Observation Carried Forward

Control No:<<t-s-566-vsign-24wdb.sas, 2020-03-10T13:46:17>>

Table S-567 Summary of Change from Baseline in Vital Signs to Week 52 in 52-Week Long-term Period with Monotherapy and Combination Therapy (PXL008-019; Long-term Safety Population)

Parameter	Observed			Change from baseline	
Treatment Visit	n	Mean (SD)	Median [Min, Max]	Mean (SD)	Median [Min, Max]
Systolic Blood Pressure (mmHg)					
Imeglimin (N = 134)					
Baseline	134	128.229 (14.8318)	125.835 [94.67, 166.00]		
Week 24	130	125.526 (14.5155)	123.165 [94.33, 164.00]	-2.441 (11.1876)	-3.335 [-33.67, 31.00]
Week 52	126	128.389 (14.9899)	126.670 [96.00, 170.67]	0.349 (11.0677)	0.165 [-38.66, 32.00]
LOCF Endpoint	134	128.211 (14.7440)	126.670 [96.00, 170.67]	-0.018 (10.9859)	-0.335 [-38.66, 32.00]
Imeglimin + SU (N = 127)					
Baseline	127	127.721 (13.0092)	128.330 [92.67, 167.33]		
Week 24	122	128.830 (13.2999)	129.165 [89.00, 170.67]	0.940 (11.4875)	-0.670 [-27.33, 40.66]
Week 52	116	128.859 (12.7264)	129.330 [95.00, 164.00]	1.023 (10.7885)	1.335 [-37.67, 30.66]
LOCF Endpoint	127	128.488 (12.7434)	129.000 [95.00, 164.00]	0.767 (11.4321)	1.330 [-37.67, 30.66]
Imeglimin + GLIN (N = 64)					
Baseline	64	127.270 (12.8855)	128.000 [96.00, 154.33]		
Week 24	62	127.737 (14.0810)	126.670 [99.33, 169.33]	0.307 (11.4363)	-2.335 [-20.00, 36.67]
Week 52	59	128.751 (14.8404)	126.670 [100.33, 165.00]	1.452 (10.4907)	0.670 [-22.33, 32.33]
LOCF Endpoint	64	128.687 (14.5049)	126.835 [100.33, 165.00]	1.417 (10.3534)	1.170 [-22.33, 32.33]
Imeglimin + BIG (N = 64)					
Baseline	64	133.448 (12.8821)	130.665 [110.00, 176.67]		
Week 24	63	128.852 (13.4918)	128.000 [94.00, 156.67]	-4.687 (10.0740)	-3.340 [-26.67, 17.34]
Week 52	58	133.765 (15.0758)	134.835 [100.67, 189.00]	0.438 (10.7872)	-0.335 [-26.34, 32.67]
LOCF Endpoint	64	133.881 (14.7919)	134.835 [100.67, 189.00]	0.433 (10.3680)	-0.335 [-26.34, 32.67]
Imeglimin + AGI (N = 64)					
Baseline	64	129.145 (13.4978)	126.835 [99.33, 171.33]		
Week 24	63	130.274 (12.7207)	129.000 [103.00, 161.00]	0.910 (11.7642)	1.660 [-38.67, 33.00]
Week 52	62	131.209 (13.4538)	129.835 [104.33, 173.67]	1.806 (11.6549)	3.330 [-24.00, 22.00]
LOCF Endpoint	64	130.895 (13.4003)	129.500 [104.33, 173.67]	1.750 (11.4729)	2.835 [-24.00, 22.00]
Imeglimin + TZD (N = 65)					
Baseline	65	127.389 (11.7463)	128.670 [108.00, 155.00]		

Parameter	Observed			Change from baseline	
Treatment Visit	n	Mean (SD)	Median [Min, Max]	Mean (SD)	Median [Min, Max]
Week 24	65	127.544 (12.4670)	127.000 [101.33, 167.00]	0.155 (12.5507)	-1.330 [-30.67, 36.00]
Week 52	65	128.257 (11.6032)	128.670 [94.67, 158.67]	0.868 (11.5022)	2.000 [-24.00, 27.33]
LOCF Endpoint	65	128.257 (11.6032)	128.670 [94.67, 158.67]	0.868 (11.5022)	2.000 [-24.00, 27.33]
Imeglimin + DPP4-I (N = 63)					
Baseline	63	129.693 (13.3742)	129.670 [106.00, 166.33]		
Week 24	61	127.246 (15.9917)	126.000 [96.67, 170.00]	-2.470 (13.0999)	-2.000 [-46.00, 35.66]
Week 52	60	130.661 (15.8624)	128.330 [99.67, 195.67]	1.411 (13.2439)	1.000 [-41.66, 44.00]
LOCF Endpoint	63	130.836 (16.0833)	129.330 [99.67, 195.67]	1.143 (13.1303)	1.000 [-41.66, 44.00]
Imeglimin + GLP1-RA (N = 70)					
Baseline	70	129.095 (13.0324)	127.670 [106.00, 172.00]		
Week 24	69	129.110 (12.4054)	129.670 [96.00, 157.33]	-0.030 (12.2347)	2.000 [-46.67, 26.00]
Week 52	67	127.642 (12.4542)	126.670 [105.00, 155.67]	-1.612 (11.9783)	0.660 [-41.33, 18.00]
LOCF Endpoint	70	127.543 (12.6121)	126.670 [105.00, 155.67]	-1.552 (12.1218)	0.660 [-41.33, 18.00]
Imeglimin + SGLT2-I (N = 63)					
Baseline	63	126.867 (13.6629)	123.330 [101.33, 172.67]		
Week 24	63	125.000 (12.8826)	124.330 [98.00, 153.33]	-1.867 (10.3936)	-1.000 [-43.34, 26.00]
Week 52	62	127.161 (13.8805)	126.500 [102.33, 177.33]	0.586 (10.7478)	0.170 [-32.00, 30.67]
LOCF Endpoint	63	126.894 (13.9304)	126.330 [102.33, 177.33]	0.027 (11.5491)	-0.330 [-34.67, 30.67]
Diastolic Blood Pressure (mmHg)					
Imeglimin (N = 134)					
Baseline	134	78.838 (8.4500)	78.500 [58.33, 98.33]		
Week 24	130	78.075 (9.5847)	77.670 [59.00, 99.00]	-0.805 (6.5013)	-0.660 [-20.34, 14.67]
Week 52	126	78.688 (9.1270)	78.670 [52.00, 99.67]	0.000 (6.8008)	0.330 [-22.67, 19.67]
LOCF Endpoint	134	78.512 (9.0998)	78.670 [52.00, 99.67]	-0.326 (6.9502)	0.165 [-22.67, 19.67]
Imeglimin + SU (N = 127)					
Baseline	127	76.236 (9.5361)	76.000 [52.33, 99.00]		
Week 24	122	76.631 (9.2824)	76.835 [53.33, 95.67]	0.205 (8.0330)	0.000 [-26.67, 30.00]
Week 52	116	76.868 (8.4266)	76.835 [57.00, 100.33]	0.316 (7.2903)	0.500 [-22.34, 19.33]
LOCF Endpoint	127	76.433 (8.4152)	76.330 [57.00, 100.33]	0.197 (7.3650)	0.660 [-22.34, 19.33]

Parameter	Observed			Change from baseline	
Treatment Visit	n	Mean (SD)	Median [Min, Max]	Mean (SD)	Median [Min, Max]
Imeglimin + GLIN (N = 64)					
Baseline	64	76.333 (8.6719)	77.330 [58.00, 97.33]		
Week 24	62	76.505 (9.7769)	76.835 [56.67, 102.67]	0.177 (6.8551)	-0.670 [-13.00, 21.33]
Week 52	59	77.045 (10.5942)	76.670 [55.67, 102.33]	0.881 (5.9472)	1.000 [-16.00, 17.34]
LOCF Endpoint	64	77.088 (10.5033)	76.835 [55.67, 102.33]	0.755 (5.9033)	0.835 [-16.00, 17.34]
Imeglimin + BIG (N = 64)					
Baseline	64	81.104 (9.0228)	80.000 [60.67, 97.33]		
Week 24	63	79.624 (9.8388)	79.000 [59.67, 98.67]	-1.566 (6.3678)	-1.670 [-14.00, 17.33]
Week 52	58	82.115 (10.2007)	81.835 [61.67, 101.33]	0.437 (6.7431)	-0.330 [-12.67, 21.67]
LOCF Endpoint	64	81.276 (10.3496)	81.000 [59.33, 101.33]	0.173 (6.6794)	-0.670 [-12.67, 21.67]
Imeglimin + AGI (N = 64)					
Baseline	64	79.521 (8.0206)	80.500 [58.00, 96.67]		
Week 24	63	79.248 (8.2812)	78.330 [63.00, 97.33]	-0.514 (7.5042)	-0.330 [-26.00, 16.00]
Week 52	62	80.188 (8.0983)	80.000 [64.67, 97.00]	0.483 (7.1107)	1.165 [-15.33, 17.33]
LOCF Endpoint	64	80.011 (8.1725)	80.000 [64.67, 97.00]	0.489 (6.9993)	1.165 [-15.33, 17.33]
Imeglimin + TZD (N = 65)					
Baseline	65	77.882 (9.9481)	76.670 [57.33, 98.33]		
Week 24	65	78.042 (10.1888)	77.670 [50.67, 104.67]	0.160 (8.3849)	-1.330 [-19.33, 29.00]
Week 52	65	77.559 (10.6907)	76.330 [57.33, 107.67]	-0.323 (8.2404)	-0.660 [-20.67, 22.00]
LOCF Endpoint	65	77.559 (10.6907)	76.330 [57.33, 107.67]	-0.323 (8.2404)	-0.660 [-20.67, 22.00]
Imeglimin + DPP4-I (N = 63)					
Baseline	63	77.957 (9.6063)	78.670 [59.00, 96.00]		
Week 24	61	76.551 (10.5550)	77.000 [55.00, 102.67]	-1.755 (8.2027)	-1.670 [-25.33, 14.33]
Week 52	60	77.855 (10.9449)	77.000 [57.67, 103.67]	-0.178 (8.9876)	0.000 [-23.00, 23.67]
LOCF Endpoint	63	77.756 (10.9806)	77.000 [57.67, 103.67]	-0.201 (8.8671)	0.000 [-23.00, 23.67]
Imeglimin + GLP1-RA (N = 70)					
Baseline	70	78.991 (9.7433)	79.330 [58.00, 97.33]		
Week 24	69	78.526 (9.1065)	79.330 [59.33, 96.67]	-0.517 (6.2503)	-0.660 [-16.33, 18.00]
Week 52	67	77.378 (8.2466)	77.330 [61.00, 94.33]	-1.791 (6.6279)	-2.000 [-19.66, 13.00]

Parameter Treatment Visit	Observed n	Mean (SD)	Median [Min, Max]	Change from baseline Mean (SD)	Median [Min, Max]
LOCF Endpoint	70	77.214 (8.4062)	77.000 [61.00, 94.33]	-1.776 (6.7522)	-1.670 [-19.66, 13.00]
Imeglimin + SGLT2-I (N = 63)					
Baseline	63	77.132 (8.6058)	76.000 [61.00, 97.33]		
Week 24	63	75.836 (9.8452)	74.670 [57.33, 96.33]	-1.296 (5.4121)	-1.000 [-16.00, 9.00]
Week 52	62	77.011 (8.9369)	78.000 [59.00, 103.67]	0.027 (6.5858)	0.165 [-16.00, 23.34]
LOCF Endpoint	63	77.069 (8.8765)	78.670 [59.00, 103.67]	-0.063 (6.5717)	0.000 [-16.00, 23.34]
Heart Rate (beats/min)					
Imeglimin (N = 134)					
Baseline	134	69.0 (10.94)	68.0 [44, 101]		
Week 24	130	68.1 (9.66)	67.5 [48, 96]	-0.9 (7.15)	0.0 [-17, 20]
Week 52	126	69.8 (12.54)	69.0 [51, 125]	0.9 (9.23)	0.0 [-25, 44]
LOCF Endpoint	134	70.1 (12.46)	70.0 [51, 125]	1.2 (9.31)	0.0 [-25, 44]
Imeglimin + SU (N = 127)					
Baseline	127	70.6 (10.81)	68.0 [52, 101]		
Week 24	122	70.0 (10.95)	68.0 [50, 97]	-0.5 (7.45)	0.0 [-23, 17]
Week 52	116	70.9 (11.13)	70.0 [49, 101]	0.2 (7.68)	0.0 [-18, 30]
LOCF Endpoint	127	71.0 (11.01)	70.0 [49, 101]	0.4 (7.74)	0.0 [-18, 30]
Imeglimin + GLIN (N = 64)					
Baseline	64	67.9 (10.01)	67.0 [46, 90]		
Week 24	62	67.5 (11.29)	66.5 [42, 90]	-0.5 (7.99)	-1.0 [-24, 30]
Week 52	59	68.6 (10.85)	69.0 [50, 95]	0.3 (8.03)	-1.0 [-21, 22]
LOCF Endpoint	64	68.2 (10.79)	69.0 [50, 95]	0.3 (7.94)	-0.5 [-21, 22]
Imeglimin + BIG (N = 64)					
Baseline	64	71.0 (9.53)	69.5 [48, 104]		
Week 24	63	70.7 (9.54)	71.0 [50, 95]	-0.5 (7.80)	0.0 [-22, 20]
Week 52	58	70.3 (8.03)	68.5 [53, 86]	-0.8 (7.14)	-1.0 [-18, 24]
LOCF Endpoint	64	70.0 (8.13)	68.5 [53, 86]	-1.0 (7.43)	-1.0 [-22, 24]
Imeglimin + AGI (N = 64)					
Baseline	64	69.4 (12.88)	69.0 [43, 103]		
Week 24	63	68.6 (11.93)	67.0 [48, 98]	-1.2 (7.81)	-1.0 [-23, 12]
Week 52	62	70.0 (12.05)	69.0 [44, 99]	0.5 (9.57)	0.0 [-23, 27]
LOCF Endpoint	64	70.6 (12.27)	69.5 [44, 99]	1.2 (10.31)	0.5 [-23, 32]
Imeglimin + TZD (N = 65)					
Baseline	65	68.9 (11.65)	67.0 [50, 97]		
Week 24	65	69.8 (11.35)	67.0 [47, 97]	0.9 (7.16)	0.0 [-12, 24]
Week 52	65	70.2 (12.52)	69.0 [51, 110]	1.3 (9.09)	0.0 [-21, 42]
LOCF Endpoint	65	70.2 (12.52)	69.0 [51, 110]	1.3 (9.09)	0.0 [-21, 42]
Imeglimin + DPP4-I (N = 63)					
Baseline	63	69.8 (10.56)	67.0 [52, 103]		
Week 24	61	70.2 (11.41)	68.0 [53, 115]	0.4 (8.00)	0.0 [-19, 34]
Week 52	60	70.0 (10.18)	69.0 [51, 97]	0.4 (6.62)	0.0 [-23, 15]
LOCF Endpoint	63	70.2 (10.35)	69.0 [51, 97]	0.4 (6.52)	0.0 [-23, 15]
Imeglimin + GLP1-RA (N = 70)					
Baseline	70	75.0 (8.94)	76.5 [57, 100]		

