Table S-166 Subgroup Analysis of Treatment Emergent Adverse Events by Age, System Organ Class and Preferred Term in 52-Week Long-term Period with Monotherapy and Combination Therapy (PXL008-019; Long-term Safety Population)

System Organ Class Preferred Term Age	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											
< 65 years	86	76	42	47	41	44	28	46	45	369	455
>= 65 years	48	51	22	17	23	21	35	24	18	211	259
< 75 years	127	122	61	61	62	61	58	67	61	553	680
>= 75 years	7	5	3	3	2	4	5	3	2	27	34
Any TEAE											
< 65 years	58 (67.4%)	60 (78.9%)	34 (81.0%)	35 (74.5%)	19 (46.3%)	34 (77.3%)	23 (82.1%)	35 (76.1%)	33 (73.3%)	273 (74.0%)	331 (72.7%)
>= 65 years	40 (83.3%)	42 (82.4%)	20 (90.9%)	13 (76.5%)	14 (60.9%)	16 (76.2%)	27 (77.1%)	21 (87.5%)	15 (83.3%)	168 (79.6%)	208 (80.3%)
< 75 years	92 (72.4%)	99 (81.1%)	51 (83.6%)	46 (75.4%)	31 (50.0%)	47 (77.0%)	47 (81.0%)	53 (79.1%)	46 (75.4%)	420 (75.9%)	512 (75.3%)
>= 75 years	6 (85.7%)	3 (60.0%)	3 (100.0%)	2 (66.7%)	2 (100.0%)	3 (75.0%)	3 (60.0%)	3 (100.0%)	2 (100.0%)	21 (77.8%)	27 (79.4%)
Infections and infestations (感染症および寄生虫症)											
< 65 years	39 (45.3%)	35 (46.1%)	22 (52.4%)	23 (48.9%)	9 (22.0%)	23 (52.3%)	11 (39.3%)	20 (43.5%)	20 (44.4%)	163 (44.2%)	202 (44.4%)
>= 65 years	18 (37.5%)	22 (43.1%)	15 (68.2%)	5 (29.4%)	4 (17.4%)	9 (42.9%)	17 (48.6%)	10 (41.7%)	9 (50.0%)	91 (43.1%)	109 (42.1%)
< 75 years	53 (41.7%)	56 (45.9%)	35 (57.4%)	27 (44.3%)	12 (19.4%)	30 (49.2%)	26 (44.8%)	29 (43.3%)	27 (44.3%)	242 (43.8%)	295 (43.4%)
>= 75 years	4 (57.1%)	1 (20.0%)	2 (66.7%)	1 (33.3%)	1 (50.0%)	2 (50.0%)	2 (40.0%)	1 (33.3%)	2 (100.0%)	12 (44.4%)	16 (47.1%)
Nasopharyngitis (上咽頭炎)											
< 65 years	28 (32.6%)	22 (28.9%)	17 (40.5%)	12 (25.5%)	5 (12.2%)	14 (31.8%)	7 (25.0%)	13 (28.3%)	13 (28.9%)	103 (27.9%)	131 (28.8%)
>= 65 years	12 (25.0%)	17 (33.3%)	10 (45.5%)	4 (23.5%)	0	4 (19.0%)	12 (34.3%)	7 (29.2%)	7 (38.9%)	61 (28.9%)	73 (28.2%)
< 75 years	38 (29.9%)	38 (31.1%)	26 (42.6%)	15 (24.6%)	5 (8.1%)	17 (27.9%)	17 (29.3%)	19 (28.4%)	18 (29.5%)	155 (28.0%)	193 (28.4%)
>= 75 years	2 (28.6%)	1 (20.0%)	1 (33.3%)	1 (33.3%)	0	1 (25.0%)	2 (40.0%)	1 (33.3%)	2 (100.0%)	9 (33.3%)	11 (32.4%)
Pharyngitis (咽頭炎)											
< 65 years	5 (5.8%)	3 (3.9%)	3 (7.1%)	0	2 (4.9%)	2 (4.5%)	1 (3.6%)	1 (2.2%)	4 (8.9%)	16 (4.3%)	21 (4.6%)
>= 65 years	3 (6.3%)	2 (3.9%)	1 (4.5%)	0	0	1 (4.8%)	2 (5.7%)	0	1 (5.6%)	7 (3.3%)	10 (3.9%)
< 75 years	8 (6.3%)	5 (4.1%)	4 (6.6%)	0	2 (3.2%)	2 (3.3%)	3 (5.2%)	1 (1.5%)	5 (8.2%)	22 (4.0%)	30 (4.4%)

System Organ Class Preferred Term Age	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
>= 75 years	0	0	0	0	0	1 (25.0%)	0	0	0	1 (3.7%)	1 (2.9%)
Influenza (インフルエンザ)											
< 65 years	1 (1.2%)	5 (6.6%)	0	3 (6.4%)	0	2 (4.5%)	1 (3.6%)	1 (2.2%)	2 (4.4%)	14 (3.8%)	15 (3.3%)
>= 65 years	3 (6.3%)	4 (7.8%)	2 (9.1%)	2 (11.8%)	1 (4.3%)	1 (4.8%)	0	0	0	10 (4.7%)	13 (5.0%)
< 75 years	3 (2.4%)	9 (7.4%)	1 (1.6%)	4 (6.6%)	1 (1.6%)	3 (4.9%)	1 (1.7%)	1 (1.5%)	2 (3.3%)	22 (4.0%)	25 (3.7%)
>= 75 years	1 (14.3%)	0	1 (33.3%)	1 (33.3%)	0	0	0	0	0	2 (7.4%)	3 (8.8%)
Bronchitis (気管支炎)											
< 65 years	1 (1.2%)	1 (1.3%)	2 (4.8%)	2 (4.3%)	0	4 (9.1%)	0	0	2 (4.4%)	11 (3.0%)	12 (2.6%)
>= 65 years	0	0	2 (9.1%)	0	0	0	0	0	0	2 (0.9%)	2 (0.8%)
< 75 years	1 (0.8%)	1 (0.8%)	4 (6.6%)	2 (3.3%)	0	4 (6.6%)	0	0	2 (3.3%)	13 (2.4%)	14 (2.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Gastroenteritis (胃腸炎)											
< 65 years	2 (2.3%)	0	3 (7.1%)	3 (6.4%)	1 (2.4%)	1 (2.3%)	1 (3.6%)	1 (2.2%)	1 (2.2%)	11 (3.0%)	13 (2.9%)
>= 65 years	0	0	0	0	0	0	0	1 (4.2%)	0	1 (0.5%)	1 (0.4%)
< 75 years	2 (1.6%)	0	3 (4.9%)	3 (4.9%)	1 (1.6%)	1 (1.6%)	1 (1.7%)	2 (3.0%)	1 (1.6%)	12 (2.2%)	14 (2.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Periodontitis (歯周炎)											
< 65 years	0	3 (3.9%)	0	2 (4.3%)	0	1 (2.3%)	1 (3.6%)	1 (2.2%)	0	8 (2.2%)	8 (1.8%)
>= 65 years	0	0	1 (4.5%)	0	0	2 (9.5%)	1 (2.9%)	0	0	4 (1.9%)	4 (1.5%)
< 75 years	0	3 (2.5%)	1 (1.6%)	2 (3.3%)	0	3 (4.9%)	2 (3.4%)	1 (1.5%)	0	12 (2.2%)	12 (1.8%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Cystitis (膀胱炎)											
< 65 years	1 (1.2%)	0	1 (2.4%)	0	0	1 (2.3%)	0	1 (2.2%)	0	3 (0.8%)	4 (0.9%)
>= 65 years	0	2 (3.9%)	1 (4.5%)	0	0	0	2 (5.7%)	1 (4.2%)	1 (5.6%)	7 (3.3%)	7 (2.7%)
< 75 years	1 (0.8%)	2 (1.6%)	2 (3.3%)	0	0	1 (1.6%)	1 (1.7%)	2 (3.0%)	1 (1.6%)	9 (1.6%)	10 (1.5%)
>= 75 years	0	0	0	0	0	0	1 (20.0%)	0	0	1 (3.7%)	1 (2.9%)
Herpes zoster (帯状疱疹)											

System Organ Class Preferred Term Age	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
< 65 years	0	1 (1.3%)	0	0	0	1 (2.3%)	1 (3.6%)	1 (2.2%)	1 (2.2%)	5 (1.4%)	5 (1.1%)
>= 65 years	2 (4.2%)	0	1 (4.5%)	0	0	0	0	0	1 (5.6%)	2 (0.9%)	4 (1.5%)
< 75 years	1 (0.8%)	1 (0.8%)	1 (1.6%)	0	0	1 (1.6%)	1 (1.7%)	1 (1.5%)	2 (3.3%)	7 (1.3%)	8 (1.2%)
>= 75 years	1 (14.3%)	0	0	0	0	0	0	0	0	0	1 (2.9%)
Upper respiratory tract infection (上気道感染)											
< 65 years	2 (2.3%)	1 (1.3%)	0	0	0	0	2 (7.1%)	0	1 (2.2%)	4 (1.1%)	6 (1.3%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	2 (1.6%)	1 (0.8%)	0	0	0	0	2 (3.4%)	0	1 (1.6%)	4 (0.7%)	6 (0.9%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Pneumonia (肺炎)											
< 65 years	0	0	0	1 (2.1%)	0	1 (2.3%)	0	0	1 (2.2%)	3 (0.8%)	3 (0.7%)
>= 65 years	0	1 (2.0%)	1 (4.5%)	0	0	0	0	0	0	2 (0.9%)	2 (0.8%)
< 75 years	0	1 (0.8%)	1 (1.6%)	1 (1.6%)	0	1 (1.6%)	0	0	1 (1.6%)	5 (0.9%)	5 (0.7%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Tinea pedis (足部白癬)											
< 65 years	0	0	0	0	0	0	0	1 (2.2%)	1 (2.2%)	2 (0.5%)	2 (0.4%)
>= 65 years	0	1 (2.0%)	0	0	1 (4.3%)	0	1 (2.9%)	0	0	3 (1.4%)	3 (1.2%)
< 75 years	0	1 (0.8%)	0	0	1 (1.6%)	0	1 (1.7%)	1 (1.5%)	1 (1.6%)	5 (0.9%)	5 (0.7%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Urinary tract infection (尿路感染)											
< 65 years	0	0	0	0	2 (4.9%)	0	0	0	0	2 (0.5%)	2 (0.4%)
>= 65 years	0	0	0	0	1 (4.3%)	2 (9.5%)	0	0	0	3 (1.4%)	3 (1.2%)
< 75 years	0	0	0	0	3 (4.8%)	1 (1.6%)	0	0	0	4 (0.7%)	4 (0.6%)
>= 75 years	0	0	0	0	0	1 (25.0%)	0	0	0	1 (3.7%)	1 (2.9%)
Conjunctivitis (結膜炎)											
< 65 years	0	2 (2.6%)	0	0	0	1 (2.3%)	0	0	0	3 (0.8%)	3 (0.7%)

System Organ Class Preferred Term Age	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
>= 65 years	1 (2.1%)	0	0	0	0	0	0	0	0	0	1 (0.4%)
< 75 years	1 (0.8%)	2 (1.6%)	0	0	0	1 (1.6%)	0	0	0	3 (0.5%)	4 (0.6%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Gingivitis (歯肉炎)											
< 65 years	0	1 (1.3%)	0	0	0	1 (2.3%)	0	2 (4.3%)	0	4 (1.1%)	4 (0.9%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	1 (0.8%)	0	0	0	1 (1.6%)	0	2 (3.0%)	0	4 (0.7%)	4 (0.6%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Otitis externa (外耳炎)											
< 65 years	2 (2.3%)	0	0	0	0	1 (2.3%)	0	0	0	1 (0.3%)	3 (0.7%)
>= 65 years	0	1 (2.0%)	0	0	0	0	0	0	0	1 (0.5%)	1 (0.4%)
< 75 years	2 (1.6%)	1 (0.8%)	0	0	0	1 (1.6%)	0	0	0	2 (0.4%)	4 (0.6%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Pericoronitis (歯冠周囲炎)											
< 65 years	0	0	0	0	1 (2.4%)	0	0	2 (4.3%)	1 (2.2%)	4 (1.1%)	4 (0.9%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	0	0	1 (1.6%)	0	0	2 (3.0%)	1 (1.6%)	4 (0.7%)	4 (0.6%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Dermatophytosis of nail (爪の皮膚糸状菌症)											
< 65 years	0	1 (1.3%)	0	0	0	0	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	1 (2.0%)	0	0	0	1 (4.8%)	0	0	0	2 (0.9%)	2 (0.8%)
< 75 years	0	2 (1.6%)	0	0	0	1 (1.6%)	0	0	0	3 (0.5%)	3 (0.4%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Oral herpes (口腔ヘルペス)											
< 65 years	0	1 (1.3%)	0	0	0	0	1 (3.6%)	0	0	2 (0.5%)	2 (0.4%)
>= 65 years	0	0	1 (4.5%)	0	0	0	0	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	1 (0.8%)	1 (1.6%)	0	0	0	1 (1.7%)	0	0	3 (0.5%)	3 (0.4%)

System Organ Class Preferred Term Age	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
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Sinusitis (副鼻腔炎)											
< 65 years	0	1 (1.3%)	0	1 (2.1%)	0	0	0	0	0	2 (0.5%)	2 (0.4%)
>= 65 years	0	0	0	0	1 (4.3%)	0	0	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	1 (0.8%)	0	1 (1.6%)	0	0	0	0	0	2 (0.4%)	2 (0.3%)
>= 75 years	0	0	0	0	1 (50.0%)	0	0	0	0	1 (3.7%)	1 (2.9%)
Appendicitis (虫垂炎)											
< 65 years	0	0	0	1 (2.1%)	0	0	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	1 (2.1%)	0	0	0	0	0	0	0	0	0	1 (0.4%)
< 75 years	1 (0.8%)	0	0	1 (1.6%)	0	0	0	0	0	1 (0.2%)	2 (0.3%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Asymptomatic bacteriuria (無症候性細菌尿)											
< 65 years	0	1 (1.3%)	0	0	0	0	0	1 (2.2%)	0	2 (0.5%)	2 (0.4%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	1 (0.8%)	0	0	0	0	0	1 (1.5%)	0	2 (0.4%)	2 (0.3%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Chronic sinusitis (慢性副鼻腔炎)											
< 65 years	0	0	0	0	0	1 (2.3%)	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	1 (5.6%)	1 (0.5%)	1 (0.4%)
< 75 years	0	0	0	0	0	1 (1.6%)	0	0	1 (1.6%)	2 (0.4%)	2 (0.3%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Diverticulitis (憩室炎)											
< 65 years	0	0	0	1 (2.1%)	0	1 (2.3%)	0	0	0	2 (0.5%)	2 (0.4%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	0	1 (1.6%)	0	1 (1.6%)	0	0	0	2 (0.4%)	2 (0.3%)

System Organ Class Preferred Term Age	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
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Enteritis infectious (感染性腸炎)											
< 65 years	0	1 (1.3%)	0	0	0	0	1 (3.6%)	0	0	2 (0.5%)	2 (0.4%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	1 (0.8%)	0	0	0	0	1 (1.7%)	0	0	2 (0.4%)	2 (0.3%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Folliculitis (毛包炎)											
< 65 years	1 (1.2%)	0	0	0	0	0	0	0	1 (2.2%)	1 (0.3%)	2 (0.4%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	1 (0.8%)	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	2 (0.3%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Gastroenteritis viral (ウイルス性胃腸炎)											
< 65 years	0	0	0	1 (2.1%)	1 (2.4%)	0	0	0	0	2 (0.5%)	2 (0.4%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	0	1 (1.6%)	1 (1.6%)	0	0	0	0	2 (0.4%)	2 (0.3%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Helicobacter infection (ヘリコバクター感染)											
< 65 years	0	0	0	1 (2.1%)	0	0	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	1 (4.2%)	0	1 (0.5%)	1 (0.4%)
< 75 years	0	0	0	1 (1.6%)	0	0	0	1 (1.5%)	0	2 (0.4%)	2 (0.3%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Impetigo (膿痂疹)											
< 65 years	0	1 (1.3%)	0	0	0	0	0	1 (2.2%)	0	2 (0.5%)	2 (0.4%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0

System Organ Class Preferred Term Age	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
< 75 years	0	1 (0.8%)	0	0	0	0	0	1 (1.5%)	0	2 (0.4%)	2 (0.3%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Otitis media (中耳炎)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	1 (2.0%)	0	0	0	0	0	0	1 (5.6%)	2 (0.9%)	2 (0.8%)
< 75 years	0	1 (0.8%)	0	0	0	0	0	0	1 (1.6%)	2 (0.4%)	2 (0.3%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Otitis media acute (急性中耳炎)											
< 65 years	0	0	0	0	0	0	0	1 (2.2%)	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	1 (2.0%)	0	0	0	0	0	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	1 (0.8%)	0	0	0	0	0	1 (1.5%)	0	2 (0.4%)	2 (0.3%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Paronychia (爪囲炎)											
< 65 years	0	0	0	0	0	1 (2.3%)	0	1 (2.2%)	0	2 (0.5%)	2 (0.4%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	0	0	0	1 (1.6%)	0	1 (1.5%)	0	2 (0.4%)	2 (0.3%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Pneumonia bacterial (細菌性肺炎)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	0	0	1 (5.9%)	0	1 (4.8%)	0	0	0	2 (0.9%)	2 (0.8%)
< 75 years	0	0	0	0	0	1 (1.6%)	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	1 (33.3%)	0	0	0	0	0	1 (3.7%)	1 (2.9%)
Pulpitis dental (歯髄炎)											
< 65 years	0	0	0	0	0	0	0	0	1 (2.2%)	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	1 (2.9%)	0	0	1 (0.5%)	1 (0.4%)

System Organ Class Preferred Term Age	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
< 75 years	0	0	0	0	0	0	1 (1.7%)	0	1 (1.6%)	2 (0.4%)	2 (0.3%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Rhinitis (鼻炎)											
< 65 years	0	0	0	0	0	1 (2.3%)	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	1 (2.0%)	0	0	0	0	0	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	1 (0.8%)	0	0	0	1 (1.6%)	0	0	0	2 (0.4%)	2 (0.3%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Acute sinusitis (急性副鼻腔炎)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	1 (2.0%)	0	0	0	0	0	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Bacterial vulvovaginitis (細菌性外陰腟炎)											
< 65 years	0	0	1 (2.4%)	0	0	0	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	1 (1.6%)	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Cellulitis (蜂巣炎)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	0	0	0	0	0	1 (2.9%)	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	0	0	0	0	0	1 (1.7%)	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Eczema impetiginous (膿痂疹性湿疹)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	0	0	0	0	0	1 (2.9%)	0	0	1 (0.5%)	1 (0.4%)

System Organ Class Preferred Term Age	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
< 75 years	0	0	0	0	0	0	1 (1.7%)	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Endometritis (子宮内膜炎)											
< 65 years	0	0	0	1 (2.1%)	0	0	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	0	1 (1.6%)	0	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Enterocolitis viral (ウイルス性腸炎)											
< 65 years	0	0	0	0	0	1 (2.3%)	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	0	0	0	1 (1.6%)	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Furuncle (せつ)											
< 65 years	0	0	0	0	0	0	1 (3.6%)	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	0	0	0	0	1 (1.7%)	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Nasal vestibulitis (鼻前庭炎)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	0	0	0	0	0	1 (2.9%)	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	0	0	0	0	0	1 (1.7%)	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Skin bacterial infection (皮膚細菌感染)											
< 65 years	0	0	0	0	0	1 (2.3%)	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0

System Organ Class Preferred Term Age	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
< 75 years	0	0	0	0	0	1 (1.6%)	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Skin infection (皮膚感染)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	0	1 (4.5%)	0	0	0	0	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	0	1 (1.6%)	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Streptococcal infection (レンサ球菌感染)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	1 (2.0%)	0	0	0	0	0	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Subcutaneous abscess (皮下組織膿瘍)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	0	0	0	0	0	1 (2.9%)	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	0	0	0	0	0	1 (1.7%)	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Tinea infection (白癬感染)											
< 65 years	0	0	0	0	0	0	0	1 (2.2%)	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	0	0	0	0	0	1 (1.5%)	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Vaginal infection (膣感染)											
< 65 years	0	0	0	0	0	0	1 (3.6%)	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0

System Organ Class Preferred Term Age	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
< 75 years	0	0	0	0	0	0	1 (1.7%)	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Gastrointestinal disorders (胃腸障害)											
< 65 years	17 (19.8%)	16 (21.1%)	11 (26.2%)	18 (38.3%)	1 (2.4%)	7 (15.9%)	8 (28.6%)	7 (15.2%)	7 (15.6%)	75 (20.3%)	92 (20.2%)
>= 65 years	12 (25.0%)	12 (23.5%)	1 (4.5%)	7 (41.2%)	4 (17.4%)	2 (9.5%)	13 (37.1%)	7 (29.2%)	8 (44.4%)	54 (25.6%)	66 (25.5%)
< 75 years	26 (20.5%)	28 (23.0%)	12 (19.7%)	24 (39.3%)	4 (6.5%)	8 (13.1%)	20 (34.5%)	13 (19.4%)	14 (23.0%)	123 (22.2%)	149 (21.9%)
>= 75 years	3 (42.9%)	0	0	1 (33.3%)	1 (50.0%)	1 (25.0%)	1 (20.0%)	1 (33.3%)	1 (50.0%)	6 (22.2%)	9 (26.5%)
Nausea (悪心)											
< 65 years	4 (4.7%)	0	0	7 (14.9%)	1 (2.4%)	1 (2.3%)	0	0	2 (4.4%)	11 (3.0%)	15 (3.3%)
>= 65 years	5 (10.4%)	1 (2.0%)	0	1 (5.9%)	0	0	5 (14.3%)	3 (12.5%)	2 (11.1%)	12 (5.7%)	17 (6.6%)
< 75 years	7 (5.5%)	1 (0.8%)	0	8 (13.1%)	1 (1.6%)	1 (1.6%)	4 (6.9%)	2 (3.0%)	3 (4.9%)	20 (3.6%)	27 (4.0%)
>= 75 years	2 (28.6%)	0	0	0	0	0	1 (20.0%)	1 (33.3%)	1 (50.0%)	3 (11.1%)	5 (14.7%)
Diarrhoea (下痢)											
< 65 years	2 (2.3%)	3 (3.9%)	4 (9.5%)	7 (14.9%)	0	2 (4.5%)	1 (3.6%)	3 (6.5%)	1 (2.2%)	21 (5.7%)	23 (5.1%)
>= 65 years	2 (4.2%)	0	0	4 (23.5%)	0	0	1 (2.9%)	0	1 (5.6%)	6 (2.8%)	8 (3.1%)
< 75 years	4 (3.1%)	3 (2.5%)	4 (6.6%)	11 (18.0%)	0	2 (3.3%)	2 (3.4%)	3 (4.5%)	2 (3.3%)	27 (4.9%)	31 (4.6%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Constipation (便秘)											
< 65 years	1 (1.2%)	6 (7.9%)	1 (2.4%)	1 (2.1%)	0	1 (2.3%)	0	0	1 (2.2%)	10 (2.7%)	11 (2.4%)
>= 65 years	4 (8.3%)	2 (3.9%)	1 (4.5%)	0	2 (8.7%)	0	5 (14.3%)	1 (4.2%)	1 (5.6%)	12 (5.7%)	16 (6.2%)
< 75 years	5 (3.9%)	8 (6.6%)	2 (3.3%)	1 (1.6%)	2 (3.2%)	1 (1.6%)	5 (8.6%)	1 (1.5%)	2 (3.3%)	22 (4.0%)	27 (4.0%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Gastrooesophageal reflux disease (胃食道逆流性疾患)											
< 65 years	1 (1.2%)	4 (5.3%)	1 (2.4%)	1 (2.1%)	0	0	0	0	0	6 (1.6%)	7 (1.5%)
>= 65 years	2 (4.2%)	5 (9.8%)	0	1 (5.9%)	0	0	0	1 (4.2%)	0	7 (3.3%)	9 (3.5%)

System Organ Class Preferred Term Age	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
< 75 years	3 (2.4%)	9 (7.4%)	1 (1.6%)	2 (3.3%)	0	0	0	1 (1.5%)	0	13 (2.4%)	16 (2.4%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Abdominal pain upper (上腹部痛)											
< 65 years	4 (4.7%)	0	0	2 (4.3%)	0	0	1 (3.6%)	0	0	3 (0.8%)	7 (1.5%)
>= 65 years	0	1 (2.0%)	1 (4.5%)	1 (5.9%)	0	0	1 (2.9%)	1 (4.2%)	0	5 (2.4%)	5 (1.9%)
< 75 years	4 (3.1%)	1 (0.8%)	1 (1.6%)	3 (4.9%)	0	0	2 (3.4%)	1 (1.5%)	0	8 (1.4%)	12 (1.8%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Dental caries (齲歯)											
< 65 years	3 (3.5%)	0	1 (2.4%)	1 (2.1%)	0	3 (6.8%)	1 (3.6%)	0	0	6 (1.6%)	9 (2.0%)
>= 65 years	2 (4.2%)	0	0	0	0	0	1 (2.9%)	0	0	1 (0.5%)	3 (1.2%)
< 75 years	4 (3.1%)	0	1 (1.6%)	1 (1.6%)	0	3 (4.9%)	2 (3.4%)	0	0	7 (1.3%)	11 (1.6%)
>= 75 years	1 (14.3%)	0	0	0	0	0	0	0	0	0	1 (2.9%)
Vomiting (嘔吐)											
< 65 years	0	0	0	3 (6.4%)	0	1 (2.3%)	1 (3.6%)	0	0	5 (1.4%)	5 (1.1%)
>= 65 years	1 (2.1%)	0	0	1 (5.9%)	0	1 (4.8%)	1 (2.9%)	2 (8.3%)	1 (5.6%)	6 (2.8%)	7 (2.7%)
< 75 years	1 (0.8%)	0	0	4 (6.6%)	0	1 (1.6%)	1 (1.7%)	1 (1.5%)	0	7 (1.3%)	8 (1.2%)
>= 75 years	0	0	0	0	0	1 (25.0%)	1 (20.0%)	1 (33.3%)	1 (50.0%)	4 (14.8%)	4 (11.8%)
Abdominal discomfort (腹部不快感)											
< 65 years	0	2 (2.6%)	1 (2.4%)	1 (2.1%)	0	0	1 (3.6%)	0	0	5 (1.4%)	5 (1.1%)
>= 65 years	0	0	0	2 (11.8%)	1 (4.3%)	0	1 (2.9%)	0	0	4 (1.9%)	4 (1.5%)
< 75 years	0	2 (1.6%)	1 (1.6%)	2 (3.3%)	1 (1.6%)	0	2 (3.4%)	0	0	8 (1.4%)	8 (1.2%)
>= 75 years	0	0	0	1 (33.3%)	0	0	0	0	0	1 (3.7%)	1 (2.9%)
Chronic gastritis (慢性胃炎)											
< 65 years	0	1 (1.3%)	0	1 (2.1%)	0	0	1 (3.6%)	0	1 (2.2%)	4 (1.1%)	4 (0.9%)
>= 65 years	0	1 (2.0%)	0	0	0	0	1 (2.9%)	1 (4.2%)	0	3 (1.4%)	3 (1.2%)

System Organ Class Preferred Term Age	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
< 75 years	0	2 (1.6%)	0	1 (1.6%)	0	0	2 (3.4%)	1 (1.5%)	1 (1.6%)	7 (1.3%)	7 (1.0%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Dyspepsia (消化不良)											
< 65 years	0	1 (1.3%)	1 (2.4%)	0	0	0	2 (7.1%)	1 (2.2%)	0	5 (1.4%)	5 (1.1%)
>= 65 years	0	1 (2.0%)	0	0	0	0	0	1 (4.2%)	0	2 (0.9%)	2 (0.8%)
< 75 years	0	2 (1.6%)	1 (1.6%)	0	0	0	2 (3.4%)	1 (1.5%)	0	6 (1.1%)	6 (0.9%)
>= 75 years	0	0	0	0	0	0	0	1 (33.3%)	0	1 (3.7%)	1 (2.9%)
Faeces soft (軟便)											
< 65 years	1 (1.2%)	0	1 (2.4%)	1 (2.1%)	0	0	0	0	1 (2.2%)	3 (0.8%)	4 (0.9%)
>= 65 years	0	1 (2.0%)	0	1 (5.9%)	0	0	0	0	0	2 (0.9%)	2 (0.8%)
< 75 years	1 (0.8%)	1 (0.8%)	1 (1.6%)	2 (3.3%)	0	0	0	0	1 (1.6%)	5 (0.9%)	6 (0.9%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Large intestine polyp (大腸ポリープ)											
< 65 years	0	0	0	2 (4.3%)	0	0	0	0	1 (2.2%)	3 (0.8%)	3 (0.7%)
>= 65 years	1 (2.1%)	0	0	0	0	0	1 (2.9%)	1 (4.2%)	0	2 (0.9%)	3 (1.2%)
< 75 years	1 (0.8%)	0	0	2 (3.3%)	0	0	1 (1.7%)	1 (1.5%)	1 (1.6%)	5 (0.9%)	6 (0.9%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Abdominal pain (腹痛)											
< 65 years	0	1 (1.3%)	1 (2.4%)	0	0	0	1 (3.6%)	0	0	3 (0.8%)	3 (0.7%)
>= 65 years	0	0	0	0	0	0	0	0	1 (5.6%)	1 (0.5%)	1 (0.4%)
< 75 years	0	1 (0.8%)	1 (1.6%)	0	0	0	1 (1.7%)	0	0	3 (0.5%)	3 (0.4%)
>= 75 years	0	0	0	0	0	0	0	0	1 (50.0%)	1 (3.7%)	1 (2.9%)
Gastritis (胃炎)											
< 65 years	0	0	0	0	0	0	0	1 (2.2%)	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	1 (4.3%)	0	0	0	2 (11.1%)	3 (1.4%)	3 (1.2%)
< 75 years	0	0	0	0	0	0	0	1 (1.5%)	2 (3.3%)	3 (0.5%)	3 (0.4%)
>= 75 years	0	0	0	0	1 (50.0%)	0	0	0	0	1 (3.7%)	1 (2.9%)

System Organ Class Preferred Term Age	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
Abdominal distension (腹部膨満)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	0	0	0	0	0	1 (2.9%)	0	2 (11.1%)	3 (1.4%)	3 (1.2%)
< 75 years	0	0	0	0	0	0	1 (1.7%)	0	2 (3.3%)	3 (0.5%)	3 (0.4%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Aphthous ulcer (アフタ性潰瘍)											
< 65 years	1 (1.2%)	0	0	0	0	0	1 (3.6%)	0	0	1 (0.3%)	2 (0.4%)
>= 65 years	0	0	0	1 (5.9%)	0	0	0	0	0	1 (0.5%)	1 (0.4%)
< 75 years	1 (0.8%)	0	0	1 (1.6%)	0	0	1 (1.7%)	0	0	2 (0.4%)	3 (0.4%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Food poisoning (食中毒)											
< 65 years	1 (1.2%)	0	0	0	0	0	0	0	1 (2.2%)	1 (0.3%)	2 (0.4%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	1 (0.8%)	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	2 (0.3%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Abdominal pain lower (下腹部痛)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	0	0	0	0	0	1 (2.9%)	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	0	0	0	0	0	1 (1.7%)	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Change of bowel habit (便習慣変化)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	0	0	0	0	0	0	1 (4.2%)	0	1 (0.5%)	1 (0.4%)

System Organ Class Preferred Term Age	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
< 75 years	0	0	0	0	0	0	0	1 (1.5%)	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Colitis (大腸炎)											
< 65 years	0	1 (1.3%)	0	0	0	0	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Colitis ulcerative (潰瘍性大腸炎)											
< 65 years	1 (1.2%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	1 (0.8%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Diverticulum intestinal (腸憩室)											
< 65 years	0	1 (1.3%)	0	0	0	0	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Enteritis (小腸炎)											
< 65 years	0	0	0	0	0	0	1 (3.6%)	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	0	0	0	0	1 (1.7%)	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Enterocolitis (腸炎)											
< 65 years	0	0	0	0	0	1 (2.3%)	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0

System Organ Class Preferred Term Age	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
< 75 years	0	0	0	0	0	1 (1.6%)	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Enterovesical fistula (腸膀胱瘻)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	0	0	0	0	1 (4.8%)	0	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	0	0	0	0	1 (1.6%)	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Epigastric discomfort (心窩部不快感)											
< 65 years	0	0	0	0	0	0	0	1 (2.2%)	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	0	0	0	0	0	1 (1.5%)	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Flatulence (鼓腸)											
< 65 years	0	0	1 (2.4%)	0	0	0	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	1 (1.6%)	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Gastric polyps (胃ポリープ)											
< 65 years	0	0	0	0	0	0	1 (3.6%)	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	0	0	0	0	1 (1.7%)	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Gastritis erosive (びらん性胃炎)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0

System Organ Class Preferred Term Age	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
>= 65 years	0	1 (2.0%)	0	0	0	0	0	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Gastrointestinal disorder (胃腸障害)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	0	0	0	0	0	0	0	1 (5.6%)	1 (0.5%)	1 (0.4%)
< 75 years	0	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Glossitis (舌炎)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	0	0	0	0	0	0	1 (4.2%)	0	1 (0.5%)	1 (0.4%)
< 75 years	0	0	0	0	0	0	0	1 (1.5%)	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Haematochezia (血便排泄)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	1 (2.0%)	0	0	0	0	0	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Inguinal hernia (鼠径ヘルニア)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	0	0	1 (5.9%)	0	0	0	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	0	0	1 (1.6%)	0	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Irritable bowel syndrome (過敏性腸症候群)											

System Organ Class Preferred Term Age	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
< 65 years	1 (1.2%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	1 (0.8%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Lower gastrointestinal haemorrhage (下部消化管出血)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	1 (2.0%)	0	0	0	0	0	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Mouth ulceration (口腔内潰瘍形成)											
< 65 years	0	0	0	0	0	0	0	0	1 (2.2%)	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Pancreatic steatosis (膵脂肪変性)											
< 65 years	0	0	0	0	0	1 (2.3%)	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	0	0	0	1 (1.6%)	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Periodontal disease (歯周病)											
< 65 years	0	1 (1.3%)	0	0	0	0	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Stomatitis (口内炎)											

System Organ Class Preferred Term Age	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
< 65 years	0	0	0	0	0	0	0	1 (2.2%)	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	0	0	0	0	0	1 (1.5%)	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Tooth loss (歯の脱落)											
< 65 years	1 (1.2%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	1 (0.8%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Toothache (歯痛)											
< 65 years	0	0	1 (2.4%)	0	0	0	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	1 (1.6%)	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Musculoskeletal and connective tissue disorders (筋骨格系および結合組織障害)											
< 65 years	7 (8.1%)	12 (15.8%)	5 (11.9%)	5 (10.6%)	3 (7.3%)	2 (4.5%)	8 (28.6%)	4 (8.7%)	1 (2.2%)	40 (10.8%)	47 (10.3%)
>= 65 years	8 (16.7%)	10 (19.6%)	5 (22.7%)	2 (11.8%)	3 (13.0%)	4 (19.0%)	8 (22.9%)	7 (29.2%)	3 (16.7%)	42 (19.9%)	50 (19.3%)
< 75 years	13 (10.2%)	22 (18.0%)	9 (14.8%)	6 (9.8%)	5 (8.1%)	6 (9.8%)	16 (27.6%)	11 (16.4%)	3 (4.9%)	78 (14.1%)	91 (13.4%)
>= 75 years	2 (28.6%)	0	1 (33.3%)	1 (33.3%)	1 (50.0%)	0	0	0	1 (50.0%)	4 (14.8%)	6 (17.6%)
Back pain (背部痛)											
< 65 years	4 (4.7%)	6 (7.9%)	3 (7.1%)	1 (2.1%)	1 (2.4%)	2 (4.5%)	1 (3.6%)	0	0	14 (3.8%)	18 (4.0%)
>= 65 years	1 (2.1%)	4 (7.8%)	0	0	1 (4.3%)	2 (9.5%)	0	0	0	7 (3.3%)	8 (3.1%)
< 75 years	5 (3.9%)	10 (8.2%)	3 (4.9%)	1 (1.6%)	2 (3.2%)	4 (6.6%)	1 (1.7%)	0	0	21 (3.8%)	26 (3.8%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Arthralgia (関節痛)											