Parameter	Observed			Change from baseline	
Treatment Visit	n	Mean (SD)	Median [Min, Max]	Mean (SD)	Median [Min, Max]
Week 24	69	75.4 (10.53)	74.0 [52, 105]	0.3 (7.19)	0.0 [-18, 18]
Week 52	67	75.5 (10.96)	76.0 [54, 117]	0.5 (6.62)	1.0 [-19, 17]
LOCF Endpoint	70	75.3 (11.06)	75.5 [54, 117]	0.3 (6.79)	1.0 [-19, 17]
Imeglimin + SGLT2-I (N = 63)					
Baseline	63	69.8 (11.16)	68.0 [51, 106]		
Week 24	63	69.0 (11.02)	67.0 [50, 101]	-0.8 (6.71)	-1.0 [-18, 13]
Week 52	62	68.0 (11.28)	66.5 [47, 97]	-1.5 (7.17)	-1.0 [-21, 15]
LOCF Endpoint	63	68.0 (11.20)	67.0 [47, 97]	-1.8 (7.53)	-1.0 [-21, 15]

- Abbreviations: SD, standard deviation; LOCF, Last Observation Carried Forward; SU, Sulphonylurea; GLIN, Glinide; BIG, Biguanide; AGI, Alpha glucosidase inhibitor; TZD, Thiazolidinedione; DPP4-I, Dipeptidyl peptidase-4 inhibitor; GLP1-RA, Glucagon-like peptide 1 receptor agonist; SGLT2-I, Sodium glucose cotransporter 2 inhibitor
- "Imeglimin" in this table means "Imeglimin 1000 mg twice daily".

Control No:<<t-s-567-vsign-019lt.sas, 2020-03-10T11:51:56>>

Table S-568 Summary of Change from Baseline in Vital Signs at All Visits in 52-Week Long-term Period with Monotherapy and Combination Therapy (PXL008-019; Long-term Safety Population)

Parameter	Observed			Change from baseline	
Treatment Visit	n	Mean (SD)	Median [Min, Max]	Mean (SD)	Median [Min, Max]
Systolic Blood Pressure (mmHg)					
Imeglimin (N = 134)					
Baseline	134	128.229 (14.8318)	125.835 [94.67, 166.00]		
Week 4	134	125.997 (13.5124)	126.330 [96.00, 162.00]	-2.232 (10.6411)	-2.170 [-28.67, 34.00]
Week 8	132	124.644 (14.1774)	121.670 [90.67, 161.33]	-3.377 (10.1955)	-3.170 [-37.67, 28.33]
Week 12	131	125.061 (14.6510)	123.000 [96.67, 160.00]	-2.863 (10.3768)	-3.000 [-42.00, 25.67]
Week 16	130	124.200 (15.1382)	122.835 [94.00, 169.00]	-3.767 (10.7900)	-3.000 [-30.34, 35.00]
Week 20	130	125.059 (14.5441)	123.670 [97.33, 160.33]	-2.908 (12.0577)	-3.170 [-33.67, 37.00]
Week 24	130	125.526 (14.5155)	123.165 [94.33, 164.00]	-2.441 (11.1876)	-3.335 [-33.67, 31.00]
Week 28	129	125.848 (15.3683)	122.670 [97.33, 193.67]	-2.197 (12.2228)	-4.330 [-35.00, 39.67]
Week 32	128	126.755 (14.6690)	128.330 [95.67, 162.33]	-1.284 (11.2151)	-1.830 [-37.34, 34.00]
Week 36	128	128.482 (14.5982)	128.670 [98.67, 168.00]	0.443 (11.4639)	0.835 [-35.33, 38.67]
Week 40	128	128.643 (14.6700)	129.330 [94.67, 161.67]	0.604 (11.3328)	0.000 [-33.33, 26.33]
Week 44	127	127.556 (14.1517)	126.670 [96.67, 159.33]	-0.541 (12.0235)	0.660 [-45.33, 31.34]
Week 48	127	127.129 (13.8176)	126.670 [96.00, 164.00]	-0.969 (11.1076)	-1.000 [-38.33, 29.00]
Week 52	126	128.389 (14.9899)	126.670 [96.00, 170.67]	0.349 (11.0677)	0.165 [-38.66, 32.00]
LOCF Endpoint	134	128.211 (14.7440)	126.670 [96.00, 170.67]	-0.018 (10.9859)	-0.335 [-38.66, 32.00]
Imeglimin + SU (N = 127)					
Baseline	127	127.721 (13.0092)	128.330 [92.67, 167.33]		
Week 4	127	127.923 (12.4875)	130.000 [94.33, 158.00]	0.202 (9.5059)	0.000 [-26.33, 32.00]
Week 8	126	126.198 (12.2764)	126.500 [100.33, 170.00]	-1.598 (10.3474)	-1.330 [-38.66, 27.00]
Week 12	123	126.973 (13.2486)	127.670 [90.00, 158.67]	-0.992 (10.8732)	-1.330 [-33.00, 34.33]
Week 16	123	126.561 (14.2958)	127.330 [93.33, 176.67]	-1.403 (11.6784)	-1.660 [-38.66, 31.34]
Week 20	123	127.431 (12.6687)	128.330 [86.67, 160.00]	-0.533 (11.1526)	-0.330 [-36.00, 30.66]
Week 24	122	128.830 (13.2999)	129.165 [89.00, 170.67]	0.940 (11.4875)	-0.670 [-27.33, 40.66]
Week 28	122	129.779 (13.6851)	130.000 [94.67, 172.00]	1.888 (10.8057)	1.000 [-27.33, 29.33]
Week 32	120	127.769 (13.6816)	129.165 [83.33, 170.00]	-0.231 (12.4809)	-2.000 [-36.66, 42.00]

Parameter	Observed			Change from baseline	
Treatment Visit	n	Mean (SD)	Median [Min, Max]	Mean (SD)	Median [Min, Max]
Week 36	120	128.506 (14.0028)	128.500 [93.33, 174.00]	0.506 (12.4136)	0.165 [-28.33, 28.67]
Week 40	120	129.309 (14.4753)	131.000 [88.00, 175.33]	1.309 (12.4078)	0.665 [-40.67, 52.33]
Week 44	119	128.109 (14.7127)	126.670 [97.67, 174.00]	0.211 (12.7595)	1.000 [-40.00, 28.67]
Week 48	116	127.816 (13.9559)	128.330 [98.67, 174.67]	-0.020 (11.9685)	0.000 [-32.00, 37.00]
Week 52	116	128.859 (12.7264)	129.330 [95.00, 164.00]	1.023 (10.7885)	1.335 [-37.67, 30.66]
LOCF Endpoint	127	128.488 (12.7434)	129.000 [95.00, 164.00]	0.767 (11.4321)	1.330 [-37.67, 30.66]
Imeglimin + GLIN (N = 64)					
Baseline	64	127.270 (12.8855)	128.000 [96.00, 154.33]		
Week 4	64	125.260 (13.4633)	125.330 [95.00, 157.67]	-2.010 (9.1346)	-1.670 [-24.00, 24.00]
Week 8	63	124.444 (13.1830)	124.330 [97.33, 160.00]	-2.666 (9.6014)	-3.000 [-24.00, 20.33]
Week 12	63	125.730 (12.9567)	127.330 [99.67, 153.00]	-1.381 (9.7528)	-2.340 [-19.33, 25.00]
Week 16	63	125.529 (12.5197)	126.000 [98.67, 160.67]	-1.581 (10.2807)	-1.000 [-24.66, 26.67]
Week 20	62	126.919 (11.8006)	128.330 [104.00, 157.67]	-0.511 (10.3633)	-2.335 [-33.67, 22.67]
Week 24	62	127.737 (14.0810)	126.670 [99.33, 169.33]	0.307 (11.4363)	-2.335 [-20.00, 36.67]
Week 28	62	128.650 (14.5149)	128.335 [96.33, 171.33]	1.220 (11.5717)	1.500 [-20.00, 38.66]
Week 32	62	129.161 (12.4197)	128.665 [104.33, 161.33]	1.731 (10.2062)	2.000 [-23.66, 23.33]
Week 36	60	128.939 (11.8184)	128.835 [99.67, 153.00]	1.189 (11.9487)	1.000 [-28.67, 25.33]
Week 40	60	130.422 (13.9332)	132.500 [94.00, 161.33]	2.672 (12.2740)	2.835 [-26.33, 27.67]
Week 44	60	129.850 (13.2807)	129.500 [101.67, 161.00]	2.101 (11.1907)	2.000 [-20.66, 27.00]
Week 48	60	128.318 (12.9348)	130.835 [98.67, 150.33]	0.568 (10.5079)	0.165 [-22.33, 23.33]
Week 52	59	128.751 (14.8404)	126.670 [100.33, 165.00]	1.452 (10.4907)	0.670 [-22.33, 32.33]
LOCF Endpoint	64	128.687 (14.5049)	126.835 [100.33, 165.00]	1.417 (10.3534)	1.170 [-22.33, 32.33]
Imeglimin + BIG (N = 64)					
Baseline	64	133.448 (12.8821)	130.665 [110.00, 176.67]		
Week 4	64	131.671 (13.2816)	133.165 [104.00, 168.67]	-1.776 (10.0538)	-0.170 [-30.00, 17.34]
Week 8	64	129.834 (13.8669)	129.165 [105.00, 176.33]	-3.614 (9.6237)	-3.670 [-22.33, 25.66]
Week 12	64	129.760 (12.5688)	128.165 [106.00, 167.00]	-3.688 (9.5317)	-2.670 [-23.33, 17.33]
Week 16	64	127.594 (12.4625)	127.330 [100.00, 153.00]	-5.854 (12.0909)	-6.000 [-44.67, 14.67]

Parameter	Observed			Change from baseline	
Treatment Visit	n	Mean (SD)	Median [Min, Max]	Mean (SD)	Median [Min, Max]
Week 20	63	128.254 (13.5186)	128.000 [93.33, 155.67]	-5.286 (13.6491)	-4.000 [-42.33, 31.00]
Week 24	63	128.852 (13.4918)	128.000 [94.00, 156.67]	-4.687 (10.0740)	-3.340 [-26.67, 17.34]
Week 28	61	131.284 (11.9300)	131.330 [96.33, 160.00]	-2.481 (13.4041)	-1.330 [-45.34, 28.00]
Week 32	60	131.044 (14.2832)	129.500 [101.67, 182.67]	-2.728 (11.2734)	-2.330 [-24.33, 32.00]
Week 36	60	132.883 (13.7659)	133.670 [100.33, 159.33]	-0.889 (11.6196)	-1.505 [-30.00, 29.00]
Week 40	59	134.317 (13.5477)	134.000 [97.67, 162.67]	0.842 (10.9628)	0.340 [-23.67, 23.67]
Week 44	59	133.921 (13.7526)	135.670 [101.33, 160.33]	0.446 (12.2086)	2.330 [-26.33, 24.33]
Week 48	58	135.466 (14.5927)	134.670 [104.67, 173.67]	2.138 (12.6812)	0.835 [-29.67, 36.00]
Week 52	58	133.765 (15.0758)	134.835 [100.67, 189.00]	0.438 (10.7872)	-0.335 [-26.34, 32.67]
LOCF Endpoint	64	133.881 (14.7919)	134.835 [100.67, 189.00]	0.433 (10.3680)	-0.335 [-26.34, 32.67]
Imeglimin + AGI (N = 64)					
Baseline	64	129.145 (13.4978)	126.835 [99.33, 171.33]		
Week 4	64	129.121 (12.2248)	128.000 [108.67, 175.67]	-0.025 (10.5677)	-1.665 [-32.00, 27.34]
Week 8	64	127.286 (12.0948)	126.335 [104.00, 158.00]	-1.859 (10.0064)	-1.835 [-28.33, 17.67]
Week 12	64	128.975 (12.1598)	129.500 [103.33, 169.33]	-0.171 (11.0099)	0.500 [-24.33, 27.00]
Week 16	64	129.911 (12.8703)	128.330 [107.67, 169.00]	0.766 (13.9040)	0.500 [-25.33, 53.34]
Week 20	64	130.875 (13.6039)	129.335 [97.67, 166.00]	1.730 (12.0170)	3.165 [-28.33, 38.67]
Week 24	63	130.274 (12.7207)	129.000 [103.00, 161.00]	0.910 (11.7642)	1.660 [-38.67, 33.00]
Week 28	64	128.651 (12.9010)	127.165 [103.33, 160.00]	-0.495 (11.3891)	-1.000 [-37.33, 27.67]
Week 32	62	131.075 (12.1215)	130.665 [111.33, 166.67]	1.672 (11.9667)	3.670 [-41.00, 25.00]
Week 36	62	131.000 (13.3385)	129.000 [100.67, 164.67]	1.597 (11.0936)	3.000 [-35.33, 22.67]
Week 40	62	132.054 (13.2321)	133.170 [106.00, 175.00]	2.651 (9.4773)	3.170 [-20.33, 22.33]
Week 44	62	132.306 (13.7266)	130.500 [102.33, 192.67]	2.903 (12.1073)	3.170 [-23.00, 31.00]
Week 48	62	129.730 (13.5124)	128.165 [103.00, 180.33]	0.327 (14.4218)	3.000 [-27.00, 36.67]
Week 52	62	131.209 (13.4538)	129.835 [104.33, 173.67]	1.806 (11.6549)	3.330 [-24.00, 22.00]
LOCF Endpoint	64	130.895 (13.4003)	129.500 [104.33, 173.67]	1.750 (11.4729)	2.835 [-24.00, 22.00]
Imeglimin + TZD (N = 65)					
Baseline	65	127.389 (11.7463)	128.670 [108.00, 155.00]		