System Organ Class Preferred Term Age	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
< 65 years	1 (1.2%)	2 (2.6%)	0	2 (4.3%)	0	0	2 (7.1%)	1 (2.2%)	0	7 (1.9%)	8 (1.8%)
>= 65 years	0	1 (2.0%)	0	0	0	2 (9.5%)	0	1 (4.2%)	1 (5.6%)	5 (2.4%)	5 (1.9%)
< 75 years	1 (0.8%)	3 (2.5%)	0	2 (3.3%)	0	2 (3.3%)	2 (3.4%)	2 (3.0%)	1 (1.6%)	12 (2.2%)	13 (1.9%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Pain in extremity (四肢痛)											
< 65 years	0	2 (2.6%)	2 (4.8%)	0	0	0	0	0	0	4 (1.1%)	4 (0.9%)
>= 65 years	1 (2.1%)	1 (2.0%)	0	0	0	0	1 (2.9%)	1 (4.2%)	1 (5.6%)	4 (1.9%)	5 (1.9%)
< 75 years	1 (0.8%)	3 (2.5%)	2 (3.3%)	0	0	0	1 (1.7%)	1 (1.5%)	1 (1.6%)	8 (1.4%)	9 (1.3%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Myalgia (筋肉痛)											
< 65 years	1 (1.2%)	1 (1.3%)	0	1 (2.1%)	1 (2.4%)	0	0	0	0	3 (0.8%)	4 (0.9%)
>= 65 years	1 (2.1%)	0	1 (4.5%)	0	0	0	0	0	2 (11.1%)	3 (1.4%)	4 (1.5%)
< 75 years	2 (1.6%)	1 (0.8%)	1 (1.6%)	1 (1.6%)	1 (1.6%)	0	0	0	1 (1.6%)	5 (0.9%)	7 (1.0%)
>= 75 years	0	0	0	0	0	0	0	0	1 (50.0%)	1 (3.7%)	1 (2.9%)
Spinal osteoarthritis (変形性脊椎症)											
< 65 years	0	0	0	0	0	0	1 (3.6%)	0	1 (2.2%)	2 (0.5%)	2 (0.4%)
>= 65 years	1 (2.1%)	0	0	0	1 (4.3%)	0	3 (8.6%)	1 (4.2%)	0	5 (2.4%)	6 (2.3%)
< 75 years	1 (0.8%)	0	0	0	0	0	4 (6.9%)	1 (1.5%)	1 (1.6%)	6 (1.1%)	7 (1.0%)
>= 75 years	0	0	0	0	1 (50.0%)	0	0	0	0	1 (3.7%)	1 (2.9%)
Intervertebral disc protrusion (椎間板突出)											
< 65 years	0	0	0	0	0	0	1 (3.6%)	1 (2.2%)	0	2 (0.5%)	2 (0.4%)
>= 65 years	0	0	1 (4.5%)	0	1 (4.3%)	0	3 (8.6%)	0	0	5 (2.4%)	5 (1.9%)
< 75 years	0	0	1 (1.6%)	0	1 (1.6%)	0	4 (6.9%)	1 (1.5%)	0	7 (1.3%)	7 (1.0%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Osteoarthritis (変形性関節症)											
< 65 years	1 (1.2%)	0	1 (2.4%)	0	0	0	1 (3.6%)	0	0	2 (0.5%)	3 (0.7%)

System Organ Class Preferred Term Age	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
>= 65 years	1 (2.1%)	0	0	1 (5.9%)	0	0	1 (2.9%)	0	0	2 (0.9%)	3 (1.2%)
< 75 years	1 (0.8%)	0	1 (1.6%)	0	0	0	2 (3.4%)	0	0	3 (0.5%)	4 (0.6%)
>= 75 years	1 (14.3%)	0	0	1 (33.3%)	0	0	0	0	0	1 (3.7%)	2 (5.9%)
Periarthritis (関節周囲炎)											
< 65 years	0	1 (1.3%)	1 (2.4%)	0	0	0	1 (3.6%)	1 (2.2%)	0	4 (1.1%)	4 (0.9%)
>= 65 years	1 (2.1%)	0	0	0	0	0	0	0	0	0	1 (0.4%)
< 75 years	1 (0.8%)	1 (0.8%)	1 (1.6%)	0	0	0	1 (1.7%)	1 (1.5%)	0	4 (0.7%)	5 (0.7%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Lumbar spinal stenosis (腰部脊柱管狭窄症)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	1 (2.1%)	0	0	0	0	0	1 (2.9%)	2 (8.3%)	0	3 (1.4%)	4 (1.5%)
< 75 years	1 (0.8%)	0	0	0	0	0	1 (1.7%)	2 (3.0%)	0	3 (0.5%)	4 (0.6%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Muscle spasms (筋痙縮)											
< 65 years	0	0	1 (2.4%)	0	0	0	1 (3.6%)	0	0	2 (0.5%)	2 (0.4%)
>= 65 years	0	1 (2.0%)	1 (4.5%)	0	0	0	0	0	0	2 (0.9%)	2 (0.8%)
< 75 years	0	1 (0.8%)	1 (1.6%)	0	0	0	1 (1.7%)	0	0	3 (0.5%)	3 (0.4%)
>= 75 years	0	0	1 (33.3%)	0	0	0	0	0	0	1 (3.7%)	1 (2.9%)
Musculoskeletal stiffness (筋骨格硬直)											
< 65 years	0	1 (1.3%)	0	0	0	0	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	1 (2.0%)	2 (9.1%)	0	0	0	0	0	0	3 (1.4%)	3 (1.2%)
< 75 years	0	2 (1.6%)	2 (3.3%)	0	0	0	0	0	0	4 (0.7%)	4 (0.6%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Trigger finger (弾発指)											
< 65 years	0	0	0	0	0	0	2 (7.1%)	0	0	2 (0.5%)	2 (0.4%)

System Organ Class Preferred Term Age	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
>= 65 years	0	0	0	0	0	0	0	2 (8.3%)	0	2 (0.9%)	2 (0.8%)
< 75 years	0	0	0	0	0	0	2 (3.4%)	2 (3.0%)	0	4 (0.7%)	4 (0.6%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Musculoskeletal pain (筋骨格痛)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	2 (4.2%)	0	0	0	0	0	0	0	0	0	2 (0.8%)
< 75 years	1 (0.8%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
>= 75 years	1 (14.3%)	0	0	0	0	0	0	0	0	0	1 (2.9%)
Neck pain (頚部痛)											
< 65 years	0	0	0	0	1 (2.4%)	0	0	1 (2.2%)	0	2 (0.5%)	2 (0.4%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	0	0	1 (1.6%)	0	0	1 (1.5%)	0	2 (0.4%)	2 (0.3%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Arthritis (関節炎)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	0	0	0	0	0	0	1 (4.2%)	0	1 (0.5%)	1 (0.4%)
< 75 years	0	0	0	0	0	0	0	1 (1.5%)	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Flank pain (側腹部痛)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	0	0	1 (5.9%)	0	0	0	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	0	0	1 (1.6%)	0	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Joint contracture (関節拘縮)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	0	0	0	0	0	1 (2.9%)	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	0	0	0	0	0	1 (1.7%)	0	0	1 (0.2%)	1 (0.1%)

System Organ Class Preferred Term Age	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
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Plantar fasciitis (足底筋膜炎)											
< 65 years	0	0	0	1 (2.1%)	0	0	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	0	1 (1.6%)	0	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Spondylolisthesis (脊椎すべり症)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	1 (2.1%)	0	0	0	0	0	0	0	0	0	1 (0.4%)
< 75 years	1 (0.8%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Synovitis (滑膜炎)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	1 (2.0%)	0	0	0	0	0	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Temporomandibular joint syndrome (顎関節症候群)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	0	1 (4.5%)	0	0	0	0	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	0	1 (1.6%)	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Tendon pain (腱痛)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	1 (2.0%)	0	0	0	0	0	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0

System Organ Class Preferred Term Age	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
Metabolism and nutrition disorders (代謝および栄養障害)											
< 65 years	7 (8.1%)	19 (25.0%)	5 (11.9%)	4 (8.5%)	3 (7.3%)	5 (11.4%)	3 (10.7%)	11 (23.9%)	3 (6.7%)	53 (14.4%)	60 (13.2%)
>= 65 years	6 (12.5%)	9 (17.6%)	5 (22.7%)	4 (23.5%)	1 (4.3%)	0	5 (14.3%)	2 (8.3%)	3 (16.7%)	29 (13.7%)	35 (13.5%)
< 75 years	11 (8.7%)	28 (23.0%)	9 (14.8%)	7 (11.5%)	4 (6.5%)	5 (8.2%)	8 (13.8%)	12 (17.9%)	5 (8.2%)	78 (14.1%)	89 (13.1%)
>= 75 years	2 (28.6%)	0	1 (33.3%)	1 (33.3%)	0	0	0	1 (33.3%)	1 (50.0%)	4 (14.8%)	6 (17.6%)
Hypoglycaemia (低血糖)											
< 65 years	3 (3.5%)	12 (15.8%)	5 (11.9%)	3 (6.4%)	2 (4.9%)	2 (4.5%)	2 (7.1%)	2 (4.3%)	1 (2.2%)	29 (7.9%)	32 (7.0%)
>= 65 years	2 (4.2%)	9 (17.6%)	4 (18.2%)	3 (17.6%)	0	0	3 (8.6%)	0	3 (16.7%)	22 (10.4%)	24 (9.3%)
< 75 years	5 (3.9%)	21 (17.2%)	8 (13.1%)	5 (8.2%)	2 (3.2%)	2 (3.3%)	5 (8.6%)	2 (3.0%)	3 (4.9%)	48 (8.7%)	53 (7.8%)
>= 75 years	0	0	1 (33.3%)	1 (33.3%)	0	0	0	0	1 (50.0%)	3 (11.1%)	3 (8.8%)
Hyperglycaemia (高血糖)											
< 65 years	4 (4.7%)	7 (9.2%)	0	0	1 (2.4%)	1 (2.3%)	1 (3.6%)	8 (17.4%)	1 (2.2%)	19 (5.1%)	23 (5.1%)
>= 65 years	1 (2.1%)	0	0	0	0	0	1 (2.9%)	0	0	1 (0.5%)	2 (0.8%)
< 75 years	5 (3.9%)	7 (5.7%)	0	0	1 (1.6%)	1 (1.6%)	2 (3.4%)	8 (11.9%)	1 (1.6%)	20 (3.6%)	25 (3.7%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Decreased appetite (食欲減退)											
< 65 years	0	0	0	1 (2.1%)	0	2 (4.5%)	0	1 (2.2%)	0	4 (1.1%)	4 (0.9%)
>= 65 years	3 (6.3%)	0	0	1 (5.9%)	0	0	2 (5.7%)	2 (8.3%)	1 (5.6%)	6 (2.8%)	9 (3.5%)
< 75 years	1 (0.8%)	0	0	2 (3.3%)	0	2 (3.3%)	2 (3.4%)	2 (3.0%)	0	8 (1.4%)	9 (1.3%)
>= 75 years	2 (28.6%)	0	0	0	0	0	0	1 (33.3%)	1 (50.0%)	2 (7.4%)	4 (11.8%)
Hyperuricaemia (高尿酸血症)											
< 65 years	0	0	0	0	0	0	0	0	1 (2.2%)	1 (0.3%)	1 (0.2%)
>= 65 years	0	2 (3.9%)	0	0	0	0	0	0	0	2 (0.9%)	2 (0.8%)
< 75 years	0	2 (1.6%)	0	0	0	0	0	0	1 (1.6%)	3 (0.5%)	3 (0.4%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Dehydration (脱水)											

System Organ Class Preferred Term Age	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
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	0	0	0	1 (4.3%)	0	0	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	0	0	0	1 (1.6%)	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Dyslipidaemia (脂質異常症)											
< 65 years	0	1 (1.3%)	0	0	0	0	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Gout (痛風)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	0	1 (4.5%)	0	0	0	0	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	0	1 (1.6%)	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Injury, poisoning and procedural complications (傷害、中毒および処置合併症)											
< 65 years	5 (5.8%)	6 (7.9%)	7 (16.7%)	3 (6.4%)	3 (7.3%)	3 (6.8%)	9 (32.1%)	4 (8.7%)	3 (6.7%)	38 (10.3%)	43 (9.5%)
>= 65 years	6 (12.5%)	7 (13.7%)	1 (4.5%)	2 (11.8%)	1 (4.3%)	3 (14.3%)	5 (14.3%)	3 (12.5%)	1 (5.6%)	23 (10.9%)	29 (11.2%)
< 75 years	9 (7.1%)	12 (9.8%)	8 (13.1%)	4 (6.6%)	4 (6.5%)	5 (8.2%)	14 (24.1%)	7 (10.4%)	4 (6.6%)	58 (10.5%)	67 (9.9%)
>= 75 years	2 (28.6%)	1 (20.0%)	0	1 (33.3%)	0	1 (25.0%)	0	0	0	3 (11.1%)	5 (14.7%)
Contusion (挫傷)											
< 65 years	1 (1.2%)	0	0	1 (2.1%)	0	0	1 (3.6%)	0	0	2 (0.5%)	3 (0.7%)
>= 65 years	2 (4.2%)	3 (5.9%)	0	1 (5.9%)	0	0	2 (5.7%)	0	0	6 (2.8%)	8 (3.1%)
< 75 years	2 (1.6%)	3 (2.5%)	0	2 (3.3%)	0	0	3 (5.2%)	0	0	8 (1.4%)	10 (1.5%)
>= 75 years	1 (14.3%)	0	0	0	0	0	0	0	0	0	1 (2.9%)
Ligament sprain (靱帯捻挫)											

System Organ Class Preferred Term Age	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
< 65 years	1 (1.2%)	1 (1.3%)	1 (2.4%)	0	0	1 (2.3%)	0	1 (2.2%)	0	4 (1.1%)	5 (1.1%)
>= 65 years	0	0	1 (4.5%)	0	0	0	0	0	0	1 (0.5%)	1 (0.4%)
< 75 years	1 (0.8%)	1 (0.8%)	2 (3.3%)	0	0	1 (1.6%)	0	1 (1.5%)	0	5 (0.9%)	6 (0.9%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Thermal burn (熱傷)											
< 65 years	1 (1.2%)	0	0	1 (2.1%)	0	0	1 (3.6%)	0	0	2 (0.5%)	3 (0.7%)
>= 65 years	0	0	0	1 (5.9%)	0	0	0	1 (4.2%)	0	2 (0.9%)	2 (0.8%)
< 75 years	1 (0.8%)	0	0	1 (1.6%)	0	0	1 (1.7%)	1 (1.5%)	0	3 (0.5%)	4 (0.6%)
>= 75 years	0	0	0	1 (33.3%)	0	0	0	0	0	1 (3.7%)	1 (2.9%)
Heat illness (熱中症)											
< 65 years	0	0	1 (2.4%)	0	1 (2.4%)	0	1 (3.6%)	0	0	3 (0.8%)	3 (0.7%)
>= 65 years	0	0	0	0	0	0	0	1 (4.2%)	0	1 (0.5%)	1 (0.4%)
< 75 years	0	0	1 (1.6%)	0	1 (1.6%)	0	1 (1.7%)	1 (1.5%)	0	4 (0.7%)	4 (0.6%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Rib fracture (肋骨骨折)											
< 65 years	0	1 (1.3%)	0	0	0	0	1 (3.6%)	0	1 (2.2%)	3 (0.8%)	3 (0.7%)
>= 65 years	0	1 (2.0%)	0	0	0	0	0	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	1 (0.8%)	0	0	0	0	1 (1.7%)	0	1 (1.6%)	3 (0.5%)	3 (0.4%)
>= 75 years	0	1 (20.0%)	0	0	0	0	0	0	0	1 (3.7%)	1 (2.9%)
Wound (創傷)											
< 65 years	1 (1.2%)	0	0	0	0	0	0	1 (2.2%)	0	1 (0.3%)	2 (0.4%)
>= 65 years	1 (2.1%)	0	0	0	0	1 (4.8%)	0	0	0	1 (0.5%)	2 (0.8%)
< 75 years	1 (0.8%)	0	0	0	0	1 (1.6%)	0	1 (1.5%)	0	2 (0.4%)	3 (0.4%)
>= 75 years	1 (14.3%)	0	0	0	0	0	0	0	0	0	1 (2.9%)
Arthropod bite (節足動物咬傷)											
< 65 years	0	0	1 (2.4%)	0	0	0	1 (3.6%)	1 (2.2%)	0	3 (0.8%)	3 (0.7%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	1 (1.6%)	0	0	0	1 (1.7%)	1 (1.5%)	0	3 (0.5%)	3 (0.4%)

System Organ Class Preferred Term Age	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
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Arthropod sting (節足動物刺傷)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	0	0	1 (5.9%)	1 (4.3%)	0	1 (2.9%)	0	0	3 (1.4%)	3 (1.2%)
< 75 years	0	0	0	1 (1.6%)	1 (1.6%)	0	1 (1.7%)	0	0	3 (0.5%)	3 (0.4%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Foot fracture (足骨折)											
< 65 years	0	0	1 (2.4%)	0	0	0	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	1 (2.9%)	1 (4.2%)	0	2 (0.9%)	2 (0.8%)
< 75 years	0	0	1 (1.6%)	0	0	0	1 (1.7%)	1 (1.5%)	0	3 (0.5%)	3 (0.4%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Radius fracture (橈骨骨折)											
< 65 years	0	0	0	0	0	0	2 (7.1%)	0	0	2 (0.5%)	2 (0.4%)
>= 65 years	1 (2.1%)	0	0	0	0	0	0	0	0	0	1 (0.4%)
< 75 years	1 (0.8%)	0	0	0	0	0	2 (3.4%)	0	0	2 (0.4%)	3 (0.4%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Avulsion fracture (剥離骨折)											
< 65 years	0	0	0	0	0	1 (2.3%)	0	0	1 (2.2%)	2 (0.5%)	2 (0.4%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	0	0	0	1 (1.6%)	0	0	1 (1.6%)	2 (0.4%)	2 (0.3%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Hand fracture (手骨折)											
< 65 years	0	0	1 (2.4%)	0	0	0	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	1 (4.2%)	0	1 (0.5%)	1 (0.4%)
< 75 years	0	0	1 (1.6%)	0	0	0	0	1 (1.5%)	0	2 (0.4%)	2 (0.3%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0

System Organ Class Preferred Term Age	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
Ligament injury (靱帯損傷)											
< 65 years	1 (1.2%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
>= 65 years	0	0	0	0	0	1 (4.8%)	0	0	0	1 (0.5%)	1 (0.4%)
< 75 years	1 (0.8%)	0	0	0	0	1 (1.6%)	0	0	0	1 (0.2%)	2 (0.3%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Muscle strain (肉離れ)											
< 65 years	0	0	0	0	0	0	1 (3.6%)	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	1 (2.1%)	0	0	0	0	0	0	0	0	0	1 (0.4%)
< 75 years	1 (0.8%)	0	0	0	0	0	1 (1.7%)	0	0	1 (0.2%)	2 (0.3%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Tendon rupture (腱断裂)											
< 65 years	0	0	2 (4.8%)	0	0	0	0	0	0	2 (0.5%)	2 (0.4%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	2 (3.3%)	0	0	0	0	0	0	2 (0.4%)	2 (0.3%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Animal bite (動物咬傷)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	1 (2.1%)	0	0	0	0	0	0	0	0	0	1 (0.4%)
< 75 years	0	0	0	0	0	0	0	0	0	0	0
>= 75 years	1 (14.3%)	0	0	0	0	0	0	0	0	0	1 (2.9%)
Clavicle fracture (鎖骨骨折)											
< 65 years	0	1 (1.3%)	0	0	0	0	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Closed globe injury (閉鎖性眼球損傷)											

System Organ Class Preferred Term Age	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
< 65 years	0	0	0	0	0	1 (2.3%)	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	0	0	0	1 (1.6%)	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Concussion (脳振盪)											
< 65 years	0	1 (1.3%)	0	0	0	0	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Craniocerebral injury (頭蓋脳損傷)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	0	0	0	0	1 (4.8%)	0	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	0	0	0	0	0	0	0	0	0	0
>= 75 years	0	0	0	0	0	1 (25.0%)	0	0	0	1 (3.7%)	1 (2.9%)
Epicondylitis (上顆炎)											
< 65 years	0	0	1 (2.4%)	0	0	0	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	1 (1.6%)	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Fractured coccyx (尾骨骨折)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	1 (2.0%)	0	0	0	0	0	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Fractured ischium (坐骨骨折)											
< 65 years	0	0	0	0	0	0	1 (3.6%)	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0

System Organ Class Preferred Term Age	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
< 75 years	0	0	0	0	0	0	1 (1.7%)	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Heat stroke (熱射病)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	0	0	0	0	0	1 (2.9%)	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	0	0	0	0	0	1 (1.7%)	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Laceration (裂傷)											
< 65 years	1 (1.2%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	1 (0.8%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Lower limb fracture (下肢骨折)											
< 65 years	0	1 (1.3%)	0	0	0	0	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Meniscus injury (半月板損傷)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	0	0	0	0	0	0	0	1 (5.6%)	1 (0.5%)	1 (0.4%)
< 75 years	0	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Multiple fractures (多発骨折)											
< 65 years	0	0	0	0	0	0	1 (3.6%)	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	0	0	0	0	1 (1.7%)	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0

System Organ Class Preferred Term Age	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
Nasal injury (鼻部損傷)											
< 65 years	0	0	0	0	0	0	0	1 (2.2%)	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	0	0	0	0	0	1 (1.5%)	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Pneumothorax traumatic (外傷性気胸)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	1 (2.0%)	0	0	0	0	0	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	0	0	0	0	0	0	0	0	0	0
>= 75 years	0	1 (20.0%)	0	0	0	0	0	0	0	1 (3.7%)	1 (2.9%)
Post procedural haemorrhage (処置後出血)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	1 (2.1%)	0	0	0	0	0	0	0	0	0	1 (0.4%)
< 75 years	1 (0.8%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Post-traumatic neck syndrome (外傷後頚部症候群)											
< 65 years	0	0	0	0	1 (2.4%)	0	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	0	0	1 (1.6%)	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Procedural pain (処置による疼痛)											
< 65 years	0	0	0	0	1 (2.4%)	0	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	0	0	1 (1.6%)	0	0	0	0	1 (0.2%)	1 (0.1%)

System Organ Class Preferred Term Age	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
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Pubis fracture (恥骨骨折)											
< 65 years	0	0	0	0	0	0	1 (3.6%)	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	0	0	0	0	1 (1.7%)	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Skin abrasion (皮膚擦過傷)											
< 65 years	0	1 (1.3%)	0	0	0	0	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Spinal compression fracture (脊椎圧迫骨折)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	1 (2.0%)	0	0	0	0	0	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Spinal fracture (脊椎骨折)											
< 65 years	0	0	0	0	0	0	0	0	1 (2.2%)	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Subarachnoid haemorrhage (くも膜下出血)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	1 (2.1%)	0	0	0	0	0	0	0	0	0	1 (0.4%)
< 75 years	1 (0.8%)	0	0	0	0	0	0	0	0	0	1 (0.1%)

System Organ Class Preferred Term Age	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
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Subdural haematoma (硬膜下血腫)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	1 (2.0%)	0	0	0	0	0	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Tooth fracture (歯牙破折)											
< 65 years	0	0	0	1 (2.1%)	0	0	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	0	1 (1.6%)	0	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Traumatic intracranial haemorrhage (外傷性頭蓋内出血)											
< 65 years	0	0	0	0	0	0	1 (3.6%)	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	0	0	0	0	1 (1.7%)	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Skin and subcutaneous tissue disorders (皮膚および皮下組織障害)											
< 65 years	2 (2.3%)	5 (6.6%)	5 (11.9%)	2 (4.3%)	0	3 (6.8%)	4 (14.3%)	3 (6.5%)	3 (6.7%)	25 (6.8%)	27 (5.9%)
>= 65 years	2 (4.2%)	5 (9.8%)	1 (4.5%)	1 (5.9%)	0	1 (4.8%)	8 (22.9%)	4 (16.7%)	2 (11.1%)	22 (10.4%)	24 (9.3%)
< 75 years	4 (3.1%)	10 (8.2%)	6 (9.8%)	3 (4.9%)	0	4 (6.6%)	11 (19.0%)	6 (9.0%)	5 (8.2%)	45 (8.1%)	49 (7.2%)
>= 75 years	0	0	0	0	0	0	1 (20.0%)	1 (33.3%)	0	2 (7.4%)	2 (5.9%)

System Organ Class Preferred Term Age	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
Eczema (湿疹)											
< 65 years	2 (2.3%)	1 (1.3%)	3 (7.1%)	0	0	1 (2.3%)	3 (10.7%)	1 (2.2%)	2 (4.4%)	11 (3.0%)	13 (2.9%)
>= 65 years	0	3 (5.9%)	0	0	0	0	2 (5.7%)	3 (12.5%)	0	8 (3.8%)	8 (3.1%)
< 75 years	2 (1.6%)	4 (3.3%)	3 (4.9%)	0	0	1 (1.6%)	5 (8.6%)	3 (4.5%)	2 (3.3%)	18 (3.3%)	20 (2.9%)
>= 75 years	0	0	0	0	0	0	0	1 (33.3%)	0	1 (3.7%)	1 (2.9%)
Acne (ざ瘡)											
< 65 years	0	1 (1.3%)	2 (4.8%)	0	0	0	0	0	0	3 (0.8%)	3 (0.7%)
>= 65 years	0	0	0	1 (5.9%)	0	0	0	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	1 (0.8%)	2 (3.3%)	1 (1.6%)	0	0	0	0	0	4 (0.7%)	4 (0.6%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Dermal cyst (皮膚嚢腫)											
< 65 years	0	0	1 (2.4%)	0	0	0	1 (3.6%)	0	0	2 (0.5%)	2 (0.4%)
>= 65 years	0	1 (2.0%)	0	0	0	0	0	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	1 (0.8%)	1 (1.6%)	0	0	0	1 (1.7%)	0	0	3 (0.5%)	3 (0.4%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Hyperkeratosis (過角化)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	1 (2.0%)	0	0	0	0	0	0	2 (11.1%)	3 (1.4%)	3 (1.2%)
< 75 years	0	1 (0.8%)	0	0	0	0	0	0	2 (3.3%)	3 (0.5%)	3 (0.4%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Dermatitis (皮膚炎)											
< 65 years	0	0	0	0	0	0	0	0	1 (2.2%)	1 (0.3%)	1 (0.2%)
>= 65 years	1 (2.1%)	0	0	0	0	0	0	0	0	0	1 (0.4%)
< 75 years	1 (0.8%)	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	2 (0.3%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Drug eruption (薬疹)											
< 65 years	0	0	0	1 (2.1%)	0	0	0	0	0	1 (0.3%)	1 (0.2%)

System Organ Class Preferred Term Age	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
>= 65 years	0	0	0	0	0	0	1 (2.9%)	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	0	0	1 (1.6%)	0	0	1 (1.7%)	0	0	2 (0.4%)	2 (0.3%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Dry skin (皮膚乾燥)											
< 65 years	0	0	0	1 (2.1%)	0	0	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	1 (4.2%)	0	1 (0.5%)	1 (0.4%)
< 75 years	0	0	0	1 (1.6%)	0	0	0	1 (1.5%)	0	2 (0.4%)	2 (0.3%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Eczema asteatotic (皮脂欠乏性湿疹)											
< 65 years	0	2 (2.6%)	0	0	0	0	0	0	0	2 (0.5%)	2 (0.4%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	2 (1.6%)	0	0	0	0	0	0	0	2 (0.4%)	2 (0.3%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Rash (発疹)											
< 65 years	0	0	0	0	0	0	0	1 (2.2%)	0	1 (0.3%)	1 (0.2%)
>= 65 years	1 (2.1%)	0	0	0	0	0	0	0	0	0	1 (0.4%)
< 75 years	1 (0.8%)	0	0	0	0	0	0	1 (1.5%)	0	1 (0.2%)	2 (0.3%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Asteatosis (皮脂欠乏症)											
< 65 years	0	0	0	0	0	1 (2.3%)	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	0	0	0	1 (1.6%)	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Dermatitis allergic (アレルギー性皮膚炎)											
< 65 years	0	0	0	0	0	0	0	1 (2.2%)	0	1 (0.3%)	1 (0.2%)

System Organ Class Preferred Term Age	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
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	0	0	0	0	0	1 (1.5%)	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Dyshidrotic eczema (異汗性湿疹)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	0	1 (4.5%)	0	0	0	0	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	0	1 (1.6%)	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Erythema (紅斑)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	0	0	0	0	0	1 (2.9%)	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	0	0	0	0	0	1 (1.7%)	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Haemorrhage subcutaneous (皮下出血)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	0	0	0	0	0	1 (2.9%)	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	0	0	0	0	0	0	0	0	0	0
>= 75 years	0	0	0	0	0	0	1 (20.0%)	0	0	1 (3.7%)	1 (2.9%)
Leukoderma (白斑)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	0	0	0	0	0	1 (2.9%)	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	0	0	0	0	0	1 (1.7%)	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Miliaria (汗疹)											
< 65 years	0	1 (1.3%)	0	0	0	0	0	0	0	1 (0.3%)	1 (0.2%)

System Organ Class Preferred Term Age	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
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Nail disorder (爪の障害)											
< 65 years	0	1 (1.3%)	0	0	0	0	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Pruritus (そう痒症)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	0	0	0	0	1 (4.8%)	0	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	0	0	0	0	1 (1.6%)	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Seborrhoeic dermatitis (脂漏性皮膚炎)											
< 65 years	0	0	0	0	0	1 (2.3%)	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	0	0	0	1 (1.6%)	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Skin mass (皮膚腫瘤)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	0	0	0	0	0	1 (2.9%)	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	0	0	0	0	0	1 (1.7%)	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Urticaria (蕁麻疹)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	0	0	0	0	0	1 (2.9%)	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	0	0	0	0	0	1 (1.7%)	0	0	1 (0.2%)	1 (0.1%)

System Organ Class Preferred Term Age	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
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Respiratory, thoracic and mediastinal disorders (呼吸器、胸郭および縦隔障害)											
< 65 years	5 (5.8%)	6 (7.9%)	3 (7.1%)	1 (2.1%)	2 (4.9%)	3 (6.8%)	2 (7.1%)	1 (2.2%)	5 (11.1%)	23 (6.2%)	28 (6.2%)
>= 65 years	2 (4.2%)	7 (13.7%)	1 (4.5%)	0	3 (13.0%)	2 (9.5%)	0	1 (4.2%)	0	14 (6.6%)	16 (6.2%)
< 75 years	7 (5.5%)	12 (9.8%)	4 (6.6%)	1 (1.6%)	5 (8.1%)	5 (8.2%)	2 (3.4%)	2 (3.0%)	5 (8.2%)	36 (6.5%)	43 (6.3%)
>= 75 years	0	1 (20.0%)	0	0	0	0	0	0	0	1 (3.7%)	1 (2.9%)
Upper respiratory tract inflammation (上気道の炎症)											
< 65 years	1 (1.2%)	1 (1.3%)	2 (4.8%)	0	0	2 (4.5%)	2 (7.1%)	0	3 (6.7%)	10 (2.7%)	11 (2.4%)
>= 65 years	0	0	0	0	1 (4.3%)	0	0	0	0	1 (0.5%)	1 (0.4%)
< 75 years	1 (0.8%)	1 (0.8%)	2 (3.3%)	0	1 (1.6%)	2 (3.3%)	2 (3.4%)	0	3 (4.9%)	11 (2.0%)	12 (1.8%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Cough (咳嗽)											
< 65 years	2 (2.3%)	2 (2.6%)	1 (2.4%)	1 (2.1%)	0	0	0	1 (2.2%)	0	5 (1.4%)	7 (1.5%)
>= 65 years	1 (2.1%)	0	0	0	0	1 (4.8%)	0	0	0	1 (0.5%)	2 (0.8%)
< 75 years	3 (2.4%)	2 (1.6%)	1 (1.6%)	1 (1.6%)	0	1 (1.6%)	0	1 (1.5%)	0	6 (1.1%)	9 (1.3%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Oropharyngeal pain (口腔咽頭痛)											
< 65 years	1 (1.2%)	0	0	0	0	0	0	0	1 (2.2%)	1 (0.3%)	2 (0.4%)
>= 65 years	0	1 (2.0%)	0	0	0	1 (4.8%)	0	1 (4.2%)	0	3 (1.4%)	3 (1.2%)
< 75 years	1 (0.8%)	1 (0.8%)	0	0	0	1 (1.6%)	0	1 (1.5%)	1 (1.6%)	4 (0.7%)	5 (0.7%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0

System Organ Class Preferred Term Age	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
Rhinitis allergic (アレルギー性鼻炎)											
< 65 years	0	0	0	0	0	1 (2.3%)	1 (3.6%)	0	0	2 (0.5%)	2 (0.4%)
>= 65 years	0	1 (2.0%)	1 (4.5%)	0	1 (4.3%)	0	0	0	0	3 (1.4%)	3 (1.2%)
< 75 years	0	1 (0.8%)	1 (1.6%)	0	1 (1.6%)	1 (1.6%)	1 (1.7%)	0	0	5 (0.9%)	5 (0.7%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Asthma (喘息)											
< 65 years	0	1 (1.3%)	0	0	1 (2.4%)	0	0	0	1 (2.2%)	3 (0.8%)	3 (0.7%)
>= 65 years	0	0	0	0	0	1 (4.8%)	0	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	1 (0.8%)	0	0	1 (1.6%)	1 (1.6%)	0	0	1 (1.6%)	4 (0.7%)	4 (0.6%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Bronchitis chronic (慢性気管支炎)											
< 65 years	0	1 (1.3%)	0	0	1 (2.4%)	0	0	0	0	2 (0.5%)	2 (0.4%)
>= 65 years	0	1 (2.0%)	0	0	0	0	0	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	2 (1.6%)	0	0	1 (1.6%)	0	0	0	0	3 (0.5%)	3 (0.4%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Epistaxis (鼻出血)											
< 65 years	1 (1.2%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
>= 65 years	0	2 (3.9%)	0	0	0	0	0	0	0	2 (0.9%)	2 (0.8%)
< 75 years	1 (0.8%)	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	2 (0.3%)
>= 75 years	0	1 (20.0%)	0	0	0	0	0	0	0	1 (3.7%)	1 (2.9%)
Allergic cough (アレルギー性咳嗽)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	1 (2.1%)	0	0	0	0	0	0	0	0	0	1 (0.4%)
< 75 years	1 (0.8%)	0	0	0	0	0	0	0	0	0	1 (0.1%)

System Organ Class Preferred Term Age	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
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Hiccups (しゃっくり)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	0	0	0	1 (4.3%)	0	0	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	0	0	0	1 (1.6%)	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Nasal congestion (鼻閉)											
< 65 years	0	0	0	1 (2.1%)	0	0	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	0	1 (1.6%)	0	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Pleural thickening (胸膜肥厚)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	1 (2.0%)	0	0	0	0	0	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Productive cough (湿性咳嗽)											
< 65 years	0	1 (1.3%)	0	0	0	0	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Rhinorrhoea (鼻漏)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	1 (2.0%)	0	0	0	0	0	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0

System Organ Class Preferred Term Age	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
Eye disorders (眼障害)											
< 65 years	1 (1.2%)	2 (2.6%)	5 (11.9%)	2 (4.3%)	0	3 (6.8%)	2 (7.1%)	4 (8.7%)	3 (6.7%)	21 (5.7%)	22 (4.8%)
>= 65 years	4 (8.3%)	5 (9.8%)	3 (13.6%)	0	0	3 (14.3%)	3 (8.6%)	1 (4.2%)	1 (5.6%)	16 (7.6%)	20 (7.7%)
< 75 years	5 (3.9%)	7 (5.7%)	8 (13.1%)	2 (3.3%)	0	6 (9.8%)	5 (8.6%)	5 (7.5%)	3 (4.9%)	36 (6.5%)	41 (6.0%)
>= 75 years	0	0	0	0	0	0	0	0	1 (50.0%)	1 (3.7%)	1 (2.9%)
Diabetic retinopathy (糖尿病網膜症)											
< 65 years	1 (1.2%)	1 (1.3%)	0	0	0	1 (2.3%)	2 (7.1%)	1 (2.2%)	0	5 (1.4%)	6 (1.3%)
>= 65 years	1 (2.1%)	0	1 (4.5%)	0	0	1 (4.8%)	1 (2.9%)	0	0	3 (1.4%)	4 (1.5%)
< 75 years	2 (1.6%)	1 (0.8%)	1 (1.6%)	0	0	2 (3.3%)	3 (5.2%)	1 (1.5%)	0	8 (1.4%)	10 (1.5%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Blepharitis (眼瞼炎)											
< 65 years	0	1 (1.3%)	0	0	0	0	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	1 (2.1%)	1 (2.0%)	1 (4.5%)	0	0	0	0	0	1 (5.6%)	3 (1.4%)	4 (1.5%)
< 75 years	1 (0.8%)	2 (1.6%)	1 (1.6%)	0	0	0	0	0	0	3 (0.5%)	4 (0.6%)
>= 75 years	0	0	0	0	0	0	0	0	1 (50.0%)	1 (3.7%)	1 (2.9%)
Dry eye (眼乾燥)											
< 65 years	0	0	0	0	0	1 (2.3%)	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	1 (2.1%)	1 (2.0%)	1 (4.5%)	0	0	0	1 (2.9%)	0	0	3 (1.4%)	4 (1.5%)
< 75 years	1 (0.8%)	1 (0.8%)	1 (1.6%)	0	0	1 (1.6%)	1 (1.7%)	0	0	4 (0.7%)	5 (0.7%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Asthenopia (眼精疲労)											
< 65 years	0	0	2 (4.8%)	0	0	0	0	0	0	2 (0.5%)	2 (0.4%)
>= 65 years	0	1 (2.0%)	0	0	0	0	0	1 (4.2%)	0	2 (0.9%)	2 (0.8%)
< 75 years	0	1 (0.8%)	2 (3.3%)	0	0	0	0	1 (1.5%)	0	4 (0.7%)	4 (0.6%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0

System Organ Class Preferred Term Age	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
Conjunctivitis allergic (アレルギー性結膜炎)											
< 65 years	0	0	1 (2.4%)	1 (2.1%)	0	0	0	1 (2.2%)	1 (2.2%)	4 (1.1%)	4 (0.9%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	1 (1.6%)	1 (1.6%)	0	0	0	1 (1.5%)	1 (1.6%)	4 (0.7%)	4 (0.6%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Cataract (白内障)											
< 65 years	0	0	0	0	0	1 (2.3%)	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	1 (2.1%)	0	1 (4.5%)	0	0	0	0	0	0	1 (0.5%)	2 (0.8%)
< 75 years	1 (0.8%)	0	1 (1.6%)	0	0	1 (1.6%)	0	0	0	2 (0.4%)	3 (0.4%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Glaucoma (緑内障)											
< 65 years	0	0	1 (2.4%)	0	0	1 (2.3%)	0	0	0	2 (0.5%)	2 (0.4%)
>= 65 years	0	0	0	0	0	0	1 (2.9%)	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	0	1 (1.6%)	0	0	1 (1.6%)	1 (1.7%)	0	0	3 (0.5%)	3 (0.4%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Ocular hyperaemia (眼充血)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	2 (3.9%)	0	0	0	0	0	0	0	2 (0.9%)	2 (0.8%)
< 75 years	0	2 (1.6%)	0	0	0	0	0	0	0	2 (0.4%)	2 (0.3%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Posterior capsule opacification (後嚢部混濁)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	1 (2.0%)	0	0	0	1 (4.8%)	0	0	0	2 (0.9%)	2 (0.8%)
< 75 years	0	1 (0.8%)	0	0	0	1 (1.6%)	0	0	0	2 (0.4%)	2 (0.3%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0

System Organ Class Preferred Term Age	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
Arteriosclerotic retinopathy (動脈硬化性網膜症)											
< 65 years	0	0	1 (2.4%)	0	0	0	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	1 (1.6%)	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Conjunctival haemorrhage (結膜出血)											
< 65 years	0	0	0	0	0	0	0	1 (2.2%)	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	0	0	0	0	0	1 (1.5%)	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Diabetic retinal oedema (糖尿病性網膜浮腫)											
< 65 years	0	0	0	0	0	0	0	1 (2.2%)	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	0	0	0	0	0	1 (1.5%)	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Eye pain (眼痛)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	1 (2.1%)	0	0	0	0	0	0	0	0	0	1 (0.4%)
< 75 years	1 (0.8%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Macular oedema (黄斑浮腫)											
< 65 years	0	0	0	0	0	0	0	0	1 (2.2%)	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	1 (0.1%)

System Organ Class Preferred Term Age	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
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Pingueculitis (瞼裂斑炎)											
< 65 years	0	0	0	0	0	0	0	0	1 (2.2%)	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Retinal haemorrhage (網膜出血)											
< 65 years	0	0	1 (2.4%)	0	0	0	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	1 (1.6%)	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Retinal vein occlusion (網膜静脈閉塞)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	0	0	0	0	1 (4.8%)	0	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	0	0	0	0	1 (1.6%)	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Scintillating scotoma (閃輝暗点)											
< 65 years	0	0	0	1 (2.1%)	0	0	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	0	1 (1.6%)	0	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Nervous system disorders (神経系障害)											

System Organ Class Preferred Term Age	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
< 65 years	4 (4.7%)	1 (1.3%)	2 (4.8%)	1 (2.1%)	3 (7.3%)	3 (6.8%)	1 (3.6%)	2 (4.3%)	3 (6.7%)	16 (4.3%)	20 (4.4%)
>= 65 years	4 (8.3%)	2 (3.9%)	3 (13.6%)	1 (5.9%)	1 (4.3%)	3 (14.3%)	3 (8.6%)	2 (8.3%)	1 (5.6%)	16 (7.6%)	20 (7.7%)
< 75 years	6 (4.7%)	3 (2.5%)	5 (8.2%)	2 (3.3%)	4 (6.5%)	5 (8.2%)	4 (6.9%)	3 (4.5%)	4 (6.6%)	30 (5.4%)	36 (5.3%)
>= 75 years	2 (28.6%)	0	0	0	0	1 (25.0%)	0	1 (33.3%)	0	2 (7.4%)	4 (11.8%)
Headache (頭痛)											
< 65 years	2 (2.3%)	1 (1.3%)	0	0	1 (2.4%)	1 (2.3%)	0	0	1 (2.2%)	4 (1.1%)	6 (1.3%)
>= 65 years	0	0	1 (4.5%)	0	0	1 (4.8%)	0	0	0	2 (0.9%)	2 (0.8%)
< 75 years	2 (1.6%)	1 (0.8%)	1 (1.6%)	0	1 (1.6%)	1 (1.6%)	0	0	1 (1.6%)	5 (0.9%)	7 (1.0%)
>= 75 years	0	0	0	0	0	1 (25.0%)	0	0	0	1 (3.7%)	1 (2.9%)
Diabetic neuropathy (糖尿病性ニューロパチー)											
< 65 years	1 (1.2%)	0	0	0	0	0	0	1 (2.2%)	1 (2.2%)	2 (0.5%)	3 (0.7%)
>= 65 years	0	0	0	0	0	0	2 (5.7%)	1 (4.2%)	0	3 (1.4%)	3 (1.2%)
< 75 years	1 (0.8%)	0	0	0	0	0	2 (3.4%)	2 (3.0%)	1 (1.6%)	5 (0.9%)	6 (0.9%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Carotid arteriosclerosis (頚動脈硬化症)											
< 65 years	0	0	0	0	0	1 (2.3%)	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	1 (4.5%)	1 (5.9%)	0	1 (4.8%)	0	0	0	3 (1.4%)	3 (1.2%)
< 75 years	0	0	1 (1.6%)	1 (1.6%)	0	2 (3.3%)	0	0	0	4 (0.7%)	4 (0.6%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Cervicobrachial syndrome (頚腕症候群)											
< 65 years	1 (1.2%)	0	0	0	2 (4.9%)	0	0	0	0	2 (0.5%)	3 (0.7%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	1 (0.8%)	0	0	0	2 (3.2%)	0	0	0	0	2 (0.4%)	3 (0.4%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0

System Organ Class Preferred Term Age	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
Dizziness (浮動性めまい)											
< 65 years	0	0	0	0	0	0	0	0	1 (2.2%)	1 (0.3%)	1 (0.2%)
>= 65 years	2 (4.2%)	0	0	0	0	0	0	0	0	0	2 (0.8%)
< 75 years	1 (0.8%)	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	2 (0.3%)
>= 75 years	1 (14.3%)	0	0	0	0	0	0	0	0	0	1 (2.9%)
Intercostal neuralgia (肋間神経痛)											
< 65 years	0	0	2 (4.8%)	0	0	0	0	0	0	2 (0.5%)	2 (0.4%)
>= 65 years	0	0	1 (4.5%)	0	0	0	0	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	0	3 (4.9%)	0	0	0	0	0	0	3 (0.5%)	3 (0.4%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Loss of consciousness (意識消失)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	0	0	0	1 (4.3%)	1 (4.8%)	0	0	0	2 (0.9%)	2 (0.8%)
< 75 years	0	0	0	0	1 (1.6%)	1 (1.6%)	0	0	0	2 (0.4%)	2 (0.3%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Sciatica (坐骨神経痛)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	1 (2.1%)	0	0	0	0	0	1 (2.9%)	0	0	1 (0.5%)	2 (0.8%)
< 75 years	1 (0.8%)	0	0	0	0	0	1 (1.7%)	0	0	1 (0.2%)	2 (0.3%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Carotid artery stenosis (頚動脈狭窄)											
< 65 years	0	0	0	0	0	0	0	1 (2.2%)	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	0	0	0	0	0	1 (1.5%)	0	1 (0.2%)	1 (0.1%)

System Organ Class Preferred Term Age	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
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Carpal tunnel syndrome (手根管症候群)											
< 65 years	0	0	0	0	0	0	1 (3.6%)	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	0	0	0	0	1 (1.7%)	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Cerebral infarction (脳梗塞)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	0	0	0	0	0	0	1 (4.2%)	0	1 (0.5%)	1 (0.4%)
< 75 years	0	0	0	0	0	0	0	0	0	0	0
>= 75 years	0	0	0	0	0	0	0	1 (33.3%)	0	1 (3.7%)	1 (2.9%)
Dysaesthesia (異常感覚)											
< 65 years	0	0	0	0	0	1 (2.3%)	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	0	0	0	1 (1.6%)	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Hypoaesthesia (感覚鈍麻)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	1 (2.0%)	0	0	0	0	0	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Lacunar infarction (ラクナ梗塞)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	0	0	0	0	0	0	0	1 (5.6%)	1 (0.5%)	1 (0.4%)
< 75 years	0	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	1 (0.1%)

System Organ Class Preferred Term Age	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
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Paraesthesia (錯感覚)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	1 (2.0%)	0	0	0	0	0	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Post herpetic neuralgia (ヘルペス後神経痛)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	1 (2.1%)	0	0	0	0	0	0	0	0	0	1 (0.4%)
< 75 years	0	0	0	0	0	0	0	0	0	0	0
>= 75 years	1 (14.3%)	0	0	0	0	0	0	0	0	0	1 (2.9%)
Presyncope (失神寸前の状態)											
< 65 years	0	0	0	1 (2.1%)	0	0	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	0	1 (1.6%)	0	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Syncope (失神)											
< 65 years	0	0	0	0	0	0	0	0	1 (2.2%)	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Investigations (臨床検査)											
< 65 years	3 (3.5%)	3 (3.9%)	1 (2.4%)	1 (2.1%)	1 (2.4%)	1 (2.3%)	4 (14.3%)	1 (2.2%)	2 (4.4%)	14 (3.8%)	17 (3.7%)
>= 65 years	3 (6.3%)	5 (9.8%)	1 (4.5%)	1 (5.9%)	2 (8.7%)	1 (4.8%)	2 (5.7%)	0	0	12 (5.7%)	15 (5.8%)
< 75 years	6 (4.7%)	8 (6.6%)	2 (3.3%)	2 (3.3%)	3 (4.8%)	2 (3.3%)	6 (10.3%)	1 (1.5%)	2 (3.3%)	26 (4.7%)	32 (4.7%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0

System Organ Class Preferred Term Age	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
Lipase increased (リパーゼ増加)											
< 65 years	0	2 (2.6%)	0	0	0	0	3 (10.7%)	0	0	5 (1.4%)	5 (1.1%)
>= 65 years	1 (2.1%)	0	0	0	1 (4.3%)	1 (4.8%)	0	0	0	2 (0.9%)	3 (1.2%)
< 75 years	1 (0.8%)	2 (1.6%)	0	0	1 (1.6%)	1 (1.6%)	3 (5.2%)	0	0	7 (1.3%)	8 (1.2%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Weight decreased (体重減少)											
< 65 years	2 (2.3%)	0	0	0	0	0	0	1 (2.2%)	0	1 (0.3%)	3 (0.7%)
>= 65 years	0	0	0	1 (5.9%)	1 (4.3%)	0	1 (2.9%)	0	0	3 (1.4%)	3 (1.2%)
< 75 years	2 (1.6%)	0	0	1 (1.6%)	1 (1.6%)	0	1 (1.7%)	1 (1.5%)	0	4 (0.7%)	6 (0.9%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Amylase increased (アミラーゼ増加)											
< 65 years	0	1 (1.3%)	1 (2.4%)	0	0	0	1 (3.6%)	0	0	3 (0.8%)	3 (0.7%)
>= 65 years	0	0	0	0	0	1 (4.8%)	0	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	1 (0.8%)	1 (1.6%)	0	0	1 (1.6%)	1 (1.7%)	0	0	4 (0.7%)	4 (0.6%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Blood creatine phosphokinase increased (血中クレアチンホスホキナーゼ増加)											
< 65 years	0	0	0	0	0	1 (2.3%)	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	1 (2.1%)	0	0	0	0	0	1 (2.9%)	0	0	1 (0.5%)	2 (0.8%)
< 75 years	1 (0.8%)	0	0	0	0	1 (1.6%)	1 (1.7%)	0	0	2 (0.4%)	3 (0.4%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Hepatic enzyme increased (肝酵素上昇)											
< 65 years	0	1 (1.3%)	0	0	0	0	0	0	1 (2.2%)	2 (0.5%)	2 (0.4%)

System Organ Class Preferred Term Age	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
>= 65 years	0	1 (2.0%)	0	0	0	0	0	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	2 (1.6%)	0	0	0	0	0	0	1 (1.6%)	3 (0.5%)	3 (0.4%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Blood lactic acid increased (血中乳酸増加)											
< 65 years	0	1 (1.3%)	0	0	0	0	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	1 (2.0%)	0	0	0	0	0	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	2 (1.6%)	0	0	0	0	0	0	0	2 (0.4%)	2 (0.3%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Gamma-glutamyltransferase increased (γ－グルタミルトランスフェラーゼ増加)											
< 65 years	0	0	0	0	0	0	1 (3.6%)	0	1 (2.2%)	2 (0.5%)	2 (0.4%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	0	0	0	0	1 (1.7%)	0	1 (1.6%)	2 (0.4%)	2 (0.3%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Platelet count decreased (血小板数減少)											
< 65 years	0	0	0	1 (2.1%)	0	0	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	1 (2.1%)	0	0	0	0	0	0	0	0	0	1 (0.4%)
< 75 years	1 (0.8%)	0	0	1 (1.6%)	0	0	0	0	0	1 (0.2%)	2 (0.3%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Blood creatinine increased (血中クレアチニン増加)											
< 65 years	0	0	0	0	1 (2.4%)	0	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	0	0	1 (1.6%)	0	0	0	0	1 (0.2%)	1 (0.1%)

System Organ Class Preferred Term Age	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
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
C-reactive protein increased (C－反応性蛋白増加)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	0	1 (4.5%)	0	0	0	0	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	0	1 (1.6%)	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Electrocardiogram repolarisation abnormality (心電図再分極異常)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	1 (2.0%)	0	0	0	0	0	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Intraocular pressure increased (眼圧上昇)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	1 (2.0%)	0	0	0	0	0	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Occult blood (便潜血)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	1 (2.0%)	0	0	0	0	0	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Occult blood positive (便潜血陽性)											

System Organ Class Preferred Term Age	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
< 65 years	1 (1.2%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	1 (0.8%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
White blood cell count increased (白血球数増加)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	1 (2.1%)	0	0	0	0	0	0	0	0	0	1 (0.4%)
< 75 years	1 (0.8%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Vascular disorders (血管障害)											
< 65 years	1 (1.2%)	3 (3.9%)	1 (2.4%)	1 (2.1%)	2 (4.9%)	1 (2.3%)	0	1 (2.2%)	1 (2.2%)	10 (2.7%)	11 (2.4%)
>= 65 years	1 (2.1%)	4 (7.8%)	1 (4.5%)	0	2 (8.7%)	2 (9.5%)	1 (2.9%)	1 (4.2%)	0	11 (5.2%)	12 (4.6%)
< 75 years	2 (1.6%)	7 (5.7%)	2 (3.3%)	1 (1.6%)	4 (6.5%)	2 (3.3%)	1 (1.7%)	1 (1.5%)	1 (1.6%)	19 (3.4%)	21 (3.1%)
>= 75 years	0	0	0	0	0	1 (25.0%)	0	1 (33.3%)	0	2 (7.4%)	2 (5.9%)
Hypertension (高血圧)											
< 65 years	0	3 (3.9%)	1 (2.4%)	1 (2.1%)	1 (2.4%)	1 (2.3%)	0	1 (2.2%)	1 (2.2%)	9 (2.4%)	9 (2.0%)
>= 65 years	0	4 (7.8%)	1 (4.5%)	0	2 (8.7%)	2 (9.5%)	1 (2.9%)	1 (4.2%)	0	11 (5.2%)	11 (4.2%)
< 75 years	0	7 (5.7%)	2 (3.3%)	1 (1.6%)	3 (4.8%)	2 (3.3%)	1 (1.7%)	1 (1.5%)	1 (1.6%)	18 (3.3%)	18 (2.6%)
>= 75 years	0	0	0	0	0	1 (25.0%)	0	1 (33.3%)	0	2 (7.4%)	2 (5.9%)
Orthostatic hypotension (起立性低血圧)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	1 (2.1%)	0	1 (4.5%)	0	0	0	0	0	0	1 (0.5%)	2 (0.8%)
< 75 years	1 (0.8%)	0	1 (1.6%)	0	0	0	0	0	0	1 (0.2%)	2 (0.3%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Arteriosclerosis (動脈硬化症)											

System Organ Class Preferred Term Age	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
< 65 years	0	0	0	0	1 (2.4%)	0	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	0	0	1 (1.6%)	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Hypotension (低血圧)											
< 65 years	1 (1.2%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	1 (0.8%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Renal and urinary disorders (腎および尿路障害)											
< 65 years	0	0	1 (2.4%)	1 (2.1%)	1 (2.4%)	3 (6.8%)	1 (3.6%)	3 (6.5%)	2 (4.4%)	12 (3.3%)	12 (2.6%)
>= 65 years	1 (2.1%)	2 (3.9%)	0	0	2 (8.7%)	0	2 (5.7%)	1 (4.2%)	1 (5.6%)	8 (3.8%)	9 (3.5%)
< 75 years	1 (0.8%)	2 (1.6%)	1 (1.6%)	1 (1.6%)	3 (4.8%)	3 (4.9%)	3 (5.2%)	4 (6.0%)	3 (4.9%)	20 (3.6%)	21 (3.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Diabetic nephropathy (糖尿病性腎症)											
< 65 years	0	0	0	1 (2.1%)	1 (2.4%)	1 (2.3%)	0	0	1 (2.2%)	4 (1.1%)	4 (0.9%)
>= 65 years	0	1 (2.0%)	0	0	1 (4.3%)	0	1 (2.9%)	0	0	3 (1.4%)	3 (1.2%)
< 75 years	0	1 (0.8%)	0	1 (1.6%)	2 (3.2%)	1 (1.6%)	1 (1.7%)	0	1 (1.6%)	7 (1.3%)	7 (1.0%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Nephrolithiasis (腎結石症)											
< 65 years	0	0	0	0	1 (2.4%)	2 (4.5%)	0	1 (2.2%)	0	4 (1.1%)	4 (0.9%)
>= 65 years	1 (2.1%)	0	0	0	1 (4.3%)	0	1 (2.9%)	0	0	2 (0.9%)	3 (1.2%)
< 75 years	1 (0.8%)	0	0	0	2 (3.2%)	2 (3.3%)	1 (1.7%)	1 (1.5%)	0	6 (1.1%)	7 (1.0%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0

System Organ Class Preferred Term Age	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
Pollakiuria (頻尿)											
< 65 years	0	0	0	0	0	0	0	2 (4.3%)	1 (2.2%)	3 (0.8%)	3 (0.7%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	0	0	0	0	0	2 (3.0%)	1 (1.6%)	3 (0.5%)	3 (0.4%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Calculus urinary (尿路結石)											
< 65 years	0	0	1 (2.4%)	0	0	0	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	1 (1.6%)	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Haematuria (血尿)											
< 65 years	0	0	0	0	0	0	1 (3.6%)	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	0	0	0	0	1 (1.7%)	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Hypertonic bladder (緊張性膀胱)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	0	0	0	0	0	0	0	1 (5.6%)	1 (0.5%)	1 (0.4%)
< 75 years	0	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Polyuria (多尿)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	1 (2.0%)	0	0	0	0	0	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Renal cyst (腎嚢胞)											

System Organ Class Preferred Term Age	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
< 65 years	0	0	0	0	1 (2.4%)	0	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	0	0	1 (1.6%)	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Urinary tract disorder (尿路障害)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	0	0	0	0	0	0	1 (4.2%)	0	1 (0.5%)	1 (0.4%)
< 75 years	0	0	0	0	0	0	0	1 (1.5%)	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Cardiac disorders (心臓障害)											
< 65 years	2 (2.3%)	2 (2.6%)	0	3 (6.4%)	1 (2.4%)	0	0	2 (4.3%)	1 (2.2%)	9 (2.4%)	11 (2.4%)
>= 65 years	0	1 (2.0%)	0	1 (5.9%)	0	2 (9.5%)	1 (2.9%)	2 (8.3%)	0	7 (3.3%)	7 (2.7%)
< 75 years	2 (1.6%)	3 (2.5%)	0	3 (4.9%)	1 (1.6%)	2 (3.3%)	1 (1.7%)	3 (4.5%)	1 (1.6%)	14 (2.5%)	16 (2.4%)
>= 75 years	0	0	0	1 (33.3%)	0	0	0	1 (33.3%)	0	2 (7.4%)	2 (5.9%)
Atrial fibrillation (心房細動)											
< 65 years	1 (1.2%)	0	0	0	0	0	0	1 (2.2%)	0	1 (0.3%)	2 (0.4%)
>= 65 years	0	0	0	0	0	1 (4.8%)	1 (2.9%)	0	0	2 (0.9%)	2 (0.8%)
< 75 years	1 (0.8%)	0	0	0	0	1 (1.6%)	1 (1.7%)	1 (1.5%)	0	3 (0.5%)	4 (0.6%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Angina unstable (不安定狭心症)											
< 65 years	0	0	0	0	1 (2.4%)	0	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	1 (2.0%)	0	0	0	0	0	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	1 (0.8%)	0	0	1 (1.6%)	0	0	0	0	2 (0.4%)	2 (0.3%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0

System Organ Class Preferred Term Age	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
Coronary artery stenosis (冠動脈狭窄)											
< 65 years	0	0	0	0	0	0	0	1 (2.2%)	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	1 (4.2%)	0	1 (0.5%)	1 (0.4%)
< 75 years	0	0	0	0	0	0	0	1 (1.5%)	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	1 (33.3%)	0	1 (3.7%)	1 (2.9%)
Palpitations (動悸)											
< 65 years	0	0	0	2 (4.3%)	0	0	0	0	0	2 (0.5%)	2 (0.4%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	0	2 (3.3%)	0	0	0	0	0	2 (0.4%)	2 (0.3%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Sinus bradycardia (洞性徐脈)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	0	0	0	0	2 (9.5%)	0	0	0	2 (0.9%)	2 (0.8%)
< 75 years	0	0	0	0	0	2 (3.3%)	0	0	0	2 (0.4%)	2 (0.3%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Ventricular extrasystoles (心室性期外収縮)											
< 65 years	1 (1.2%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	1 (4.2%)	0	1 (0.5%)	1 (0.4%)
< 75 years	1 (0.8%)	0	0	0	0	0	0	1 (1.5%)	0	1 (0.2%)	2 (0.3%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Acute myocardial infarction (急性心筋梗塞)											
< 65 years	0	1 (1.3%)	0	0	0	0	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)

System Organ Class Preferred Term Age	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
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Aortic valve incompetence (大動脈弁閉鎖不全症)											
< 65 years	0	1 (1.3%)	0	0	0	0	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Cardiac aneurysm (心臓瘤)											
< 65 years	0	1 (1.3%)	0	0	0	0	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Cardiac failure (心不全)											
< 65 years	0	0	0	0	0	0	0	0	1 (2.2%)	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Extrasystoles (期外収縮)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	0	0	0	0	1 (4.8%)	0	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	0	0	0	0	1 (1.6%)	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Myocardial infarction (心筋梗塞)											
< 65 years	0	0	0	1 (2.1%)	0	0	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	0	1 (1.6%)	0	0	0	0	0	1 (0.2%)	1 (0.1%)

System Organ Class Preferred Term Age	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
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Myocardial ischaemia (心筋虚血)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	0	0	1 (5.9%)	0	0	0	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	0	0	0	0	0	0	0	0	0	0
>= 75 years	0	0	0	1 (33.3%)	0	0	0	0	0	1 (3.7%)	1 (2.9%)
Sinus tachycardia (洞性頻脈)											
< 65 years	1 (1.2%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	1 (0.8%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Supraventricular extrasystoles (上室性期外収縮)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	0	0	0	0	1 (4.8%)	0	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	0	0	0	0	1 (1.6%)	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
General disorders and administration site conditions (一般・全身障害および投与部位の状態)											
< 65 years	4 (4.7%)	0	1 (2.4%)	0	0	2 (4.5%)	2 (7.1%)	1 (2.2%)	2 (4.4%)	8 (2.2%)	12 (2.6%)
>= 65 years	0	1 (2.0%)	0	2 (11.8%)	0	0	2 (5.7%)	0	0	5 (2.4%)	5 (1.9%)
< 75 years	4 (3.1%)	1 (0.8%)	1 (1.6%)	2 (3.3%)	0	2 (3.3%)	4 (6.9%)	1 (1.5%)	2 (3.3%)	13 (2.4%)	17 (2.5%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0

System Organ Class Preferred Term Age	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
Fatigue (疲労)											
< 65 years	1 (1.2%)	0	1 (2.4%)	0	0	0	2 (7.1%)	0	1 (2.2%)	4 (1.1%)	5 (1.1%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	1 (0.8%)	0	1 (1.6%)	0	0	0	2 (3.4%)	0	1 (1.6%)	4 (0.7%)	5 (0.7%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Chest pain (胸痛)											
< 65 years	0	0	0	0	0	0	0	0	1 (2.2%)	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	1 (5.9%)	0	0	0	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	0	0	1 (1.6%)	0	0	0	0	1 (1.6%)	2 (0.4%)	2 (0.3%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Non-cardiac chest pain (非心臓性胸痛)											
< 65 years	0	0	0	0	0	1 (2.3%)	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	1 (2.9%)	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	0	0	0	0	1 (1.6%)	1 (1.7%)	0	0	2 (0.4%)	2 (0.3%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Pyrexia (発熱)											
< 65 years	1 (1.2%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
>= 65 years	0	0	0	1 (5.9%)	0	0	0	0	0	1 (0.5%)	1 (0.4%)
< 75 years	1 (0.8%)	0	0	1 (1.6%)	0	0	0	0	0	1 (0.2%)	2 (0.3%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Chest discomfort (胸部不快感)											
< 65 years	1 (1.2%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	1 (0.8%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Early satiety (早期満腹)											

System Organ Class Preferred Term Age	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
< 65 years	1 (1.2%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	1 (0.8%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Inflammation (炎症)											
< 65 years	0	0	0	0	0	1 (2.3%)	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	0	0	0	1 (1.6%)	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Malaise (倦怠感)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	0	0	0	0	0	1 (2.9%)	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	0	0	0	0	0	1 (1.7%)	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Oedema peripheral (末梢性浮腫)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	1 (2.0%)	0	0	0	0	0	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Thirst (口渇)											
< 65 years	0	0	0	0	0	0	0	1 (2.2%)	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	0	0	0	0	0	1 (1.5%)	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Psychiatric disorders (精神障害)											
< 65 years	2 (2.3%)	1 (1.3%)	1 (2.4%)	1 (2.1%)	0	1 (2.3%)	1 (3.6%)	1 (2.2%)	0	6 (1.6%)	8 (1.8%)

System Organ Class Preferred Term Age	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
>= 65 years	1 (2.1%)	1 (2.0%)	0	1 (5.9%)	0	0	2 (5.7%)	1 (4.2%)	1 (5.6%)	6 (2.8%)	7 (2.7%)
< 75 years	3 (2.4%)	2 (1.6%)	1 (1.6%)	2 (3.3%)	0	1 (1.6%)	3 (5.2%)	2 (3.0%)	1 (1.6%)	12 (2.2%)	15 (2.2%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Insomnia (不眠症)											
< 65 years	2 (2.3%)	0	0	1 (2.1%)	0	1 (2.3%)	1 (3.6%)	0	0	3 (0.8%)	5 (1.1%)
>= 65 years	0	1 (2.0%)	0	1 (5.9%)	0	0	2 (5.7%)	1 (4.2%)	1 (5.6%)	6 (2.8%)	6 (2.3%)
< 75 years	2 (1.6%)	1 (0.8%)	0	2 (3.3%)	0	1 (1.6%)	3 (5.2%)	1 (1.5%)	1 (1.6%)	9 (1.6%)	11 (1.6%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Apathy (無感情)											
< 65 years	0	0	0	0	0	0	0	1 (2.2%)	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	0	0	0	0	0	1 (1.5%)	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Depressed mood (抑うつ気分)											
< 65 years	0	0	0	0	0	0	1 (3.6%)	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	0	0	0	0	1 (1.7%)	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Depression (うつ病)											
< 65 years	0	1 (1.3%)	0	0	0	0	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Mental fatigue (精神疲労)											
< 65 years	0	0	1 (2.4%)	0	0	0	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	1 (1.6%)	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0

System Organ Class Preferred Term Age	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
Stress (ストレス)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	1 (2.1%)	0	0	0	0	0	0	0	0	0	1 (0.4%)
< 75 years	1 (0.8%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Hepatobiliary disorders (肝胆道系障害)											
< 65 years	0	2 (2.6%)	0	0	0	2 (4.5%)	0	3 (6.5%)	1 (2.2%)	8 (2.2%)	8 (1.8%)
>= 65 years	0	0	1 (4.5%)	0	2 (8.7%)	1 (4.8%)	0	2 (8.3%)	0	6 (2.8%)	6 (2.3%)
< 75 years	0	2 (1.6%)	0	0	2 (3.2%)	3 (4.9%)	0	5 (7.5%)	1 (1.6%)	13 (2.4%)	13 (1.9%)
>= 75 years	0	0	1 (33.3%)	0	0	0	0	0	0	1 (3.7%)	1 (2.9%)
Hepatic steatosis (脂肪肝)											
< 65 years	0	1 (1.3%)	0	0	0	1 (2.3%)	0	2 (4.3%)	0	4 (1.1%)	4 (0.9%)
>= 65 years	0	0	1 (4.5%)	0	0	0	0	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	1 (0.8%)	0	0	0	1 (1.6%)	0	2 (3.0%)	0	4 (0.7%)	4 (0.6%)
>= 75 years	0	0	1 (33.3%)	0	0	0	0	0	0	1 (3.7%)	1 (2.9%)
Alcoholic liver disease (アルコール性肝疾患)											
< 65 years	0	1 (1.3%)	0	0	0	0	0	1 (2.2%)	0	2 (0.5%)	2 (0.4%)
>= 65 years	0	0	0	0	0	0	0	1 (4.2%)	0	1 (0.5%)	1 (0.4%)
< 75 years	0	1 (0.8%)	0	0	0	0	0	2 (3.0%)	0	3 (0.5%)	3 (0.4%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Cholelithiasis (胆石症)											
< 65 years	0	0	0	0	0	0	0	1 (2.2%)	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	1 (4.3%)	0	0	1 (4.2%)	0	2 (0.9%)	2 (0.8%)
< 75 years	0	0	0	0	1 (1.6%)	0	0	2 (3.0%)	0	3 (0.5%)	3 (0.4%)

System Organ Class Preferred Term Age	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
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Drug-induced liver injury (薬物性肝障害)											
< 65 years	0	0	0	0	0	0	0	0	1 (2.2%)	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	1 (4.3%)	1 (4.8%)	0	0	0	2 (0.9%)	2 (0.8%)
< 75 years	0	0	0	0	1 (1.6%)	1 (1.6%)	0	0	1 (1.6%)	3 (0.5%)	3 (0.4%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Gallbladder polyp (胆嚢ポリープ)											
< 65 years	0	0	0	0	0	0	0	2 (4.3%)	0	2 (0.5%)	2 (0.4%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	0	0	0	0	0	2 (3.0%)	0	2 (0.4%)	2 (0.3%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Cholecystitis (胆嚢炎)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	0	0	0	1 (4.3%)	0	0	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	0	0	0	1 (1.6%)	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Non-alcoholic steatohepatitis (非アルコール性脂肪性肝炎)											
< 65 years	0	0	0	0	0	1 (2.3%)	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	0	0	0	1 (1.6%)	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Surgical and medical procedures (外科および内科処置)											
< 65 years	2 (2.3%)	1 (1.3%)	0	2 (4.3%)	1 (2.4%)	0	0	0	0	4 (1.1%)	6 (1.3%)

System Organ Class Preferred Term Age	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
>= 65 years	1 (2.1%)	2 (3.9%)	1 (4.5%)	1 (5.9%)	0	0	0	1 (4.2%)	0	5 (2.4%)	6 (2.3%)
< 75 years	3 (2.4%)	3 (2.5%)	1 (1.6%)	3 (4.9%)	1 (1.6%)	0	0	1 (1.5%)	0	9 (1.6%)	12 (1.8%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Cataract operation (白内障手術)											
< 65 years	0	1 (1.3%)	0	1 (2.1%)	1 (2.4%)	0	0	0	0	3 (0.8%)	3 (0.7%)
>= 65 years	1 (2.1%)	2 (3.9%)	1 (4.5%)	1 (5.9%)	0	0	0	0	0	4 (1.9%)	5 (1.9%)
< 75 years	1 (0.8%)	3 (2.5%)	1 (1.6%)	2 (3.3%)	1 (1.6%)	0	0	0	0	7 (1.3%)	8 (1.2%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Large intestinal polypectomy (大腸ポリープ切除)											
< 65 years	0	0	0	1 (2.1%)	0	0	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	1 (4.2%)	0	1 (0.5%)	1 (0.4%)
< 75 years	0	0	0	1 (1.6%)	0	0	0	1 (1.5%)	0	2 (0.4%)	2 (0.3%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Endodontic procedure (歯内療法)											
< 65 years	1 (1.2%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	1 (0.8%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Ptosis repair (眼瞼下垂修復)											
< 65 years	1 (1.2%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	1 (0.8%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0

System Organ Class Preferred Term Age	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
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）)											
< 65 years	0	1 (1.3%)	1 (2.4%)	0	0	1 (2.3%)	1 (3.6%)	1 (2.2%)	0	5 (1.4%)	5 (1.1%)
>= 65 years	0	3 (5.9%)	0	1 (5.9%)	0	0	0	1 (4.2%)	1 (5.6%)	6 (2.8%)	6 (2.3%)
< 75 years	0	4 (3.3%)	1 (1.6%)	1 (1.6%)	0	1 (1.6%)	1 (1.7%)	2 (3.0%)	1 (1.6%)	11 (2.0%)	11 (1.6%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Benign neoplasm of spinal cord (脊髄の良性新生物)											
< 65 years	0	0	0	0	0	1 (2.3%)	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	0	0	0	1 (1.6%)	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Cholangiocarcinoma (胆管細胞癌)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	0	0	1 (5.9%)	0	0	0	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	0	0	1 (1.6%)	0	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Colon adenoma (大腸腺腫)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	0	0	0	0	0	0	0	1 (5.6%)	1 (0.5%)	1 (0.4%)
< 75 years	0	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0

System Organ Class Preferred Term Age	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
Colon cancer stage I (結腸癌第1期)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	1 (2.0%)	0	0	0	0	0	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Endometrial cancer stage III (子宮内膜癌第3期)											
< 65 years	0	0	0	0	0	0	1 (3.6%)	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	0	0	0	0	1 (1.7%)	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Haemangioma of liver (肝臓血管腫)											
< 65 years	0	0	0	0	0	0	0	1 (2.2%)	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	0	0	0	0	0	1 (1.5%)	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Invasive ductal breast carcinoma (浸潤性乳管癌)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	0	0	0	0	0	0	1 (4.2%)	0	1 (0.5%)	1 (0.4%)
< 75 years	0	0	0	0	0	0	0	1 (1.5%)	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Rectal cancer (直腸癌)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	1 (2.0%)	0	0	0	0	0	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)

System Organ Class Preferred Term Age	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
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Skin papilloma (皮膚乳頭腫)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	1 (2.0%)	0	0	0	0	0	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Testis cancer (精巣癌)											
< 65 years	0	0	1 (2.4%)	0	0	0	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	1 (1.6%)	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Thyroid neoplasm (甲状腺新生物)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	0	0	0	0	0	0	1 (4.2%)	0	1 (0.5%)	1 (0.4%)
< 75 years	0	0	0	0	0	0	0	1 (1.5%)	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Uterine leiomyoma (子宮平滑筋腫)											
< 65 years	0	1 (1.3%)	0	0	0	0	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Reproductive system and breast disorders (生殖系および乳房障害)											

System Organ Class Preferred Term Age	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
< 65 years	2 (2.3%)	1 (1.3%)	0	0	1 (2.4%)	0	3 (10.7%)	1 (2.2%)	0	6 (1.6%)	8 (1.8%)
>= 65 years	1 (2.1%)	0	2 (9.1%)	0	0	0	0	0	0	2 (0.9%)	3 (1.2%)
< 75 years	3 (2.4%)	1 (0.8%)	1 (1.6%)	0	1 (1.6%)	0	3 (5.2%)	1 (1.5%)	0	7 (1.3%)	10 (1.5%)
>= 75 years	0	0	1 (33.3%)	0	0	0	0	0	0	1 (3.7%)	1 (2.9%)
Benign prostatic hyperplasia (良性前立腺肥大症)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	1 (2.1%)	0	2 (9.1%)	0	0	0	0	0	0	2 (0.9%)	3 (1.2%)
< 75 years	1 (0.8%)	0	1 (1.6%)	0	0	0	0	0	0	1 (0.2%)	2 (0.3%)
>= 75 years	0	0	1 (33.3%)	0	0	0	0	0	0	1 (3.7%)	1 (2.9%)
Dysmenorrhoea (月経困難症)											
< 65 years	1 (1.2%)	1 (1.3%)	0	0	0	0	0	1 (2.2%)	0	2 (0.5%)	3 (0.7%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	1 (0.8%)	1 (0.8%)	0	0	0	0	0	1 (1.5%)	0	2 (0.4%)	3 (0.4%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Erectile dysfunction (勃起不全)											
< 65 years	0	0	0	0	0	0	1 (3.6%)	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	0	0	0	0	1 (1.7%)	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Genital haemorrhage (性器出血)											
< 65 years	0	0	0	0	0	0	1 (3.6%)	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	0	0	0	0	1 (1.7%)	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Metrorrhagia (不正子宮出血)											