Parameter	Observed			Change from baseline	
Treatment Visit	n	Mean (SD)	Median [Min, Max]	Mean (SD)	Median [Min, Max]
Week 4	65	127.364 (12.1321)	128.330 [98.67, 153.00]	-0.025 (8.6555)	-0.670 [-21.67, 18.67]
Week 8	65	126.457 (11.6528)	126.670 [101.33, 147.67]	-0.932 (8.9222)	-1.330 [-25.67, 18.67]
Week 12	65	126.698 (11.3947)	127.670 [95.33, 159.33]	-0.691 (11.0415)	-0.660 [-32.67, 25.34]
Week 16	64	124.562 (11.7882)	122.670 [100.67, 149.67]	-2.562 (10.3398)	-2.665 [-36.00, 18.00]
Week 20	65	125.877 (12.1207)	125.000 [94.00, 152.00]	-1.512 (11.7135)	-0.670 [-37.34, 24.33]
Week 24	65	127.544 (12.4670)	127.000 [101.33, 167.00]	0.155 (12.5507)	-1.330 [-30.67, 36.00]
Week 28	65	127.164 (10.3532)	127.000 [100.67, 150.00]	-0.225 (11.2610)	2.000 [-37.34, 22.67]
Week 32	65	128.687 (11.8579)	129.000 [104.67, 165.00]	1.298 (10.7959)	0.330 [-23.66, 31.67]
Week 36	65	129.492 (12.2751)	129.000 [101.33, 157.00]	2.103 (10.6170)	2.000 [-24.67, 34.00]
Week 40	65	127.820 (9.9465)	129.330 [106.00, 151.67]	0.431 (10.4822)	1.340 [-19.33, 23.34]
Week 44	65	127.292 (10.5418)	128.330 [93.33, 148.33]	-0.097 (11.1267)	2.670 [-27.34, 23.67]
Week 48	65	126.344 (12.2675)	126.330 [95.33, 161.67]	-1.045 (11.8518)	-0.330 [-30.67, 28.34]
Week 52	65	128.257 (11.6032)	128.670 [94.67, 158.67]	0.868 (11.5022)	2.000 [-24.00, 27.33]
LOCF Endpoint	65	128.257 (11.6032)	128.670 [94.67, 158.67]	0.868 (11.5022)	2.000 [-24.00, 27.33]
Imeglimin + DPP4-I (N = 63)					
Baseline	63	129.693 (13.3742)	129.670 [106.00, 166.33]		
Week 4	63	127.503 (14.3106)	128.330 [100.00, 162.33]	-2.190 (10.6513)	-1.670 [-29.34, 18.33]
Week 8	62	127.844 (15.7018)	125.335 [92.00, 164.67]	-1.963 (9.6122)	-2.165 [-28.33, 25.67]
Week 12	62	127.263 (14.5491)	127.170 [101.67, 162.67]	-2.543 (9.1520)	-1.330 [-28.00, 16.00]
Week 16	62	125.650 (14.0858)	122.500 [102.00, 155.33]	-4.157 (9.7522)	-3.340 [-26.00, 16.66]
Week 20	61	126.398 (13.4331)	126.000 [93.00, 166.33]	-3.318 (10.2802)	-3.330 [-27.00, 21.33]
Week 24	61	127.246 (15.9917)	126.000 [96.67, 170.00]	-2.470 (13.0999)	-2.000 [-46.00, 35.66]
Week 28	59	127.915 (15.4468)	128.330 [95.33, 166.67]	-2.029 (11.7618)	-2.000 [-35.34, 19.00]
Week 32	60	129.816 (14.4133)	129.335 [105.33, 171.67]	-0.290 (11.3903)	-0.670 [-29.66, 28.00]
Week 36	60	128.983 (14.1672)	127.165 [100.00, 157.00]	-1.123 (12.0571)	-0.660 [-38.00, 38.00]
Week 40	60	131.051 (13.7740)	130.670 [92.00, 159.00]	1.801 (12.5708)	0.835 [-39.66, 37.34]
Week 44	60	129.939 (13.6138)	130.665 [105.00, 156.00]	0.689 (12.2527)	0.335 [-35.33, 30.67]

Parameter	Observed			Change from baseline	
Treatment Visit	n	Mean (SD)	Median [Min, Max]	Mean (SD)	Median [Min, Max]
Week 48	60	129.767 (14.3178)	128.330 [104.67, 176.00]	0.516 (12.8947)	1.665 [-39.00, 35.67]
Week 52	60	130.661 (15.8624)	128.330 [99.67, 195.67]	1.411 (13.2439)	1.000 [-41.66, 44.00]
LOCF Endpoint	63	130.836 (16.0833)	129.330 [99.67, 195.67]	1.143 (13.1303)	1.000 [-41.66, 44.00]
Imeglimin + GLP1-RA (N = 70)					
Baseline	70	129.095 (13.0324)	127.670 [106.00, 172.00]		
Week 4	70	130.395 (13.3158)	132.335 [95.33, 163.33]	1.300 (10.1657)	1.495 [-23.67, 22.00]
Week 8	69	127.739 (12.7301)	129.000 [97.00, 152.33]	-1.402 (12.6799)	0.000 [-49.33, 24.67]
Week 12	68	128.343 (13.1925)	127.000 [101.33, 160.33]	-0.917 (12.8363)	-0.835 [-49.33, 34.00]
Week 16	69	127.502 (12.6228)	128.330 [99.00, 154.33]	-1.638 (13.6419)	-1.670 [-64.67, 29.00]
Week 20	69	130.590 (11.9577)	130.670 [100.00, 161.33]	1.450 (12.9890)	2.000 [-32.33, 35.00]
Week 24	69	129.110 (12.4054)	129.670 [96.00, 157.33]	-0.030 (12.2347)	2.000 [-46.67, 26.00]
Week 28	69	129.662 (12.9642)	129.330 [95.00, 156.67]	0.521 (10.5979)	-1.330 [-20.34, 36.00]
Week 32	69	130.024 (13.6953)	130.330 [102.33, 154.67]	0.884 (12.4989)	0.670 [-30.67, 27.67]
Week 36	69	130.561 (12.8960)	131.000 [106.00, 160.67]	1.420 (12.4035)	0.670 [-34.33, 34.34]
Week 40	69	130.956 (13.7259)	130.000 [93.67, 168.67]	1.816 (13.4896)	0.330 [-29.67, 46.67]
Week 44	67	127.428 (13.8475)	130.000 [98.00, 156.33]	-1.826 (14.2909)	-0.330 [-43.67, 30.00]
Week 48	66	128.824 (12.8335)	129.165 [95.33, 157.67]	-0.146 (12.2252)	0.830 [-41.00, 31.34]
Week 52	67	127.642 (12.4542)	126.670 [105.00, 155.67]	-1.612 (11.9783)	0.660 [-41.33, 18.00]
LOCF Endpoint	70	127.543 (12.6121)	126.670 [105.00, 155.67]	-1.552 (12.1218)	0.660 [-41.33, 18.00]
Imeglimin + SGLT2-I (N = 63)					
Baseline	63	126.867 (13.6629)	123.330 [101.33, 172.67]		
Week 4	63	124.783 (13.4758)	121.670 [93.33, 161.67]	-2.084 (9.8209)	-0.660 [-31.00, 19.67]
Week 8	63	125.238 (13.5443)	125.330 [95.00, 160.67]	-1.630 (12.5503)	-1.000 [-41.34, 26.67]
Week 12	63	125.000 (12.9117)	125.330 [97.67, 163.33]	-1.867 (8.9460)	-2.330 [-28.67, 18.33]
Week 16	63	123.058 (12.8199)	122.000 [90.67, 151.00]	-3.809 (11.3424)	-3.330 [-40.67, 25.00]
Week 20	63	125.386 (12.6706)	123.330 [96.33, 156.33]	-1.481 (11.6784)	-2.330 [-39.34, 27.34]
Week 24	63	125.000 (12.8826)	124.330 [98.00, 153.33]	-1.867 (10.3936)	-1.000 [-43.34, 26.00]
Week 28	63	126.249 (12.6387)	126.670 [94.67, 160.00]	-0.618 (11.1571)	-0.670 [-41.67, 25.67]

Parameter	Observed			Change from baseline	
Treatment Visit	n	Mean (SD)	Median [Min, Max]	Mean (SD)	Median [Min, Max]
Week 32	63	127.069 (11.2175)	127.000 [92.33, 152.00]	0.201 (10.6356)	0.330 [-45.67, 32.00]
Week 36	63	127.095 (13.9227)	126.330 [102.33, 173.00]	0.228 (11.5631)	-1.000 [-32.00, 31.00]
Week 40	63	127.995 (12.2756)	128.330 [101.67, 156.67]	1.127 (11.4185)	2.000 [-49.34, 26.00]
Week 44	62	128.328 (12.5184)	128.670 [97.00, 155.67]	1.754 (10.7726)	1.835 [-35.67, 21.34]
Week 48	63	125.810 (13.5786)	126.000 [94.33, 165.33]	-1.057 (11.2271)	-1.670 [-34.67, 29.00]
Week 52	62	127.161 (13.8805)	126.500 [102.33, 177.33]	0.586 (10.7478)	0.170 [-32.00, 30.67]
LOCF Endpoint	63	126.894 (13.9304)	126.330 [102.33, 177.33]	0.027 (11.5491)	-0.330 [-34.67, 30.67]
Diastolic Blood Pressure (mmHg)					
Imeglimin (N = 134)					
Baseline	134	78.838 (8.4500)	78.500 [58.33, 98.33]		
Week 4	134	77.699 (9.0491)	78.000 [50.67, 108.33]	-1.139 (5.9781)	-1.165 [-24.00, 16.34]
Week 8	132	76.968 (8.9439)	78.000 [50.00, 98.67]	-1.941 (5.8812)	-1.500 [-24.67, 13.33]
Week 12	131	77.031 (8.7742)	76.670 [60.67, 97.67]	-1.763 (5.5092)	-1.340 [-22.00, 10.33]
Week 16	130	76.490 (10.0928)	76.165 [51.33, 98.00]	-2.390 (6.5324)	-1.835 [-19.33, 15.34]
Week 20	130	76.472 (9.9553)	76.165 [56.67, 100.67]	-2.408 (6.8757)	-2.000 [-21.34, 20.67]
Week 24	130	78.075 (9.5847)	77.670 [59.00, 99.00]	-0.805 (6.5013)	-0.660 [-20.34, 14.67]
Week 28	129	78.044 (9.9215)	77.330 [60.67, 106.00]	-0.861 (7.0664)	-0.660 [-19.00, 21.33]
Week 32	128	78.732 (9.3892)	78.330 [52.67, 98.00]	-0.117 (7.0566)	-0.335 [-18.67, 19.34]
Week 36	128	79.091 (9.5959)	79.165 [59.33, 104.00]	0.242 (7.3743)	0.165 [-18.34, 32.00]
Week 40	128	78.911 (9.3885)	79.330 [52.67, 104.00]	0.063 (7.5093)	1.000 [-25.33, 20.67]
Week 44	127	79.071 (9.2927)	78.670 [60.00, 106.67]	0.257 (6.6606)	0.330 [-20.00, 16.33]
Week 48	127	78.520 (9.1227)	78.000 [55.00, 99.67]	-0.294 (6.9147)	0.000 [-15.34, 18.67]
Week 52	126	78.688 (9.1270)	78.670 [52.00, 99.67]	0.000 (6.8008)	0.330 [-22.67, 19.67]
LOCF Endpoint	134	78.512 (9.0998)	78.670 [52.00, 99.67]	-0.326 (6.9502)	0.165 [-22.67, 19.67]
Imeglimin + SU (N = 127)					
Baseline	127	76.236 (9.5361)	76.000 [52.33, 99.00]		
Week 4	127	76.045 (9.3098)	76.000 [54.00, 94.67]	-0.191 (6.5326)	-0.340 [-20.00, 17.34]
Week 8	126	75.516 (8.9564)	74.835 [55.33, 95.00]	-0.825 (6.6653)	-0.670 [-18.66, 15.33]