System Organ Class Preferred Term Age	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
< 65 years	1 (1.2%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	1 (0.8%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Ovarian cyst (卵巣嚢胞)											
< 65 years	0	0	0	0	1 (2.4%)	0	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	0	0	1 (1.6%)	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Prostatitis (前立腺炎)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	0	1 (4.5%)	0	0	0	0	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	0	0	0	0	0	0	0	0	0	0
>= 75 years	0	0	1 (33.3%)	0	0	0	0	0	0	1 (3.7%)	1 (2.9%)
Uterine polyp (子宮ポリープ)											
< 65 years	0	0	0	0	0	0	1 (3.6%)	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	0	0	0	0	1 (1.7%)	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Ear and labyrinth disorders (耳および迷路障害)											
< 65 years	1 (1.2%)	1 (1.3%)	1 (2.4%)	3 (6.4%)	0	0	0	1 (2.2%)	0	6 (1.6%)	7 (1.5%)
>= 65 years	1 (2.1%)	0	0	0	0	1 (4.8%)	0	1 (4.2%)	0	2 (0.9%)	3 (1.2%)
< 75 years	2 (1.6%)	1 (0.8%)	1 (1.6%)	3 (4.9%)	0	0	0	2 (3.0%)	0	7 (1.3%)	9 (1.3%)
>= 75 years	0	0	0	0	0	1 (25.0%)	0	0	0	1 (3.7%)	1 (2.9%)
Vertigo (回転性めまい)											
< 65 years	0	0	0	2 (4.3%)	0	0	0	1 (2.2%)	0	3 (0.8%)	3 (0.7%)

System Organ Class Preferred Term Age	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
>= 65 years	1 (2.1%)	0	0	0	0	0	0	0	0	0	1 (0.4%)
< 75 years	1 (0.8%)	0	0	2 (3.3%)	0	0	0	1 (1.5%)	0	3 (0.5%)	4 (0.6%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Tinnitus (耳鳴)											
< 65 years	0	0	1 (2.4%)	0	0	0	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	1 (4.8%)	0	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	0	1 (1.6%)	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	1 (25.0%)	0	0	0	1 (3.7%)	1 (2.9%)
Deafness transitory (一過性難聴)											
< 65 years	0	0	0	1 (2.1%)	0	0	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	0	1 (1.6%)	0	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
External ear inflammation (外耳の炎症)											
< 65 years	0	1 (1.3%)	0	0	0	0	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Middle ear inflammation (中耳の炎症)											
< 65 years	0	1 (1.3%)	0	0	0	0	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0

System Organ Class Preferred Term Age	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
Sudden hearing loss (突発性難聴)											
< 65 years	1 (1.2%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	1 (0.8%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Vertigo positional (頭位性回転性めまい)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	0	0	0	0	0	0	1 (4.2%)	0	1 (0.5%)	1 (0.4%)
< 75 years	0	0	0	0	0	0	0	1 (1.5%)	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Immune system disorders (免疫系障害)											
< 65 years	1 (1.2%)	0	1 (2.4%)	1 (2.1%)	0	1 (2.3%)	0	2 (4.3%)	0	5 (1.4%)	6 (1.3%)
>= 65 years	1 (2.1%)	0	0	0	0	0	0	1 (4.2%)	1 (5.6%)	2 (0.9%)	3 (1.2%)
< 75 years	2 (1.6%)	0	1 (1.6%)	1 (1.6%)	0	1 (1.6%)	0	3 (4.5%)	0	6 (1.1%)	8 (1.2%)
>= 75 years	0	0	0	0	0	0	0	0	1 (50.0%)	1 (3.7%)	1 (2.9%)
Seasonal allergy (季節性アレルギー)											
< 65 years	0	0	1 (2.4%)	1 (2.1%)	0	1 (2.3%)	0	0	0	3 (0.8%)	3 (0.7%)
>= 65 years	1 (2.1%)	0	0	0	0	0	0	1 (4.2%)	1 (5.6%)	2 (0.9%)	3 (1.2%)
< 75 years	1 (0.8%)	0	1 (1.6%)	1 (1.6%)	0	1 (1.6%)	0	1 (1.5%)	0	4 (0.7%)	5 (0.7%)
>= 75 years	0	0	0	0	0	0	0	0	1 (50.0%)	1 (3.7%)	1 (2.9%)
Allergy to arthropod sting (節足動物刺傷アレルギー)											

System Organ Class Preferred Term Age	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
< 65 years	0	0	0	0	0	0	0	2 (4.3%)	0	2 (0.5%)	2 (0.4%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	0	0	0	0	0	2 (3.0%)	0	2 (0.4%)	2 (0.3%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Food allergy (食物アレルギー)											
< 65 years	1 (1.2%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	1 (0.8%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Blood and lymphatic system disorders (血液およびリンパ系障害)											
< 65 years	0	1 (1.3%)	0	1 (2.1%)	0	1 (2.3%)	0	1 (2.2%)	1 (2.2%)	5 (1.4%)	5 (1.1%)
>= 65 years	2 (4.2%)	0	0	0	0	0	0	0	1 (5.6%)	1 (0.5%)	3 (1.2%)
< 75 years	2 (1.6%)	1 (0.8%)	0	1 (1.6%)	0	1 (1.6%)	0	1 (1.5%)	2 (3.3%)	6 (1.1%)	8 (1.2%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Anaemia (貧血)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	2 (4.2%)	0	0	0	0	0	0	0	0	0	2 (0.8%)
< 75 years	2 (1.6%)	0	0	0	0	0	0	0	0	0	2 (0.3%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Lymphadenitis (リンパ節炎)											
< 65 years	0	0	0	0	0	0	0	1 (2.2%)	1 (2.2%)	2 (0.5%)	2 (0.4%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	0	0	0	0	0	1 (1.5%)	1 (1.6%)	2 (0.4%)	2 (0.3%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0

System Organ Class Preferred Term Age	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
Anaemia macrocytic (大球性貧血)											
< 65 years	0	0	0	0	0	1 (2.3%)	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	0	0	0	1 (1.6%)	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Anaemia megaloblastic (巨赤芽球性貧血)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	0	0	0	0	0	0	0	1 (5.6%)	1 (0.5%)	1 (0.4%)
< 75 years	0	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Lymphadenopathy (リンパ節症)											
< 65 years	0	0	0	1 (2.1%)	0	0	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	0	1 (1.6%)	0	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Normocytic anaemia (正球性貧血)											
< 65 years	0	1 (1.3%)	0	0	0	0	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Endocrine disorders (内分泌障害)											

System Organ Class Preferred Term Age	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
< 65 years	0	1 (1.3%)	0	0	0	1 (2.3%)	0	0	0	2 (0.5%)	2 (0.4%)
>= 65 years	0	0	0	0	0	1 (4.8%)	0	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	1 (0.8%)	0	0	0	1 (1.6%)	0	0	0	2 (0.4%)	2 (0.3%)
>= 75 years	0	0	0	0	0	1 (25.0%)	0	0	0	1 (3.7%)	1 (2.9%)
Autoimmune thyroiditis (自己免疫性甲状腺炎)											
< 65 years	0	1 (1.3%)	0	0	0	0	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Hypothyroidism (甲状腺機能低下症)											
< 65 years	0	0	0	0	0	1 (2.3%)	0	0	0	1 (0.3%)	1 (0.2%)
>= 65 years	0	0	0	0	0	0	0	0	0	0	0
< 75 years	0	0	0	0	0	1 (1.6%)	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Inappropriate antidiuretic hormone secretion (抗利尿ホルモン不適合分泌)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	0	0	0	0	1 (4.8%)	0	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	0	0	0	0	0	0	0	0	0	0
>= 75 years	0	0	0	0	0	1 (25.0%)	0	0	0	1 (3.7%)	1 (2.9%)
Congenital, familial and genetic disorders (先天性、家族性および遺伝性障害)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0

System Organ Class Preferred Term Age	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
>= 65 years	0	0	0	0	0	0	0	1 (4.2%)	0	1 (0.5%)	1 (0.4%)
< 75 years	0	0	0	0	0	0	0	1 (1.5%)	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Dermoid cyst (皮様嚢腫)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	0	0	0	0	0	0	1 (4.2%)	0	1 (0.5%)	1 (0.4%)
< 75 years	0	0	0	0	0	0	0	1 (1.5%)	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Product issues (製品の問題)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	1 (2.0%)	0	0	0	0	0	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	0
Device dislocation (医療機器位置異常)											
< 65 years	0	0	0	0	0	0	0	0	0	0	0
>= 65 years	0	1 (2.0%)	0	0	0	0	0	0	0	1 (0.5%)	1 (0.4%)
< 75 years	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
>= 75 years	0	0	0	0	0	0	0	0	0	0	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
- "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.
- All adverse events were coded using MedDRA dictionary version 20.1.
- Percentages are based on "Number of patients".

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Table S-167 Subgroup Analysis of Treatment Emergent Adverse Events by Sex, System Organ Class and Preferred Term in 52-Week Long-term Period with Monotherapy and Combination Therapy (PXL008-019; Long-term Safety Population)

System Organ Class Preferred Term Sex	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											
Male	106	101	43	46	48	54	39	44	45	420	526
Female	28	26	21	18	16	11	24	26	18	160	188
Any TEAE											
Male	74 (69.8%)	83 (82.2%)	35 (81.4%)	32 (69.6%)	23 (47.9%)	40 (74.1%)	28 (71.8%)	33 (75.0%)	36 (80.0%)	310 (73.8%)	384 (73.0%)
Female	24 (85.7%)	19 (73.1%)	19 (90.5%)	16 (88.9%)	10 (62.5%)	10 (90.9%)	22 (91.7%)	23 (88.5%)	12 (66.7%)	131 (81.9%)	155 (82.4%)
Infections and infestations (感染症および寄生虫症)											
Male	44 (41.5%)	44 (43.6%)	20 (46.5%)	18 (39.1%)	9 (18.8%)	24 (44.4%)	14 (35.9%)	16 (36.4%)	21 (46.7%)	166 (39.5%)	210 (39.9%)
Female	13 (46.4%)	13 (50.0%)	17 (81.0%)	10 (55.6%)	4 (25.0%)	8 (72.7%)	14 (58.3%)	14 (53.8%)	8 (44.4%)	88 (55.0%)	101 (53.7%)
Nasopharyngitis (上咽頭炎)											
Male	30 (28.3%)	29 (28.7%)	14 (32.6%)	10 (21.7%)	3 (6.3%)	12 (22.2%)	10 (25.6%)	12 (27.3%)	14 (31.1%)	104 (24.8%)	134 (25.5%)
Female	10 (35.7%)	10 (38.5%)	13 (61.9%)	6 (33.3%)	2 (12.5%)	6 (54.5%)	9 (37.5%)	8 (30.8%)	6 (33.3%)	60 (37.5%)	70 (37.2%)
Pharyngitis (咽頭炎)											
Male	5 (4.7%)	4 (4.0%)	4 (9.3%)	0	1 (2.1%)	3 (5.6%)	1 (2.6%)	1 (2.3%)	3 (6.7%)	17 (4.0%)	22 (4.2%)
Female	3 (10.7%)	1 (3.8%)	0	0	1 (6.3%)	0	2 (8.3%)	0	2 (11.1%)	6 (3.8%)	9 (4.8%)
Influenza (インフルエンザ)											
Male	4 (3.8%)	7 (6.9%)	1 (2.3%)	3 (6.5%)	1 (2.1%)	2 (3.7%)	1 (2.6%)	1 (2.3%)	2 (4.4%)	18 (4.3%)	22 (4.2%)
Female	0	2 (7.7%)	1 (4.8%)	2 (11.1%)	0	1 (9.1%)	0	0	0	6 (3.8%)	6 (3.2%)
Bronchitis (気管支炎)											
Male	1 (0.9%)	1 (1.0%)	2 (4.7%)	1 (2.2%)	0	4 (7.4%)	0	0	2 (4.4%)	10 (2.4%)	11 (2.1%)
Female	0	0	2 (9.5%)	1 (5.6%)	0	0	0	0	0	3 (1.9%)	3 (1.6%)
Gastroenteritis (胃腸炎)											
Male	0	0	1 (2.3%)	1 (2.2%)	1 (2.1%)	1 (1.9%)	0	1 (2.3%)	1 (2.2%)	6 (1.4%)	6 (1.1%)

System Organ Class Preferred Term Sex	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
Female	2 (7.1%)	0	2 (9.5%)	2 (11.1%)	0	0	1 (4.2%)	1 (3.8%)	0	6 (3.8%)	8 (4.3%)
Periodontitis (歯周炎)											
Male	0	3 (3.0%)	1 (2.3%)	1 (2.2%)	0	2 (3.7%)	0	1 (2.3%)	0	8 (1.9%)	8 (1.5%)
Female	0	0	0	1 (5.6%)	0	1 (9.1%)	2 (8.3%)	0	0	4 (2.5%)	4 (2.1%)
Cystitis (膀胱炎)											
Male	0	1 (1.0%)	0	0	0	0	0	0	1 (2.2%)	2 (0.5%)	2 (0.4%)
Female	1 (3.6%)	1 (3.8%)	2 (9.5%)	0	0	1 (9.1%)	2 (8.3%)	2 (7.7%)	0	8 (5.0%)	9 (4.8%)
Herpes zoster (帯状疱疹)											
Male	2 (1.9%)	1 (1.0%)	1 (2.3%)	0	0	1 (1.9%)	0	0	1 (2.2%)	4 (1.0%)	6 (1.1%)
Female	0	0	0	0	0	0	1 (4.2%)	1 (3.8%)	1 (5.6%)	3 (1.9%)	3 (1.6%)
Upper respiratory tract infection (上気道感染)											
Male	2 (1.9%)	1 (1.0%)	0	0	0	0	2 (5.1%)	0	0	3 (0.7%)	5 (1.0%)
Female	0	0	0	0	0	0	0	0	1 (5.6%)	1 (0.6%)	1 (0.5%)
Pneumonia (肺炎)											
Male	0	1 (1.0%)	0	0	0	1 (1.9%)	0	0	1 (2.2%)	3 (0.7%)	3 (0.6%)
Female	0	0	1 (4.8%)	1 (5.6%)	0	0	0	0	0	2 (1.3%)	2 (1.1%)
Tinea pedis (足部白癬)											
Male	0	0	0	0	0	0	1 (2.6%)	1 (2.3%)	1 (2.2%)	3 (0.7%)	3 (0.6%)
Female	0	1 (3.8%)	0	0	1 (6.3%)	0	0	0	0	2 (1.3%)	2 (1.1%)
Urinary tract infection (尿路感染)											
Male	0	0	0	0	2 (4.2%)	2 (3.7%)	0	0	0	4 (1.0%)	4 (0.8%)
Female	0	0	0	0	1 (6.3%)	0	0	0	0	1 (0.6%)	1 (0.5%)
Conjunctivitis (結膜炎)											
Male	1 (0.9%)	2 (2.0%)	0	0	0	1 (1.9%)	0	0	0	3 (0.7%)	4 (0.8%)
Female	0	0	0	0	0	0	0	0	0	0	0

System Organ Class Preferred Term Sex	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
Gingivitis (歯肉炎)											
Male	0	1 (1.0%)	0	0	0	1 (1.9%)	0	2 (4.5%)	0	4 (1.0%)	4 (0.8%)
Female	0	0	0	0	0	0	0	0	0	0	0
Otitis externa (外耳炎)											
Male	1 (0.9%)	1 (1.0%)	0	0	0	1 (1.9%)	0	0	0	2 (0.5%)	3 (0.6%)
Female	1 (3.6%)	0	0	0	0	0	0	0	0	0	1 (0.5%)
Pericoronitis (歯冠周囲炎)											
Male	0	0	0	0	1 (2.1%)	0	0	2 (4.5%)	1 (2.2%)	4 (1.0%)	4 (0.8%)
Female	0	0	0	0	0	0	0	0	0	0	0
Dermatophytosis of nail (爪の皮膚糸状菌症)											
Male	0	1 (1.0%)	0	0	0	1 (1.9%)	0	0	0	2 (0.5%)	2 (0.4%)
Female	0	1 (3.8%)	0	0	0	0	0	0	0	1 (0.6%)	1 (0.5%)
Oral herpes (口腔ヘルペス)											
Male	0	1 (1.0%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	1 (4.8%)	0	0	0	1 (4.2%)	0	0	2 (1.3%)	2 (1.1%)
Sinusitis (副鼻腔炎)											
Male	0	1 (1.0%)	0	0	1 (2.1%)	0	0	0	0	2 (0.5%)	2 (0.4%)
Female	0	0	0	1 (5.6%)	0	0	0	0	0	1 (0.6%)	1 (0.5%)
Appendicitis (虫垂炎)											
Male	1 (0.9%)	0	0	1 (2.2%)	0	0	0	0	0	1 (0.2%)	2 (0.4%)
Female	0	0	0	0	0	0	0	0	0	0	0
Asymptomatic bacteriuria (無症候性細菌尿)											
Male	0	0	0	0	0	0	0	0	0	0	0
Female	0	1 (3.8%)	0	0	0	0	0	1 (3.8%)	0	2 (1.3%)	2 (1.1%)

System Organ Class Preferred Term Sex	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
Chronic sinusitis (慢性副鼻腔炎)											
Male	0	0	0	0	0	0	0	0	0	0	0
Female	0	0	0	0	0	1 (9.1%)	0	0	1 (5.6%)	2 (1.3%)	2 (1.1%)
Diverticulitis (憩室炎)											
Male	0	0	0	1 (2.2%)	0	1 (1.9%)	0	0	0	2 (0.5%)	2 (0.4%)
Female	0	0	0	0	0	0	0	0	0	0	0
Enteritis infectious (感染性腸炎)											
Male	0	1 (1.0%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	1 (4.2%)	0	0	1 (0.6%)	1 (0.5%)
Folliculitis (毛包炎)											
Male	1 (0.9%)	0	0	0	0	0	0	0	1 (2.2%)	1 (0.2%)	2 (0.4%)
Female	0	0	0	0	0	0	0	0	0	0	0
Gastroenteritis viral (ウイルス性胃腸炎)											
Male	0	0	0	1 (2.2%)	1 (2.1%)	0	0	0	0	2 (0.5%)	2 (0.4%)
Female	0	0	0	0	0	0	0	0	0	0	0
Helicobacter infection (ヘリコバクター感染)											
Male	0	0	0	1 (2.2%)	0	0	0	1 (2.3%)	0	2 (0.5%)	2 (0.4%)
Female	0	0	0	0	0	0	0	0	0	0	0
Impetigo (膿痂疹)											
Male	0	1 (1.0%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	1 (3.8%)	0	1 (0.6%)	1 (0.5%)
Otitis media (中耳炎)											

System Organ Class Preferred Term Sex	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
Male	0	1 (1.0%)	0	0	0	0	0	0	1 (2.2%)	2 (0.5%)	2 (0.4%)
Female	0	0	0	0	0	0	0	0	0	0	0
Otitis media acute (急性中耳炎)											
Male	0	0	0	0	0	0	0	0	0	0	0
Female	0	1 (3.8%)	0	0	0	0	0	1 (3.8%)	0	2 (1.3%)	2 (1.1%)
Paronychia (爪囲炎)											
Male	0	0	0	0	0	1 (1.9%)	0	1 (2.3%)	0	2 (0.5%)	2 (0.4%)
Female	0	0	0	0	0	0	0	0	0	0	0
Pneumonia bacterial (細菌性肺炎)											
Male	0	0	0	1 (2.2%)	0	1 (1.9%)	0	0	0	2 (0.5%)	2 (0.4%)
Female	0	0	0	0	0	0	0	0	0	0	0
Pulpitis dental (歯髄炎)											
Male	0	0	0	0	0	0	0	0	1 (2.2%)	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	1 (4.2%)	0	0	1 (0.6%)	1 (0.5%)
Rhinitis (鼻炎)											
Male	0	1 (1.0%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	1 (9.1%)	0	0	0	1 (0.6%)	1 (0.5%)
Acute sinusitis (急性副鼻腔炎)											
Male	0	0	0	0	0	0	0	0	0	0	0
Female	0	1 (3.8%)	0	0	0	0	0	0	0	1 (0.6%)	1 (0.5%)
Bacterial vulvovaginitis (細菌性外陰腟炎)											
Male	0	0	0	0	0	0	0	0	0	0	0
Female	0	0	1 (4.8%)	0	0	0	0	0	0	1 (0.6%)	1 (0.5%)

System Organ Class Preferred Term Sex	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
Cellulitis (蜂巣炎)											
Male	0	0	0	0	0	0	1 (2.6%)	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Eczema impetiginous (膿痂疹性湿疹)											
Male	0	0	0	0	0	0	1 (2.6%)	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Endometritis (子宮内膜炎)											
Male	0	0	0	0	0	0	0	0	0	0	0
Female	0	0	0	1 (5.6%)	0	0	0	0	0	1 (0.6%)	1 (0.5%)
Enterocolitis viral (ウイルス性腸炎)											
Male	0	0	0	0	0	1 (1.9%)	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Furuncle (せつ)											
Male	0	0	0	0	0	0	1 (2.6%)	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Nasal vestibulitis (鼻前庭炎)											
Male	0	0	0	0	0	0	1 (2.6%)	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Skin bacterial infection (皮膚細菌感染)											
Male	0	0	0	0	0	1 (1.9%)	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Skin infection (皮膚感染)											
Male	0	0	0	0	0	0	0	0	0	0	0

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Female	0	0	1 (4.8%)	0	0	0	0	0	0	1 (0.6%)	1 (0.5%)
Streptococcal infection (レンサ球菌感染)											
Male	0	1 (1.0%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Subcutaneous abscess (皮下組織膿瘍)											
Male	0	0	0	0	0	0	1 (2.6%)	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Tinea infection (白癬感染)											
Male	0	0	0	0	0	0	0	1 (2.3%)	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Vaginal infection (膣感染)											
Male	0	0	0	0	0	0	0	0	0	0	0
Female	0	0	0	0	0	0	1 (4.2%)	0	0	1 (0.6%)	1 (0.5%)
Gastrointestinal disorders (胃腸障害)											
Male	18 (17.0%)	21 (20.8%)	6 (14.0%)	15 (32.6%)	3 (6.3%)	5 (9.3%)	10 (25.6%)	5 (11.4%)	12 (26.7%)	77 (18.3%)	95 (18.1%)
Female	11 (39.3%)	7 (26.9%)	6 (28.6%)	10 (55.6%)	2 (12.5%)	4 (36.4%)	11 (45.8%)	9 (34.6%)	3 (16.7%)	52 (32.5%)	63 (33.5%)
Nausea (悪心)											
Male	6 (5.7%)	1 (1.0%)	0	5 (10.9%)	0	0	2 (5.1%)	1 (2.3%)	3 (6.7%)	12 (2.9%)	18 (3.4%)
Female	3 (10.7%)	0	0	3 (16.7%)	1 (6.3%)	1 (9.1%)	3 (12.5%)	2 (7.7%)	1 (5.6%)	11 (6.9%)	14 (7.4%)
Diarrhoea (下痢)											
Male	4 (3.8%)	3 (3.0%)	3 (7.0%)	6 (13.0%)	0	0	2 (5.1%)	1 (2.3%)	2 (4.4%)	17 (4.0%)	21 (4.0%)
Female	0	0	1 (4.8%)	5 (27.8%)	0	2 (18.2%)	0	2 (7.7%)	0	10 (6.3%)	10 (5.3%)

System Organ Class Preferred Term Sex	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
Constipation (便秘)											
Male	1 (0.9%)	7 (6.9%)	0	0	2 (4.2%)	0	2 (5.1%)	1 (2.3%)	2 (4.4%)	14 (3.3%)	15 (2.9%)
Female	4 (14.3%)	1 (3.8%)	2 (9.5%)	1 (5.6%)	0	1 (9.1%)	3 (12.5%)	0	0	8 (5.0%)	12 (6.4%)
Gastrooesophageal reflux disease (胃食道逆流性疾患)											
Male	2 (1.9%)	6 (5.9%)	1 (2.3%)	0	0	0	0	1 (2.3%)	0	8 (1.9%)	10 (1.9%)
Female	1 (3.6%)	3 (11.5%)	0	2 (11.1%)	0	0	0	0	0	5 (3.1%)	6 (3.2%)
Abdominal pain upper (上腹部痛)											
Male	1 (0.9%)	1 (1.0%)	0	0	0	0	1 (2.6%)	0	0	2 (0.5%)	3 (0.6%)
Female	3 (10.7%)	0	1 (4.8%)	3 (16.7%)	0	0	1 (4.2%)	1 (3.8%)	0	6 (3.8%)	9 (4.8%)
Dental caries (齲歯)											
Male	3 (2.8%)	0	0	1 (2.2%)	0	2 (3.7%)	2 (5.1%)	0	0	5 (1.2%)	8 (1.5%)
Female	2 (7.1%)	0	1 (4.8%)	0	0	1 (9.1%)	0	0	0	2 (1.3%)	4 (2.1%)
Vomiting (嘔吐)											
Male	1 (0.9%)	0	0	1 (2.2%)	0	0	0	0	0	1 (0.2%)	2 (0.4%)
Female	0	0	0	3 (16.7%)	0	2 (18.2%)	2 (8.3%)	2 (7.7%)	1 (5.6%)	10 (6.3%)	10 (5.3%)
Abdominal discomfort (腹部不快感)											
Male	0	1 (1.0%)	0	1 (2.2%)	1 (2.1%)	0	1 (2.6%)	0	0	4 (1.0%)	4 (0.8%)
Female	0	1 (3.8%)	1 (4.8%)	2 (11.1%)	0	0	1 (4.2%)	0	0	5 (3.1%)	5 (2.7%)
Chronic gastritis (慢性胃炎)											
Male	0	2 (2.0%)	0	1 (2.2%)	0	0	0	1 (2.3%)	1 (2.2%)	5 (1.2%)	5 (1.0%)
Female	0	0	0	0	0	0	2 (8.3%)	0	0	2 (1.3%)	2 (1.1%)
Dyspepsia (消化不良)											
Male	0	2 (2.0%)	1 (2.3%)	0	0	0	0	0	0	3 (0.7%)	3 (0.6%)

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Female	0	0	0	0	0	0	2 (8.3%)	2 (7.7%)	0	4 (2.5%)	4 (2.1%)
Faeces soft (軟便)											
Male	1 (0.9%)	0	1 (2.3%)	2 (4.3%)	0	0	0	0	1 (2.2%)	4 (1.0%)	5 (1.0%)
Female	0	1 (3.8%)	0	0	0	0	0	0	0	1 (0.6%)	1 (0.5%)
Large intestine polyp (大腸ポリープ)											
Male	1 (0.9%)	0	0	2 (4.3%)	0	0	0	1 (2.3%)	1 (2.2%)	4 (1.0%)	5 (1.0%)
Female	0	0	0	0	0	0	1 (4.2%)	0	0	1 (0.6%)	1 (0.5%)
Abdominal pain (腹痛)											
Male	0	0	1 (2.3%)	0	0	0	1 (2.6%)	0	0	2 (0.5%)	2 (0.4%)
Female	0	1 (3.8%)	0	0	0	0	0	0	1 (5.6%)	2 (1.3%)	2 (1.1%)
Gastritis (胃炎)											
Male	0	0	0	0	0	0	0	1 (2.3%)	1 (2.2%)	2 (0.5%)	2 (0.4%)
Female	0	0	0	0	1 (6.3%)	0	0	0	1 (5.6%)	2 (1.3%)	2 (1.1%)
Abdominal distension (腹部膨満)											
Male	0	0	0	0	0	0	1 (2.6%)	0	2 (4.4%)	3 (0.7%)	3 (0.6%)
Female	0	0	0	0	0	0	0	0	0	0	0
Aphthous ulcer (アフタ性潰瘍)											
Male	0	0	0	1 (2.2%)	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Female	1 (3.6%)	0	0	0	0	0	1 (4.2%)	0	0	1 (0.6%)	2 (1.1%)
Food poisoning (食中毒)											
Male	1 (0.9%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
Female	0	0	0	0	0	0	0	0	1 (5.6%)	1 (0.6%)	1 (0.5%)

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Abdominal pain lower (下腹部痛)											
Male	0	0	0	0	0	0	0	0	0	0	0
Female	0	0	0	0	0	0	1 (4.2%)	0	0	1 (0.6%)	1 (0.5%)
Change of bowel habit (便習慣変化)											
Male	0	0	0	0	0	0	0	0	0	0	0
Female	0	0	0	0	0	0	0	1 (3.8%)	0	1 (0.6%)	1 (0.5%)
Colitis (大腸炎)											
Male	0	1 (1.0%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Colitis ulcerative (潰瘍性大腸炎)											
Male	1 (0.9%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Diverticulum intestinal (腸憩室)											
Male	0	1 (1.0%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Enteritis (小腸炎)											
Male	0	0	0	0	0	0	1 (2.6%)	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Enterocolitis (腸炎)											
Male	0	0	0	0	0	1 (1.9%)	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0

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Enterovesical fistula (腸膀胱瘻)											
Male	0	0	0	0	0	1 (1.9%)	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Epigastric discomfort (心窩部不快感)											
Male	0	0	0	0	0	0	0	1 (2.3%)	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Flatulence (鼓腸)											
Male	0	0	1 (2.3%)	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Gastric polyps (胃ポリープ)											
Male	0	0	0	0	0	0	0	0	0	0	0
Female	0	0	0	0	0	0	1 (4.2%)	0	0	1 (0.6%)	1 (0.5%)
Gastritis erosive (びらん性胃炎)											
Male	0	1 (1.0%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Gastrointestinal disorder (胃腸障害)											
Male	0	0	0	0	0	0	0	0	1 (2.2%)	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Glossitis (舌炎)											
Male	0	0	0	0	0	0	0	0	0	0	0
Female	0	0	0	0	0	0	0	1 (3.8%)	0	1 (0.6%)	1 (0.5%)
Haematochezia (血便排泄)											

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Male	0	0	0	0	0	0	0	0	0	0	0
Female	0	1 (3.8%)	0	0	0	0	0	0	0	1 (0.6%)	1 (0.5%)
Inguinal hernia (鼠径ヘルニア)											
Male	0	0	0	1 (2.2%)	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Irritable bowel syndrome (過敏性腸症候群)											
Male	1 (0.9%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Lower gastrointestinal haemorrhage (下部消化管出血)											
Male	0	0	0	0	0	0	0	0	0	0	0
Female	0	1 (3.8%)	0	0	0	0	0	0	0	1 (0.6%)	1 (0.5%)
Mouth ulceration (口腔内潰瘍形成)											
Male	0	0	0	0	0	0	0	0	1 (2.2%)	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Pancreatic steatosis (膵脂肪変性)											
Male	0	0	0	0	0	1 (1.9%)	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Periodontal disease (歯周病)											
Male	0	1 (1.0%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Stomatitis (口内炎)											

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Male	0	0	0	0	0	0	0	0	0	0	0
Female	0	0	0	0	0	0	0	1 (3.8%)	0	1 (0.6%)	1 (0.5%)
Tooth loss (歯の脱落)											
Male	1 (0.9%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Toothache (歯痛)											
Male	0	0	0	0	0	0	0	0	0	0	0
Female	0	0	1 (4.8%)	0	0	0	0	0	0	1 (0.6%)	1 (0.5%)
Musculoskeletal and connective tissue disorders (筋骨格系および結合組織障害)											
Male	12 (11.3%)	19 (18.8%)	5 (11.6%)	4 (8.7%)	4 (8.3%)	5 (9.3%)	5 (12.8%)	8 (18.2%)	2 (4.4%)	52 (12.4%)	64 (12.2%)
Female	3 (10.7%)	3 (11.5%)	5 (23.8%)	3 (16.7%)	2 (12.5%)	1 (9.1%)	11 (45.8%)	3 (11.5%)	2 (11.1%)	30 (18.8%)	33 (17.6%)
Back pain (背部痛)											
Male	4 (3.8%)	9 (8.9%)	1 (2.3%)	1 (2.2%)	2 (4.2%)	4 (7.4%)	0	0	0	17 (4.0%)	21 (4.0%)
Female	1 (3.6%)	1 (3.8%)	2 (9.5%)	0	0	0	1 (4.2%)	0	0	4 (2.5%)	5 (2.7%)
Arthralgia (関節痛)											
Male	1 (0.9%)	3 (3.0%)	0	0	0	1 (1.9%)	0	1 (2.3%)	0	5 (1.2%)	6 (1.1%)
Female	0	0	0	2 (11.1%)	0	1 (9.1%)	2 (8.3%)	1 (3.8%)	1 (5.6%)	7 (4.4%)	7 (3.7%)
Pain in extremity (四肢痛)											
Male	0	3 (3.0%)	1 (2.3%)	0	0	0	0	1 (2.3%)	1 (2.2%)	6 (1.4%)	6 (1.1%)
Female	1 (3.6%)	0	1 (4.8%)	0	0	0	1 (4.2%)	0	0	2 (1.3%)	3 (1.6%)
Myalgia (筋肉痛)											
Male	2 (1.9%)	1 (1.0%)	0	1 (2.2%)	0	0	0	0	1 (2.2%)	3 (0.7%)	5 (1.0%)
Female	0	0	1 (4.8%)	0	1 (6.3%)	0	0	0	1 (5.6%)	3 (1.9%)	3 (1.6%)

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Spinal osteoarthritis (変形性脊椎症)											
Male	1 (0.9%)	0	0	0	0	0	1 (2.6%)	1 (2.3%)	1 (2.2%)	3 (0.7%)	4 (0.8%)
Female	0	0	0	0	1 (6.3%)	0	3 (12.5%)	0	0	4 (2.5%)	4 (2.1%)
Intervertebral disc protrusion (椎間板突出)											
Male	0	0	1 (2.3%)	0	1 (2.1%)	0	2 (5.1%)	1 (2.3%)	0	5 (1.2%)	5 (1.0%)
Female	0	0	0	0	0	0	2 (8.3%)	0	0	2 (1.3%)	2 (1.1%)
Osteoarthritis (変形性関節症)											
Male	2 (1.9%)	0	0	1 (2.2%)	0	0	1 (2.6%)	0	0	2 (0.5%)	4 (0.8%)
Female	0	0	1 (4.8%)	0	0	0	1 (4.2%)	0	0	2 (1.3%)	2 (1.1%)
Periarthritis (関節周囲炎)											
Male	1 (0.9%)	1 (1.0%)	0	0	0	0	0	1 (2.3%)	0	2 (0.5%)	3 (0.6%)
Female	0	0	1 (4.8%)	0	0	0	1 (4.2%)	0	0	2 (1.3%)	2 (1.1%)
Lumbar spinal stenosis (腰部脊柱管狭窄症)											
Male	1 (0.9%)	0	0	0	0	0	0	2 (4.5%)	0	2 (0.5%)	3 (0.6%)
Female	0	0	0	0	0	0	1 (4.2%)	0	0	1 (0.6%)	1 (0.5%)
Muscle spasms (筋痙縮)											
Male	0	0	2 (4.7%)	0	0	0	0	0	0	2 (0.5%)	2 (0.4%)
Female	0	1 (3.8%)	0	0	0	0	1 (4.2%)	0	0	2 (1.3%)	2 (1.1%)
Musculoskeletal stiffness (筋骨格硬直)											
Male	0	1 (1.0%)	2 (4.7%)	0	0	0	0	0	0	3 (0.7%)	3 (0.6%)
Female	0	1 (3.8%)	0	0	0	0	0	0	0	1 (0.6%)	1 (0.5%)
Trigger finger (弾発指)											

System Organ Class Preferred Term Sex	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
Male	0	0	0	0	0	0	0	1 (2.3%)	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	2 (8.3%)	1 (3.8%)	0	3 (1.9%)	3 (1.6%)
Musculoskeletal pain (筋骨格痛)											
Male	1 (0.9%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
Female	1 (3.6%)	0	0	0	0	0	0	0	0	0	1 (0.5%)
Neck pain (頚部痛)											
Male	0	0	0	0	1 (2.1%)	0	0	1 (2.3%)	0	2 (0.5%)	2 (0.4%)
Female	0	0	0	0	0	0	0	0	0	0	0
Arthritis (関節炎)											
Male	0	0	0	0	0	0	0	0	0	0	0
Female	0	0	0	0	0	0	0	1 (3.8%)	0	1 (0.6%)	1 (0.5%)
Flank pain (側腹部痛)											
Male	0	0	0	0	0	0	0	0	0	0	0
Female	0	0	0	1 (5.6%)	0	0	0	0	0	1 (0.6%)	1 (0.5%)
Joint contracture (関節拘縮)											
Male	0	0	0	0	0	0	1 (2.6%)	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Plantar fasciitis (足底筋膜炎)											
Male	0	0	0	1 (2.2%)	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Spondylolisthesis (脊椎すべり症)											
Male	1 (0.9%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Synovitis (滑膜炎)											

System Organ Class Preferred Term Sex	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
Male	0	1 (1.0%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Temporomandibular joint syndrome (顎関節症候群)											
Male	0	0	1 (2.3%)	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Tendon pain (腱痛)											
Male	0	1 (1.0%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Metabolism and nutrition disorders (代謝および栄養障害)											
Male	10 (9.4%)	21 (20.8%)	6 (14.0%)	6 (13.0%)	4 (8.3%)	4 (7.4%)	6 (15.4%)	9 (20.5%)	4 (8.9%)	60 (14.3%)	70 (13.3%)
Female	3 (10.7%)	7 (26.9%)	4 (19.0%)	2 (11.1%)	0	1 (9.1%)	2 (8.3%)	4 (15.4%)	2 (11.1%)	22 (13.8%)	25 (13.3%)
Hypoglycaemia (低血糖)											
Male	5 (4.7%)	16 (15.8%)	5 (11.6%)	4 (8.7%)	2 (4.2%)	2 (3.7%)	3 (7.7%)	2 (4.5%)	2 (4.4%)	36 (8.6%)	41 (7.8%)
Female	0	5 (19.2%)	4 (19.0%)	2 (11.1%)	0	0	2 (8.3%)	0	2 (11.1%)	15 (9.4%)	15 (8.0%)
Hyperglycaemia (高血糖)											
Male	4 (3.8%)	5 (5.0%)	0	0	1 (2.1%)	1 (1.9%)	2 (5.1%)	5 (11.4%)	1 (2.2%)	15 (3.6%)	19 (3.6%)
Female	1 (3.6%)	2 (7.7%)	0	0	0	0	0	3 (11.5%)	0	5 (3.1%)	6 (3.2%)
Decreased appetite (食欲減退)											
Male	1 (0.9%)	0	0	2 (4.3%)	0	1 (1.9%)	2 (5.1%)	2 (4.5%)	0	7 (1.7%)	8 (1.5%)
Female	2 (7.1%)	0	0	0	0	1 (9.1%)	0	1 (3.8%)	1 (5.6%)	3 (1.9%)	5 (2.7%)
Hyperuricaemia (高尿酸血症)											
Male	0	2 (2.0%)	0	0	0	0	0	0	1 (2.2%)	3 (0.7%)	3 (0.6%)
Female	0	0	0	0	0	0	0	0	0	0	0
Dehydration (脱水)											

System Organ Class Preferred Term Sex	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
Male	0	0	0	0	1 (2.1%)	0	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Dyslipidaemia (脂質異常症)											
Male	0	0	0	0	0	0	0	0	0	0	0
Female	0	1 (3.8%)	0	0	0	0	0	0	0	1 (0.6%)	1 (0.5%)
Gout (痛風)											
Male	0	0	1 (2.3%)	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Injury, poisoning and procedural complications (傷害、中毒および処置合併症)											
Male	8 (7.5%)	10 (9.9%)	5 (11.6%)	2 (4.3%)	1 (2.1%)	5 (9.3%)	5 (12.8%)	4 (9.1%)	2 (4.4%)	34 (8.1%)	42 (8.0%)
Female	3 (10.7%)	3 (11.5%)	3 (14.3%)	3 (16.7%)	3 (18.8%)	1 (9.1%)	9 (37.5%)	3 (11.5%)	2 (11.1%)	27 (16.9%)	30 (16.0%)
Contusion (挫傷)											
Male	2 (1.9%)	2 (2.0%)	0	0	0	0	0	0	0	2 (0.5%)	4 (0.8%)
Female	1 (3.6%)	1 (3.8%)	0	2 (11.1%)	0	0	3 (12.5%)	0	0	6 (3.8%)	7 (3.7%)
Ligament sprain (靱帯捻挫)											
Male	1 (0.9%)	1 (1.0%)	1 (2.3%)	0	0	1 (1.9%)	0	1 (2.3%)	0	4 (1.0%)	5 (1.0%)
Female	0	0	1 (4.8%)	0	0	0	0	0	0	1 (0.6%)	1 (0.5%)
Thermal burn (熱傷)											
Male	1 (0.9%)	0	0	1 (2.2%)	0	0	0	1 (2.3%)	0	2 (0.5%)	3 (0.6%)
Female	0	0	0	1 (5.6%)	0	0	1 (4.2%)	0	0	2 (1.3%)	2 (1.1%)
Heat illness (熱中症)											
Male	0	0	0	0	1 (2.1%)	0	1 (2.6%)	0	0	2 (0.5%)	2 (0.4%)
Female	0	0	1 (4.8%)	0	0	0	0	1 (3.8%)	0	2 (1.3%)	2 (1.1%)
Rib fracture (肋骨骨折)											

System Organ Class Preferred Term Sex	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
Male	0	2 (2.0%)	0	0	0	0	1 (2.6%)	0	1 (2.2%)	4 (1.0%)	4 (0.8%)
Female	0	0	0	0	0	0	0	0	0	0	0
Wound (創傷)											
Male	1 (0.9%)	0	0	0	0	1 (1.9%)	0	1 (2.3%)	0	2 (0.5%)	3 (0.6%)
Female	1 (3.6%)	0	0	0	0	0	0	0	0	0	1 (0.5%)
Arthropod bite (節足動物咬傷)											
Male	0	0	0	0	0	0	0	0	0	0	0
Female	0	0	1 (4.8%)	0	0	0	1 (4.2%)	1 (3.8%)	0	3 (1.9%)	3 (1.6%)
Arthropod sting (節足動物刺傷)											
Male	0	0	0	0	0	0	0	0	0	0	0
Female	0	0	0	1 (5.6%)	1 (6.3%)	0	1 (4.2%)	0	0	3 (1.9%)	3 (1.6%)
Foot fracture (足骨折)											
Male	0	0	1 (2.3%)	0	0	0	1 (2.6%)	0	0	2 (0.5%)	2 (0.4%)
Female	0	0	0	0	0	0	0	1 (3.8%)	0	1 (0.6%)	1 (0.5%)
Radius fracture (橈骨骨折)											
Male	1 (0.9%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
Female	0	0	0	0	0	0	2 (8.3%)	0	0	2 (1.3%)	2 (1.1%)
Avulsion fracture (剥離骨折)											
Male	0	0	0	0	0	1 (1.9%)	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	1 (5.6%)	1 (0.6%)	1 (0.5%)
Hand fracture (手骨折)											
Male	0	0	1 (2.3%)	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	1 (3.8%)	0	1 (0.6%)	1 (0.5%)
Ligament injury (靱帯損傷)											
Male	0	0	0	0	0	0	0	0	0	0	0

System Organ Class Preferred Term Sex	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
Female	1 (3.6%)	0	0	0	0	1 (9.1%)	0	0	0	1 (0.6%)	2 (1.1%)
Muscle strain (肉離れ)											
Male	1 (0.9%)	0	0	0	0	0	1 (2.6%)	0	0	1 (0.2%)	2 (0.4%)
Female	0	0	0	0	0	0	0	0	0	0	0
Tendon rupture (腱断裂)											
Male	0	0	2 (4.7%)	0	0	0	0	0	0	2 (0.5%)	2 (0.4%)
Female	0	0	0	0	0	0	0	0	0	0	0
Animal bite (動物咬傷)											
Male	1 (0.9%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Clavicle fracture (鎖骨骨折)											
Male	0	1 (1.0%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Closed globe injury (閉鎖性眼球損傷)											
Male	0	0	0	0	0	1 (1.9%)	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Concussion (脳振盪)											
Male	0	0	0	0	0	0	0	0	0	0	0
Female	0	1 (3.8%)	0	0	0	0	0	0	0	1 (0.6%)	1 (0.5%)
Craniocerebral injury (頭蓋脳損傷)											
Male	0	0	0	0	0	1 (1.9%)	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Epicondylitis (上顆炎)											
Male	0	0	1 (2.3%)	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)

System Organ Class Preferred Term Sex	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
Female	0	0	0	0	0	0	0	0	0	0	0
Fractured coccyx (尾骨骨折)											
Male	0	0	0	0	0	0	0	0	0	0	0
Female	0	1 (3.8%)	0	0	0	0	0	0	0	1 (0.6%)	1 (0.5%)
Fractured ischium (坐骨骨折)											
Male	0	0	0	0	0	0	0	0	0	0	0
Female	0	0	0	0	0	0	1 (4.2%)	0	0	1 (0.6%)	1 (0.5%)
Heat stroke (熱射病)											
Male	0	0	0	0	0	0	0	0	0	0	0
Female	0	0	0	0	0	0	1 (4.2%)	0	0	1 (0.6%)	1 (0.5%)
Laceration (裂傷)											
Male	1 (0.9%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Lower limb fracture (下肢骨折)											
Male	0	1 (1.0%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Meniscus injury (半月板損傷)											
Male	0	0	0	0	0	0	0	0	0	0	0
Female	0	0	0	0	0	0	0	0	1 (5.6%)	1 (0.6%)	1 (0.5%)
Multiple fractures (多発骨折)											
Male	0	0	0	0	0	0	1 (2.6%)	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Nasal injury (鼻部損傷)											
Male	0	0	0	0	0	0	0	1 (2.3%)	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0

System Organ Class Preferred Term Sex	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
Pneumothorax traumatic (外傷性気胸)											
Male	0	1 (1.0%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Post procedural haemorrhage (処置後出血)											
Male	1 (0.9%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Post-traumatic neck syndrome (外傷後頚部症候群)											
Male	0	0	0	0	0	0	0	0	0	0	0
Female	0	0	0	0	1 (6.3%)	0	0	0	0	1 (0.6%)	1 (0.5%)
Procedural pain (処置による疼痛)											
Male	0	0	0	0	0	0	0	0	0	0	0
Female	0	0	0	0	1 (6.3%)	0	0	0	0	1 (0.6%)	1 (0.5%)
Pubis fracture (恥骨骨折)											
Male	0	0	0	0	0	0	0	0	0	0	0
Female	0	0	0	0	0	0	1 (4.2%)	0	0	1 (0.6%)	1 (0.5%)
Skin abrasion (皮膚擦過傷)											
Male	0	1 (1.0%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Spinal compression fracture (脊椎圧迫骨折)											
Male	0	1 (1.0%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0

System Organ Class Preferred Term Sex	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
Spinal fracture (脊椎骨折)											
Male	0	0	0	0	0	0	0	0	1 (2.2%)	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Subarachnoid haemorrhage (くも膜下出血)											
Male	1 (0.9%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Subdural haematoma (硬膜下血腫)											
Male	0	1 (1.0%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Tooth fracture (歯牙破折)											
Male	0	0	0	1 (2.2%)	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Traumatic intracranial haemorrhage (外傷性頭蓋内出血)											
Male	0	0	0	0	0	0	1 (2.6%)	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Skin and subcutaneous tissue disorders (皮膚および皮下組織障害)											
Male	4 (3.8%)	8 (7.9%)	4 (9.3%)	2 (4.3%)	0	4 (7.4%)	5 (12.8%)	3 (6.8%)	3 (6.7%)	29 (6.9%)	33 (6.3%)
Female	0	2 (7.7%)	2 (9.5%)	1 (5.6%)	0	0	7 (29.2%)	4 (15.4%)	2 (11.1%)	18 (11.3%)	18 (9.6%)
Eczema (湿疹)											

System Organ Class Preferred Term Sex	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
Male	2 (1.9%)	4 (4.0%)	3 (7.0%)	0	0	1 (1.9%)	1 (2.6%)	1 (2.3%)	2 (4.4%)	12 (2.9%)	14 (2.7%)
Female	0	0	0	0	0	0	4 (16.7%)	3 (11.5%)	0	7 (4.4%)	7 (3.7%)
Acne (ざ瘡)											
Male	0	1 (1.0%)	1 (2.3%)	1 (2.2%)	0	0	0	0	0	3 (0.7%)	3 (0.6%)
Female	0	0	1 (4.8%)	0	0	0	0	0	0	1 (0.6%)	1 (0.5%)
Dermal cyst (皮膚嚢腫)											
Male	0	0	1 (2.3%)	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	1 (3.8%)	0	0	0	0	1 (4.2%)	0	0	2 (1.3%)	2 (1.1%)
Hyperkeratosis (過角化)											
Male	0	0	0	0	0	0	0	0	0	0	0
Female	0	1 (3.8%)	0	0	0	0	0	0	2 (11.1%)	3 (1.9%)	3 (1.6%)
Dermatitis (皮膚炎)											
Male	1 (0.9%)	0	0	0	0	0	0	0	1 (2.2%)	1 (0.2%)	2 (0.4%)
Female	0	0	0	0	0	0	0	0	0	0	0
Drug eruption (薬疹)											
Male	0	0	0	0	0	0	1 (2.6%)	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	1 (5.6%)	0	0	0	0	0	1 (0.6%)	1 (0.5%)
Dry skin (皮膚乾燥)											
Male	0	0	0	1 (2.2%)	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	1 (3.8%)	0	1 (0.6%)	1 (0.5%)
Eczema asteatotic (皮脂欠乏性湿疹)											
Male	0	2 (2.0%)	0	0	0	0	0	0	0	2 (0.5%)	2 (0.4%)
Female	0	0	0	0	0	0	0	0	0	0	0
Rash (発疹)											
Male	1 (0.9%)	0	0	0	0	0	0	1 (2.3%)	0	1 (0.2%)	2 (0.4%)

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Female	0	0	0	0	0	0	0	0	0	0	0
Asteatosis (皮脂欠乏症)											
Male	0	0	0	0	0	1 (1.9%)	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Dermatitis allergic (アレルギー性皮膚炎)											
Male	0	0	0	0	0	0	0	1 (2.3%)	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Dyshidrotic eczema (異汗性湿疹)											
Male	0	0	0	0	0	0	0	0	0	0	0
Female	0	0	1 (4.8%)	0	0	0	0	0	0	1 (0.6%)	1 (0.5%)
Erythema (紅斑)											
Male	0	0	0	0	0	0	1 (2.6%)	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Haemorrhage subcutaneous (皮下出血)											
Male	0	0	0	0	0	0	0	0	0	0	0
Female	0	0	0	0	0	0	1 (4.2%)	0	0	1 (0.6%)	1 (0.5%)
Leukoderma (白斑)											
Male	0	0	0	0	0	0	1 (2.6%)	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Miliaria (汗疹)											
Male	0	1 (1.0%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Nail disorder (爪の障害)											

System Organ Class Preferred Term Sex	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
Male	0	1 (1.0%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Pruritus (そう痒症)											
Male	0	0	0	0	0	1 (1.9%)	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Seborrhoeic dermatitis (脂漏性皮膚炎)											
Male	0	0	0	0	0	1 (1.9%)	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Skin mass (皮膚腫瘤)											
Male	0	0	0	0	0	0	0	0	0	0	0
Female	0	0	0	0	0	0	1 (4.2%)	0	0	1 (0.6%)	1 (0.5%)
Urticaria (蕁麻疹)											
Male	0	0	0	0	0	0	1 (2.6%)	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Respiratory, thoracic and mediastinal disorders (呼吸器、胸郭および縦隔障害)											
Male	4 (3.8%)	10 (9.9%)	3 (7.0%)	0	3 (6.3%)	2 (3.7%)	1 (2.6%)	0	4 (8.9%)	23 (5.5%)	27 (5.1%)
Female	3 (10.7%)	3 (11.5%)	1 (4.8%)	1 (5.6%)	2 (12.5%)	3 (27.3%)	1 (4.2%)	2 (7.7%)	1 (5.6%)	14 (8.8%)	17 (9.0%)
Upper respiratory tract inflammation (上気道の炎症)											
Male	0	1 (1.0%)	2 (4.7%)	0	1 (2.1%)	1 (1.9%)	1 (2.6%)	0	3 (6.7%)	9 (2.1%)	9 (1.7%)
Female	1 (3.6%)	0	0	0	0	1 (9.1%)	1 (4.2%)	0	0	2 (1.3%)	3 (1.6%)
Cough (咳嗽)											
Male	3 (2.8%)	1 (1.0%)	1 (2.3%)	0	0	0	0	0	0	2 (0.5%)	5 (1.0%)

System Organ Class Preferred Term Sex	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
Female	0	1 (3.8%)	0	1 (5.6%)	0	1 (9.1%)	0	1 (3.8%)	0	4 (2.5%)	4 (2.1%)
Oropharyngeal pain (口腔咽頭痛)											
Male	1 (0.9%)	1 (1.0%)	0	0	0	0	0	0	0	1 (0.2%)	2 (0.4%)
Female	0	0	0	0	0	1 (9.1%)	0	1 (3.8%)	1 (5.6%)	3 (1.9%)	3 (1.6%)
Rhinitis allergic (アレルギー性鼻炎)											
Male	0	1 (1.0%)	0	0	0	0	1 (2.6%)	0	0	2 (0.5%)	2 (0.4%)
Female	0	0	1 (4.8%)	0	1 (6.3%)	1 (9.1%)	0	0	0	3 (1.9%)	3 (1.6%)
Asthma (喘息)											
Male	0	1 (1.0%)	0	0	0	1 (1.9%)	0	0	1 (2.2%)	3 (0.7%)	3 (0.6%)
Female	0	0	0	0	1 (6.3%)	0	0	0	0	1 (0.6%)	1 (0.5%)
Bronchitis chronic (慢性気管支炎)											
Male	0	2 (2.0%)	0	0	1 (2.1%)	0	0	0	0	3 (0.7%)	3 (0.6%)
Female	0	0	0	0	0	0	0	0	0	0	0
Epistaxis (鼻出血)											
Male	0	1 (1.0%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Female	1 (3.6%)	1 (3.8%)	0	0	0	0	0	0	0	1 (0.6%)	2 (1.1%)
Allergic cough (アレルギー性咳嗽)											
Male	0	0	0	0	0	0	0	0	0	0	0
Female	1 (3.6%)	0	0	0	0	0	0	0	0	0	1 (0.5%)
Hiccups (しゃっくり)											
Male	0	0	0	0	1 (2.1%)	0	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0

System Organ Class Preferred Term Sex	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
Nasal congestion (鼻閉)											
Male	0	0	0	0	0	0	0	0	0	0	0
Female	0	0	0	1 (5.6%)	0	0	0	0	0	1 (0.6%)	1 (0.5%)
Pleural thickening (胸膜肥厚)											
Male	0	1 (1.0%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Productive cough (湿性咳嗽)											
Male	0	0	0	0	0	0	0	0	0	0	0
Female	0	1 (3.8%)	0	0	0	0	0	0	0	1 (0.6%)	1 (0.5%)
Rhinorrhoea (鼻漏)											
Male	0	1 (1.0%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Eye disorders (眼障害)											
Male	5 (4.7%)	5 (5.0%)	4 (9.3%)	1 (2.2%)	0	4 (7.4%)	2 (5.1%)	2 (4.5%)	3 (6.7%)	21 (5.0%)	26 (4.9%)
Female	0	2 (7.7%)	4 (19.0%)	1 (5.6%)	0	2 (18.2%)	3 (12.5%)	3 (11.5%)	1 (5.6%)	16 (10.0%)	16 (8.5%)
Diabetic retinopathy (糖尿病網膜症)											
Male	2 (1.9%)	0	1 (2.3%)	0	0	2 (3.7%)	1 (2.6%)	1 (2.3%)	0	5 (1.2%)	7 (1.3%)
Female	0	1 (3.8%)	0	0	0	0	2 (8.3%)	0	0	3 (1.9%)	3 (1.6%)
Blepharitis (眼瞼炎)											
Male	1 (0.9%)	2 (2.0%)	0	0	0	0	0	0	0	2 (0.5%)	3 (0.6%)
Female	0	0	1 (4.8%)	0	0	0	0	0	1 (5.6%)	2 (1.3%)	2 (1.1%)
Dry eye (眼乾燥)											
Male	1 (0.9%)	1 (1.0%)	1 (2.3%)	0	0	1 (1.9%)	0	0	0	3 (0.7%)	4 (0.8%)
Female	0	0	0	0	0	0	1 (4.2%)	0	0	1 (0.6%)	1 (0.5%)

System Organ Class Preferred Term Sex	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
Asthenopia (眼精疲労)											
Male	0	1 (1.0%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	2 (9.5%)	0	0	0	0	1 (3.8%)	0	3 (1.9%)	3 (1.6%)
Conjunctivitis allergic (アレルギー性結膜炎)											
Male	0	0	0	0	0	0	0	0	1 (2.2%)	1 (0.2%)	1 (0.2%)
Female	0	0	1 (4.8%)	1 (5.6%)	0	0	0	1 (3.8%)	0	3 (1.9%)	3 (1.6%)
Cataract (白内障)											
Male	1 (0.9%)	0	1 (2.3%)	0	0	0	0	0	0	1 (0.2%)	2 (0.4%)
Female	0	0	0	0	0	1 (9.1%)	0	0	0	1 (0.6%)	1 (0.5%)
Glaucoma (緑内障)											
Male	0	0	1 (2.3%)	0	0	1 (1.9%)	1 (2.6%)	0	0	3 (0.7%)	3 (0.6%)
Female	0	0	0	0	0	0	0	0	0	0	0
Ocular hyperaemia (眼充血)											
Male	0	2 (2.0%)	0	0	0	0	0	0	0	2 (0.5%)	2 (0.4%)
Female	0	0	0	0	0	0	0	0	0	0	0
Posterior capsule opacification (後嚢部混濁)											
Male	0	0	0	0	0	1 (1.9%)	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	1 (3.8%)	0	0	0	0	0	0	0	1 (0.6%)	1 (0.5%)
Arteriosclerotic retinopathy (動脈硬化性網膜症)											
Male	0	0	1 (2.3%)	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Conjunctival haemorrhage (結膜出血)											

System Organ Class Preferred Term Sex	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
Male	0	0	0	0	0	0	0	1 (2.3%)	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Diabetic retinal oedema (糖尿病性網膜浮腫)											
Male	0	0	0	0	0	0	0	0	0	0	0
Female	0	0	0	0	0	0	0	1 (3.8%)	0	1 (0.6%)	1 (0.5%)
Eye pain (眼痛)											
Male	1 (0.9%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Macular oedema (黄斑浮腫)											
Male	0	0	0	0	0	0	0	0	1 (2.2%)	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Pingueculitis (瞼裂斑炎)											
Male	0	0	0	0	0	0	0	0	1 (2.2%)	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Retinal haemorrhage (網膜出血)											
Male	0	0	1 (2.3%)	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Retinal vein occlusion (網膜静脈閉塞)											
Male	0	0	0	0	0	0	0	0	0	0	0
Female	0	0	0	0	0	1 (9.1%)	0	0	0	1 (0.6%)	1 (0.5%)
Scintillating scotoma (閃輝暗点)											
Male	0	0	0	1 (2.2%)	0	0	0	0	0	1 (0.2%)	1 (0.2%)

System Organ Class Preferred Term Sex	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
Female	0	0	0	0	0	0	0	0	0	0	0
Nervous system disorders (神経系障害)											
Male	6 (5.7%)	0	2 (4.7%)	1 (2.2%)	4 (8.3%)	6 (11.1%)	1 (2.6%)	2 (4.5%)	3 (6.7%)	19 (4.5%)	25 (4.8%)
Female	2 (7.1%)	3 (11.5%)	3 (14.3%)	1 (5.6%)	0	0	3 (12.5%)	2 (7.7%)	1 (5.6%)	13 (8.1%)	15 (8.0%)
Headache (頭痛)											
Male	2 (1.9%)	0	0	0	1 (2.1%)	2 (3.7%)	0	0	1 (2.2%)	4 (1.0%)	6 (1.1%)
Female	0	1 (3.8%)	1 (4.8%)	0	0	0	0	0	0	2 (1.3%)	2 (1.1%)
Diabetic neuropathy (糖尿病性ニューロパチー)											
Male	1 (0.9%)	0	0	0	0	0	0	0	1 (2.2%)	1 (0.2%)	2 (0.4%)
Female	0	0	0	0	0	0	2 (8.3%)	2 (7.7%)	0	4 (2.5%)	4 (2.1%)
Carotid arteriosclerosis (頚動脈硬化症)											
Male	0	0	1 (2.3%)	0	0	2 (3.7%)	0	0	0	3 (0.7%)	3 (0.6%)
Female	0	0	0	1 (5.6%)	0	0	0	0	0	1 (0.6%)	1 (0.5%)
Cervicobrachial syndrome (頚腕症候群)											
Male	1 (0.9%)	0	0	0	2 (4.2%)	0	0	0	0	2 (0.5%)	3 (0.6%)
Female	0	0	0	0	0	0	0	0	0	0	0
Dizziness (浮動性めまい)											
Male	1 (0.9%)	0	0	0	0	0	0	0	1 (2.2%)	1 (0.2%)	2 (0.4%)
Female	1 (3.6%)	0	0	0	0	0	0	0	0	0	1 (0.5%)
Intercostal neuralgia (肋間神経痛)											

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Male	0	0	1 (2.3%)	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	2 (9.5%)	0	0	0	0	0	0	2 (1.3%)	2 (1.1%)
Loss of consciousness (意識消失)											
Male	0	0	0	0	1 (2.1%)	1 (1.9%)	0	0	0	2 (0.5%)	2 (0.4%)
Female	0	0	0	0	0	0	0	0	0	0	0
Sciatica (坐骨神経痛)											
Male	1 (0.9%)	0	0	0	0	0	1 (2.6%)	0	0	1 (0.2%)	2 (0.4%)
Female	0	0	0	0	0	0	0	0	0	0	0
Carotid artery stenosis (頚動脈狭窄)											
Male	0	0	0	0	0	0	0	1 (2.3%)	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Carpal tunnel syndrome (手根管症候群)											
Male	0	0	0	0	0	0	0	0	0	0	0
Female	0	0	0	0	0	0	1 (4.2%)	0	0	1 (0.6%)	1 (0.5%)
Cerebral infarction (脳梗塞)											
Male	0	0	0	0	0	0	0	1 (2.3%)	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Dysaesthesia (異常感覚)											
Male	0	0	0	0	0	1 (1.9%)	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Hypoaesthesia (感覚鈍麻)											
Male	0	0	0	0	0	0	0	0	0	0	0
Female	0	1 (3.8%)	0	0	0	0	0	0	0	1 (0.6%)	1 (0.5%)

System Organ Class Preferred Term Sex	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
Lacunar infarction (ラクナ梗塞)											
Male	0	0	0	0	0	0	0	0	0	0	0
Female	0	0	0	0	0	0	0	0	1 (5.6%)	1 (0.6%)	1 (0.5%)
Paraesthesia (錯感覚)											
Male	0	0	0	0	0	0	0	0	0	0	0
Female	0	1 (3.8%)	0	0	0	0	0	0	0	1 (0.6%)	1 (0.5%)
Post herpetic neuralgia (ヘルペス後神経痛)											
Male	0	0	0	0	0	0	0	0	0	0	0
Female	1 (3.6%)	0	0	0	0	0	0	0	0	0	1 (0.5%)
Presyncope (失神寸前の状態)											
Male	0	0	0	1 (2.2%)	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Syncope (失神)											
Male	0	0	0	0	0	0	0	0	1 (2.2%)	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Investigations (臨床検査)											
Male	5 (4.7%)	8 (7.9%)	2 (4.7%)	1 (2.2%)	3 (6.3%)	2 (3.7%)	5 (12.8%)	1 (2.3%)	2 (4.4%)	24 (5.7%)	29 (5.5%)
Female	1 (3.6%)	0	0	1 (5.6%)	0	0	1 (4.2%)	0	0	2 (1.3%)	3 (1.6%)
Lipase increased (リパーゼ増加)											
Male	1 (0.9%)	2 (2.0%)	0	0	1 (2.1%)	1 (1.9%)	2 (5.1%)	0	0	6 (1.4%)	7 (1.3%)
Female	0	0	0	0	0	0	1 (4.2%)	0	0	1 (0.6%)	1 (0.5%)
Weight decreased (体重減少)											

System Organ Class Preferred Term Sex	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
Male	2 (1.9%)	0	0	1 (2.2%)	1 (2.1%)	0	1 (2.6%)	1 (2.3%)	0	4 (1.0%)	6 (1.1%)
Female	0	0	0	0	0	0	0	0	0	0	0
Amylase increased (アミラーゼ増加)											
Male	0	1 (1.0%)	1 (2.3%)	0	0	1 (1.9%)	1 (2.6%)	0	0	4 (1.0%)	4 (0.8%)
Female	0	0	0	0	0	0	0	0	0	0	0
Blood creatine phosphokinase increased (血中クレアチンホスホキナーゼ増加)											
Male	1 (0.9%)	0	0	0	0	1 (1.9%)	1 (2.6%)	0	0	2 (0.5%)	3 (0.6%)
Female	0	0	0	0	0	0	0	0	0	0	0
Hepatic enzyme increased (肝酵素上昇)											
Male	0	2 (2.0%)	0	0	0	0	0	0	1 (2.2%)	3 (0.7%)	3 (0.6%)
Female	0	0	0	0	0	0	0	0	0	0	0
Blood lactic acid increased (血中乳酸増加)											
Male	0	2 (2.0%)	0	0	0	0	0	0	0	2 (0.5%)	2 (0.4%)
Female	0	0	0	0	0	0	0	0	0	0	0
Gamma-glutamyltransferase increased (γ－グルタミルトランスフェラーゼ増加)											
Male	0	0	0	0	0	0	1 (2.6%)	0	1 (2.2%)	2 (0.5%)	2 (0.4%)
Female	0	0	0	0	0	0	0	0	0	0	0
Platelet count decreased (血小板数減少)											

System Organ Class Preferred Term Sex	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
Male	0	0	0	0	0	0	0	0	0	0	0
Female	1 (3.6%)	0	0	1 (5.6%)	0	0	0	0	0	1 (0.6%)	2 (1.1%)
Blood creatinine increased (血中クレアチニン増加)											
Male	0	0	0	0	1 (2.1%)	0	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
C-reactive protein increased (C－反応性蛋白増加)											
Male	0	0	1 (2.3%)	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Electrocardiogram repolarisation abnormality (心電図再分極異常)											
Male	0	1 (1.0%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Intraocular pressure increased (眼圧上昇)											
Male	0	1 (1.0%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Occult blood (便潜血)											
Male	0	1 (1.0%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Occult blood positive (便潜血陽性)											
Male	1 (0.9%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0

System Organ Class Preferred Term Sex	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
White blood cell count increased (白血球数増加)											
Male	1 (0.9%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Vascular disorders (血管障害)											
Male	1 (0.9%)	6 (5.9%)	1 (2.3%)	0	3 (6.3%)	3 (5.6%)	0	1 (2.3%)	1 (2.2%)	15 (3.6%)	16 (3.0%)
Female	1 (3.6%)	1 (3.8%)	1 (4.8%)	1 (5.6%)	1 (6.3%)	0	1 (4.2%)	1 (3.8%)	0	6 (3.8%)	7 (3.7%)
Hypertension (高血圧)											
Male	0	6 (5.9%)	1 (2.3%)	0	3 (6.3%)	3 (5.6%)	0	1 (2.3%)	1 (2.2%)	15 (3.6%)	15 (2.9%)
Female	0	1 (3.8%)	1 (4.8%)	1 (5.6%)	0	0	1 (4.2%)	1 (3.8%)	0	5 (3.1%)	5 (2.7%)
Orthostatic hypotension (起立性低血圧)											
Male	1 (0.9%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
Female	0	0	1 (4.8%)	0	0	0	0	0	0	1 (0.6%)	1 (0.5%)
Arteriosclerosis (動脈硬化症)											
Male	0	0	0	0	0	0	0	0	0	0	0
Female	0	0	0	0	1 (6.3%)	0	0	0	0	1 (0.6%)	1 (0.5%)
Hypotension (低血圧)											
Male	0	0	0	0	0	0	0	0	0	0	0
Female	1 (3.6%)	0	0	0	0	0	0	0	0	0	1 (0.5%)
Renal and urinary disorders (腎および尿路障害)											
Male	1 (0.9%)	2 (2.0%)	1 (2.3%)	1 (2.2%)	3 (6.3%)	3 (5.6%)	1 (2.6%)	2 (4.5%)	3 (6.7%)	16 (3.8%)	17 (3.2%)
Female	0	0	0	0	0	0	2 (8.3%)	2 (7.7%)	0	4 (2.5%)	4 (2.1%)

System Organ Class Preferred Term Sex	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
Diabetic nephropathy (糖尿病性腎症)											
Male	0	1 (1.0%)	0	1 (2.2%)	2 (4.2%)	1 (1.9%)	0	0	1 (2.2%)	6 (1.4%)	6 (1.1%)
Female	0	0	0	0	0	0	1 (4.2%)	0	0	1 (0.6%)	1 (0.5%)
Nephrolithiasis (腎結石症)											
Male	1 (0.9%)	0	0	0	2 (4.2%)	2 (3.7%)	0	1 (2.3%)	0	5 (1.2%)	6 (1.1%)
Female	0	0	0	0	0	0	1 (4.2%)	0	0	1 (0.6%)	1 (0.5%)
Pollakiuria (頻尿)											
Male	0	0	0	0	0	0	0	0	1 (2.2%)	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	2 (7.7%)	0	2 (1.3%)	2 (1.1%)
Calculus urinary (尿路結石)											
Male	0	0	1 (2.3%)	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Haematuria (血尿)											
Male	0	0	0	0	0	0	1 (2.6%)	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Hypertonic bladder (緊張性膀胱)											
Male	0	0	0	0	0	0	0	0	1 (2.2%)	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Polyuria (多尿)											
Male	0	1 (1.0%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Renal cyst (腎嚢胞)											
Male	0	0	0	0	1 (2.1%)	0	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0

System Organ Class Preferred Term Sex	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
Urinary tract disorder (尿路障害)											
Male	0	0	0	0	0	0	0	1 (2.3%)	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Cardiac disorders (心臓障害)											
Male	2 (1.9%)	2 (2.0%)	0	4 (8.7%)	1 (2.1%)	2 (3.7%)	0	4 (9.1%)	1 (2.2%)	14 (3.3%)	16 (3.0%)
Female	0	1 (3.8%)	0	0	0	0	1 (4.2%)	0	0	2 (1.3%)	2 (1.1%)
Atrial fibrillation (心房細動)											
Male	1 (0.9%)	0	0	0	0	1 (1.9%)	0	1 (2.3%)	0	2 (0.5%)	3 (0.6%)
Female	0	0	0	0	0	0	1 (4.2%)	0	0	1 (0.6%)	1 (0.5%)
Angina unstable (不安定狭心症)											
Male	0	1 (1.0%)	0	0	1 (2.1%)	0	0	0	0	2 (0.5%)	2 (0.4%)
Female	0	0	0	0	0	0	0	0	0	0	0
Coronary artery stenosis (冠動脈狭窄)											
Male	0	0	0	0	0	0	0	2 (4.5%)	0	2 (0.5%)	2 (0.4%)
Female	0	0	0	0	0	0	0	0	0	0	0
Palpitations (動悸)											
Male	0	0	0	2 (4.3%)	0	0	0	0	0	2 (0.5%)	2 (0.4%)
Female	0	0	0	0	0	0	0	0	0	0	0
Sinus bradycardia (洞性徐脈)											
Male	0	0	0	0	0	2 (3.7%)	0	0	0	2 (0.5%)	2 (0.4%)
Female	0	0	0	0	0	0	0	0	0	0	0

System Organ Class Preferred Term Sex	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
Ventricular extrasystoles (心室性期外収縮)											
Male	1 (0.9%)	0	0	0	0	0	0	1 (2.3%)	0	1 (0.2%)	2 (0.4%)
Female	0	0	0	0	0	0	0	0	0	0	0
Acute myocardial infarction (急性心筋梗塞)											
Male	0	1 (1.0%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Aortic valve incompetence (大動脈弁閉鎖不全症)											
Male	0	0	0	0	0	0	0	0	0	0	0
Female	0	1 (3.8%)	0	0	0	0	0	0	0	1 (0.6%)	1 (0.5%)
Cardiac aneurysm (心臓瘤)											
Male	0	1 (1.0%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Cardiac failure (心不全)											
Male	0	0	0	0	0	0	0	0	1 (2.2%)	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Extrasystoles (期外収縮)											
Male	0	0	0	0	0	1 (1.9%)	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Myocardial infarction (心筋梗塞)											
Male	0	0	0	1 (2.2%)	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0

System Organ Class Preferred Term Sex	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
Myocardial ischaemia (心筋虚血)											
Male	0	0	0	1 (2.2%)	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Sinus tachycardia (洞性頻脈)											
Male	1 (0.9%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Supraventricular extrasystoles (上室性期外収縮)											
Male	0	0	0	0	0	1 (1.9%)	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
General disorders and administration site conditions (一般・全身障害および投与部位の状態)											
Male	3 (2.8%)	1 (1.0%)	1 (2.3%)	1 (2.2%)	0	2 (3.7%)	2 (5.1%)	0	2 (4.4%)	9 (2.1%)	12 (2.3%)
Female	1 (3.6%)	0	0	1 (5.6%)	0	0	2 (8.3%)	1 (3.8%)	0	4 (2.5%)	5 (2.7%)
Fatigue (疲労)											
Male	0	0	1 (2.3%)	0	0	0	1 (2.6%)	0	1 (2.2%)	3 (0.7%)	3 (0.6%)
Female	1 (3.6%)	0	0	0	0	0	1 (4.2%)	0	0	1 (0.6%)	2 (1.1%)
Chest pain (胸痛)											
Male	0	0	0	0	0	0	0	0	1 (2.2%)	1 (0.2%)	1 (0.2%)
Female	0	0	0	1 (5.6%)	0	0	0	0	0	1 (0.6%)	1 (0.5%)
Non-cardiac chest pain (非心臓性胸痛)											

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Male	0	0	0	0	0	1 (1.9%)	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	1 (4.2%)	0	0	1 (0.6%)	1 (0.5%)
Pyrexia (発熱)											
Male	1 (0.9%)	0	0	1 (2.2%)	0	0	0	0	0	1 (0.2%)	2 (0.4%)
Female	0	0	0	0	0	0	0	0	0	0	0
Chest discomfort (胸部不快感)											
Male	1 (0.9%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Early satiety (早期満腹)											
Male	1 (0.9%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Inflammation (炎症)											
Male	0	0	0	0	0	1 (1.9%)	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Malaise (倦怠感)											
Male	0	0	0	0	0	0	1 (2.6%)	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Oedema peripheral (末梢性浮腫)											
Male	0	1 (1.0%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Thirst (口渇)											
Male	0	0	0	0	0	0	0	0	0	0	0
Female	0	0	0	0	0	0	0	1 (3.8%)	0	1 (0.6%)	1 (0.5%)
Psychiatric disorders (精神障害)											