Parameter	Observed			Change from baseline	
Treatment Visit	n	Mean (SD)	Median [Min, Max]	Mean (SD)	Median [Min, Max]
Week 12	123	75.995 (9.2220)	76.000 [55.00, 96.00]	-0.493 (7.4050)	-0.670 [-26.00, 21.33]
Week 16	123	75.364 (8.8510)	74.000 [59.67, 94.00]	-1.124 (7.6655)	-1.000 [-22.00, 19.67]
Week 20	123	75.425 (8.7268)	75.670 [50.00, 95.67]	-1.062 (7.7793)	-1.330 [-27.00, 17.67]
Week 24	122	76.631 (9.2824)	76.835 [53.33, 95.67]	0.205 (8.0330)	0.000 [-26.67, 30.00]
Week 28	122	77.688 (9.1192)	77.835 [55.00, 102.33]	1.262 (7.2535)	1.330 [-20.66, 21.33]
Week 32	120	76.983 (9.1981)	76.000 [56.33, 102.00]	0.381 (7.9058)	-0.165 [-19.67, 24.67]
Week 36	120	76.706 (9.0789)	77.000 [55.33, 97.67]	0.103 (7.7928)	0.835 [-25.33, 23.00]
Week 40	120	76.967 (9.4881)	77.665 [52.00, 105.00]	0.364 (7.8211)	-0.495 [-17.67, 24.67]
Week 44	119	75.496 (8.8119)	76.330 [51.00, 97.00]	-1.059 (7.5789)	-0.660 [-25.00, 16.00]
Week 48	116	75.721 (8.9747)	75.165 [51.33, 98.67]	-0.830 (8.0009)	-0.660 [-29.34, 18.00]
Week 52	116	76.868 (8.4266)	76.835 [57.00, 100.33]	0.316 (7.2903)	0.500 [-22.34, 19.33]
LOCF Endpoint	127	76.433 (8.4152)	76.330 [57.00, 100.33]	0.197 (7.3650)	0.660 [-22.34, 19.33]
Imeglimin + GLIN (N = 64)					
Baseline	64	76.333 (8.6719)	77.330 [58.00, 97.33]		
Week 4	64	75.172 (9.7432)	73.670 [53.67, 98.33]	-1.162 (5.9142)	-0.835 [-14.00, 14.00]
Week 8	63	76.148 (9.3984)	76.330 [53.33, 95.67]	-0.074 (5.9806)	-1.330 [-13.34, 14.00]
Week 12	63	76.100 (10.0776)	75.330 [57.00, 100.67]	-0.122 (7.2144)	0.000 [-13.34, 20.00]
Week 16	63	75.921 (9.4510)	75.670 [56.00, 96.67]	-0.301 (5.9421)	0.000 [-13.67, 15.00]
Week 20	62	77.548 (9.4755)	78.835 [60.33, 96.67]	1.220 (6.8425)	1.330 [-13.34, 22.67]
Week 24	62	76.505 (9.7769)	76.835 [56.67, 102.67]	0.177 (6.8551)	-0.670 [-13.00, 21.33]
Week 28	62	77.516 (10.2582)	77.170 [56.00, 98.33]	1.188 (6.7428)	1.495 [-17.67, 21.34]
Week 32	62	77.785 (9.6070)	77.000 [61.67, 98.33]	1.457 (6.6135)	1.165 [-12.00, 28.00]
Week 36	60	76.395 (8.7690)	75.335 [58.00, 94.00]	0.317 (6.7096)	-0.165 [-15.33, 20.00]
Week 40	60	78.144 (9.2062)	77.500 [60.00, 101.00]	2.066 (7.9556)	0.830 [-14.00, 21.33]
Week 44	60	77.623 (8.7188)	76.670 [62.67, 97.33]	1.545 (5.7158)	1.170 [-13.34, 19.34]
Week 48	60	76.445 (10.1828)	76.500 [53.67, 99.67]	0.367 (7.1338)	0.165 [-22.00, 19.67]
Week 52	59	77.045 (10.5942)	76.670 [55.67, 102.33]	0.881 (5.9472)	1.000 [-16.00, 17.34]

Parameter	Observed			Change from baseline	
Treatment Visit	n	Mean (SD)	Median [Min, Max]	Mean (SD)	Median [Min, Max]
LOCF Endpoint	64	77.088 (10.5033)	76.835 [55.67, 102.33]	0.755 (5.9033)	0.835 [-16.00, 17.34]
Imeglimin + BIG (N = 64)					
Baseline	64	81.104 (9.0228)	80.000 [60.67, 97.33]		
Week 4	64	81.474 (9.7805)	79.665 [66.00, 105.67]	0.370 (5.8245)	0.330 [-13.33, 14.66]
Week 8	64	80.328 (9.6835)	80.165 [58.67, 103.67]	-0.776 (5.6464)	-0.670 [-16.66, 10.00]
Week 12	64	80.989 (9.1946)	83.000 [59.33, 98.00]	-0.115 (5.2462)	-0.660 [-12.33, 10.66]
Week 16	64	79.229 (9.8401)	78.670 [59.00, 99.33]	-1.875 (6.0442)	-1.665 [-14.67, 10.00]
Week 20	63	79.148 (10.5499)	77.330 [59.67, 99.33]	-2.042 (7.9124)	-1.670 [-22.00, 18.67]
Week 24	63	79.624 (9.8388)	79.000 [59.67, 98.67]	-1.566 (6.3678)	-1.670 [-14.00, 17.33]
Week 28	61	80.197 (9.8940)	80.000 [50.00, 97.67]	-0.945 (7.7953)	-0.340 [-26.33, 18.67]
Week 32	60	79.967 (9.3190)	79.665 [63.00, 98.67]	-1.216 (6.2547)	-1.330 [-13.66, 15.00]
Week 36	60	80.789 (9.5244)	80.500 [59.33, 98.33]	-0.394 (5.7187)	-0.330 [-11.66, 16.33]
Week 40	59	82.266 (9.6168)	84.670 [59.67, 100.00]	0.735 (6.5142)	1.330 [-13.33, 18.67]
Week 44	59	80.865 (9.5537)	81.000 [59.67, 97.33]	-0.666 (7.1832)	-0.670 [-21.33, 15.67]
Week 48	58	81.851 (10.0633)	83.665 [52.67, 98.33]	0.173 (6.7536)	1.000 [-20.33, 13.67]
Week 52	58	82.115 (10.2007)	81.835 [61.67, 101.33]	0.437 (6.7431)	-0.330 [-12.67, 21.67]
LOCF Endpoint	64	81.276 (10.3496)	81.000 [59.33, 101.33]	0.173 (6.6794)	-0.670 [-12.67, 21.67]
Imeglimin + AGI (N = 64)					
Baseline	64	79.521 (8.0206)	80.500 [58.00, 96.67]		
Week 4	64	80.005 (8.2589)	80.670 [61.33, 95.33]	0.484 (7.1194)	1.000 [-13.00, 19.67]
Week 8	64	78.593 (8.3279)	78.330 [61.67, 97.00]	-0.928 (6.1753)	-0.835 [-17.34, 13.34]
Week 12	64	79.713 (8.7571)	78.665 [55.67, 100.00]	0.192 (7.3231)	-0.165 [-18.00, 21.67]
Week 16	64	79.979 (8.5917)	78.000 [58.67, 96.67]	0.457 (8.8370)	-0.670 [-23.00, 27.33]
Week 20	64	80.244 (8.1063)	79.500 [60.67, 100.00]	0.723 (7.7008)	0.660 [-21.00, 24.67]
Week 24	63	79.248 (8.2812)	78.330 [63.00, 97.33]	-0.514 (7.5042)	-0.330 [-26.00, 16.00]
Week 28	64	80.068 (7.8733)	78.835 [66.00, 96.33]	0.547 (7.0047)	1.330 [-15.67, 22.00]
Week 32	62	79.720 (8.0258)	80.335 [61.33, 96.00]	0.015 (7.7034)	0.165 [-18.67, 16.67]
Week 36	62	80.844 (8.7627)	79.330 [60.00, 105.00]	1.139 (7.3520)	0.835 [-15.33, 23.33]

Parameter	Observed			Change from baseline	
Treatment Visit	n	Mean (SD)	Median [Min, Max]	Mean (SD)	Median [Min, Max]
Week 40	62	80.710 (8.4092)	81.000 [61.33, 99.33]	1.005 (6.9182)	2.495 [-17.00, 16.67]
Week 44	62	80.710 (7.5020)	80.500 [63.00, 103.67]	1.005 (7.0334)	1.670 [-15.67, 17.67]
Week 48	62	79.543 (9.1145)	79.500 [58.67, 102.00]	-0.162 (8.4002)	0.495 [-21.00, 21.00]
Week 52	62	80.188 (8.0983)	80.000 [64.67, 97.00]	0.483 (7.1107)	1.165 [-15.33, 17.33]
LOCF Endpoint	64	80.011 (8.1725)	80.000 [64.67, 97.00]	0.489 (6.9993)	1.165 [-15.33, 17.33]
Imeglimin + TZD (N = 65)					
Baseline	65	77.882 (9.9481)	76.670 [57.33, 98.33]		
Week 4	65	77.733 (10.3764)	78.670 [55.67, 97.33]	-0.148 (6.2756)	0.660 [-16.00, 19.00]
Week 8	65	77.821 (10.3288)	77.670 [53.00, 97.67]	-0.061 (6.7832)	-1.330 [-13.33, 22.00]
Week 12	65	77.528 (9.4477)	79.000 [51.33, 93.33]	-0.353 (7.0525)	0.000 [-14.33, 15.33]
Week 16	64	76.739 (10.4309)	77.165 [52.67, 100.67]	-1.000 (7.3760)	-1.000 [-19.00, 18.66]
Week 20	65	77.451 (10.9358)	76.670 [51.33, 98.00]	-0.430 (7.4376)	-0.660 [-20.00, 19.67]
Week 24	65	78.042 (10.1888)	77.670 [50.67, 104.67]	0.160 (8.3849)	-1.330 [-19.33, 29.00]
Week 28	65	78.201 (9.8369)	79.670 [59.67, 96.67]	0.319 (7.0086)	0.340 [-18.00, 14.66]
Week 32	65	78.626 (11.0128)	79.670 [56.33, 112.00]	0.744 (8.2208)	-0.670 [-13.66, 36.33]
Week 36	65	78.718 (10.5333)	79.000 [52.00, 100.67]	0.837 (7.6601)	1.000 [-18.67, 18.00]
Week 40	65	78.795 (9.8496)	79.000 [53.33, 100.00]	0.913 (7.2787)	1.660 [-18.00, 18.66]
Week 44	65	78.605 (9.9986)	79.670 [55.00, 105.67]	0.724 (7.7317)	1.000 [-17.00, 17.67]
Week 48	65	77.959 (10.9984)	78.330 [49.00, 104.67]	0.077 (8.5925)	-2.000 [-15.67, 24.00]
Week 52	65	77.559 (10.6907)	76.330 [57.33, 107.67]	-0.323 (8.2404)	-0.660 [-20.67, 22.00]
LOCF Endpoint	65	77.559 (10.6907)	76.330 [57.33, 107.67]	-0.323 (8.2404)	-0.660 [-20.67, 22.00]
Imeglimin + DPP4-I (N = 63)					
Baseline	63	77.957 (9.6063)	78.670 [59.00, 96.00]		
Week 4	63	76.312 (9.9430)	75.000 [49.33, 99.00]	-1.646 (6.8926)	-0.670 [-23.67, 14.33]
Week 8	62	76.225 (10.4724)	75.170 [51.33, 104.67]	-2.000 (6.7993)	-1.165 [-20.33, 17.67]
Week 12	62	76.129 (9.9301)	75.835 [56.67, 100.67]	-2.097 (6.8202)	-2.000 [-17.66, 11.66]
Week 16	62	75.123 (10.2748)	73.165 [51.67, 97.00]	-3.102 (7.0143)	-2.665 [-21.00, 9.66]
Week 20	61	76.017 (9.4026)	75.330 [53.67, 103.33]	-2.289 (7.6842)	-2.670 [-20.00, 14.00]

Parameter	Observed			Change from baseline	
Treatment Visit	n	Mean (SD)	Median [Min, Max]	Mean (SD)	Median [Min, Max]
Week 24	61	76.551 (10.5550)	77.000 [55.00, 102.67]	-1.755 (8.2027)	-1.670 [-25.33, 14.33]
Week 28	59	77.028 (10.3416)	75.330 [58.33, 102.00]	-1.656 (7.9624)	-1.330 [-21.00, 18.34]
Week 32	60	77.583 (9.7488)	77.165 [58.33, 100.33]	-0.983 (7.8695)	-0.665 [-18.33, 12.67]
Week 36	60	77.628 (9.9859)	77.670 [52.00, 100.33]	-0.939 (7.8250)	-0.665 [-15.34, 17.00]
Week 40	60	77.894 (9.6262)	78.500 [56.33, 98.67]	-0.140 (8.8224)	0.835 [-21.00, 25.00]
Week 44	60	77.407 (9.7316)	78.000 [50.00, 98.33]	-0.627 (7.5550)	-0.495 [-18.33, 15.66]
Week 48	60	76.994 (10.0516)	76.330 [55.00, 97.67]	-1.039 (8.3836)	-0.665 [-19.00, 17.33]
Week 52	60	77.855 (10.9449)	77.000 [57.67, 103.67]	-0.178 (8.9876)	0.000 [-23.00, 23.67]
LOCF Endpoint	63	77.756 (10.9806)	77.000 [57.67, 103.67]	-0.201 (8.8671)	0.000 [-23.00, 23.67]
Imeglimin + GLP1-RA (N = 70)					
Baseline	70	78.991 (9.7433)	79.330 [58.00, 97.33]		
Week 4	70	79.567 (9.1299)	79.165 [59.33, 99.33]	0.576 (6.0273)	0.165 [-13.33, 16.33]
Week 8	69	77.995 (9.4049)	79.000 [54.00, 95.00]	-1.049 (7.1594)	-2.000 [-15.66, 12.67]
Week 12	68	78.500 (9.0813)	79.000 [57.33, 97.33]	-0.774 (7.2187)	-0.330 [-15.67, 19.67]
Week 16	69	77.367 (9.2274)	78.330 [54.33, 97.00]	-1.677 (6.6756)	-2.660 [-15.67, 14.33]
Week 20	69	78.424 (9.0573)	79.330 [50.33, 93.00]	-0.619 (7.0465)	-1.000 [-15.33, 17.33]
Week 24	69	78.526 (9.1065)	79.330 [59.33, 96.67]	-0.517 (6.2503)	-0.660 [-16.33, 18.00]
Week 28	69	78.270 (9.1095)	78.330 [55.67, 97.33]	-0.773 (7.1145)	-1.000 [-16.33, 17.66]
Week 32	69	78.995 (10.0680)	81.000 [58.33, 100.67]	-0.048 (7.9407)	0.000 [-20.67, 18.66]
Week 36	69	79.440 (9.3296)	79.000 [58.33, 98.33]	0.396 (7.3325)	-0.670 [-13.00, 20.33]
Week 40	69	78.909 (8.7674)	80.000 [58.33, 97.67]	-0.135 (7.8723)	-0.660 [-17.33, 18.66]
Week 44	67	78.030 (9.1385)	77.330 [58.00, 98.33]	-1.140 (7.7305)	-2.000 [-18.00, 25.00]
Week 48	66	77.944 (9.6497)	79.500 [56.67, 97.00]	-1.243 (7.9219)	-1.335 [-21.33, 18.66]
Week 52	67	77.378 (8.2466)	77.330 [61.00, 94.33]	-1.791 (6.6279)	-2.000 [-19.66, 13.00]
LOCF Endpoint	70	77.214 (8.4062)	77.000 [61.00, 94.33]	-1.776 (6.7522)	-1.670 [-19.66, 13.00]
Imeglimin + SGLT2-I (N = 63)					
Baseline	63	77.132 (8.6058)	76.000 [61.00, 97.33]		
Week 4	63	76.322 (9.4340)	75.330 [55.33, 98.67]	-0.810 (6.1712)	0.330 [-19.33, 12.00]