System Organ Class Preferred Term Sex	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
Male	3 (2.8%)	2 (2.0%)	0	1 (2.2%)	0	1 (1.9%)	2 (5.1%)	2 (4.5%)	0	8 (1.9%)	11 (2.1%)
Female	0	0	1 (4.8%)	1 (5.6%)	0	0	1 (4.2%)	0	1 (5.6%)	4 (2.5%)	4 (2.1%)
Insomnia (不眠症)											
Male	2 (1.9%)	1 (1.0%)	0	1 (2.2%)	0	1 (1.9%)	2 (5.1%)	1 (2.3%)	0	6 (1.4%)	8 (1.5%)
Female	0	0	0	1 (5.6%)	0	0	1 (4.2%)	0	1 (5.6%)	3 (1.9%)	3 (1.6%)
Apathy (無感情)											
Male	0	0	0	0	0	0	0	1 (2.3%)	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Depressed mood (抑うつ気分)											
Male	0	0	0	0	0	0	0	0	0	0	0
Female	0	0	0	0	0	0	1 (4.2%)	0	0	1 (0.6%)	1 (0.5%)
Depression (うつ病)											
Male	0	1 (1.0%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Mental fatigue (精神疲労)											
Male	0	0	0	0	0	0	0	0	0	0	0
Female	0	0	1 (4.8%)	0	0	0	0	0	0	1 (0.6%)	1 (0.5%)
Stress (ストレス)											
Male	1 (0.9%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Hepatobiliary disorders (肝胆道系障害)											
Male	0	1 (1.0%)	1 (2.3%)	0	1 (2.1%)	3 (5.6%)	0	4 (9.1%)	1 (2.2%)	11 (2.6%)	11 (2.1%)
Female	0	1 (3.8%)	0	0	1 (6.3%)	0	0	1 (3.8%)	0	3 (1.9%)	3 (1.6%)
Hepatic steatosis (脂肪肝)											

System Organ Class Preferred Term Sex	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
Male	0	0	1 (2.3%)	0	0	1 (1.9%)	0	1 (2.3%)	0	3 (0.7%)	3 (0.6%)
Female	0	1 (3.8%)	0	0	0	0	0	1 (3.8%)	0	2 (1.3%)	2 (1.1%)
Alcoholic liver disease (アルコール性肝疾患)											
Male	0	1 (1.0%)	0	0	0	0	0	2 (4.5%)	0	3 (0.7%)	3 (0.6%)
Female	0	0	0	0	0	0	0	0	0	0	0
Cholelithiasis (胆石症)											
Male	0	0	0	0	0	0	0	2 (4.5%)	0	2 (0.5%)	2 (0.4%)
Female	0	0	0	0	1 (6.3%)	0	0	0	0	1 (0.6%)	1 (0.5%)
Drug-induced liver injury (薬物性肝障害)											
Male	0	0	0	0	1 (2.1%)	1 (1.9%)	0	0	1 (2.2%)	3 (0.7%)	3 (0.6%)
Female	0	0	0	0	0	0	0	0	0	0	0
Gallbladder polyp (胆嚢ポリープ)											
Male	0	0	0	0	0	0	0	1 (2.3%)	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	1 (3.8%)	0	1 (0.6%)	1 (0.5%)
Cholecystitis (胆嚢炎)											
Male	0	0	0	0	1 (2.1%)	0	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Non-alcoholic steatohepatitis (非アルコール性脂肪性肝炎)											
Male	0	0	0	0	0	1 (1.9%)	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Surgical and medical procedures (外科および内科処置)											

System Organ Class Preferred Term Sex	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
Male	2 (1.9%)	3 (3.0%)	1 (2.3%)	2 (4.3%)	1 (2.1%)	0	0	0	0	7 (1.7%)	9 (1.7%)
Female	1 (3.6%)	0	0	1 (5.6%)	0	0	0	1 (3.8%)	0	2 (1.3%)	3 (1.6%)
Cataract operation (白内障手術)											
Male	1 (0.9%)	3 (3.0%)	1 (2.3%)	1 (2.2%)	1 (2.1%)	0	0	0	0	6 (1.4%)	7 (1.3%)
Female	0	0	0	1 (5.6%)	0	0	0	0	0	1 (0.6%)	1 (0.5%)
Large intestinal polypectomy (大腸ポリープ切除)											
Male	0	0	0	1 (2.2%)	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	1 (3.8%)	0	1 (0.6%)	1 (0.5%)
Endodontic procedure (歯内療法)											
Male	1 (0.9%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Ptosis repair (眼瞼下垂修復)											
Male	0	0	0	0	0	0	0	0	0	0	0
Female	1 (3.6%)	0	0	0	0	0	0	0	0	0	1 (0.5%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）)											
Male	0	1 (1.0%)	1 (2.3%)	1 (2.2%)	0	1 (1.9%)	0	1 (2.3%)	1 (2.2%)	6 (1.4%)	6 (1.1%)
Female	0	3 (11.5%)	0	0	0	0	1 (4.2%)	1 (3.8%)	0	5 (3.1%)	5 (2.7%)
Benign neoplasm of spinal cord (脊髄の良性新生物)											

System Organ Class Preferred Term Sex	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
Male	0	0	0	0	0	1 (1.9%)	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Cholangiocarcinoma (胆管細胞癌)											
Male	0	0	0	1 (2.2%)	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Colon adenoma (大腸腺腫)											
Male	0	0	0	0	0	0	0	0	1 (2.2%)	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Colon cancer stage I (結腸癌第1期)											
Male	0	1 (1.0%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Endometrial cancer stage III (子宮内膜癌第3期)											
Male	0	0	0	0	0	0	0	0	0	0	0
Female	0	0	0	0	0	0	1 (4.2%)	0	0	1 (0.6%)	1 (0.5%)
Haemangioma of liver (肝臓血管腫)											
Male	0	0	0	0	0	0	0	1 (2.3%)	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Invasive ductal breast carcinoma (浸潤性乳管癌)											
Male	0	0	0	0	0	0	0	0	0	0	0
Female	0	0	0	0	0	0	0	1 (3.8%)	0	1 (0.6%)	1 (0.5%)
Rectal cancer (直腸癌)											
Male	0	0	0	0	0	0	0	0	0	0	0

System Organ Class Preferred Term Sex	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
Female	0	1 (3.8%)	0	0	0	0	0	0	0	1 (0.6%)	1 (0.5%)
Skin papilloma (皮膚乳頭腫)											
Male	0	0	0	0	0	0	0	0	0	0	0
Female	0	1 (3.8%)	0	0	0	0	0	0	0	1 (0.6%)	1 (0.5%)
Testis cancer (精巣癌)											
Male	0	0	1 (2.3%)	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Thyroid neoplasm (甲状腺新生物)											
Male	0	0	0	0	0	0	0	0	0	0	0
Female	0	0	0	0	0	0	0	1 (3.8%)	0	1 (0.6%)	1 (0.5%)
Uterine leiomyoma (子宮平滑筋腫)											
Male	0	0	0	0	0	0	0	0	0	0	0
Female	0	1 (3.8%)	0	0	0	0	0	0	0	1 (0.6%)	1 (0.5%)
Reproductive system and breast disorders (生殖系および乳房障害)											
Male	1 (0.9%)	0	2 (4.7%)	0	0	0	1 (2.6%)	0	0	3 (0.7%)	4 (0.8%)
Female	2 (7.1%)	1 (3.8%)	0	0	1 (6.3%)	0	2 (8.3%)	1 (3.8%)	0	5 (3.1%)	7 (3.7%)
Benign prostatic hyperplasia (良性前立腺肥大症)											
Male	1 (0.9%)	0	2 (4.7%)	0	0	0	0	0	0	2 (0.5%)	3 (0.6%)
Female	0	0	0	0	0	0	0	0	0	0	0
Dysmenorrhoea (月経困難症)											
Male	0	0	0	0	0	0	0	0	0	0	0

System Organ Class Preferred Term Sex	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
Female	1 (3.6%)	1 (3.8%)	0	0	0	0	0	1 (3.8%)	0	2 (1.3%)	3 (1.6%)
Erectile dysfunction (勃起不全)											
Male	0	0	0	0	0	0	1 (2.6%)	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Genital haemorrhage (性器出血)											
Male	0	0	0	0	0	0	0	0	0	0	0
Female	0	0	0	0	0	0	1 (4.2%)	0	0	1 (0.6%)	1 (0.5%)
Metrorrhagia (不正子宮出血)											
Male	0	0	0	0	0	0	0	0	0	0	0
Female	1 (3.6%)	0	0	0	0	0	0	0	0	0	1 (0.5%)
Ovarian cyst (卵巣嚢胞)											
Male	0	0	0	0	0	0	0	0	0	0	0
Female	0	0	0	0	1 (6.3%)	0	0	0	0	1 (0.6%)	1 (0.5%)
Prostatitis (前立腺炎)											
Male	0	0	1 (2.3%)	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Uterine polyp (子宮ポリープ)											
Male	0	0	0	0	0	0	0	0	0	0	0
Female	0	0	0	0	0	0	1 (4.2%)	0	0	1 (0.6%)	1 (0.5%)
Ear and labyrinth disorders (耳および迷路障害)											
Male	2 (1.9%)	1 (1.0%)	1 (2.3%)	2 (4.3%)	0	1 (1.9%)	0	1 (2.3%)	0	6 (1.4%)	8 (1.5%)
Female	0	0	0	1 (5.6%)	0	0	0	1 (3.8%)	0	2 (1.3%)	2 (1.1%)

System Organ Class Preferred Term Sex	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
Vertigo (回転性めまい)											
Male	1 (0.9%)	0	0	1 (2.2%)	0	0	0	1 (2.3%)	0	2 (0.5%)	3 (0.6%)
Female	0	0	0	1 (5.6%)	0	0	0	0	0	1 (0.6%)	1 (0.5%)
Tinnitus (耳鳴)											
Male	0	0	1 (2.3%)	0	0	1 (1.9%)	0	0	0	2 (0.5%)	2 (0.4%)
Female	0	0	0	0	0	0	0	0	0	0	0
Deafness transitory (一過性難聴)											
Male	0	0	0	1 (2.2%)	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
External ear inflammation (外耳の炎症)											
Male	0	1 (1.0%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Middle ear inflammation (中耳の炎症)											
Male	0	1 (1.0%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Sudden hearing loss (突発性難聴)											
Male	1 (0.9%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Vertigo positional (頭位性回転性めまい)											
Male	0	0	0	0	0	0	0	0	0	0	0
Female	0	0	0	0	0	0	0	1 (3.8%)	0	1 (0.6%)	1 (0.5%)

System Organ Class Preferred Term Sex	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
Immune system disorders (免疫系障害)											
Male	1 (0.9%)	0	0	1 (2.2%)	0	1 (1.9%)	0	1 (2.3%)	0	3 (0.7%)	4 (0.8%)
Female	1 (3.6%)	0	1 (4.8%)	0	0	0	0	2 (7.7%)	1 (5.6%)	4 (2.5%)	5 (2.7%)
Seasonal allergy (季節性アレルギー)											
Male	1 (0.9%)	0	0	1 (2.2%)	0	1 (1.9%)	0	0	0	2 (0.5%)	3 (0.6%)
Female	0	0	1 (4.8%)	0	0	0	0	1 (3.8%)	1 (5.6%)	3 (1.9%)	3 (1.6%)
Allergy to arthropod sting (節足動物刺傷アレルギー)											
Male	0	0	0	0	0	0	0	1 (2.3%)	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	1 (3.8%)	0	1 (0.6%)	1 (0.5%)
Food allergy (食物アレルギー)											
Male	0	0	0	0	0	0	0	0	0	0	0
Female	1 (3.6%)	0	0	0	0	0	0	0	0	0	1 (0.5%)
Blood and lymphatic system disorders (血液およびリンパ系障害)											
Male	1 (0.9%)	1 (1.0%)	0	1 (2.2%)	0	1 (1.9%)	0	0	0	3 (0.7%)	4 (0.8%)
Female	1 (3.6%)	0	0	0	0	0	0	1 (3.8%)	2 (11.1%)	3 (1.9%)	4 (2.1%)
Anaemia (貧血)											
Male	1 (0.9%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
Female	1 (3.6%)	0	0	0	0	0	0	0	0	0	1 (0.5%)

System Organ Class Preferred Term Sex	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
Lymphadenitis (リンパ節炎)											
Male	0	0	0	0	0	0	0	0	0	0	0
Female	0	0	0	0	0	0	0	1 (3.8%)	1 (5.6%)	2 (1.3%)	2 (1.1%)
Anaemia macrocytic (大球性貧血)											
Male	0	0	0	0	0	1 (1.9%)	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Anaemia megaloblastic (巨赤芽球性貧血)											
Male	0	0	0	0	0	0	0	0	0	0	0
Female	0	0	0	0	0	0	0	0	1 (5.6%)	1 (0.6%)	1 (0.5%)
Lymphadenopathy (リンパ節症)											
Male	0	0	0	1 (2.2%)	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Normocytic anaemia (正球性貧血)											
Male	0	1 (1.0%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Endocrine disorders (内分泌障害)											
Male	0	1 (1.0%)	0	0	0	1 (1.9%)	0	0	0	2 (0.5%)	2 (0.4%)
Female	0	0	0	0	0	1 (9.1%)	0	0	0	1 (0.6%)	1 (0.5%)
Autoimmune thyroiditis (自己免疫性甲状腺炎)											

System Organ Class Preferred Term Sex	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
Male	0	1 (1.0%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Hypothyroidism (甲状腺機能低下症)											
Male	0	0	0	0	0	0	0	0	0	0	0
Female	0	0	0	0	0	1 (9.1%)	0	0	0	1 (0.6%)	1 (0.5%)
Inappropriate antidiuretic hormone secretion (抗利尿ホルモン不適合分泌)											
Male	0	0	0	0	0	1 (1.9%)	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Congenital, familial and genetic disorders (先天性、家族性および遺伝性障害)											
Male	0	0	0	0	0	0	0	1 (2.3%)	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Dermoid cyst (皮様嚢腫)											
Male	0	0	0	0	0	0	0	1 (2.3%)	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Product issues (製品の問題)											
Male	0	1 (1.0%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Female	0	0	0	0	0	0	0	0	0	0	0
Device dislocation (医療機器位置異常)											
Male	0	1 (1.0%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)

System Organ Class Preferred Term Sex	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
Female	0	0	0	0	0	0	0	0	0	0	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
- "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.
- All adverse events were coded using MedDRA dictionary version 20.1.
- Percentages are based on "Number of patients".

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Table S-168 Subgroup Analysis of Treatment Emergent Adverse Events by Renal Function, System Organ Class and Preferred Term in 52-Week Long-term Period with Monotherapy and Combination Therapy (PXL008-019; Long-term Safety Population)

System Organ Class Preferred Term Renal function	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											
CKD Stage 1	24	22	12	18	13	16	9	16	21	127	151
CKD Stage 2	91	96	50	42	49	44	47	51	40	419	510
CKD Stage 3a	19	9	2	4	2	5	7	3	2	34	53
Any TEAE											
CKD Stage 1	16 (66.7%)	20 (90.9%)	9 (75.0%)	15 (83.3%)	6 (46.2%)	13 (81.3%)	7 (77.8%)	15 (93.8%)	17 (81.0%)	102 (80.3%)	118 (78.1%)
CKD Stage 2	68 (74.7%)	75 (78.1%)	43 (86.0%)	30 (71.4%)	25 (51.0%)	34 (77.3%)	37 (78.7%)	39 (76.5%)	30 (75.0%)	313 (74.7%)	381 (74.7%)
CKD Stage 3a	14 (73.7%)	7 (77.8%)	2 (100.0%)	3 (75.0%)	2 (100.0%)	3 (60.0%)	6 (85.7%)	2 (66.7%)	1 (50.0%)	26 (76.5%)	40 (75.5%)
Infections and infestations (感染症および寄生虫症)											
CKD Stage 1	10 (41.7%)	14 (63.6%)	9 (75.0%)	11 (61.1%)	2 (15.4%)	7 (43.8%)	4 (44.4%)	8 (50.0%)	11 (52.4%)	66 (52.0%)	76 (50.3%)
CKD Stage 2	41 (45.1%)	39 (40.6%)	26 (52.0%)	15 (35.7%)	10 (20.4%)	23 (52.3%)	21 (44.7%)	22 (43.1%)	17 (42.5%)	173 (41.3%)	214 (42.0%)
CKD Stage 3a	6 (31.6%)	4 (44.4%)	2 (100.0%)	2 (50.0%)	1 (50.0%)	2 (40.0%)	3 (42.9%)	0	1 (50.0%)	15 (44.1%)	21 (39.6%)
Nasopharyngitis (上咽頭炎)											
CKD Stage 1	6 (25.0%)	13 (59.1%)	7 (58.3%)	8 (44.4%)	2 (15.4%)	6 (37.5%)	3 (33.3%)	5 (31.3%)	6 (28.6%)	50 (39.4%)	56 (37.1%)
CKD Stage 2	31 (34.1%)	24 (25.0%)	20 (40.0%)	7 (16.7%)	3 (6.1%)	11 (25.0%)	14 (29.8%)	15 (29.4%)	13 (32.5%)	107 (25.5%)	138 (27.1%)
CKD Stage 3a	3 (15.8%)	2 (22.2%)	0	1 (25.0%)	0	1 (20.0%)	2 (28.6%)	0	1 (50.0%)	7 (20.6%)	10 (18.9%)
Pharyngitis (咽頭炎)											
CKD Stage 1	2 (8.3%)	0	1 (8.3%)	0	0	1 (6.3%)	0	0	1 (4.8%)	3 (2.4%)	5 (3.3%)
CKD Stage 2	5 (5.5%)	5 (5.2%)	2 (4.0%)	0	2 (4.1%)	2 (4.5%)	2 (4.3%)	1 (2.0%)	4 (10.0%)	18 (4.3%)	23 (4.5%)
CKD Stage 3a	1 (5.3%)	0	1 (50.0%)	0	0	0	1 (14.3%)	0	0	2 (5.9%)	3 (5.7%)
Influenza (インフルエンザ)											
CKD Stage 1	1 (4.2%)	1 (4.5%)	0	2 (11.1%)	0	1 (6.3%)	0	1 (6.3%)	0	5 (3.9%)	6 (4.0%)
CKD Stage 2	2 (2.2%)	8 (8.3%)	2 (4.0%)	3 (7.1%)	1 (2.0%)	1 (2.3%)	1 (2.1%)	0	2 (5.0%)	18 (4.3%)	20 (3.9%)

System Organ Class Preferred Term Renal function	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
CKD Stage 3a	1 (5.3%)	0	0	0	0	1 (20.0%)	0	0	0	1 (2.9%)	2 (3.8%)
Bronchitis (気管支炎)											
CKD Stage 1	0	1 (4.5%)	2 (16.7%)	1 (5.6%)	0	2 (12.5%)	0	0	1 (4.8%)	7 (5.5%)	7 (4.6%)
CKD Stage 2	1 (1.1%)	0	2 (4.0%)	1 (2.4%)	0	2 (4.5%)	0	0	1 (2.5%)	6 (1.4%)	7 (1.4%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Gastroenteritis (胃腸炎)											
CKD Stage 1	0	0	2 (16.7%)	1 (5.6%)	0	0	0	0	1 (4.8%)	4 (3.1%)	4 (2.6%)
CKD Stage 2	2 (2.2%)	0	1 (2.0%)	2 (4.8%)	1 (2.0%)	1 (2.3%)	1 (2.1%)	2 (3.9%)	0	8 (1.9%)	10 (2.0%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Periodontitis (歯周炎)											
CKD Stage 1	0	0	0	2 (11.1%)	0	0	0	1 (6.3%)	0	3 (2.4%)	3 (2.0%)
CKD Stage 2	0	3 (3.1%)	1 (2.0%)	0	0	3 (6.8%)	2 (4.3%)	0	0	9 (2.1%)	9 (1.8%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Cystitis (膀胱炎)											
CKD Stage 1	0	0	0	0	0	0	0	0	1 (4.8%)	1 (0.8%)	1 (0.7%)
CKD Stage 2	1 (1.1%)	2 (2.1%)	1 (2.0%)	0	0	1 (2.3%)	2 (4.3%)	2 (3.9%)	0	8 (1.9%)	9 (1.8%)
CKD Stage 3a	0	0	1 (50.0%)	0	0	0	0	0	0	1 (2.9%)	1 (1.9%)
Herpes zoster (帯状疱疹)											
CKD Stage 1	0	0	0	0	0	0	1 (11.1%)	1 (6.3%)	1 (4.8%)	3 (2.4%)	3 (2.0%)
CKD Stage 2	2 (2.2%)	1 (1.0%)	1 (2.0%)	0	0	1 (2.3%)	0	0	1 (2.5%)	4 (1.0%)	6 (1.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Upper respiratory tract infection (上気道感染)											
CKD Stage 1	1 (4.2%)	0	0	0	0	0	0	0	0	0	1 (0.7%)
CKD Stage 2	1 (1.1%)	1 (1.0%)	0	0	0	0	2 (4.3%)	0	1 (2.5%)	4 (1.0%)	5 (1.0%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Pneumonia (肺炎)											

System Organ Class Preferred Term Renal function	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
CKD Stage 1	0	0	1 (8.3%)	0	0	0	0	0	0	1 (0.8%)	1 (0.7%)
CKD Stage 2	0	1 (1.0%)	0	0	0	1 (2.3%)	0	0	1 (2.5%)	3 (0.7%)	3 (0.6%)
CKD Stage 3a	0	0	0	1 (25.0%)	0	0	0	0	0	1 (2.9%)	1 (1.9%)
Tinea pedis (足部白癬)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	1 (1.0%)	0	0	1 (2.0%)	0	1 (2.1%)	1 (2.0%)	1 (2.5%)	5 (1.2%)	5 (1.0%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Urinary tract infection (尿路感染)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	3 (6.1%)	2 (4.5%)	0	0	0	5 (1.2%)	5 (1.0%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Conjunctivitis (結膜炎)											
CKD Stage 1	0	1 (4.5%)	0	0	0	0	0	0	0	1 (0.8%)	1 (0.7%)
CKD Stage 2	1 (1.1%)	1 (1.0%)	0	0	0	1 (2.3%)	0	0	0	2 (0.5%)	3 (0.6%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Gingivitis (歯肉炎)											
CKD Stage 1	0	0	0	0	0	1 (6.3%)	0	0	0	1 (0.8%)	1 (0.7%)
CKD Stage 2	0	0	0	0	0	0	0	2 (3.9%)	0	2 (0.5%)	2 (0.4%)
CKD Stage 3a	0	1 (11.1%)	0	0	0	0	0	0	0	1 (2.9%)	1 (1.9%)
Otitis externa (外耳炎)											
CKD Stage 1	1 (4.2%)	0	0	0	0	1 (6.3%)	0	0	0	1 (0.8%)	2 (1.3%)
CKD Stage 2	1 (1.1%)	1 (1.0%)	0	0	0	0	0	0	0	1 (0.2%)	2 (0.4%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Pericoronitis (歯冠周囲炎)											
CKD Stage 1	0	0	0	0	0	0	0	0	1 (4.8%)	1 (0.8%)	1 (0.7%)
CKD Stage 2	0	0	0	0	1 (2.0%)	0	0	2 (3.9%)	0	3 (0.7%)	3 (0.6%)

System Organ Class Preferred Term Renal function	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
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Dermatophytosis of nail (爪の皮膚糸状菌症)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	2 (2.1%)	0	0	0	1 (2.3%)	0	0	0	3 (0.7%)	3 (0.6%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Oral herpes (口腔ヘルペス)											
CKD Stage 1	0	0	0	0	0	0	1 (11.1%)	0	0	1 (0.8%)	1 (0.7%)
CKD Stage 2	0	1 (1.0%)	1 (2.0%)	0	0	0	0	0	0	2 (0.5%)	2 (0.4%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Sinusitis (副鼻腔炎)											
CKD Stage 1	0	1 (4.5%)	0	0	0	0	0	0	0	1 (0.8%)	1 (0.7%)
CKD Stage 2	0	0	0	1 (2.4%)	0	0	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	1 (50.0%)	0	0	0	0	1 (2.9%)	1 (1.9%)
Appendicitis (虫垂炎)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	1 (2.4%)	0	0	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	1 (5.3%)	0	0	0	0	0	0	0	0	0	1 (1.9%)
Asymptomatic bacteriuria (無症候性細菌尿)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	0	0	1 (2.0%)	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	1 (11.1%)	0	0	0	0	0	0	0	1 (2.9%)	1 (1.9%)
Chronic sinusitis (慢性副鼻腔炎)											
CKD Stage 1	0	0	0	0	0	0	0	0	1 (4.8%)	1 (0.8%)	1 (0.7%)
CKD Stage 2	0	0	0	0	0	0	0	0	0	0	0

System Organ Class Preferred Term Renal function	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
CKD Stage 3a	0	0	0	0	0	1 (20.0%)	0	0	0	1 (2.9%)	1 (1.9%)
Diverticulitis (憩室炎)											
CKD Stage 1	0	0	0	0	0	1 (6.3%)	0	0	0	1 (0.8%)	1 (0.7%)
CKD Stage 2	0	0	0	1 (2.4%)	0	0	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Enteritis infectious (感染性腸炎)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	0	1 (2.1%)	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	1 (11.1%)	0	0	0	0	0	0	0	1 (2.9%)	1 (1.9%)
Folliculitis (毛包炎)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	1 (1.1%)	0	0	0	0	0	0	0	1 (2.5%)	1 (0.2%)	2 (0.4%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Gastroenteritis viral (ウイルス性胃腸炎)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	1 (2.4%)	1 (2.0%)	0	0	0	0	2 (0.5%)	2 (0.4%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Helicobacter infection (ヘリコバクター感染)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	1 (2.4%)	0	0	0	1 (2.0%)	0	2 (0.5%)	2 (0.4%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Impetigo (膿痂疹)											
CKD Stage 1	0	0	0	0	0	0	0	1 (6.3%)	0	1 (0.8%)	1 (0.7%)
CKD Stage 2	0	1 (1.0%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)

System Organ Class Preferred Term Renal function	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
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Otitis media (中耳炎)											
CKD Stage 1	0	1 (4.5%)	0	0	0	0	0	0	0	1 (0.8%)	1 (0.7%)
CKD Stage 2	0	0	0	0	0	0	0	0	1 (2.5%)	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Otitis media acute (急性中耳炎)											
CKD Stage 1	0	1 (4.5%)	0	0	0	0	0	1 (6.3%)	0	2 (1.6%)	2 (1.3%)
CKD Stage 2	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Paronychia (爪囲炎)											
CKD Stage 1	0	0	0	0	0	1 (6.3%)	0	0	0	1 (0.8%)	1 (0.7%)
CKD Stage 2	0	0	0	0	0	0	0	1 (2.0%)	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Pneumonia bacterial (細菌性肺炎)											
CKD Stage 1	0	0	0	1 (5.6%)	0	0	0	0	0	1 (0.8%)	1 (0.7%)
CKD Stage 2	0	0	0	0	0	1 (2.3%)	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Pulpitis dental (歯髄炎)											
CKD Stage 1	0	0	0	0	0	0	0	0	1 (4.8%)	1 (0.8%)	1 (0.7%)
CKD Stage 2	0	0	0	0	0	0	1 (2.1%)	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Rhinitis (鼻炎)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	1 (1.0%)	0	0	0	1 (2.3%)	0	0	0	2 (0.5%)	2 (0.4%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0

System Organ Class Preferred Term Renal function	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
Acute sinusitis (急性副鼻腔炎)											
CKD Stage 1	0	1 (4.5%)	0	0	0	0	0	0	0	1 (0.8%)	1 (0.7%)
CKD Stage 2	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Bacterial vulvovaginitis (細菌性外陰腟炎)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	1 (2.0%)	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Cellulitis (蜂巣炎)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	0	1 (2.1%)	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Eczema impetiginous (膿痂疹性湿疹)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	0	1 (2.1%)	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Endometritis (子宮内膜炎)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	1 (2.4%)	0	0	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Enterocolitis viral (ウイルス性腸炎)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	1 (2.3%)	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0

System Organ Class Preferred Term Renal function	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
Furuncle (せつ)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	0	1 (2.1%)	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Nasal vestibulitis (鼻前庭炎)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	0	1 (2.1%)	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Skin bacterial infection (皮膚細菌感染)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	1 (2.3%)	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Skin infection (皮膚感染)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	1 (2.0%)	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Streptococcal infection (レンサ球菌感染)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	1 (1.0%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Subcutaneous abscess (皮下組織膿瘍)											
CKD Stage 1	0	0	0	0	0	0	1 (11.1%)	0	0	1 (0.8%)	1 (0.7%)
CKD Stage 2	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0

System Organ Class Preferred Term Renal function	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
Tinea infection (白癬感染)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	0	0	1 (2.0%)	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Vaginal infection (膣感染)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	0	1 (2.1%)	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Gastrointestinal disorders (胃腸障害)											
CKD Stage 1	6 (25.0%)	7 (31.8%)	3 (25.0%)	6 (33.3%)	1 (7.7%)	4 (25.0%)	3 (33.3%)	3 (18.8%)	6 (28.6%)	33 (26.0%)	39 (25.8%)
CKD Stage 2	18 (19.8%)	20 (20.8%)	9 (18.0%)	16 (38.1%)	4 (8.2%)	4 (9.1%)	15 (31.9%)	10 (19.6%)	8 (20.0%)	86 (20.5%)	104 (20.4%)
CKD Stage 3a	5 (26.3%)	1 (11.1%)	0	3 (75.0%)	0	1 (20.0%)	3 (42.9%)	1 (33.3%)	1 (50.0%)	10 (29.4%)	15 (28.3%)
Nausea (悪心)											
CKD Stage 1	1 (4.2%)	0	0	3 (16.7%)	1 (7.7%)	0	1 (11.1%)	1 (6.3%)	2 (9.5%)	8 (6.3%)	9 (6.0%)
CKD Stage 2	6 (6.6%)	1 (1.0%)	0	5 (11.9%)	0	0	2 (4.3%)	2 (3.9%)	1 (2.5%)	11 (2.6%)	17 (3.3%)
CKD Stage 3a	2 (10.5%)	0	0	0	0	1 (20.0%)	2 (28.6%)	0	1 (50.0%)	4 (11.8%)	6 (11.3%)
Diarrhoea (下痢)											
CKD Stage 1	0	1 (4.5%)	1 (8.3%)	3 (16.7%)	0	0	0	0	1 (4.8%)	6 (4.7%)	6 (4.0%)
CKD Stage 2	3 (3.3%)	2 (2.1%)	3 (6.0%)	5 (11.9%)	0	1 (2.3%)	2 (4.3%)	3 (5.9%)	1 (2.5%)	17 (4.1%)	20 (3.9%)
CKD Stage 3a	1 (5.3%)	0	0	3 (75.0%)	0	1 (20.0%)	0	0	0	4 (11.8%)	5 (9.4%)
Constipation (便秘)											
CKD Stage 1	1 (4.2%)	2 (9.1%)	0	0	0	0	0	0	1 (4.8%)	3 (2.4%)	4 (2.6%)
CKD Stage 2	3 (3.3%)	6 (6.3%)	2 (4.0%)	1 (2.4%)	2 (4.1%)	1 (2.3%)	4 (8.5%)	1 (2.0%)	1 (2.5%)	18 (4.3%)	21 (4.1%)
CKD Stage 3a	1 (5.3%)	0	0	0	0	0	1 (14.3%)	0	0	1 (2.9%)	2 (3.8%)

System Organ Class Preferred Term Renal function	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
Gastrooesophageal reflux disease (胃食道逆流性疾患)											
CKD Stage 1	0	2 (9.1%)	0	0	0	0	0	0	0	2 (1.6%)	2 (1.3%)
CKD Stage 2	3 (3.3%)	7 (7.3%)	1 (2.0%)	2 (4.8%)	0	0	0	1 (2.0%)	0	11 (2.6%)	14 (2.7%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Abdominal pain upper (上腹部痛)											
CKD Stage 1	2 (8.3%)	0	0	1 (5.6%)	0	0	1 (11.1%)	0	0	2 (1.6%)	4 (2.6%)
CKD Stage 2	2 (2.2%)	1 (1.0%)	1 (2.0%)	2 (4.8%)	0	0	1 (2.1%)	1 (2.0%)	0	6 (1.4%)	8 (1.6%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Dental caries (齲歯)											
CKD Stage 1	2 (8.3%)	0	1 (8.3%)	0	0	2 (12.5%)	1 (11.1%)	0	0	4 (3.1%)	6 (4.0%)
CKD Stage 2	3 (3.3%)	0	0	1 (2.4%)	0	1 (2.3%)	1 (2.1%)	0	0	3 (0.7%)	6 (1.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Vomiting (嘔吐)											
CKD Stage 1	0	0	0	2 (11.1%)	0	0	0	1 (6.3%)	0	3 (2.4%)	3 (2.0%)
CKD Stage 2	1 (1.1%)	0	0	2 (4.8%)	0	2 (4.5%)	2 (4.3%)	1 (2.0%)	0	7 (1.7%)	8 (1.6%)
CKD Stage 3a	0	0	0	0	0	0	0	0	1 (50.0%)	1 (2.9%)	1 (1.9%)
Abdominal discomfort (腹部不快感)											
CKD Stage 1	0	0	0	2 (11.1%)	0	0	0	0	0	2 (1.6%)	2 (1.3%)
CKD Stage 2	0	1 (1.0%)	1 (2.0%)	0	1 (2.0%)	0	2 (4.3%)	0	0	5 (1.2%)	5 (1.0%)
CKD Stage 3a	0	1 (11.1%)	0	1 (25.0%)	0	0	0	0	0	2 (5.9%)	2 (3.8%)
Chronic gastritis (慢性胃炎)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	2 (2.1%)	0	1 (2.4%)	0	0	1 (2.1%)	1 (2.0%)	1 (2.5%)	6 (1.4%)	6 (1.2%)
CKD Stage 3a	0	0	0	0	0	0	1 (14.3%)	0	0	1 (2.9%)	1 (1.9%)

System Organ Class Preferred Term Renal function	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
Dyspepsia (消化不良)											
CKD Stage 1	0	0	0	0	0	0	0	1 (6.3%)	0	1 (0.8%)	1 (0.7%)
CKD Stage 2	0	2 (2.1%)	1 (2.0%)	0	0	0	2 (4.3%)	1 (2.0%)	0	6 (1.4%)	6 (1.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Faeces soft (軟便)											
CKD Stage 1	0	0	0	1 (5.6%)	0	0	0	0	1 (4.8%)	2 (1.6%)	2 (1.3%)
CKD Stage 2	1 (1.1%)	1 (1.0%)	1 (2.0%)	1 (2.4%)	0	0	0	0	0	3 (0.7%)	4 (0.8%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Large intestine polyp (大腸ポリープ)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	1 (1.1%)	0	0	2 (4.8%)	0	0	1 (2.1%)	1 (2.0%)	1 (2.5%)	5 (1.2%)	6 (1.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Abdominal pain (腹痛)											
CKD Stage 1	0	0	0	0	0	0	1 (11.1%)	0	0	1 (0.8%)	1 (0.7%)
CKD Stage 2	0	0	1 (2.0%)	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	1 (11.1%)	0	0	0	0	0	0	1 (50.0%)	2 (5.9%)	2 (3.8%)
Gastritis (胃炎)											
CKD Stage 1	0	0	0	0	0	0	0	1 (6.3%)	1 (4.8%)	2 (1.6%)	2 (1.3%)
CKD Stage 2	0	0	0	0	1 (2.0%)	0	0	0	1 (2.5%)	2 (0.5%)	2 (0.4%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Abdominal distension (腹部膨満)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	0	1 (2.1%)	0	2 (5.0%)	3 (0.7%)	3 (0.6%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0

System Organ Class Preferred Term Renal function	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
Aphthous ulcer (アフタ性潰瘍)											
CKD Stage 1	1 (4.2%)	0	0	0	0	0	0	0	0	0	1 (0.7%)
CKD Stage 2	0	0	0	1 (2.4%)	0	0	1 (2.1%)	0	0	2 (0.5%)	2 (0.4%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Food poisoning (食中毒)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	1 (1.1%)	0	0	0	0	0	0	0	1 (2.5%)	1 (0.2%)	2 (0.4%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Abdominal pain lower (下腹部痛)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	0	1 (2.1%)	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Change of bowel habit (便習慣変化)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	0	0	1 (2.0%)	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Colitis (大腸炎)											
CKD Stage 1	0	1 (4.5%)	0	0	0	0	0	0	0	1 (0.8%)	1 (0.7%)
CKD Stage 2	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Colitis ulcerative (潰瘍性大腸炎)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	1 (1.1%)	0	0	0	0	0	0	0	0	0	1 (0.2%)

System Organ Class Preferred Term Renal function	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
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Diverticulum intestinal (腸憩室)											
CKD Stage 1	0	1 (4.5%)	0	0	0	0	0	0	0	1 (0.8%)	1 (0.7%)
CKD Stage 2	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Enteritis (小腸炎)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	0	1 (2.1%)	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Enterocolitis (腸炎)											
CKD Stage 1	0	0	0	0	0	1 (6.3%)	0	0	0	1 (0.8%)	1 (0.7%)
CKD Stage 2	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Enterovesical fistula (腸膀胱瘻)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	1 (2.3%)	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Epigastric discomfort (心窩部不快感)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 3a	0	0	0	0	0	0	0	1 (33.3%)	0	1 (2.9%)	1 (1.9%)
Flatulence (鼓腸)											
CKD Stage 1	0	0	1 (8.3%)	0	0	0	0	0	0	1 (0.8%)	1 (0.7%)
CKD Stage 2	0	0	0	0	0	0	0	0	0	0	0

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CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Gastric polyps (胃ポリープ)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	0	1 (2.1%)	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Gastritis erosive (びらん性胃炎)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	1 (1.0%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Gastrointestinal disorder (胃腸障害)											
CKD Stage 1	0	0	0	0	0	0	0	0	1 (4.8%)	1 (0.8%)	1 (0.7%)
CKD Stage 2	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Glossitis (舌炎)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	0	0	1 (2.0%)	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Haematochezia (血便排泄)											
CKD Stage 1	0	1 (4.5%)	0	0	0	0	0	0	0	1 (0.8%)	1 (0.7%)
CKD Stage 2	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Inguinal hernia (鼠径ヘルニア)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	0	0	0	0	0	0

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CKD Stage 3a	0	0	0	1 (25.0%)	0	0	0	0	0	1 (2.9%)	1 (1.9%)
Irritable bowel syndrome (過敏性腸症候群)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 3a	1 (5.3%)	0	0	0	0	0	0	0	0	0	1 (1.9%)
Lower gastrointestinal haemorrhage (下部消化管出血)											
CKD Stage 1	0	1 (4.5%)	0	0	0	0	0	0	0	1 (0.8%)	1 (0.7%)
CKD Stage 2	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Mouth ulceration (口腔内潰瘍形成)											
CKD Stage 1	0	0	0	0	0	0	0	0	1 (4.8%)	1 (0.8%)	1 (0.7%)
CKD Stage 2	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Pancreatic steatosis (膵脂肪変性)											
CKD Stage 1	0	0	0	0	0	1 (6.3%)	0	0	0	1 (0.8%)	1 (0.7%)
CKD Stage 2	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Periodontal disease (歯周病)											
CKD Stage 1	0	1 (4.5%)	0	0	0	0	0	0	0	1 (0.8%)	1 (0.7%)
CKD Stage 2	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Stomatitis (口内炎)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0

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CKD Stage 2	0	0	0	0	0	0	0	1 (2.0%)	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Tooth loss (歯の脱落)											
CKD Stage 1	1 (4.2%)	0	0	0	0	0	0	0	0	0	1 (0.7%)
CKD Stage 2	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Toothache (歯痛)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	1 (2.0%)	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Musculoskeletal and connective tissue disorders (筋骨格系および結合組織障害)											
CKD Stage 1	2 (8.3%)	2 (9.1%)	2 (16.7%)	4 (22.2%)	1 (7.7%)	2 (12.5%)	3 (33.3%)	4 (25.0%)	1 (4.8%)	19 (15.0%)	21 (13.9%)
CKD Stage 2	12 (13.2%)	20 (20.8%)	7 (14.0%)	3 (7.1%)	5 (10.2%)	4 (9.1%)	12 (25.5%)	5 (9.8%)	2 (5.0%)	58 (13.8%)	70 (13.7%)
CKD Stage 3a	1 (5.3%)	0	1 (50.0%)	0	0	0	1 (14.3%)	2 (66.7%)	1 (50.0%)	5 (14.7%)	6 (11.3%)
Back pain (背部痛)											
CKD Stage 1	2 (8.3%)	1 (4.5%)	2 (16.7%)	0	1 (7.7%)	2 (12.5%)	1 (11.1%)	0	0	7 (5.5%)	9 (6.0%)
CKD Stage 2	3 (3.3%)	9 (9.4%)	1 (2.0%)	1 (2.4%)	1 (2.0%)	2 (4.5%)	0	0	0	14 (3.3%)	17 (3.3%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Arthralgia (関節痛)											
CKD Stage 1	0	0	0	2 (11.1%)	0	0	1 (11.1%)	1 (6.3%)	1 (4.8%)	5 (3.9%)	5 (3.3%)
CKD Stage 2	1 (1.1%)	3 (3.1%)	0	0	0	2 (4.5%)	1 (2.1%)	1 (2.0%)	0	7 (1.7%)	8 (1.6%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Pain in extremity (四肢痛)											
CKD Stage 1	0	1 (4.5%)	1 (8.3%)	0	0	0	0	0	0	2 (1.6%)	2 (1.3%)

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CKD Stage 2	1 (1.1%)	2 (2.1%)	1 (2.0%)	0	0	0	1 (2.1%)	1 (2.0%)	1 (2.5%)	6 (1.4%)	7 (1.4%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Myalgia (筋肉痛)											
CKD Stage 1	0	0	0	1 (5.6%)	0	0	0	0	0	1 (0.8%)	1 (0.7%)
CKD Stage 2	1 (1.1%)	1 (1.0%)	0	0	1 (2.0%)	0	0	0	1 (2.5%)	3 (0.7%)	4 (0.8%)
CKD Stage 3a	1 (5.3%)	0	1 (50.0%)	0	0	0	0	0	1 (50.0%)	2 (5.9%)	3 (5.7%)
Spinal osteoarthritis (変形性脊椎症)											
CKD Stage 1	0	0	0	0	0	0	1 (11.1%)	0	0	1 (0.8%)	1 (0.7%)
CKD Stage 2	1 (1.1%)	0	0	0	1 (2.0%)	0	3 (6.4%)	1 (2.0%)	1 (2.5%)	6 (1.4%)	7 (1.4%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Intervertebral disc protrusion (椎間板突出)											
CKD Stage 1	0	0	0	0	0	0	1 (11.1%)	0	0	1 (0.8%)	1 (0.7%)
CKD Stage 2	0	0	1 (2.0%)	0	1 (2.0%)	0	3 (6.4%)	1 (2.0%)	0	6 (1.4%)	6 (1.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Osteoarthritis (変形性関節症)											
CKD Stage 1	0	0	0	1 (5.6%)	0	0	1 (11.1%)	0	0	2 (1.6%)	2 (1.3%)
CKD Stage 2	2 (2.2%)	0	1 (2.0%)	0	0	0	1 (2.1%)	0	0	2 (0.5%)	4 (0.8%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Periarthritis (関節周囲炎)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	1 (1.1%)	1 (1.0%)	1 (2.0%)	0	0	0	1 (2.1%)	1 (2.0%)	0	4 (1.0%)	5 (1.0%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Lumbar spinal stenosis (腰部脊柱管狭窄症)											
CKD Stage 1	0	0	0	0	0	0	0	1 (6.3%)	0	1 (0.8%)	1 (0.7%)

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CKD Stage 2	1 (1.1%)	0	0	0	0	0	1 (2.1%)	1 (2.0%)	0	2 (0.5%)	3 (0.6%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Muscle spasms (筋痙縮)											
CKD Stage 1	0	0	1 (8.3%)	0	0	0	0	0	0	1 (0.8%)	1 (0.7%)
CKD Stage 2	0	1 (1.0%)	1 (2.0%)	0	0	0	1 (2.1%)	0	0	3 (0.7%)	3 (0.6%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Musculoskeletal stiffness (筋骨格硬直)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	2 (2.1%)	2 (4.0%)	0	0	0	0	0	0	4 (1.0%)	4 (0.8%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Trigger finger (弾発指)											
CKD Stage 1	0	0	0	0	0	0	0	2 (12.5%)	0	2 (1.6%)	2 (1.3%)
CKD Stage 2	0	0	0	0	0	0	2 (4.3%)	0	0	2 (0.5%)	2 (0.4%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Musculoskeletal pain (筋骨格痛)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	2 (2.2%)	0	0	0	0	0	0	0	0	0	2 (0.4%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Neck pain (頚部痛)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	1 (2.0%)	0	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	1 (33.3%)	0	1 (2.9%)	1 (1.9%)
Arthritis (関節炎)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	0	0	0	0	0	0

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CKD Stage 3a	0	0	0	0	0	0	0	1 (33.3%)	0	1 (2.9%)	1 (1.9%)
Flank pain (側腹部痛)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	1 (2.4%)	0	0	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Joint contracture (関節拘縮)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 3a	0	0	0	0	0	0	1 (14.3%)	0	0	1 (2.9%)	1 (1.9%)
Plantar fasciitis (足底筋膜炎)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	1 (2.4%)	0	0	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Spondylolisthesis (脊椎すべり症)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	1 (1.1%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Synovitis (滑膜炎)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	1 (1.0%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Temporomandibular joint syndrome (顎関節症候群)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	1 (2.0%)	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0

System Organ Class Preferred Term Renal function	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
Tendon pain (腱痛)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	1 (1.0%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Metabolism and nutrition disorders (代謝および栄養障害)											
CKD Stage 1	2 (8.3%)	11 (50.0%)	1 (8.3%)	4 (22.2%)	2 (15.4%)	2 (12.5%)	0	4 (25.0%)	0	24 (18.9%)	26 (17.2%)
CKD Stage 2	8 (8.8%)	15 (15.6%)	8 (16.0%)	4 (9.5%)	2 (4.1%)	1 (2.3%)	7 (14.9%)	9 (17.6%)	5 (12.5%)	51 (12.2%)	59 (11.6%)
CKD Stage 3a	3 (15.8%)	2 (22.2%)	1 (50.0%)	0	0	2 (40.0%)	1 (14.3%)	0	1 (50.0%)	7 (20.6%)	10 (18.9%)
Hypoglycaemia (低血糖)											
CKD Stage 1	2 (8.3%)	7 (31.8%)	1 (8.3%)	4 (22.2%)	1 (7.7%)	1 (6.3%)	0	1 (6.3%)	0	15 (11.8%)	17 (11.3%)
CKD Stage 2	2 (2.2%)	12 (12.5%)	7 (14.0%)	2 (4.8%)	1 (2.0%)	1 (2.3%)	4 (8.5%)	1 (2.0%)	3 (7.5%)	31 (7.4%)	33 (6.5%)
CKD Stage 3a	1 (5.3%)	2 (22.2%)	1 (50.0%)	0	0	0	1 (14.3%)	0	1 (50.0%)	5 (14.7%)	6 (11.3%)
Hyperglycaemia (高血糖)											
CKD Stage 1	0	4 (18.2%)	0	0	1 (7.7%)	1 (6.3%)	0	3 (18.8%)	0	9 (7.1%)	9 (6.0%)
CKD Stage 2	5 (5.5%)	3 (3.1%)	0	0	0	0	2 (4.3%)	5 (9.8%)	1 (2.5%)	11 (2.6%)	16 (3.1%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Decreased appetite (食欲減退)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	1 (1.1%)	0	0	2 (4.8%)	0	0	2 (4.3%)	3 (5.9%)	0	7 (1.7%)	8 (1.6%)
CKD Stage 3a	2 (10.5%)	0	0	0	0	2 (40.0%)	0	0	1 (50.0%)	3 (8.8%)	5 (9.4%)
Hyperuricaemia (高尿酸血症)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	1 (1.0%)	0	0	0	0	0	0	1 (2.5%)	2 (0.5%)	2 (0.4%)
CKD Stage 3a	0	1 (11.1%)	0	0	0	0	0	0	0	1 (2.9%)	1 (1.9%)
Dehydration (脱水)											

System Organ Class Preferred Term Renal function	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
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	1 (2.0%)	0	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Dyslipidaemia (脂質異常症)											
CKD Stage 1	0	1 (4.5%)	0	0	0	0	0	0	0	1 (0.8%)	1 (0.7%)
CKD Stage 2	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Gout (痛風)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	1 (2.0%)	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Injury, poisoning and procedural complications (傷害、中毒および処置合併症)											
CKD Stage 1	1 (4.2%)	1 (4.5%)	3 (25.0%)	1 (5.6%)	2 (15.4%)	2 (12.5%)	4 (44.4%)	3 (18.8%)	3 (14.3%)	19 (15.0%)	20 (13.2%)
CKD Stage 2	9 (9.9%)	12 (12.5%)	5 (10.0%)	4 (9.5%)	2 (4.1%)	3 (6.8%)	10 (21.3%)	4 (7.8%)	1 (2.5%)	41 (9.8%)	50 (9.8%)
CKD Stage 3a	1 (5.3%)	0	0	0	0	1 (20.0%)	0	0	0	1 (2.9%)	2 (3.8%)
Contusion (挫傷)											
CKD Stage 1	0	0	0	0	0	0	1 (11.1%)	0	0	1 (0.8%)	1 (0.7%)
CKD Stage 2	2 (2.2%)	3 (3.1%)	0	2 (4.8%)	0	0	2 (4.3%)	0	0	7 (1.7%)	9 (1.8%)
CKD Stage 3a	1 (5.3%)	0	0	0	0	0	0	0	0	0	1 (1.9%)
Ligament sprain (靱帯捻挫)											
CKD Stage 1	1 (4.2%)	0	0	0	0	0	0	0	0	0	1 (0.7%)
CKD Stage 2	0	1 (1.0%)	2 (4.0%)	0	0	0	0	1 (2.0%)	0	4 (1.0%)	4 (0.8%)
CKD Stage 3a	0	0	0	0	0	1 (20.0%)	0	0	0	1 (2.9%)	1 (1.9%)
Thermal burn (熱傷)											

System Organ Class Preferred Term Renal function	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
CKD Stage 1	0	0	0	1 (5.6%)	0	0	0	1 (6.3%)	0	2 (1.6%)	2 (1.3%)
CKD Stage 2	1 (1.1%)	0	0	1 (2.4%)	0	0	1 (2.1%)	0	0	2 (0.5%)	3 (0.6%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Heat illness (熱中症)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	1 (2.0%)	0	1 (2.0%)	0	1 (2.1%)	1 (2.0%)	0	4 (1.0%)	4 (0.8%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Rib fracture (肋骨骨折)											
CKD Stage 1	0	0	0	0	0	0	0	0	1 (4.8%)	1 (0.8%)	1 (0.7%)
CKD Stage 2	0	2 (2.1%)	0	0	0	0	1 (2.1%)	0	0	3 (0.7%)	3 (0.6%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Wound (創傷)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	2 (2.2%)	0	0	0	0	1 (2.3%)	0	1 (2.0%)	0	2 (0.5%)	4 (0.8%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Arthropod bite (節足動物咬傷)											
CKD Stage 1	0	0	0	0	0	0	1 (11.1%)	0	0	1 (0.8%)	1 (0.7%)
CKD Stage 2	0	0	1 (2.0%)	0	0	0	0	1 (2.0%)	0	2 (0.5%)	2 (0.4%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Arthropod sting (節足動物刺傷)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	1 (2.4%)	1 (2.0%)	0	1 (2.1%)	0	0	3 (0.7%)	3 (0.6%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Foot fracture (足骨折)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	1 (2.0%)	0	0	0	1 (2.1%)	1 (2.0%)	0	3 (0.7%)	3 (0.6%)

System Organ Class Preferred Term Renal function	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
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Radius fracture (橈骨骨折)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	1 (1.1%)	0	0	0	0	0	2 (4.3%)	0	0	2 (0.5%)	3 (0.6%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Avulsion fracture (剥離骨折)											
CKD Stage 1	0	0	0	0	0	1 (6.3%)	0	0	1 (4.8%)	2 (1.6%)	2 (1.3%)
CKD Stage 2	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Hand fracture (手骨折)											
CKD Stage 1	0	0	1 (8.3%)	0	0	0	0	1 (6.3%)	0	2 (1.6%)	2 (1.3%)
CKD Stage 2	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Ligament injury (靱帯損傷)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	1 (1.1%)	0	0	0	0	1 (2.3%)	0	0	0	1 (0.2%)	2 (0.4%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Muscle strain (肉離れ)											
CKD Stage 1	0	0	0	0	0	0	1 (11.1%)	0	0	1 (0.8%)	1 (0.7%)
CKD Stage 2	1 (1.1%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Tendon rupture (腱断裂)											
CKD Stage 1	0	0	2 (16.7%)	0	0	0	0	0	0	2 (1.6%)	2 (1.3%)
CKD Stage 2	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Animal bite (動物咬傷)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0

System Organ Class Preferred Term Renal function	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
CKD Stage 2	1 (1.1%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Clavicle fracture (鎖骨骨折)											
CKD Stage 1	0	1 (4.5%)	0	0	0	0	0	0	0	1 (0.8%)	1 (0.7%)
CKD Stage 2	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Closed globe injury (閉鎖性眼球損傷)											
CKD Stage 1	0	0	0	0	0	1 (6.3%)	0	0	0	1 (0.8%)	1 (0.7%)
CKD Stage 2	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Concussion (脳振盪)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	1 (1.0%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Craniocerebral injury (頭蓋脳損傷)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	1 (2.3%)	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Epicondylitis (上顆炎)											
CKD Stage 1	0	0	1 (8.3%)	0	0	0	0	0	0	1 (0.8%)	1 (0.7%)
CKD Stage 2	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Fractured coccyx (尾骨骨折)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	1 (1.0%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)

System Organ Class Preferred Term Renal function	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
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Fractured ischium (坐骨骨折)											
CKD Stage 1	0	0	0	0	0	0	1 (11.1%)	0	0	1 (0.8%)	1 (0.7%)
CKD Stage 2	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Heat stroke (熱射病)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	0	1 (2.1%)	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Laceration (裂傷)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	1 (1.1%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Lower limb fracture (下肢骨折)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	1 (1.0%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Meniscus injury (半月板損傷)											
CKD Stage 1	0	0	0	0	0	0	0	0	1 (4.8%)	1 (0.8%)	1 (0.7%)
CKD Stage 2	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Multiple fractures (多発骨折)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	0	1 (2.1%)	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Nasal injury (鼻部損傷)											

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CKD Stage 1	0	0	0	0	0	0	0	1 (6.3%)	0	1 (0.8%)	1 (0.7%)
CKD Stage 2	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Pneumothorax traumatic (外傷性気胸)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	1 (1.0%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Post procedural haemorrhage (処置後出血)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	1 (1.1%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Post-traumatic neck syndrome (外傷後頚部症候群)											
CKD Stage 1	0	0	0	0	1 (7.7%)	0	0	0	0	1 (0.8%)	1 (0.7%)
CKD Stage 2	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Procedural pain (処置による疼痛)											
CKD Stage 1	0	0	0	0	1 (7.7%)	0	0	0	0	1 (0.8%)	1 (0.7%)
CKD Stage 2	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Pubis fracture (恥骨骨折)											
CKD Stage 1	0	0	0	0	0	0	1 (11.1%)	0	0	1 (0.8%)	1 (0.7%)
CKD Stage 2	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0

System Organ Class Preferred Term Renal function	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
Skin abrasion (皮膚擦過傷)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	1 (1.0%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Spinal compression fracture (脊椎圧迫骨折)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	1 (1.0%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Spinal fracture (脊椎骨折)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	0	0	0	1 (2.5%)	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Subarachnoid haemorrhage (くも膜下出血)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	1 (1.1%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Subdural haematoma (硬膜下血腫)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	1 (1.0%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Tooth fracture (歯牙破折)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	1 (2.4%)	0	0	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0

System Organ Class Preferred Term Renal function	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
Traumatic intracranial haemorrhage (外傷性頭蓋内出血)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	0	1 (2.1%)	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Skin and subcutaneous tissue disorders (皮膚および皮下組織障害)											
CKD Stage 1	0	1 (4.5%)	2 (16.7%)	1 (5.6%)	0	0	1 (11.1%)	2 (12.5%)	3 (14.3%)	10 (7.9%)	10 (6.6%)
CKD Stage 2	4 (4.4%)	8 (8.3%)	4 (8.0%)	2 (4.8%)	0	4 (9.1%)	10 (21.3%)	4 (7.8%)	2 (5.0%)	34 (8.1%)	38 (7.5%)
CKD Stage 3a	0	1 (11.1%)	0	0	0	0	1 (14.3%)	1 (33.3%)	0	3 (8.8%)	3 (5.7%)
Eczema (湿疹)											
CKD Stage 1	0	0	0	0	0	0	0	1 (6.3%)	1 (4.8%)	2 (1.6%)	2 (1.3%)
CKD Stage 2	2 (2.2%)	4 (4.2%)	3 (6.0%)	0	0	1 (2.3%)	4 (8.5%)	2 (3.9%)	1 (2.5%)	15 (3.6%)	17 (3.3%)
CKD Stage 3a	0	0	0	0	0	0	1 (14.3%)	1 (33.3%)	0	2 (5.9%)	2 (3.8%)
Acne (ざ瘡)											
CKD Stage 1	0	0	1 (8.3%)	0	0	0	0	0	0	1 (0.8%)	1 (0.7%)
CKD Stage 2	0	1 (1.0%)	1 (2.0%)	1 (2.4%)	0	0	0	0	0	3 (0.7%)	3 (0.6%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Dermal cyst (皮膚嚢腫)											
CKD Stage 1	0	0	1 (8.3%)	0	0	0	1 (11.1%)	0	0	2 (1.6%)	2 (1.3%)
CKD Stage 2	0	1 (1.0%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Hyperkeratosis (過角化)											
CKD Stage 1	0	0	0	0	0	0	0	0	1 (4.8%)	1 (0.8%)	1 (0.7%)

System Organ Class Preferred Term Renal function	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
CKD Stage 2	0	1 (1.0%)	0	0	0	0	0	0	1 (2.5%)	2 (0.5%)	2 (0.4%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Dermatitis (皮膚炎)											
CKD Stage 1	0	0	0	0	0	0	0	0	1 (4.8%)	1 (0.8%)	1 (0.7%)
CKD Stage 2	1 (1.1%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Drug eruption (薬疹)											
CKD Stage 1	0	0	0	1 (5.6%)	0	0	0	0	0	1 (0.8%)	1 (0.7%)
CKD Stage 2	0	0	0	0	0	0	1 (2.1%)	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Dry skin (皮膚乾燥)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	1 (2.4%)	0	0	0	1 (2.0%)	0	2 (0.5%)	2 (0.4%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Eczema asteatotic (皮脂欠乏性湿疹)											
CKD Stage 1	0	1 (4.5%)	0	0	0	0	0	0	0	1 (0.8%)	1 (0.7%)
CKD Stage 2	0	1 (1.0%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Rash (発疹)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	1 (1.1%)	0	0	0	0	0	0	1 (2.0%)	0	1 (0.2%)	2 (0.4%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Asteatosis (皮脂欠乏症)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	1 (2.3%)	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0

System Organ Class Preferred Term Renal function	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
Dermatitis allergic (アレルギー性皮膚炎)											
CKD Stage 1	0	0	0	0	0	0	0	1 (6.3%)	0	1 (0.8%)	1 (0.7%)
CKD Stage 2	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Dyshidrotic eczema (異汗性湿疹)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	1 (2.0%)	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Erythema (紅斑)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	0	1 (2.1%)	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Haemorrhage subcutaneous (皮下出血)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	0	1 (2.1%)	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Leukoderma (白斑)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	0	1 (2.1%)	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Miliaria (汗疹)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 3a	0	1 (11.1%)	0	0	0	0	0	0	0	1 (2.9%)	1 (1.9%)

System Organ Class Preferred Term Renal function	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
Nail disorder (爪の障害)											
CKD Stage 1	0	1 (4.5%)	0	0	0	0	0	0	0	1 (0.8%)	1 (0.7%)
CKD Stage 2	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Pruritus (そう痒症)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	1 (2.3%)	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Seborrhoeic dermatitis (脂漏性皮膚炎)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	1 (2.3%)	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Skin mass (皮膚腫瘤)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	0	1 (2.1%)	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Urticaria (蕁麻疹)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	0	1 (2.1%)	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Respiratory, thoracic and mediastinal disorders (呼吸器、胸郭および縦隔障害)											
CKD Stage 1	1 (4.2%)	1 (4.5%)	0	0	0	0	1 (11.1%)	0	2 (9.5%)	4 (3.1%)	5 (3.3%)
CKD Stage 2	5 (5.5%)	11 (11.5%)	4 (8.0%)	1 (2.4%)	4 (8.2%)	4 (9.1%)	1 (2.1%)	2 (3.9%)	3 (7.5%)	30 (7.2%)	35 (6.9%)

System Organ Class Preferred Term Renal function	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
CKD Stage 3a	1 (5.3%)	1 (11.1%)	0	0	1 (50.0%)	1 (20.0%)	0	0	0	3 (8.8%)	4 (7.5%)
Upper respiratory tract inflammation (上気道の炎症)											
CKD Stage 1	0	0	0	0	0	0	1 (11.1%)	0	2 (9.5%)	3 (2.4%)	3 (2.0%)
CKD Stage 2	1 (1.1%)	1 (1.0%)	2 (4.0%)	0	0	2 (4.5%)	1 (2.1%)	0	1 (2.5%)	7 (1.7%)	8 (1.6%)
CKD Stage 3a	0	0	0	0	1 (50.0%)	0	0	0	0	1 (2.9%)	1 (1.9%)
Cough (咳嗽)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	2 (2.2%)	1 (1.0%)	1 (2.0%)	1 (2.4%)	0	1 (2.3%)	0	1 (2.0%)	0	5 (1.2%)	7 (1.4%)
CKD Stage 3a	1 (5.3%)	1 (11.1%)	0	0	0	0	0	0	0	1 (2.9%)	2 (3.8%)
Oropharyngeal pain (口腔咽頭痛)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	1 (1.1%)	1 (1.0%)	0	0	0	1 (2.3%)	0	1 (2.0%)	1 (2.5%)	4 (1.0%)	5 (1.0%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Rhinitis allergic (アレルギー性鼻炎)											
CKD Stage 1	0	0	0	0	0	0	1 (11.1%)	0	0	1 (0.8%)	1 (0.7%)
CKD Stage 2	0	1 (1.0%)	1 (2.0%)	0	1 (2.0%)	0	0	0	0	3 (0.7%)	3 (0.6%)
CKD Stage 3a	0	0	0	0	0	1 (20.0%)	0	0	0	1 (2.9%)	1 (1.9%)
Asthma (喘息)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	1 (1.0%)	0	0	1 (2.0%)	1 (2.3%)	0	0	1 (2.5%)	4 (1.0%)	4 (0.8%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Bronchitis chronic (慢性気管支炎)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0

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CKD Stage 2	0	2 (2.1%)	0	0	1 (2.0%)	0	0	0	0	3 (0.7%)	3 (0.6%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Epistaxis (鼻出血)											
CKD Stage 1	1 (4.2%)	0	0	0	0	0	0	0	0	0	1 (0.7%)
CKD Stage 2	0	2 (2.1%)	0	0	0	0	0	0	0	2 (0.5%)	2 (0.4%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Allergic cough (アレルギー性咳嗽)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	1 (1.1%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Hiccups (しゃっくり)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	1 (2.0%)	0	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Nasal congestion (鼻閉)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	1 (2.4%)	0	0	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Pleural thickening (胸膜肥厚)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	1 (1.0%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Productive cough (湿性咳嗽)											
CKD Stage 1	0	1 (4.5%)	0	0	0	0	0	0	0	1 (0.8%)	1 (0.7%)
CKD Stage 2	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0

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Rhinorrhoea (鼻漏)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	1 (1.0%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Eye disorders (眼障害)											
CKD Stage 1	1 (4.2%)	1 (4.5%)	1 (8.3%)	0	0	2 (12.5%)	0	3 (18.8%)	2 (9.5%)	9 (7.1%)	10 (6.6%)
CKD Stage 2	4 (4.4%)	6 (6.3%)	7 (14.0%)	2 (4.8%)	0	3 (6.8%)	4 (8.5%)	2 (3.9%)	2 (5.0%)	26 (6.2%)	30 (5.9%)
CKD Stage 3a	0	0	0	0	0	1 (20.0%)	1 (14.3%)	0	0	2 (5.9%)	2 (3.8%)
Diabetic retinopathy (糖尿病網膜症)											
CKD Stage 1	1 (4.2%)	0	0	0	0	1 (6.3%)	0	1 (6.3%)	0	2 (1.6%)	3 (2.0%)
CKD Stage 2	1 (1.1%)	1 (1.0%)	1 (2.0%)	0	0	1 (2.3%)	3 (6.4%)	0	0	6 (1.4%)	7 (1.4%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Blepharitis (眼瞼炎)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	1 (1.1%)	2 (2.1%)	1 (2.0%)	0	0	0	0	0	1 (2.5%)	4 (1.0%)	5 (1.0%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Dry eye (眼乾燥)											
CKD Stage 1	0	0	0	0	0	1 (6.3%)	0	0	0	1 (0.8%)	1 (0.7%)
CKD Stage 2	1 (1.1%)	1 (1.0%)	1 (2.0%)	0	0	0	0	0	0	2 (0.5%)	3 (0.6%)
CKD Stage 3a	0	0	0	0	0	0	1 (14.3%)	0	0	1 (2.9%)	1 (1.9%)
Asthenopia (眼精疲労)											
CKD Stage 1	0	0	1 (8.3%)	0	0	0	0	0	0	1 (0.8%)	1 (0.7%)
CKD Stage 2	0	1 (1.0%)	1 (2.0%)	0	0	0	0	1 (2.0%)	0	3 (0.7%)	3 (0.6%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0

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Conjunctivitis allergic (アレルギー性結膜炎)											
CKD Stage 1	0	0	0	0	0	0	0	0	1 (4.8%)	1 (0.8%)	1 (0.7%)
CKD Stage 2	0	0	1 (2.0%)	1 (2.4%)	0	0	0	1 (2.0%)	0	3 (0.7%)	3 (0.6%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Cataract (白内障)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	1 (1.1%)	0	1 (2.0%)	0	0	1 (2.3%)	0	0	0	2 (0.5%)	3 (0.6%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Glaucoma (緑内障)											
CKD Stage 1	0	0	0	0	0	1 (6.3%)	0	0	0	1 (0.8%)	1 (0.7%)
CKD Stage 2	0	0	1 (2.0%)	0	0	0	1 (2.1%)	0	0	2 (0.5%)	2 (0.4%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Ocular hyperaemia (眼充血)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	2 (2.1%)	0	0	0	0	0	0	0	2 (0.5%)	2 (0.4%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Posterior capsule opacification (後嚢部混濁)											
CKD Stage 1	0	1 (4.5%)	0	0	0	0	0	0	0	1 (0.8%)	1 (0.7%)
CKD Stage 2	0	0	0	0	0	1 (2.3%)	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Arteriosclerotic retinopathy (動脈硬化性網膜症)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	1 (2.0%)	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0

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Conjunctival haemorrhage (結膜出血)											
CKD Stage 1	0	0	0	0	0	0	0	1 (6.3%)	0	1 (0.8%)	1 (0.7%)
CKD Stage 2	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Diabetic retinal oedema (糖尿病性網膜浮腫)											
CKD Stage 1	0	0	0	0	0	0	0	1 (6.3%)	0	1 (0.8%)	1 (0.7%)
CKD Stage 2	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Eye pain (眼痛)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	1 (1.1%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Macular oedema (黄斑浮腫)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	0	0	0	1 (2.5%)	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Pingueculitis (瞼裂斑炎)											
CKD Stage 1	0	0	0	0	0	0	0	0	1 (4.8%)	1 (0.8%)	1 (0.7%)
CKD Stage 2	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Retinal haemorrhage (網膜出血)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	1 (2.0%)	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0

System Organ Class Preferred Term Renal function	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
Retinal vein occlusion (網膜静脈閉塞)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 3a	0	0	0	0	0	1 (20.0%)	0	0	0	1 (2.9%)	1 (1.9%)
Scintillating scotoma (閃輝暗点)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	1 (2.4%)	0	0	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Nervous system disorders (神経系障害)											
CKD Stage 1	1 (4.2%)	1 (4.5%)	1 (8.3%)	0	1 (7.7%)	2 (12.5%)	0	0	1 (4.8%)	6 (4.7%)	7 (4.6%)
CKD Stage 2	4 (4.4%)	2 (2.1%)	4 (8.0%)	2 (4.8%)	3 (6.1%)	4 (9.1%)	4 (8.5%)	4 (7.8%)	3 (7.5%)	26 (6.2%)	30 (5.9%)
CKD Stage 3a	3 (15.8%)	0	0	0	0	0	0	0	0	0	3 (5.7%)
Headache (頭痛)											
CKD Stage 1	0	0	0	0	0	1 (6.3%)	0	0	1 (4.8%)	2 (1.6%)	2 (1.3%)
CKD Stage 2	1 (1.1%)	1 (1.0%)	1 (2.0%)	0	1 (2.0%)	1 (2.3%)	0	0	0	4 (1.0%)	5 (1.0%)
CKD Stage 3a	1 (5.3%)	0	0	0	0	0	0	0	0	0	1 (1.9%)
Diabetic neuropathy (糖尿病性ニューロパチー)											
CKD Stage 1	1 (4.2%)	0	0	0	0	0	0	0	0	0	1 (0.7%)
CKD Stage 2	0	0	0	0	0	0	2 (4.3%)	2 (3.9%)	1 (2.5%)	5 (1.2%)	5 (1.0%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0

System Organ Class Preferred Term Renal function	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
Carotid arteriosclerosis (頚動脈硬化症)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	1 (2.0%)	1 (2.4%)	0	2 (4.5%)	0	0	0	4 (1.0%)	4 (0.8%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Cervicobrachial syndrome (頚腕症候群)											
CKD Stage 1	0	0	0	0	1 (7.7%)	0	0	0	0	1 (0.8%)	1 (0.7%)
CKD Stage 2	1 (1.1%)	0	0	0	1 (2.0%)	0	0	0	0	1 (0.2%)	2 (0.4%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Dizziness (浮動性めまい)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	1 (1.1%)	0	0	0	0	0	0	0	1 (2.5%)	1 (0.2%)	2 (0.4%)
CKD Stage 3a	1 (5.3%)	0	0	0	0	0	0	0	0	0	1 (1.9%)
Intercostal neuralgia (肋間神経痛)											
CKD Stage 1	0	0	1 (8.3%)	0	0	0	0	0	0	1 (0.8%)	1 (0.7%)
CKD Stage 2	0	0	2 (4.0%)	0	0	0	0	0	0	2 (0.5%)	2 (0.4%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Loss of consciousness (意識消失)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	1 (2.0%)	1 (2.3%)	0	0	0	2 (0.5%)	2 (0.4%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Sciatica (坐骨神経痛)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	1 (1.1%)	0	0	0	0	0	1 (2.1%)	0	0	1 (0.2%)	2 (0.4%)

System Organ Class Preferred Term Renal function	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
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Carotid artery stenosis (頚動脈狭窄)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	0	0	1 (2.0%)	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Carpal tunnel syndrome (手根管症候群)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	0	1 (2.1%)	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Cerebral infarction (脳梗塞)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	0	0	1 (2.0%)	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Dysaesthesia (異常感覚)											
CKD Stage 1	0	0	0	0	0	1 (6.3%)	0	0	0	1 (0.8%)	1 (0.7%)
CKD Stage 2	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Hypoaesthesia (感覚鈍麻)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	1 (1.0%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Lacunar infarction (ラクナ梗塞)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	0	0	0	1 (2.5%)	1 (0.2%)	1 (0.2%)

System Organ Class Preferred Term Renal function	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
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Paraesthesia (錯感覚)											
CKD Stage 1	0	1 (4.5%)	0	0	0	0	0	0	0	1 (0.8%)	1 (0.7%)
CKD Stage 2	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Post herpetic neuralgia (ヘルペス後神経痛)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 3a	1 (5.3%)	0	0	0	0	0	0	0	0	0	1 (1.9%)
Presyncope (失神寸前の状態)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	1 (2.4%)	0	0	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Syncope (失神)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	0	0	0	1 (2.5%)	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Investigations (臨床検査)											
CKD Stage 1	1 (4.2%)	0	0	1 (5.6%)	0	0	1 (11.1%)	0	1 (4.8%)	3 (2.4%)	4 (2.6%)
CKD Stage 2	5 (5.5%)	8 (8.3%)	2 (4.0%)	1 (2.4%)	3 (6.1%)	2 (4.5%)	5 (10.6%)	1 (2.0%)	1 (2.5%)	23 (5.5%)	28 (5.5%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Lipase increased (リパーゼ増加)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	1 (1.1%)	2 (2.1%)	0	0	1 (2.0%)	1 (2.3%)	3 (6.4%)	0	0	7 (1.7%)	8 (1.6%)

System Organ Class Preferred Term Renal function	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
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Weight decreased (体重減少)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	2 (2.2%)	0	0	1 (2.4%)	1 (2.0%)	0	1 (2.1%)	1 (2.0%)	0	4 (1.0%)	6 (1.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Amylase increased (アミラーゼ増加)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	1 (1.0%)	1 (2.0%)	0	0	1 (2.3%)	1 (2.1%)	0	0	4 (1.0%)	4 (0.8%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Blood creatine phosphokinase increased (血中クレアチンホスホキナーゼ増加)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	1 (1.1%)	0	0	0	0	1 (2.3%)	1 (2.1%)	0	0	2 (0.5%)	3 (0.6%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Hepatic enzyme increased (肝酵素上昇)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	2 (2.1%)	0	0	0	0	0	0	1 (2.5%)	3 (0.7%)	3 (0.6%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Blood lactic acid increased (血中乳酸増加)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	2 (2.1%)	0	0	0	0	0	0	0	2 (0.5%)	2 (0.4%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0

System Organ Class Preferred Term Renal function	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
Gamma-glutamyltransferase increased (γ－グルタミルトランスフェラーゼ増加)											
CKD Stage 1	0	0	0	0	0	0	1 (11.1%)	0	1 (4.8%)	2 (1.6%)	2 (1.3%)
CKD Stage 2	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Platelet count decreased (血小板数減少)											
CKD Stage 1	0	0	0	1 (5.6%)	0	0	0	0	0	1 (0.8%)	1 (0.7%)
CKD Stage 2	1 (1.1%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Blood creatinine increased (血中クレアチニン増加)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	1 (2.0%)	0	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
C-reactive protein increased (C－反応性蛋白増加)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	1 (2.0%)	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Electrocardiogram repolarisation abnormality (心電図再分極異常)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	1 (1.0%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0