Parameter	Observed			Change from baseline	
Treatment Visit	n	Mean (SD)	Median [Min, Max]	Mean (SD)	Median [Min, Max]
Week 8	63	76.514 (10.6266)	76.670 [54.33, 98.67]	-0.618 (6.7606)	0.000 [-16.33, 11.67]
Week 12	63	76.111 (9.6125)	74.000 [56.67, 99.00]	-1.021 (5.6425)	-1.000 [-17.00, 17.34]
Week 16	63	74.286 (9.3302)	76.000 [51.00, 90.67]	-2.846 (6.2958)	-2.330 [-20.00, 13.00]
Week 20	63	76.095 (9.2043)	76.670 [53.67, 97.67]	-1.037 (6.4068)	-0.670 [-20.00, 14.00]
Week 24	63	75.836 (9.8452)	74.670 [57.33, 96.33]	-1.296 (5.4121)	-1.000 [-16.00, 9.00]
Week 28	63	76.322 (9.9603)	76.000 [52.33, 97.00]	-0.810 (6.4167)	0.000 [-19.33, 14.00]
Week 32	63	77.735 (10.6199)	77.000 [47.33, 104.00]	0.603 (7.2543)	1.670 [-28.34, 15.67]
Week 36	63	76.757 (10.1060)	76.000 [55.67, 98.67]	-0.375 (6.9933)	1.330 [-17.67, 14.00]
Week 40	63	77.413 (9.9690)	78.670 [55.33, 98.33]	0.281 (6.4543)	1.330 [-20.67, 13.33]
Week 44	62	78.075 (10.1270)	77.665 [57.67, 97.67]	1.092 (6.8991)	1.500 [-20.00, 16.33]
Week 48	63	76.809 (9.3707)	76.670 [48.33, 93.67]	-0.323 (7.4586)	0.330 [-18.67, 14.33]
Week 52	62	77.011 (8.9369)	78.000 [59.00, 103.67]	0.027 (6.5858)	0.165 [-16.00, 23.34]
LOCF Endpoint	63	77.069 (8.8765)	78.670 [59.00, 103.67]	-0.063 (6.5717)	0.000 [-16.00, 23.34]
Heart Rate (beats/min)					
Imeglimin (N = 134)					
Baseline	134	69.0 (10.94)	68.0 [44, 101]		
Week 4	134	68.8 (10.73)	69.0 [45, 106]	-0.2 (7.37)	0.0 [-29, 35]
Week 8	132	68.9 (10.11)	69.0 [48, 101]	-0.2 (8.34)	0.0 [-19, 20]
Week 12	131	68.8 (10.09)	68.0 [49, 96]	-0.1 (6.92)	0.0 [-18, 19]
Week 16	130	69.8 (10.28)	70.0 [48, 98]	0.7 (7.36)	0.0 [-23, 23]
Week 20	130	69.2 (11.02)	68.5 [49, 104]	0.2 (8.32)	0.0 [-31, 30]
Week 24	130	68.1 (9.66)	67.5 [48, 96]	-0.9 (7.15)	0.0 [-17, 20]
Week 28	129	70.1 (11.36)	69.0 [50, 106]	1.2 (8.32)	1.0 [-18, 24]
Week 32	128	71.0 (11.26)	69.0 [50, 101]	2.2 (8.39)	2.0 [-24, 23]
Week 36	128	69.5 (10.64)	68.5 [48, 100]	0.7 (9.38)	0.0 [-34, 21]
Week 40	128	69.3 (10.64)	69.0 [47, 103]	0.4 (8.03)	0.0 [-30, 23]
Week 44	127	70.0 (11.14)	70.0 [42, 115]	1.2 (8.67)	1.0 [-31, 27]
Week 48	127	68.9 (10.68)	69.0 [48, 104]	0.1 (8.60)	0.0 [-29, 24]
Week 52	126	69.8 (12.54)	69.0 [51, 125]	0.9 (9.23)	0.0 [-25, 44]
LOCF Endpoint	134	70.1 (12.46)	70.0 [51, 125]	1.2 (9.31)	0.0 [-25, 44]
Imeglimin + SU (N = 127)					
Baseline	127	70.6 (10.81)	68.0 [52, 101]		
Week 4	127	71.4 (10.28)	70.0 [52, 96]	0.8 (7.55)	1.0 [-29, 18]
Week 8	126	70.6 (10.00)	69.0 [52, 98]	0.0 (7.53)	0.0 [-26, 16]
Week 12	123	70.7 (10.88)	70.0 [49, 100]	0.1 (7.62)	0.0 [-25, 32]
Week 16	123	71.6 (12.80)	71.0 [49, 141]	1.0 (10.14)	0.0 [-30, 65]
Week 20	123	71.1 (9.87)	70.0 [52, 97]	0.5 (7.30)	0.0 [-21, 14]
Week 24	122	70.0 (10.95)	68.0 [50, 97]	-0.5 (7.45)	0.0 [-23, 17]

Parameter	Observed			Change from baseline	
Treatment Visit	n	Mean (SD)	Median [Min, Max]	Mean (SD)	Median [Min, Max]
Week 28	122	71.3 (11.26)	71.0 [49, 103]	0.8 (7.95)	0.0 [-24, 25]
Week 32	120	71.2 (11.07)	69.5 [48, 103]	0.5 (8.20)	0.0 [-26, 23]
Week 36	120	72.2 (10.97)	71.5 [48, 105]	1.6 (7.74)	2.0 [-28, 28]
Week 40	120	70.5 (10.26)	70.0 [48, 96]	-0.1 (7.43)	0.0 [-19, 21]
Week 44	119	70.9 (10.09)	70.0 [51, 100]	0.3 (7.46)	0.0 [-24, 20]
Week 48	116	71.3 (10.18)	70.0 [52, 101]	0.6 (7.48)	0.0 [-24, 18]
Week 52	116	70.9 (11.13)	70.0 [49, 101]	0.2 (7.68)	0.0 [-18, 30]
LOCF Endpoint	127	71.0 (11.01)	70.0 [49, 101]	0.4 (7.74)	0.0 [-18, 30]
Imeglimin + GLIN (N = 64)					
Baseline	64	67.9 (10.01)	67.0 [46, 90]		
Week 4	64	68.7 (10.96)	67.5 [50, 97]	0.8 (7.03)	0.0 [-14, 30]
Week 8	63	69.7 (10.52)	69.0 [46, 92]	1.7 (6.71)	2.0 [-13, 24]
Week 12	63	67.6 (10.77)	65.0 [47, 96]	-0.5 (8.59)	0.0 [-23, 36]
Week 16	63	69.2 (11.39)	70.0 [44, 96]	1.2 (8.75)	1.0 [-15, 36]
Week 20	62	69.4 (10.95)	69.0 [50, 96]	1.4 (6.88)	0.5 [-17, 18]
Week 24	62	67.5 (11.29)	66.5 [42, 90]	-0.5 (7.99)	-1.0 [-24, 30]
Week 28	62	69.4 (11.41)	68.0 [52, 104]	1.4 (9.48)	0.0 [-27, 32]
Week 32	62	70.8 (11.16)	70.0 [50, 98]	2.9 (9.29)	1.0 [-14, 37]
Week 36	60	70.2 (10.51)	69.0 [51, 92]	2.1 (7.04)	1.0 [-12, 24]
Week 40	60	68.8 (12.50)	67.5 [48, 96]	0.7 (9.66)	0.0 [-19, 30]
Week 44	60	69.2 (9.59)	68.5 [51, 88]	1.1 (7.68)	0.0 [-15, 24]
Week 48	60	69.9 (11.34)	68.5 [51, 95]	1.8 (7.21)	0.5 [-11, 24]
Week 52	59	68.6 (10.85)	69.0 [50, 95]	0.3 (8.03)	-1.0 [-21, 22]
LOCF Endpoint	64	68.2 (10.79)	69.0 [50, 95]	0.3 (7.94)	-0.5 [-21, 22]
Imeglimin + BIG (N = 64)					
Baseline	64	71.0 (9.53)	69.5 [48, 104]		
Week 4	64	72.0 (10.05)	70.0 [50, 98]	1.0 (9.86)	0.5 [-30, 32]
Week 8	64	71.7 (9.23)	72.0 [55, 95]	0.8 (8.62)	1.5 [-18, 17]
Week 12	64	71.2 (8.06)	72.0 [56, 95]	0.2 (7.51)	0.0 [-28, 16]
Week 16	64	71.0 (8.54)	71.0 [50, 95]	0.1 (8.71)	0.0 [-34, 19]
Week 20	63	71.3 (8.42)	71.0 [52, 97]	0.1 (8.96)	2.0 [-39, 17]
Week 24	63	70.7 (9.54)	71.0 [50, 95]	-0.5 (7.80)	0.0 [-22, 20]
Week 28	61	70.7 (9.01)	71.0 [51, 102]	0.0 (7.81)	0.0 [-24, 15]
Week 32	60	71.0 (7.99)	69.5 [57, 93]	0.1 (8.45)	1.0 [-25, 19]
Week 36	60	71.0 (9.17)	70.0 [50, 97]	0.1 (8.15)	0.5 [-22, 27]
Week 40	59	70.1 (8.92)	68.0 [50, 93]	-0.8 (9.17)	0.0 [-23, 18]
Week 44	59	71.8 (9.65)	71.0 [47, 98]	0.9 (6.98)	0.0 [-19, 19]
Week 48	58	70.6 (8.36)	70.0 [50, 94]	-0.5 (7.99)	0.0 [-24, 13]
Week 52	58	70.3 (8.03)	68.5 [53, 86]	-0.8 (7.14)	-1.0 [-18, 24]
LOCF Endpoint	64	70.0 (8.13)	68.5 [53, 86]	-1.0 (7.43)	-1.0 [-22, 24]
Imeglimin + AGI (N = 64)					
Baseline	64	69.4 (12.88)	69.0 [43, 103]		
Week 4	64	69.7 (12.56)	67.0 [49, 105]	0.3 (6.94)	-0.5 [-13, 18]
Week 8	64	70.0 (11.31)	69.5 [50, 104]	0.5 (8.71)	0.5 [-25, 25]
Week 12	64	68.8 (12.58)	66.5 [45, 110]	-0.6 (8.41)	-0.5 [-19, 27]
Week 16	64	69.2 (10.34)	66.5 [48, 98]	-0.3 (7.85)	1.0 [-19, 16]
Week 20	64	69.9 (11.33)	69.0 [48, 99]	0.4 (8.42)	0.5 [-15, 21]
Week 24	63	68.6 (11.93)	67.0 [48, 98]	-1.2 (7.81)	-1.0 [-23, 12]
Week 28	64	70.5 (12.11)	69.5 [44, 98]	1.0 (8.59)	1.0 [-17, 32]
Week 32	62	68.3 (11.02)	67.0 [47, 100]	-1.2 (9.19)	-1.0 [-26, 22]

Parameter	Observed			Change from baseline	
Treatment Visit	n	Mean (SD)	Median [Min, Max]	Mean (SD)	Median [Min, Max]
Week 36	62	68.7 (10.99)	68.0 [41, 101]	-0.9 (8.76)	-2.0 [-19, 24]
Week 40	62	69.3 (10.72)	67.5 [46, 98]	-0.3 (7.74)	-0.5 [-21, 23]
Week 44	62	69.4 (9.90)	69.0 [41, 93]	-0.1 (8.62)	0.0 [-20, 24]
Week 48	62	70.0 (11.32)	69.5 [45, 97]	0.5 (8.72)	-0.5 [-25, 24]
Week 52	62	70.0 (12.05)	69.0 [44, 99]	0.5 (9.57)	0.0 [-23, 27]
LOCF Endpoint	64	70.6 (12.27)	69.5 [44, 99]	1.2 (10.31)	0.5 [-23, 32]
Imeglimin + TZD (N = 65)					
Baseline	65	68.9 (11.65)	67.0 [50, 97]		
Week 4	65	71.0 (10.17)	70.0 [51, 98]	2.1 (6.60)	3.0 [-14, 20]
Week 8	65	70.5 (11.76)	67.0 [50, 96]	1.6 (6.59)	1.0 [-12, 16]
Week 12	65	69.4 (11.12)	68.0 [49, 96]	0.5 (7.51)	0.0 [-16, 22]
Week 16	64	70.4 (10.89)	68.5 [50, 99]	1.8 (7.67)	2.0 [-17, 14]
Week 20	65	71.1 (11.76)	70.0 [45, 105]	2.2 (7.74)	2.0 [-15, 23]
Week 24	65	69.8 (11.35)	67.0 [47, 97]	0.9 (7.16)	0.0 [-12, 24]
Week 28	65	70.9 (11.67)	71.0 [48, 101]	2.0 (8.36)	2.0 [-11, 27]
Week 32	65	71.3 (11.74)	72.0 [48, 104]	2.4 (7.30)	2.0 [-19, 20]
Week 36	65	72.3 (11.19)	72.0 [50, 100]	3.4 (8.48)	2.0 [-10, 30]
Week 40	65	70.1 (11.14)	70.0 [50, 103]	1.2 (6.93)	2.0 [-14, 16]
Week 44	65	72.2 (12.17)	72.0 [46, 105]	3.4 (9.11)	2.0 [-27, 37]
Week 48	65	71.2 (11.09)	69.0 [49, 97]	2.3 (8.14)	2.0 [-15, 29]
Week 52	65	70.2 (12.52)	69.0 [51, 110]	1.3 (9.09)	0.0 [-21, 42]
LOCF Endpoint	65	70.2 (12.52)	69.0 [51, 110]	1.3 (9.09)	0.0 [-21, 42]
Imeglimin + DPP4-I (N = 63)					
Baseline	63	69.8 (10.56)	67.0 [52, 103]		
Week 4	63	71.5 (10.27)	72.0 [53, 101]	1.7 (5.98)	2.0 [-11, 20]
Week 8	62	70.2 (9.59)	70.5 [53, 100]	0.3 (6.54)	-1.0 [-13, 18]
Week 12	62	69.9 (9.92)	69.5 [53, 97]	0.0 (7.04)	1.0 [-20, 14]
Week 16	62	71.0 (10.83)	71.0 [46, 95]	1.1 (8.21)	1.0 [-23, 23]
Week 20	61	71.1 (9.45)	71.0 [54, 94]	1.3 (9.13)	0.0 [-23, 24]
Week 24	61	70.2 (11.41)	68.0 [53, 115]	0.4 (8.00)	0.0 [-19, 34]
Week 28	59	70.1 (9.52)	69.0 [50, 97]	0.1 (7.93)	0.0 [-20, 25]
Week 32	60	70.8 (9.10)	70.0 [54, 97]	0.8 (5.77)	1.0 [-15, 12]
Week 36	60	70.6 (9.95)	71.0 [53, 100]	0.6 (6.52)	2.0 [-16, 16]
Week 40	60	72.5 (14.09)	70.0 [51, 148]	2.9 (13.46)	1.0 [-15, 88]
Week 44	60	71.8 (11.09)	71.0 [51, 100]	2.2 (7.65)	1.5 [-14, 31]
Week 48	60	71.0 (10.18)	69.0 [53, 99]	1.5 (6.86)	0.0 [-19, 25]
Week 52	60	70.0 (10.18)	69.0 [51, 97]	0.4 (6.62)	0.0 [-23, 15]
LOCF Endpoint	63	70.2 (10.35)	69.0 [51, 97]	0.4 (6.52)	0.0 [-23, 15]
Imeglimin + GLP1-RA (N = 70)					
Baseline	70	75.0 (8.94)	76.5 [57, 100]		
Week 4	70	75.3 (10.31)	75.0 [54, 101]	0.3 (6.68)	0.0 [-14, 22]
Week 8	69	76.8 (11.22)	78.0 [46, 105]	1.7 (7.51)	1.0 [-24, 21]
Week 12	68	75.2 (10.18)	75.0 [44, 99]	0.2 (8.07)	0.0 [-26, 24]
Week 16	69	75.5 (10.72)	77.0 [47, 102]	0.4 (7.04)	0.0 [-23, 14]
Week 20	69	75.1 (10.51)	73.0 [45, 109]	0.0 (6.91)	0.0 [-25, 12]
Week 24	69	75.4 (10.53)	74.0 [52, 105]	0.3 (7.19)	0.0 [-18, 18]
Week 28	69	75.6 (10.46)	74.0 [56, 110]	0.5 (7.53)	0.0 [-18, 21]
Week 32	69	75.9 (9.96)	76.0 [56, 101]	0.8 (6.21)	1.0 [-14, 15]
Week 36	69	75.8 (9.76)	75.0 [58, 101]	0.7 (6.22)	0.0 [-15, 15]
Week 40	69	75.3 (10.49)	73.0 [58, 115]	0.2 (8.08)	0.0 [-18, 21]

Parameter	Observed			Change from baseline	
Treatment Visit	n	Mean (SD)	Median [Min, Max]	Mean (SD)	Median [Min, Max]
Week 44	67	76.7 (9.63)	78.0 [58, 101]	1.7 (5.96)	1.0 [-13, 16]
Week 48	66	75.8 (9.84)	75.5 [60, 103]	0.9 (6.73)	1.0 [-15, 16]
Week 52	67	75.5 (10.96)	76.0 [54, 117]	0.5 (6.62)	1.0 [-19, 17]
LOCF Endpoint	70	75.3 (11.06)	75.5 [54, 117]	0.3 (6.79)	1.0 [-19, 17]
Imeglimin + SGLT2-I (N = 63)					
Baseline	63	69.8 (11.16)	68.0 [51, 106]		
Week 4	63	71.1 (10.98)	70.0 [51, 97]	1.2 (6.16)	1.0 [-16, 16]
Week 8	63	69.5 (10.35)	69.0 [48, 90]	-0.3 (6.96)	0.0 [-18, 15]
Week 12	63	68.1 (9.83)	68.0 [45, 89]	-1.7 (6.44)	-2.0 [-25, 11]
Week 16	63	70.1 (11.30)	69.0 [45, 98]	0.3 (7.18)	0.0 [-17, 17]
Week 20	63	69.2 (11.33)	69.0 [48, 96]	-0.6 (7.23)	0.0 [-21, 20]
Week 24	63	69.0 (11.02)	67.0 [50, 101]	-0.8 (6.71)	-1.0 [-18, 13]
Week 28	63	69.5 (10.35)	69.0 [48, 97]	-0.4 (6.88)	1.0 [-21, 19]
Week 32	63	70.3 (11.27)	70.0 [46, 100]	0.5 (7.89)	1.0 [-16, 17]
Week 36	63	70.0 (11.15)	68.0 [46, 95]	0.2 (7.72)	1.0 [-14, 21]
Week 40	63	70.1 (12.28)	69.0 [47, 107]	0.2 (8.03)	0.0 [-21, 21]
Week 44	62	69.8 (10.40)	70.0 [52, 95]	0.4 (8.10)	2.0 [-25, 17]
Week 48	63	69.4 (11.40)	68.0 [50, 100]	-0.4 (8.73)	-1.0 [-21, 22]
Week 52	62	68.0 (11.28)	66.5 [47, 97]	-1.5 (7.17)	-1.0 [-21, 15]
LOCF Endpoint	63	68.0 (11.20)	67.0 [47, 97]	-1.8 (7.53)	-1.0 [-21, 15]

- Abbreviations: SD, standard deviation; LOCF, Last Observation Carried Forward; SU, Sulphonylurea; GLIN, Glinide; BIG, Biguanide; AGI, Alpha glucosidase inhibitor; TZD, Thiazolidinedione; DPP4-I, Dipeptidyl peptidase-4 inhibitor; GLP1-RA, Glucagon-like peptide 1 receptor agonist; SGLT2-I, Sodium glucose cotransporter 2 inhibitor
- "Imeglimin" in this table means "Imeglimin 1000 mg twice daily".

Control No:<<t-s-568-vsign-019lt.sas, 2020-03-10T11:52:10>>

Table S-569 Summary of Change from Baseline in Vital Signs to Week 16 in 16-Week Double-blind Period in Combination with Insulin Therapy (PXL008-020; Safety Population)

Parameter	Observed			Change from baseline	
Treatment Visit	n	Mean (SD)	Median [Min, Max]	Mean (SD)	Median [Min, Max]
Systolic Blood Pressure (mmHg)					
Placebo + Insulin (N = 107)					
Baseline	107	127.003 (16.2817)	125.670 [95.33, 174.67]		
Week 16	104	127.253 (16.4098)	127.165 [86.67, 174.00]	0.118 (9.8316)	-0.670 [-25.00, 27.33]
LOCF Endpoint	106	126.673 (16.7832)	126.835 [86.67, 174.00]	-0.327 (10.1950)	-1.165 [-25.67, 27.33]
Imeglimin 1000 mg bid + Insulin (N = 108)					
Baseline	108	127.522 (14.2384)	127.000 [86.33, 162.67]		
Week 16	108	130.256 (16.0958)	129.335 [80.67, 172.67]	2.735 (11.3795)	4.330 [-37.00, 29.66]
LOCF Endpoint	108	130.256 (16.0958)	129.335 [80.67, 172.67]	2.735 (11.3795)	4.330 [-37.00, 29.66]
Diastolic Blood Pressure (mmHg)					
Placebo + Insulin (N = 107)					
Baseline	107	74.094 (10.7539)	73.330 [49.67, 97.00]		
Week 16	104	74.644 (11.0793)	74.670 [43.33, 109.33]	0.557 (5.9751)	-0.835 [-11.67, 16.33]
LOCF Endpoint	106	74.383 (11.1442)	74.670 [43.33, 109.33]	0.317 (6.5353)	-0.835 [-27.67, 16.33]
Imeglimin 1000 mg bid + Insulin (N = 108)					
Baseline	108	74.855 (10.5550)	74.500 [52.67, 104.67]		
Week 16	108	75.991 (10.9515)	74.500 [50.33, 100.33]	1.136 (8.0318)	1.835 [-20.67, 25.34]
LOCF Endpoint	108	75.991 (10.9515)	74.500 [50.33, 100.33]	1.136 (8.0318)	1.835 [-20.67, 25.34]
Heart Rate (beats/min)					
Placebo + Insulin (N = 107)					
Baseline	107	72.7 (12.73)	73.0 [48, 108]		
Week 16	104	72.5 (11.23)	72.0 [51, 99]	0.2 (8.89)	0.5 [-32, 19]
LOCF Endpoint	106	72.8 (11.53)	72.0 [51, 99]	0.2 (8.85)	1.0 [-32, 19]
Imeglimin 1000 mg bid + Insulin (N = 108)					
Baseline	108	71.6 (11.80)	70.0 [46, 102]		
Week 16	108	71.0 (11.06)	71.5 [47, 102]	-0.7 (7.39)	-1.0 [-29, 17]

Parameter	Observed			Change from baseline	
Treatment Visit	n	Mean (SD)	Median [Min, Max]	Mean (SD)	Median [Min, Max]
LOCF Endpoint	108	71.0 (11.06)	71.5 [47, 102]	-0.7 (7.39)	-1.0 [-29, 17]

- Abbreviations: bid, Twice a day; SD, standard deviation; LOCF, Last Observation Carried Forward

Control No:<<t-s-569-vsign-020db.sas, 2020-03-10T13:28:56>>

Table S-570 Summary of Change from Baseline in Vital Signs at All Visits in 16-Week Double-blind Period in Combination with Insulin Therapy (PXL008-020; Safety Population)

Parameter	Observed			Change from baseline	
Treatment Visit	n	Mean (SD)	Median [Min, Max]	Mean (SD)	Median [Min, Max]
Systolic Blood Pressure (mmHg)					
Placebo + Insulin (N = 107)					
Baseline	107	127.003 (16.2817)	125.670 [95.33, 174.67]		
Week 4	106	125.494 (17.0905)	124.670 [95.00, 164.33]	-1.506 (10.9404)	-0.330 [-35.33, 28.66]
Week 8	105	125.505 (16.4569)	127.000 [82.33, 169.00]	-1.552 (10.1419)	-0.660 [-30.00, 25.66]
Week 12	104	125.959 (16.4242)	125.500 [90.33, 162.33]	-1.176 (9.6229)	-1.330 [-23.34, 30.00]
Week 16	104	127.253 (16.4098)	127.165 [86.67, 174.00]	0.118 (9.8316)	-0.670 [-25.00, 27.33]
LOCF Endpoint	106	126.673 (16.7832)	126.835 [86.67, 174.00]	-0.327 (10.1950)	-1.165 [-25.67, 27.33]
Imeglimin 1000 mg bid + Insulin (N = 108)					
Baseline	108	127.522 (14.2384)	127.000 [86.33, 162.67]		
Week 4	108	126.043 (12.9651)	126.165 [85.33, 169.00]	-1.479 (9.1692)	-0.165 [-28.34, 19.00]
Week 8	108	128.367 (13.5430)	128.500 [92.33, 155.33]	0.845 (10.7300)	1.165 [-30.34, 31.66]
Week 12	108	128.370 (14.4938)	128.835 [83.67, 161.33]	0.848 (11.3490)	1.165 [-23.34, 41.33]
Week 16	108	130.256 (16.0958)	129.335 [80.67, 172.67]	2.735 (11.3795)	4.330 [-37.00, 29.66]
LOCF Endpoint	108	130.256 (16.0958)	129.335 [80.67, 172.67]	2.735 (11.3795)	4.330 [-37.00, 29.66]
Diastolic Blood Pressure (mmHg)					
Placebo + Insulin (N = 107)					
Baseline	107	74.094 (10.7539)	73.330 [49.67, 97.00]		
Week 4	106	73.075 (11.1216)	71.335 [49.33, 96.33]	-0.991 (6.4836)	-0.665 [-27.67, 13.00]
Week 8	105	72.654 (10.3523)	71.330 [50.33, 94.67]	-1.302 (6.0634)	-1.000 [-17.33, 16.66]
Week 12	104	73.435 (11.2608)	73.000 [49.00, 98.33]	-0.651 (5.8283)	0.165 [-15.67, 12.00]
Week 16	104	74.644 (11.0793)	74.670 [43.33, 109.33]	0.557 (5.9751)	-0.835 [-11.67, 16.33]
LOCF Endpoint	106	74.383 (11.1442)	74.670 [43.33, 109.33]	0.317 (6.5353)	-0.835 [-27.67, 16.33]
Imeglimin 1000 mg bid + Insulin (N = 108)					
Baseline	108	74.855 (10.5550)	74.500 [52.67, 104.67]		
Week 4	108	73.991 (10.3810)	73.165 [52.33, 101.67]	-0.864 (6.4373)	-0.670 [-14.33, 16.67]
Week 8	108	75.065 (9.1815)	75.000 [57.67, 100.00]	0.210 (6.8498)	0.165 [-24.00, 18.00]

Parameter	Observed			Change from baseline	
Treatment Visit	n	Mean (SD)	Median [Min, Max]	Mean (SD)	Median [Min, Max]
Week 12	108	74.530 (9.7481)	74.665 [54.33, 98.33]	-0.325 (7.6066)	-0.165 [-20.67, 17.67]
Week 16	108	75.991 (10.9515)	74.500 [50.33, 100.33]	1.136 (8.0318)	1.835 [-20.67, 25.34]
LOCF Endpoint	108	75.991 (10.9515)	74.500 [50.33, 100.33]	1.136 (8.0318)	1.835 [-20.67, 25.34]
Heart Rate (beats/min)					
Placebo + Insulin (N = 107)					
Baseline	107	72.7 (12.73)	73.0 [48, 108]		
Week 4	106	72.7 (11.97)	72.0 [47, 101]	0.1 (6.91)	0.0 [-24, 25]
Week 8	105	73.0 (11.52)	72.0 [44, 98]	0.4 (8.32)	0.0 [-29, 20]
Week 12	104	72.8 (11.27)	71.5 [50, 108]	0.5 (8.20)	0.0 [-24, 27]
Week 16	104	72.5 (11.23)	72.0 [51, 99]	0.2 (8.89)	0.5 [-32, 19]
LOCF Endpoint	106	72.8 (11.53)	72.0 [51, 99]	0.2 (8.85)	1.0 [-32, 19]
Imeglimin 1000 mg bid + Insulin (N = 108)					
Baseline	108	71.6 (11.80)	70.0 [46, 102]		
Week 4	108	71.0 (11.42)	69.5 [41, 111]	-0.6 (7.06)	0.0 [-31, 26]
Week 8	108	71.2 (11.88)	70.0 [48, 103]	-0.5 (7.79)	0.0 [-26, 27]
Week 12	108	71.1 (11.34)	71.0 [47, 107]	-0.6 (7.34)	0.0 [-24, 20]
Week 16	108	71.0 (11.06)	71.5 [47, 102]	-0.7 (7.39)	-1.0 [-29, 17]
LOCF Endpoint	108	71.0 (11.06)	71.5 [47, 102]	-0.7 (7.39)	-1.0 [-29, 17]

- Abbreviations: bid, Twice a day; SD, standard deviation; LOCF, Last Observation Carried Forward

Control No:<<t-s-570-vsign-020db.sas, 2020-03-10T13:29:10>>

Table S-571 Summary of Change from Baseline in Vital Signs to Week 52 in 52-Week Long-term Period in Combination with Insulin Therapy (PXL008-020; Long-term Safety Population)

Parameter	Observed			Change from baseline	
Treatment Visit	n	Mean (SD)	Median [Min, Max]	Mean (SD)	Median [Min, Max]
Systolic Blood Pressure (mmHg)					
Placebo/Imeglimin + Insulin (N = 101)					
Baseline	101	127.337 (16.3648)	127.330 [86.67, 174.00]		
Week 36	98	128.150 (16.1061)	125.670 [91.67, 167.67]	0.602 (10.0898)	0.995 [-26.67, 20.66]
LOCF Endpoint	101	128.142 (16.0273)	125.670 [91.67, 167.67]	0.806 (10.1692)	1.330 [-26.67, 20.66]
Imeglimin/Imeglimin + Insulin (N = 108)					
Baseline	108	127.522 (14.2384)	127.000 [86.33, 162.67]		
Week 36	108	128.701 (14.7398)	128.500 [93.33, 160.33]	1.179 (11.6537)	0.335 [-42.67, 34.00]
Week 52	107	128.579 (13.8632)	127.330 [97.33, 159.33]	1.236 (11.8689)	0.340 [-30.34, 31.00]
LOCF Endpoint	108	128.691 (13.8472)	127.330 [97.33, 159.33]	1.169 (11.8338)	0.335 [-30.34, 31.00]
Imeglimin + Insulin Total (N = 209)					
Baseline	209	127.432 (15.2660)	127.000 [86.33, 174.00]		
Week 36	206	128.439 (15.3694)	127.835 [91.67, 167.67]	0.905 (10.9151)	0.500 [-42.67, 34.00]
Week 52	107	128.579 (13.8632)	127.330 [97.33, 159.33]	1.236 (11.8689)	0.340 [-30.34, 31.00]
LOCF Endpoint	209	128.426 (14.9067)	127.330 [91.67, 167.67]	0.994 (11.0358)	0.660 [-30.34, 31.00]
Diastolic Blood Pressure (mmHg)					
Placebo/Imeglimin + Insulin (N = 101)					
Baseline	101	74.587 (11.0159)	74.670 [43.33, 109.33]		
Week 36	98	75.660 (11.4649)	74.670 [49.67, 105.00]	0.851 (6.2995)	1.505 [-15.33, 10.67]
LOCF Endpoint	101	75.469 (11.3604)	74.330 [49.67, 105.00]	0.882 (6.2243)	1.340 [-15.33, 10.67]
Imeglimin/Imeglimin + Insulin (N = 108)					
Baseline	108	74.855 (10.5550)	74.500 [52.67, 104.67]		
Week 36	108	76.284 (9.4278)	77.165 [57.67, 96.00]	1.429 (7.6830)	1.165 [-20.67, 29.33]
Week 52	107	75.610 (10.2281)	75.670 [56.33, 95.67]	0.903 (7.7347)	0.670 [-21.34, 21.33]
LOCF Endpoint	108	75.608 (10.1802)	75.500 [56.33, 95.67]	0.753 (7.8556)	0.670 [-21.34, 21.33]
Imeglimin + Insulin Total (N = 209)					

Parameter	Observed			Change from baseline	
Treatment Visit	n	Mean (SD)	Median [Min, Max]	Mean (SD)	Median [Min, Max]
Baseline	209	74.726 (10.7550)	74.670 [43.33, 109.33]		
Week 36	206	75.987 (10.4252)	75.500 [49.67, 105.00]	1.154 (7.0477)	1.340 [-20.67, 29.33]
Week 52	107	75.610 (10.2281)	75.670 [56.33, 95.67]	0.903 (7.7347)	0.670 [-21.34, 21.33]
LOCF Endpoint	209	75.541 (10.7408)	75.000 [49.67, 105.00]	0.815 (7.0975)	1.000 [-21.34, 21.33]
Heart Rate (beats/min)					
Placebo/Imeglimin + Insulin (N = 101)					
Baseline	101	72.4 (11.31)	72.0 [51, 99]		
Week 36	98	73.1 (11.19)	73.0 [48, 108]	0.4 (7.91)	0.0 [-16, 36]
LOCF Endpoint	101	72.8 (11.16)	72.0 [48, 108]	0.4 (7.82)	0.0 [-16, 36]
Imeglimin/Imeglimin + Insulin (N = 108)					
Baseline	108	71.6 (11.80)	70.0 [46, 102]		
Week 36	108	71.5 (11.77)	70.0 [47, 101]	-0.1 (7.31)	0.0 [-21, 24]
Week 52	107	72.1 (11.32)	71.0 [46, 98]	0.4 (7.64)	1.0 [-26, 21]
LOCF Endpoint	108	72.0 (11.38)	71.0 [46, 98]	0.3 (7.64)	1.0 [-26, 21]
Imeglimin + Insulin Total (N = 209)					
Baseline	209	72.0 (11.55)	72.0 [46, 102]		
Week 36	206	72.3 (11.50)	72.0 [47, 108]	0.2 (7.59)	0.0 [-21, 36]
Week 52	107	72.1 (11.32)	71.0 [46, 98]	0.4 (7.64)	1.0 [-26, 21]
LOCF Endpoint	209	72.4 (11.25)	72.0 [46, 108]	0.4 (7.71)	0.0 [-26, 36]

- Abbreviations: SD, standard deviation; LOCF, Last Observation Carried Forward
- "Imeglimin" in this table means "Imeglimin 1000 mg twice daily".
- The Long-term Safety Population excludes data during administration of placebo in the double-blind period.
- "Imeglimin + Insulin Total" is the sum of subjects in the placebo group in the open-label period and Imeglimin group in the double-blind and open-label periods.
- For "Placebo/Imeglimin + Insulin" group, baseline was defined as last visit with non-missing value prior to or at the day of first dose of Investigational Medicinal Product (IMP) in open-label treatment period. For "Imeglimin/Imeglimin + Insulin" group, baseline was the same as for the double-blind treatment period.

Control No:<<t-s-571-vsign-020lt.sas, 2020-03-10T13:29:25>>

Table S-572 Summary of Change from Baseline in Vital Signs at All Visits in 52-Week Long-term Period in Combination with Insulin Therapy (PXL008-020; Long-term Safety Population)

Parameter	Observed			Change from baseline	
Treatment Visit	n	Mean (SD)	Median [Min, Max]	Mean (SD)	Median [Min, Max]
Systolic Blood Pressure (mmHg)					
Placebo/Imeglimin + Insulin (N = 101)					
Baseline	101	127.337 (16.3648)	127.330 [86.67, 174.00]		
Week 4	101	127.317 (17.3885)	126.330 [82.33, 179.33]	-0.020 (10.5369)	0.670 [-29.33, 36.66]
Week 8	101	128.410 (17.8923)	128.670 [91.00, 181.67]	1.073 (10.3129)	0.670 [-24.00, 28.34]
Week 12	101	128.472 (16.9075)	127.000 [89.33, 171.67]	1.135 (8.8897)	1.340 [-24.00, 20.00]
Week 16	99	127.734 (17.7748)	127.330 [87.00, 176.33]	0.336 (9.5689)	1.000 [-26.34, 22.33]
Week 20	99	128.667 (16.7125)	127.000 [92.00, 170.33]	1.269 (11.2463)	1.670 [-24.66, 31.66]
Week 24	99	128.114 (17.1220)	128.330 [85.33, 172.67]	0.717 (11.2262)	1.330 [-34.67, 25.33]
Week 28	98	129.010 (17.1257)	130.500 [92.00, 175.67]	1.810 (11.5165)	1.670 [-35.66, 26.33]
Week 32	98	128.095 (16.0771)	129.000 [88.00, 163.33]	0.548 (10.9249)	0.000 [-24.67, 31.00]
Week 36	98	128.150 (16.1061)	125.670 [91.67, 167.67]	0.602 (10.0898)	0.995 [-26.67, 20.66]
LOCF Endpoint	101	128.142 (16.0273)	125.670 [91.67, 167.67]	0.806 (10.1692)	1.330 [-26.67, 20.66]
Imeglimin/Imeglimin + Insulin (N = 108)					
Baseline	108	127.522 (14.2384)	127.000 [86.33, 162.67]		
Week 4	108	126.043 (12.9651)	126.165 [85.33, 169.00]	-1.479 (9.1692)	-0.165 [-28.34, 19.00]
Week 8	108	128.367 (13.5430)	128.500 [92.33, 155.33]	0.845 (10.7300)	1.165 [-30.34, 31.66]
Week 12	108	128.370 (14.4938)	128.835 [83.67, 161.33]	0.848 (11.3490)	1.165 [-23.34, 41.33]
Week 16	108	130.256 (16.0958)	129.335 [80.67, 172.67]	2.735 (11.3795)	4.330 [-37.00, 29.66]
Week 20	108	129.062 (13.9803)	129.670 [91.33, 172.67]	1.540 (11.1213)	1.835 [-30.00, 30.00]
Week 24	108	128.880 (14.2715)	129.330 [93.00, 165.00]	1.358 (11.4617)	2.160 [-38.67, 31.33]
Week 28	108	128.951 (15.8890)	129.335 [85.33, 171.00]	1.429 (12.7556)	0.670 [-49.34, 33.34]
Week 32	108	129.142 (14.8394)	128.165 [96.67, 162.00]	1.620 (12.1898)	-0.165 [-29.67, 39.00]
Week 36	108	128.701 (14.7398)	128.500 [93.33, 160.33]	1.179 (11.6537)	0.335 [-42.67, 34.00]
Week 40	107	129.380 (14.5037)	129.330 [91.33, 164.67]	2.037 (11.7386)	2.670 [-47.00, 32.67]
Week 44	107	129.068 (13.8638)	127.670 [93.67, 164.67]	1.726 (12.5518)	2.000 [-49.67, 34.00]

Parameter Treatment Visit	Observed n	Mean (SD)	Median [Min, Max]	Change from baseline Mean (SD)	Median [Min, Max]
Week 48	107	129.277 (14.7349)	127.670 [94.00, 159.00]	1.934 (10.9025)	1.330 [-31.67, 33.67]
Week 52	107	128.579 (13.8632)	127.330 [97.33, 159.33]	1.236 (11.8689)	0.340 [-30.34, 31.00]
LOCF Endpoint	108	128.691 (13.8472)	127.330 [97.33, 159.33]	1.169 (11.8338)	0.335 [-30.34, 31.00]
Imeglimin + Insulin Total (N = 209)					
Baseline	209	127.432 (15.2660)	127.000 [86.33, 174.00]		
Week 4	209	126.659 (15.2396)	126.330 [82.33, 179.33]	-0.774 (9.8570)	0.000 [-29.33, 36.66]
Week 8	209	128.388 (15.7564)	128.670 [91.00, 181.67]	0.955 (10.5059)	1.000 [-30.34, 31.66]
Week 12	209	128.419 (15.6685)	128.670 [83.67, 171.67]	0.987 (10.2114)	1.330 [-24.00, 41.33]
Week 16	207	129.050 (16.9253)	127.670 [80.67, 176.33]	1.588 (10.5954)	2.000 [-37.00, 29.66]
Week 20	207	128.873 (15.3112)	128.330 [91.33, 172.67]	1.411 (11.1549)	1.670 [-30.00, 31.66]
Week 24	207	128.514 (15.6654)	128.670 [85.33, 172.67]	1.051 (11.3267)	1.330 [-38.67, 31.33]
Week 28	206	128.979 (16.4484)	130.165 [85.33, 175.67]	1.610 (12.1539)	1.165 [-49.34, 33.34]
Week 32	206	128.644 (15.4115)	128.330 [88.00, 163.33]	1.110 (11.5897)	-0.165 [-29.67, 39.00]
Week 36	206	128.439 (15.3694)	127.835 [91.67, 167.67]	0.905 (10.9151)	0.500 [-42.67, 34.00]
Week 40	107	129.380 (14.5037)	129.330 [91.33, 164.67]	2.037 (11.7386)	2.670 [-47.00, 32.67]
Week 44	107	129.068 (13.8638)	127.670 [93.67, 164.67]	1.726 (12.5518)	2.000 [-49.67, 34.00]
Week 48	107	129.277 (14.7349)	127.670 [94.00, 159.00]	1.934 (10.9025)	1.330 [-31.67, 33.67]
Week 52	107	128.579 (13.8632)	127.330 [97.33, 159.33]	1.236 (11.8689)	0.340 [-30.34, 31.00]
LOCF Endpoint	209	128.426 (14.9067)	127.330 [91.67, 167.67]	0.994 (11.0358)	0.660 [-30.34, 31.00]
Diastolic Blood Pressure (mmHg)					
Placebo/Imeglimin + Insulin (N = 101)					
Baseline	101	74.587 (11.0159)	74.670 [43.33, 109.33]		
Week 4	101	73.218 (11.2281)	73.000 [48.67, 97.00]	-1.369 (6.6608)	-1.000 [-28.67, 12.67]
Week 8	101	74.304 (11.1346)	74.000 [50.00, 99.00]	-0.283 (7.0279)	0.000 [-18.00, 15.34]
Week 12	101	75.135 (10.7203)	74.330 [47.33, 104.00]	0.548 (6.5679)	0.000 [-16.00, 16.34]
Week 16	99	74.343 (12.1381)	73.000 [44.33, 109.00]	-0.367 (6.9713)	0.330 [-20.67, 13.33]
Week 20	99	76.024 (11.3390)	76.000 [48.33, 110.33]	1.314 (6.9677)	0.670 [-18.67, 25.34]

Parameter	Observed			Change from baseline	
Treatment Visit	n	Mean (SD)	Median [Min, Max]	Mean (SD)	Median [Min, Max]
Week 24	99	74.435 (11.6929)	74.330 [49.33, 107.00]	-0.275 (7.6506)	0.670 [-27.34, 14.67]
Week 28	98	75.224 (11.0254)	74.500 [51.33, 100.33]	0.734 (6.4354)	0.835 [-13.67, 16.00]
Week 32	98	75.357 (11.6596)	74.835 [46.33, 104.67]	0.548 (6.5280)	0.000 [-13.67, 19.00]
Week 36	98	75.660 (11.4649)	74.670 [49.67, 105.00]	0.851 (6.2995)	1.505 [-15.33, 10.67]
LOCF Endpoint	101	75.469 (11.3604)	74.330 [49.67, 105.00]	0.882 (6.2243)	1.340 [-15.33, 10.67]
Imeglimin/Imeglimin + Insulin (N = 108)					
Baseline	108	74.855 (10.5550)	74.500 [52.67, 104.67]		
Week 4	108	73.991 (10.3810)	73.165 [52.33, 101.67]	-0.864 (6.4373)	-0.670 [-14.33, 16.67]
Week 8	108	75.065 (9.1815)	75.000 [57.67, 100.00]	0.210 (6.8498)	0.165 [-24.00, 18.00]
Week 12	108	74.530 (9.7481)	74.665 [54.33, 98.33]	-0.325 (7.6066)	-0.165 [-20.67, 17.67]
Week 16	108	75.991 (10.9515)	74.500 [50.33, 100.33]	1.136 (8.0318)	1.835 [-20.67, 25.34]
Week 20	108	76.001 (10.1825)	76.500 [49.00, 97.33]	1.146 (8.4776)	0.505 [-26.00, 23.33]
Week 24	108	75.938 (10.4164)	76.000 [56.00, 97.33]	1.083 (7.8962)	1.495 [-22.00, 30.33]
Week 28	108	75.569 (9.8156)	76.000 [50.67, 95.67]	0.714 (7.6232)	1.000 [-24.34, 23.00]
Week 32	108	75.796 (9.9519)	75.835 [53.00, 97.33]	0.941 (8.6801)	1.000 [-28.67, 31.67]
Week 36	108	76.284 (9.4278)	77.165 [57.67, 96.00]	1.429 (7.6830)	1.165 [-20.67, 29.33]
Week 40	107	75.595 (10.4229)	76.000 [55.67, 100.67]	0.888 (7.3590)	0.670 [-24.00, 21.33]
Week 44	107	75.679 (10.2345)	75.670 [54.00, 98.00]	0.972 (7.7344)	0.000 [-22.33, 26.00]
Week 48	107	75.667 (10.3893)	75.670 [56.33, 99.00]	0.960 (7.2545)	0.670 [-25.34, 22.66]
Week 52	107	75.610 (10.2281)	75.670 [56.33, 95.67]	0.903 (7.7347)	0.670 [-21.34, 21.33]
LOCF Endpoint	108	75.608 (10.1802)	75.500 [56.33, 95.67]	0.753 (7.8556)	0.670 [-21.34, 21.33]
Imeglimin + Insulin Total (N = 209)					
Baseline	209	74.726 (10.7550)	74.670 [43.33, 109.33]		
Week 4	209	73.617 (10.7795)	73.000 [48.67, 101.67]	-1.108 (6.5354)	-0.670 [-28.67, 16.67]
Week 8	209	74.697 (10.1546)	74.330 [50.00, 100.00]	-0.029 (6.9241)	0.000 [-24.00, 18.00]
Week 12	209	74.823 (10.2092)	74.330 [47.33, 104.00]	0.097 (7.1200)	0.000 [-20.67, 17.67]
Week 16	207	75.203 (11.5355)	74.000 [44.33, 109.00]	0.417 (7.5626)	1.000 [-20.67, 25.34]

Parameter	Observed			Change from baseline	
Treatment Visit	n	Mean (SD)	Median [Min, Max]	Mean (SD)	Median [Min, Max]
Week 20	207	76.012 (10.7248)	76.000 [48.33, 110.33]	1.226 (7.7739)	0.670 [-26.00, 25.34]
Week 24	207	75.219 (11.0439)	75.670 [49.33, 107.00]	0.434 (7.7906)	1.000 [-27.34, 30.33]
Week 28	206	75.405 (10.3844)	75.500 [50.67, 100.33]	0.723 (7.0660)	1.000 [-24.34, 23.00]
Week 32	206	75.587 (10.7735)	75.670 [46.33, 104.67]	0.754 (7.7155)	0.500 [-28.67, 31.67]
Week 36	206	75.987 (10.4252)	75.500 [49.67, 105.00]	1.154 (7.0477)	1.340 [-20.67, 29.33]
Week 40	107	75.595 (10.4229)	76.000 [55.67, 100.67]	0.888 (7.3590)	0.670 [-24.00, 21.33]
Week 44	107	75.679 (10.2345)	75.670 [54.00, 98.00]	0.972 (7.7344)	0.000 [-22.33, 26.00]
Week 48	107	75.667 (10.3893)	75.670 [56.33, 99.00]	0.960 (7.2545)	0.670 [-25.34, 22.66]
Week 52	107	75.610 (10.2281)	75.670 [56.33, 95.67]	0.903 (7.7347)	0.670 [-21.34, 21.33]
LOCF Endpoint	209	75.541 (10.7408)	75.000 [49.67, 105.00]	0.815 (7.0975)	1.000 [-21.34, 21.33]
Heart Rate (beats/min)					
Placebo/Imeglimin + Insulin (N = 101)					
Baseline	101	72.4 (11.31)	72.0 [51, 99]		
Week 4	101	73.0 (12.53)	72.0 [46, 108]	0.6 (8.88)	0.0 [-20, 27]
Week 8	101	73.0 (12.22)	74.0 [44, 105]	0.6 (8.89)	0.0 [-33, 36]
Week 12	101	73.9 (12.41)	73.0 [45, 107]	1.5 (7.82)	0.0 [-16, 30]
Week 16	99	72.6 (11.46)	72.0 [45, 104]	0.1 (7.11)	0.0 [-29, 23]
Week 20	99	73.2 (12.15)	72.0 [48, 109]	0.6 (7.47)	0.0 [-12, 31]
Week 24	99	73.7 (12.20)	72.0 [47, 106]	1.2 (8.62)	0.0 [-17, 30]
Week 28	98	73.2 (12.17)	72.5 [52, 120]	0.6 (9.45)	0.0 [-18, 48]
Week 32	98	73.7 (11.74)	73.0 [48, 105]	1.1 (7.74)	0.0 [-17, 33]
Week 36	98	73.1 (11.19)	73.0 [48, 108]	0.4 (7.91)	0.0 [-16, 36]
LOCF Endpoint	101	72.8 (11.16)	72.0 [48, 108]	0.4 (7.82)	0.0 [-16, 36]
Imeglimin/Imeglimin + Insulin (N = 108)					
Baseline	108	71.6 (11.80)	70.0 [46, 102]		
Week 4	108	71.0 (11.42)	69.5 [41, 111]	-0.6 (7.06)	0.0 [-31, 26]
Week 8	108	71.2 (11.88)	70.0 [48, 103]	-0.5 (7.79)	0.0 [-26, 27]
Week 12	108	71.1 (11.34)	71.0 [47, 107]	-0.6 (7.34)	0.0 [-24, 20]
Week 16	108	71.0 (11.06)	71.5 [47, 102]	-0.7 (7.39)	-1.0 [-29, 17]
Week 20	108	72.8 (11.47)	72.0 [42, 105]	1.1 (8.72)	1.0 [-32, 26]
Week 24	108	73.0 (10.57)	72.0 [46, 102]	1.3 (7.78)	1.5 [-27, 22]
Week 28	108	72.4 (10.74)	70.5 [47, 93]	0.7 (8.75)	1.0 [-30, 25]
Week 32	108	71.5 (10.90)	71.0 [46, 104]	-0.2 (9.40)	0.0 [-30, 31]
Week 36	108	71.5 (11.77)	70.0 [47, 101]	-0.1 (7.31)	0.0 [-21, 24]
Week 40	107	71.3 (11.26)	70.0 [47, 102]	-0.4 (8.30)	0.0 [-26, 25]
Week 44	107	71.2 (11.12)	72.0 [46, 96]	-0.5 (6.61)	0.0 [-21, 14]
Week 48	107	71.3 (11.22)	70.0 [48, 110]	-0.4 (8.44)	1.0 [-23, 37]
Week 52	107	72.1 (11.32)	71.0 [46, 98]	0.4 (7.64)	1.0 [-26, 21]

Parameter	Observed			Change from baseline	
Treatment Visit	n	Mean (SD)	Median [Min, Max]	Mean (SD)	Median [Min, Max]
LOCF Endpoint	108	72.0 (11.38)	71.0 [46, 98]	0.3 (7.64)	1.0 [-26, 21]
Imeglimin + Insulin Total (N = 209)					
Baseline	209	72.0 (11.55)	72.0 [46, 102]		
Week 4	209	72.0 (11.98)	70.0 [41, 111]	0.0 (8.00)	0.0 [-31, 27]
Week 8	209	72.1 (12.05)	72.0 [44, 105]	0.0 (8.34)	0.0 [-33, 36]
Week 12	209	72.4 (11.93)	72.0 [45, 107]	0.4 (7.63)	0.0 [-24, 30]
Week 16	207	71.7 (11.26)	72.0 [45, 104]	-0.3 (7.25)	-1.0 [-29, 23]
Week 20	207	73.0 (11.77)	72.0 [42, 109]	0.9 (8.13)	1.0 [-32, 31]
Week 24	207	73.3 (11.36)	72.0 [46, 106]	1.3 (8.17)	1.0 [-27, 30]
Week 28	206	72.8 (11.42)	71.5 [47, 120]	0.7 (9.07)	1.0 [-30, 48]
Week 32	206	72.6 (11.34)	72.0 [46, 105]	0.4 (8.65)	0.0 [-30, 33]
Week 36	206	72.3 (11.50)	72.0 [47, 108]	0.2 (7.59)	0.0 [-21, 36]
Week 40	107	71.3 (11.26)	70.0 [47, 102]	-0.4 (8.30)	0.0 [-26, 25]
Week 44	107	71.2 (11.12)	72.0 [46, 96]	-0.5 (6.61)	0.0 [-21, 14]
Week 48	107	71.3 (11.22)	70.0 [48, 110]	-0.4 (8.44)	1.0 [-23, 37]
Week 52	107	72.1 (11.32)	71.0 [46, 98]	0.4 (7.64)	1.0 [-26, 21]
LOCF Endpoint	209	72.4 (11.25)	72.0 [46, 108]	0.4 (7.71)	0.0 [-26, 36]

- Abbreviations: SD, standard deviation; LOCF, Last Observation Carried Forward
- "Imeglimin" in this table means "Imeglimin 1000 mg twice daily".
- The Long-term Safety Population excludes data during administration of placebo in the double-blind period.
- "Imeglimin + Insulin Total" is the sum of subjects in the placebo group in the open-label period and Imeglimin group in the double-blind and open-label periods.
- For "Placebo/Imeglimin + Insulin" group, baseline was defined as last visit with non-missing value prior to or at the day of first dose of Investigational Medicinal Product (IMP) in open-label treatment period. For "Imeglimin/Imeglimin + Insulin" group, baseline was the same as for the double-blind treatment period.

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