System Organ Class Preferred Term Renal function	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
Intraocular pressure increased (眼圧上昇)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	1 (1.0%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Occult blood (便潜血)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	1 (1.0%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Occult blood positive (便潜血陽性)											
CKD Stage 1	1 (4.2%)	0	0	0	0	0	0	0	0	0	1 (0.7%)
CKD Stage 2	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
White blood cell count increased (白血球数増加)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	1 (1.1%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Vascular disorders (血管障害)											
CKD Stage 1	0	1 (4.5%)	0	0	1 (7.7%)	1 (6.3%)	0	1 (6.3%)	1 (4.8%)	5 (3.9%)	5 (3.3%)
CKD Stage 2	2 (2.2%)	4 (4.2%)	2 (4.0%)	1 (2.4%)	3 (6.1%)	2 (4.5%)	1 (2.1%)	1 (2.0%)	0	14 (3.3%)	16 (3.1%)
CKD Stage 3a	0	2 (22.2%)	0	0	0	0	0	0	0	2 (5.9%)	2 (3.8%)
Hypertension (高血圧)											
CKD Stage 1	0	1 (4.5%)	0	0	0	1 (6.3%)	0	1 (6.3%)	1 (4.8%)	4 (3.1%)	4 (2.6%)
CKD Stage 2	0	4 (4.2%)	2 (4.0%)	1 (2.4%)	3 (6.1%)	2 (4.5%)	1 (2.1%)	1 (2.0%)	0	14 (3.3%)	14 (2.7%)
CKD Stage 3a	0	2 (22.2%)	0	0	0	0	0	0	0	2 (5.9%)	2 (3.8%)

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Orthostatic hypotension (起立性低血圧)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	1 (1.1%)	0	1 (2.0%)	0	0	0	0	0	0	1 (0.2%)	2 (0.4%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Arteriosclerosis (動脈硬化症)											
CKD Stage 1	0	0	0	0	1 (7.7%)	0	0	0	0	1 (0.8%)	1 (0.7%)
CKD Stage 2	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Hypotension (低血圧)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	1 (1.1%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Renal and urinary disorders (腎および尿路障害)											
CKD Stage 1	0	0	0	0	0	2 (12.5%)	0	0	2 (9.5%)	4 (3.1%)	4 (2.6%)
CKD Stage 2	1 (1.1%)	1 (1.0%)	1 (2.0%)	1 (2.4%)	2 (4.1%)	1 (2.3%)	3 (6.4%)	4 (7.8%)	1 (2.5%)	14 (3.3%)	15 (2.9%)
CKD Stage 3a	0	1 (11.1%)	0	0	1 (50.0%)	0	0	0	0	2 (5.9%)	2 (3.8%)
Diabetic nephropathy (糖尿病性腎症)											
CKD Stage 1	0	0	0	0	0	1 (6.3%)	0	0	1 (4.8%)	2 (1.6%)	2 (1.3%)
CKD Stage 2	0	1 (1.0%)	0	1 (2.4%)	2 (4.1%)	0	1 (2.1%)	0	0	5 (1.2%)	5 (1.0%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Nephrolithiasis (腎結石症)											
CKD Stage 1	0	0	0	0	0	1 (6.3%)	0	0	0	1 (0.8%)	1 (0.7%)
CKD Stage 2	1 (1.1%)	0	0	0	1 (2.0%)	1 (2.3%)	1 (2.1%)	1 (2.0%)	0	4 (1.0%)	5 (1.0%)

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CKD Stage 3a	0	0	0	0	1 (50.0%)	0	0	0	0	1 (2.9%)	1 (1.9%)
Pollakiuria (頻尿)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	0	0	2 (3.9%)	1 (2.5%)	3 (0.7%)	3 (0.6%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Calculus urinary (尿路結石)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	1 (2.0%)	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Haematuria (血尿)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	0	1 (2.1%)	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Hypertonic bladder (緊張性膀胱)											
CKD Stage 1	0	0	0	0	0	0	0	0	1 (4.8%)	1 (0.8%)	1 (0.7%)
CKD Stage 2	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Polyuria (多尿)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 3a	0	1 (11.1%)	0	0	0	0	0	0	0	1 (2.9%)	1 (1.9%)
Renal cyst (腎嚢胞)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	1 (2.0%)	0	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0

System Organ Class Preferred Term Renal function	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
Urinary tract disorder (尿路障害)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	0	0	1 (2.0%)	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Cardiac disorders (心臓障害)											
CKD Stage 1	1 (4.2%)	0	0	1 (5.6%)	0	0	0	1 (6.3%)	0	2 (1.6%)	3 (2.0%)
CKD Stage 2	0	2 (2.1%)	0	3 (7.1%)	1 (2.0%)	2 (4.5%)	0	3 (5.9%)	1 (2.5%)	12 (2.9%)	12 (2.4%)
CKD Stage 3a	1 (5.3%)	1 (11.1%)	0	0	0	0	1 (14.3%)	0	0	2 (5.9%)	3 (5.7%)
Atrial fibrillation (心房細動)											
CKD Stage 1	1 (4.2%)	0	0	0	0	0	0	1 (6.3%)	0	1 (0.8%)	2 (1.3%)
CKD Stage 2	0	0	0	0	0	1 (2.3%)	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	1 (14.3%)	0	0	1 (2.9%)	1 (1.9%)
Angina unstable (不安定狭心症)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	1 (1.0%)	0	0	1 (2.0%)	0	0	0	0	2 (0.5%)	2 (0.4%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Coronary artery stenosis (冠動脈狭窄)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	0	0	2 (3.9%)	0	2 (0.5%)	2 (0.4%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Palpitations (動悸)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	2 (4.8%)	0	0	0	0	0	2 (0.5%)	2 (0.4%)

System Organ Class Preferred Term Renal function	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
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Sinus bradycardia (洞性徐脈)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	2 (4.5%)	0	0	0	2 (0.5%)	2 (0.4%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Ventricular extrasystoles (心室性期外収縮)											
CKD Stage 1	1 (4.2%)	0	0	0	0	0	0	0	0	0	1 (0.7%)
CKD Stage 2	0	0	0	0	0	0	0	1 (2.0%)	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Acute myocardial infarction (急性心筋梗塞)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 3a	0	1 (11.1%)	0	0	0	0	0	0	0	1 (2.9%)	1 (1.9%)
Aortic valve incompetence (大動脈弁閉鎖不全症)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	1 (1.0%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Cardiac aneurysm (心臓瘤)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 3a	0	1 (11.1%)	0	0	0	0	0	0	0	1 (2.9%)	1 (1.9%)
Cardiac failure (心不全)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	0	0	0	1 (2.5%)	1 (0.2%)	1 (0.2%)

System Organ Class Preferred Term Renal function	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
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Extrasystoles (期外収縮)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	1 (2.3%)	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Myocardial infarction (心筋梗塞)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	1 (2.4%)	0	0	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Myocardial ischaemia (心筋虚血)											
CKD Stage 1	0	0	0	1 (5.6%)	0	0	0	0	0	1 (0.8%)	1 (0.7%)
CKD Stage 2	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Sinus tachycardia (洞性頻脈)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 3a	1 (5.3%)	0	0	0	0	0	0	0	0	0	1 (1.9%)
Supraventricular extrasystoles (上室性期外収縮)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	1 (2.3%)	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0

System Organ Class Preferred Term Renal function	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
General disorders and administration site conditions (一般・全身障害および投与部位の状態)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	3 (3.3%)	0	1 (2.0%)	2 (4.8%)	0	1 (2.3%)	3 (6.4%)	1 (2.0%)	2 (5.0%)	10 (2.4%)	13 (2.5%)
CKD Stage 3a	1 (5.3%)	1 (11.1%)	0	0	0	1 (20.0%)	1 (14.3%)	0	0	3 (8.8%)	4 (7.5%)
Fatigue (疲労)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	1 (1.1%)	0	1 (2.0%)	0	0	0	2 (4.3%)	0	1 (2.5%)	4 (1.0%)	5 (1.0%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Chest pain (胸痛)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	1 (2.4%)	0	0	0	0	1 (2.5%)	2 (0.5%)	2 (0.4%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Non-cardiac chest pain (非心臓性胸痛)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	1 (2.3%)	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	1 (14.3%)	0	0	1 (2.9%)	1 (1.9%)
Pyrexia (発熱)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	1 (1.1%)	0	0	1 (2.4%)	0	0	0	0	0	1 (0.2%)	2 (0.4%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Chest discomfort (胸部不快感)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	0	0	0	0	0	0

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CKD Stage 3a	1 (5.3%)	0	0	0	0	0	0	0	0	0	1 (1.9%)
Early satiety (早期満腹)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	1 (1.1%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Inflammation (炎症)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 3a	0	0	0	0	0	1 (20.0%)	0	0	0	1 (2.9%)	1 (1.9%)
Malaise (倦怠感)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	0	1 (2.1%)	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Oedema peripheral (末梢性浮腫)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 3a	0	1 (11.1%)	0	0	0	0	0	0	0	1 (2.9%)	1 (1.9%)
Thirst (口渇)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	0	0	1 (2.0%)	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Psychiatric disorders (精神障害)											
CKD Stage 1	0	0	0	0	0	1 (6.3%)	1 (11.1%)	2 (12.5%)	0	4 (3.1%)	4 (2.6%)
CKD Stage 2	2 (2.2%)	1 (1.0%)	1 (2.0%)	2 (4.8%)	0	0	2 (4.3%)	0	1 (2.5%)	7 (1.7%)	9 (1.8%)
CKD Stage 3a	1 (5.3%)	1 (11.1%)	0	0	0	0	0	0	0	1 (2.9%)	2 (3.8%)

System Organ Class Preferred Term Renal function	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
Insomnia (不眠症)											
CKD Stage 1	0	0	0	0	0	1 (6.3%)	1 (11.1%)	1 (6.3%)	0	3 (2.4%)	3 (2.0%)
CKD Stage 2	1 (1.1%)	0	0	2 (4.8%)	0	0	2 (4.3%)	0	1 (2.5%)	5 (1.2%)	6 (1.2%)
CKD Stage 3a	1 (5.3%)	1 (11.1%)	0	0	0	0	0	0	0	1 (2.9%)	2 (3.8%)
Apathy (無感情)											
CKD Stage 1	0	0	0	0	0	0	0	1 (6.3%)	0	1 (0.8%)	1 (0.7%)
CKD Stage 2	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Depressed mood (抑うつ気分)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	0	1 (2.1%)	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Depression (うつ病)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	1 (1.0%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Mental fatigue (精神疲労)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	1 (2.0%)	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Stress (ストレス)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	1 (1.1%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Hepatobiliary disorders (肝胆道系障害)											

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CKD Stage 1	0	0	0	0	0	2 (12.5%)	0	2 (12.5%)	0	4 (3.1%)	4 (2.6%)
CKD Stage 2	0	1 (1.0%)	1 (2.0%)	0	2 (4.1%)	1 (2.3%)	0	3 (5.9%)	1 (2.5%)	9 (2.1%)	9 (1.8%)
CKD Stage 3a	0	1 (11.1%)	0	0	0	0	0	0	0	1 (2.9%)	1 (1.9%)
Hepatic steatosis (脂肪肝)											
CKD Stage 1	0	0	0	0	0	1 (6.3%)	0	0	0	1 (0.8%)	1 (0.7%)
CKD Stage 2	0	1 (1.0%)	1 (2.0%)	0	0	0	0	2 (3.9%)	0	4 (1.0%)	4 (0.8%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Alcoholic liver disease (アルコール性肝疾患)											
CKD Stage 1	0	0	0	0	0	0	0	2 (12.5%)	0	2 (1.6%)	2 (1.3%)
CKD Stage 2	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 3a	0	1 (11.1%)	0	0	0	0	0	0	0	1 (2.9%)	1 (1.9%)
Cholelithiasis (胆石症)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	1 (2.0%)	0	0	2 (3.9%)	0	3 (0.7%)	3 (0.6%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Drug-induced liver injury (薬物性肝障害)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	1 (2.0%)	1 (2.3%)	0	0	1 (2.5%)	3 (0.7%)	3 (0.6%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Gallbladder polyp (胆嚢ポリープ)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	0	0	2 (3.9%)	0	2 (0.5%)	2 (0.4%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Cholecystitis (胆嚢炎)											

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CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	1 (2.0%)	0	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Non-alcoholic steatohepatitis (非アルコール性脂肪性肝炎)											
CKD Stage 1	0	0	0	0	0	1 (6.3%)	0	0	0	1 (0.8%)	1 (0.7%)
CKD Stage 2	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Surgical and medical procedures (外科および内科処置)											
CKD Stage 1	0	0	0	0	1 (7.7%)	0	0	0	0	1 (0.8%)	1 (0.7%)
CKD Stage 2	3 (3.3%)	2 (2.1%)	1 (2.0%)	3 (7.1%)	0	0	0	1 (2.0%)	0	7 (1.7%)	10 (2.0%)
CKD Stage 3a	0	1 (11.1%)	0	0	0	0	0	0	0	1 (2.9%)	1 (1.9%)
Cataract operation (白内障手術)											
CKD Stage 1	0	0	0	0	1 (7.7%)	0	0	0	0	1 (0.8%)	1 (0.7%)
CKD Stage 2	1 (1.1%)	2 (2.1%)	1 (2.0%)	2 (4.8%)	0	0	0	0	0	5 (1.2%)	6 (1.2%)
CKD Stage 3a	0	1 (11.1%)	0	0	0	0	0	0	0	1 (2.9%)	1 (1.9%)
Large intestinal polypectomy (大腸ポリープ切除)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	1 (2.4%)	0	0	0	1 (2.0%)	0	2 (0.5%)	2 (0.4%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Endodontic procedure (歯内療法)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	1 (1.1%)	0	0	0	0	0	0	0	0	0	1 (0.2%)

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CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Ptosis repair (眼瞼下垂修復)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	1 (1.1%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）)											
CKD Stage 1	0	2 (9.1%)	0	0	0	0	0	0	0	2 (1.6%)	2 (1.3%)
CKD Stage 2	0	2 (2.1%)	1 (2.0%)	1 (2.4%)	0	1 (2.3%)	1 (2.1%)	2 (3.9%)	1 (2.5%)	9 (2.1%)	9 (1.8%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Benign neoplasm of spinal cord (脊髄の良性新生物)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	1 (2.3%)	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Cholangiocarcinoma (胆管細胞癌)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	1 (2.4%)	0	0	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Colon adenoma (大腸腺腫)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	0	0	0	1 (2.5%)	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0

System Organ Class Preferred Term Renal function	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
Colon cancer stage I (結腸癌第1期)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	1 (1.0%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Endometrial cancer stage III (子宮内膜癌第3期)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	0	1 (2.1%)	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Haemangioma of liver (肝臓血管腫)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	0	0	1 (2.0%)	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Invasive ductal breast carcinoma (浸潤性乳管癌)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	0	0	1 (2.0%)	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Rectal cancer (直腸癌)											
CKD Stage 1	0	1 (4.5%)	0	0	0	0	0	0	0	1 (0.8%)	1 (0.7%)
CKD Stage 2	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Skin papilloma (皮膚乳頭腫)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	1 (1.0%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)

System Organ Class Preferred Term Renal function	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
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Testis cancer (精巣癌)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	1 (2.0%)	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Thyroid neoplasm (甲状腺新生物)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	0	0	1 (2.0%)	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Uterine leiomyoma (子宮平滑筋腫)											
CKD Stage 1	0	1 (4.5%)	0	0	0	0	0	0	0	1 (0.8%)	1 (0.7%)
CKD Stage 2	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Reproductive system and breast disorders (生殖系および乳房障害)											
CKD Stage 1	0	1 (4.5%)	0	0	1 (7.7%)	0	0	0	0	2 (1.6%)	2 (1.3%)
CKD Stage 2	3 (3.3%)	0	2 (4.0%)	0	0	0	3 (6.4%)	1 (2.0%)	0	6 (1.4%)	9 (1.8%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Benign prostatic hyperplasia (良性前立腺肥大症)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	1 (1.1%)	0	2 (4.0%)	0	0	0	0	0	0	2 (0.5%)	3 (0.6%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0

System Organ Class Preferred Term Renal function	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
Dysmenorrhoea (月経困難症)											
CKD Stage 1	0	1 (4.5%)	0	0	0	0	0	0	0	1 (0.8%)	1 (0.7%)
CKD Stage 2	1 (1.1%)	0	0	0	0	0	0	1 (2.0%)	0	1 (0.2%)	2 (0.4%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Erectile dysfunction (勃起不全)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	0	1 (2.1%)	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Genital haemorrhage (性器出血)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	0	1 (2.1%)	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Metrorrhagia (不正子宮出血)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	1 (1.1%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Ovarian cyst (卵巣嚢胞)											
CKD Stage 1	0	0	0	0	1 (7.7%)	0	0	0	0	1 (0.8%)	1 (0.7%)
CKD Stage 2	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Prostatitis (前立腺炎)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	1 (2.0%)	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Uterine polyp (子宮ポリープ)											

System Organ Class Preferred Term Renal function	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
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	0	1 (2.1%)	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Ear and labyrinth disorders (耳および迷路障害)											
CKD Stage 1	0	1 (4.5%)	0	0	0	0	0	1 (6.3%)	0	2 (1.6%)	2 (1.3%)
CKD Stage 2	2 (2.2%)	0	1 (2.0%)	2 (4.8%)	0	1 (2.3%)	0	1 (2.0%)	0	5 (1.2%)	7 (1.4%)
CKD Stage 3a	0	0	0	1 (25.0%)	0	0	0	0	0	1 (2.9%)	1 (1.9%)
Vertigo (回転性めまい)											
CKD Stage 1	0	0	0	0	0	0	0	1 (6.3%)	0	1 (0.8%)	1 (0.7%)
CKD Stage 2	1 (1.1%)	0	0	1 (2.4%)	0	0	0	0	0	1 (0.2%)	2 (0.4%)
CKD Stage 3a	0	0	0	1 (25.0%)	0	0	0	0	0	1 (2.9%)	1 (1.9%)
Tinnitus (耳鳴)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	1 (2.0%)	0	0	1 (2.3%)	0	0	0	2 (0.5%)	2 (0.4%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Deafness transitory (一過性難聴)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	1 (2.4%)	0	0	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
External ear inflammation (外耳の炎症)											
CKD Stage 1	0	1 (4.5%)	0	0	0	0	0	0	0	1 (0.8%)	1 (0.7%)
CKD Stage 2	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0

System Organ Class Preferred Term Renal function	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
Middle ear inflammation (中耳の炎症)											
CKD Stage 1	0	1 (4.5%)	0	0	0	0	0	0	0	1 (0.8%)	1 (0.7%)
CKD Stage 2	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Sudden hearing loss (突発性難聴)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	1 (1.1%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Vertigo positional (頭位性回転性めまい)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	0	0	1 (2.0%)	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Immune system disorders (免疫系障害)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	2 (2.2%)	0	1 (2.0%)	1 (2.4%)	0	1 (2.3%)	0	3 (5.9%)	1 (2.5%)	7 (1.7%)	9 (1.8%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Seasonal allergy (季節性アレルギー)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	1 (1.1%)	0	1 (2.0%)	1 (2.4%)	0	1 (2.3%)	0	1 (2.0%)	1 (2.5%)	5 (1.2%)	6 (1.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0

System Organ Class Preferred Term Renal function	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
Allergy to arthropod sting (節足動物刺傷アレルギー)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	0	0	2 (3.9%)	0	2 (0.5%)	2 (0.4%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Food allergy (食物アレルギー)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	1 (1.1%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Blood and lymphatic system disorders (血液およびリンパ系障害)											
CKD Stage 1	0	0	0	0	0	0	0	0	1 (4.8%)	1 (0.8%)	1 (0.7%)
CKD Stage 2	2 (2.2%)	1 (1.0%)	0	1 (2.4%)	0	1 (2.3%)	0	1 (2.0%)	1 (2.5%)	5 (1.2%)	7 (1.4%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Anaemia (貧血)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	2 (2.2%)	0	0	0	0	0	0	0	0	0	2 (0.4%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Lymphadenitis (リンパ節炎)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	0	0	1 (2.0%)	1 (2.5%)	2 (0.5%)	2 (0.4%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Anaemia macrocytic (大球性貧血)											

System Organ Class Preferred Term Renal function	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
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	1 (2.3%)	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Anaemia megaloblastic (巨赤芽球性貧血)											
CKD Stage 1	0	0	0	0	0	0	0	0	1 (4.8%)	1 (0.8%)	1 (0.7%)
CKD Stage 2	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Lymphadenopathy (リンパ節症)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	1 (2.4%)	0	0	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Normocytic anaemia (正球性貧血)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	1 (1.0%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Endocrine disorders (内分泌障害)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	1 (1.0%)	0	0	0	1 (2.3%)	0	0	0	2 (0.5%)	2 (0.4%)
CKD Stage 3a	0	0	0	0	0	1 (20.0%)	0	0	0	1 (2.9%)	1 (1.9%)
Autoimmune thyroiditis (自己免疫性甲状腺炎)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0

System Organ Class Preferred Term Renal function	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
CKD Stage 2	0	1 (1.0%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Hypothyroidism (甲状腺機能低下症)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 3a	0	0	0	0	0	1 (20.0%)	0	0	0	1 (2.9%)	1 (1.9%)
Inappropriate antidiuretic hormone secretion (抗利尿ホルモン不適合分泌)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	1 (2.3%)	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Congenital, familial and genetic disorders (先天性、家族性および遺伝性障害)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	0	0	1 (2.0%)	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Dermoid cyst (皮様嚢腫)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	0	0	0	0	0	0	1 (2.0%)	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Product issues (製品の問題)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0

System Organ Class Preferred Term Renal function	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
CKD Stage 2	0	1 (1.0%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	0
Device dislocation (医療機器位置異常)											
CKD Stage 1	0	0	0	0	0	0	0	0	0	0	0
CKD Stage 2	0	1 (1.0%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
CKD Stage 3a	0	0	0	0	0	0	0	0	0	0	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; 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.
- "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.
- All adverse events were coded using MedDRA dictionary version 20.1.
- Percentages are based on "Number of patients".

Control No:<<t-s-168-subae-019lt.sas, 2020-03-06T00:12:36>>

Table S-169 Subgroup Analysis of Treatment Emergent Adverse Events by Hepatic Parameter Abnormality, System Organ Class and Preferred Term in 52-Week Long-term Period with Monotherapy and Combination Therapy (PXL008-019; Long-term Safety Population)

System Organ Class Preferred Term Hepatic parameter abnormality	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	18	16	11	10	9	9	12	20	13	100	118
No	116	111	53	54	55	56	51	50	50	480	596
Any TEAE											
Yes	10 (55.6%)	12 (75.0%)	9 (81.8%)	7 (70.0%)	5 (55.6%)	9 (100.0%)	11 (91.7%)	13 (65.0%)	12 (92.3%)	78 (78.0%)	88 (74.6%)
No	88 (75.9%)	90 (81.1%)	45 (84.9%)	41 (75.9%)	28 (50.9%)	41 (73.2%)	39 (76.5%)	43 (86.0%)	36 (72.0%)	363 (75.6%)	451 (75.7%)
Infections and infestations (感染症および寄生虫症)											
Yes	6 (33.3%)	5 (31.3%)	5 (45.5%)	4 (40.0%)	1 (11.1%)	5 (55.6%)	7 (58.3%)	3 (15.0%)	5 (38.5%)	35 (35.0%)	41 (34.7%)
No	51 (44.0%)	52 (46.8%)	32 (60.4%)	24 (44.4%)	12 (21.8%)	27 (48.2%)	21 (41.2%)	27 (54.0%)	24 (48.0%)	219 (45.6%)	270 (45.3%)
Nasopharyngitis (上咽頭炎)											
Yes	5 (27.8%)	2 (12.5%)	4 (36.4%)	2 (20.0%)	1 (11.1%)	4 (44.4%)	4 (33.3%)	3 (15.0%)	3 (23.1%)	23 (23.0%)	28 (23.7%)
No	35 (30.2%)	37 (33.3%)	23 (43.4%)	14 (25.9%)	4 (7.3%)	14 (25.0%)	15 (29.4%)	17 (34.0%)	17 (34.0%)	141 (29.4%)	176 (29.5%)
Pharyngitis (咽頭炎)											
Yes	0	1 (6.3%)	0	0	0	1 (11.1%)	0	0	0	2 (2.0%)	2 (1.7%)
No	8 (6.9%)	4 (3.6%)	4 (7.5%)	0	2 (3.6%)	2 (3.6%)	3 (5.9%)	1 (2.0%)	5 (10.0%)	21 (4.4%)	29 (4.9%)
Influenza (インフルエンザ)											
Yes	0	0	0	2 (20.0%)	0	0	1 (8.3%)	0	0	3 (3.0%)	3 (2.5%)
No	4 (3.4%)	9 (8.1%)	2 (3.8%)	3 (5.6%)	1 (1.8%)	3 (5.4%)	0	1 (2.0%)	2 (4.0%)	21 (4.4%)	25 (4.2%)
Bronchitis (気管支炎)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	1 (0.9%)	1 (0.9%)	4 (7.5%)	2 (3.7%)	0	4 (7.1%)	0	0	2 (4.0%)	13 (2.7%)	14 (2.3%)
Gastroenteritis (胃腸炎)											

System Organ Class Preferred Term Hepatic parameter abnormality	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
Yes	0	0	1 (9.1%)	0	0	0	0	0	0	1 (1.0%)	1 (0.8%)
No	2 (1.7%)	0	2 (3.8%)	3 (5.6%)	1 (1.8%)	1 (1.8%)	1 (2.0%)	2 (4.0%)	1 (2.0%)	11 (2.3%)	13 (2.2%)
Periodontitis (歯周炎)											
Yes	0	0	0	1 (10.0%)	0	0	1 (8.3%)	0	0	2 (2.0%)	2 (1.7%)
No	0	3 (2.7%)	1 (1.9%)	1 (1.9%)	0	3 (5.4%)	1 (2.0%)	1 (2.0%)	0	10 (2.1%)	10 (1.7%)
Cystitis (膀胱炎)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	1 (0.9%)	2 (1.8%)	2 (3.8%)	0	0	1 (1.8%)	2 (3.9%)	2 (4.0%)	1 (2.0%)	10 (2.1%)	11 (1.8%)
Herpes zoster (帯状疱疹)											
Yes	0	1 (6.3%)	0	0	0	1 (11.1%)	0	0	0	2 (2.0%)	2 (1.7%)
No	2 (1.7%)	0	1 (1.9%)	0	0	0	1 (2.0%)	1 (2.0%)	2 (4.0%)	5 (1.0%)	7 (1.2%)
Upper respiratory tract infection (上気道感染)											
Yes	0	0	0	0	0	0	1 (8.3%)	0	1 (7.7%)	2 (2.0%)	2 (1.7%)
No	2 (1.7%)	1 (0.9%)	0	0	0	0	1 (2.0%)	0	0	2 (0.4%)	4 (0.7%)
Pneumonia (肺炎)											
Yes	0	0	0	0	0	0	0	0	1 (7.7%)	1 (1.0%)	1 (0.8%)
No	0	1 (0.9%)	1 (1.9%)	1 (1.9%)	0	1 (1.8%)	0	0	0	4 (0.8%)	4 (0.7%)
Tinea pedis (足部白癬)											
Yes	0	0	0	0	0	0	1 (8.3%)	0	0	1 (1.0%)	1 (0.8%)
No	0	1 (0.9%)	0	0	1 (1.8%)	0	0	1 (2.0%)	1 (2.0%)	4 (0.8%)	4 (0.7%)
Urinary tract infection (尿路感染)											
Yes	0	0	0	0	1 (11.1%)	0	0	0	0	1 (1.0%)	1 (0.8%)
No	0	0	0	0	2 (3.6%)	2 (3.6%)	0	0	0	4 (0.8%)	4 (0.7%)
Conjunctivitis (結膜炎)											

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Yes	0	0	0	0	0	0	0	0	0	0	0
No	1 (0.9%)	2 (1.8%)	0	0	0	1 (1.8%)	0	0	0	3 (0.6%)	4 (0.7%)
Gingivitis (歯肉炎)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	1 (0.9%)	0	0	0	1 (1.8%)	0	2 (4.0%)	0	4 (0.8%)	4 (0.7%)
Otitis externa (外耳炎)											
Yes	1 (5.6%)	0	0	0	0	0	0	0	0	0	1 (0.8%)
No	1 (0.9%)	1 (0.9%)	0	0	0	1 (1.8%)	0	0	0	2 (0.4%)	3 (0.5%)
Pericoronitis (歯冠周囲炎)											
Yes	0	0	0	0	0	0	0	0	1 (7.7%)	1 (1.0%)	1 (0.8%)
No	0	0	0	0	1 (1.8%)	0	0	2 (4.0%)	0	3 (0.6%)	3 (0.5%)
Dermatophytosis of nail (爪の皮膚糸状菌症)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	2 (1.8%)	0	0	0	1 (1.8%)	0	0	0	3 (0.6%)	3 (0.5%)
Oral herpes (口腔ヘルペス)											
Yes	0	1 (6.3%)	0	0	0	0	0	0	0	1 (1.0%)	1 (0.8%)
No	0	0	1 (1.9%)	0	0	0	1 (2.0%)	0	0	2 (0.4%)	2 (0.3%)
Sinusitis (副鼻腔炎)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	1 (0.9%)	0	1 (1.9%)	1 (1.8%)	0	0	0	0	3 (0.6%)	3 (0.5%)
Appendicitis (虫垂炎)											
Yes	0	0	0	1 (10.0%)	0	0	0	0	0	1 (1.0%)	1 (0.8%)
No	1 (0.9%)	0	0	0	0	0	0	0	0	0	1 (0.2%)

System Organ Class Preferred Term Hepatic parameter abnormality	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
Asymptomatic bacteriuria (無症候性細菌尿)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	1 (0.9%)	0	0	0	0	0	1 (2.0%)	0	2 (0.4%)	2 (0.3%)
Chronic sinusitis (慢性副鼻腔炎)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	0	1 (1.8%)	0	0	1 (2.0%)	2 (0.4%)	2 (0.3%)
Diverticulitis (憩室炎)											
Yes	0	0	0	0	0	1 (11.1%)	0	0	0	1 (1.0%)	1 (0.8%)
No	0	0	0	1 (1.9%)	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Enteritis infectious (感染性腸炎)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	1 (0.9%)	0	0	0	0	1 (2.0%)	0	0	2 (0.4%)	2 (0.3%)
Folliculitis (毛包炎)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	1 (0.9%)	0	0	0	0	0	0	0	1 (2.0%)	1 (0.2%)	2 (0.3%)
Gastroenteritis viral (ウイルス性胃腸炎)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	1 (1.9%)	1 (1.8%)	0	0	0	0	2 (0.4%)	2 (0.3%)
Helicobacter infection (ヘリコバクター感染)											
Yes	0	0	0	0	0	0	0	0	0	0	0

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No	0	0	0	1 (1.9%)	0	0	0	1 (2.0%)	0	2 (0.4%)	2 (0.3%)
Impetigo (膿痂疹)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	1 (0.9%)	0	0	0	0	0	1 (2.0%)	0	2 (0.4%)	2 (0.3%)
Otitis media (中耳炎)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	1 (0.9%)	0	0	0	0	0	0	1 (2.0%)	2 (0.4%)	2 (0.3%)
Otitis media acute (急性中耳炎)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	1 (0.9%)	0	0	0	0	0	1 (2.0%)	0	2 (0.4%)	2 (0.3%)
Paronychia (爪囲炎)											
Yes	0	0	0	0	0	1 (11.1%)	0	0	0	1 (1.0%)	1 (0.8%)
No	0	0	0	0	0	0	0	1 (2.0%)	0	1 (0.2%)	1 (0.2%)
Pneumonia bacterial (細菌性肺炎)											
Yes	0	0	0	1 (10.0%)	0	1 (11.1%)	0	0	0	2 (2.0%)	2 (1.7%)
No	0	0	0	0	0	0	0	0	0	0	0
Pulpitis dental (歯髄炎)											
Yes	0	0	0	0	0	0	1 (8.3%)	0	1 (7.7%)	2 (2.0%)	2 (1.7%)
No	0	0	0	0	0	0	0	0	0	0	0
Rhinitis (鼻炎)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	1 (0.9%)	0	0	0	1 (1.8%)	0	0	0	2 (0.4%)	2 (0.3%)
Acute sinusitis (急性副鼻腔炎)											

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Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	1 (0.9%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Bacterial vulvovaginitis (細菌性外陰腟炎)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	1 (1.9%)	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Cellulitis (蜂巣炎)											
Yes	0	0	0	0	0	0	1 (8.3%)	0	0	1 (1.0%)	1 (0.8%)
No	0	0	0	0	0	0	0	0	0	0	0
Eczema impetiginous (膿痂疹性湿疹)											
Yes	0	0	0	0	0	0	1 (8.3%)	0	0	1 (1.0%)	1 (0.8%)
No	0	0	0	0	0	0	0	0	0	0	0
Endometritis (子宮内膜炎)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	1 (1.9%)	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Enterocolitis viral (ウイルス性腸炎)											
Yes	0	0	0	0	0	1 (11.1%)	0	0	0	1 (1.0%)	1 (0.8%)
No	0	0	0	0	0	0	0	0	0	0	0
Furuncle (せつ)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	0	0	1 (2.0%)	0	0	1 (0.2%)	1 (0.2%)
Nasal vestibulitis (鼻前庭炎)											
Yes	0	0	0	0	0	0	1 (8.3%)	0	0	1 (1.0%)	1 (0.8%)
No	0	0	0	0	0	0	0	0	0	0	0

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Skin bacterial infection (皮膚細菌感染)											
Yes	0	0	0	0	0	1 (11.1%)	0	0	0	1 (1.0%)	1 (0.8%)
No	0	0	0	0	0	0	0	0	0	0	0
Skin infection (皮膚感染)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	1 (1.9%)	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Streptococcal infection (レンサ球菌感染)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	1 (0.9%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Subcutaneous abscess (皮下組織膿瘍)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	0	0	1 (2.0%)	0	0	1 (0.2%)	1 (0.2%)
Tinea infection (白癬感染)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	0	0	0	1 (2.0%)	0	1 (0.2%)	1 (0.2%)
Vaginal infection (膣感染)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	0	0	1 (2.0%)	0	0	1 (0.2%)	1 (0.2%)
Gastrointestinal disorders (胃腸障害)											
Yes	3 (16.7%)	5 (31.3%)	2 (18.2%)	5 (50.0%)	0	0	2 (16.7%)	4 (20.0%)	4 (30.8%)	22 (22.0%)	25 (21.2%)

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No	26 (22.4%)	23 (20.7%)	10 (18.9%)	20 (37.0%)	5 (9.1%)	9 (16.1%)	19 (37.3%)	10 (20.0%)	11 (22.0%)	107 (22.3%)	133 (22.3%)
Nausea (悪心)											
Yes	0	0	0	1 (10.0%)	0	0	0	1 (5.0%)	1 (7.7%)	3 (3.0%)	3 (2.5%)
No	9 (7.8%)	1 (0.9%)	0	7 (13.0%)	1 (1.8%)	1 (1.8%)	5 (9.8%)	2 (4.0%)	3 (6.0%)	20 (4.2%)	29 (4.9%)
Diarrhoea (下痢)											
Yes	1 (5.6%)	0	2 (18.2%)	3 (30.0%)	0	0	0	0	0	5 (5.0%)	6 (5.1%)
No	3 (2.6%)	3 (2.7%)	2 (3.8%)	8 (14.8%)	0	2 (3.6%)	2 (3.9%)	3 (6.0%)	2 (4.0%)	22 (4.6%)	25 (4.2%)
Constipation (便秘)											
Yes	0	0	0	1 (10.0%)	0	0	1 (8.3%)	0	0	2 (2.0%)	2 (1.7%)
No	5 (4.3%)	8 (7.2%)	2 (3.8%)	0	2 (3.6%)	1 (1.8%)	4 (7.8%)	1 (2.0%)	2 (4.0%)	20 (4.2%)	25 (4.2%)
Gastrooesophageal reflux disease (胃食道逆流性疾患)											
Yes	1 (5.6%)	3 (18.8%)	0	0	0	0	0	0	0	3 (3.0%)	4 (3.4%)
No	2 (1.7%)	6 (5.4%)	1 (1.9%)	2 (3.7%)	0	0	0	1 (2.0%)	0	10 (2.1%)	12 (2.0%)
Abdominal pain upper (上腹部痛)											
Yes	0	1 (6.3%)	0	0	0	0	0	1 (5.0%)	0	2 (2.0%)	2 (1.7%)
No	4 (3.4%)	0	1 (1.9%)	3 (5.6%)	0	0	2 (3.9%)	0	0	6 (1.3%)	10 (1.7%)
Dental caries (齲歯)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	5 (4.3%)	0	1 (1.9%)	1 (1.9%)	0	3 (5.4%)	2 (3.9%)	0	0	7 (1.5%)	12 (2.0%)
Vomiting (嘔吐)											
Yes	0	0	0	1 (10.0%)	0	0	0	0	0	1 (1.0%)	1 (0.8%)
No	1 (0.9%)	0	0	3 (5.6%)	0	2 (3.6%)	2 (3.9%)	2 (4.0%)	1 (2.0%)	10 (2.1%)	11 (1.8%)
Abdominal discomfort (腹部不快感)											

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Yes	0	0	0	2 (20.0%)	0	0	0	0	0	2 (2.0%)	2 (1.7%)
No	0	2 (1.8%)	1 (1.9%)	1 (1.9%)	1 (1.8%)	0	2 (3.9%)	0	0	7 (1.5%)	7 (1.2%)
Chronic gastritis (慢性胃炎)											
Yes	0	1 (6.3%)	0	0	0	0	0	0	0	1 (1.0%)	1 (0.8%)
No	0	1 (0.9%)	0	1 (1.9%)	0	0	2 (3.9%)	1 (2.0%)	1 (2.0%)	6 (1.3%)	6 (1.0%)
Dyspepsia (消化不良)											
Yes	0	1 (6.3%)	0	0	0	0	0	0	0	1 (1.0%)	1 (0.8%)
No	0	1 (0.9%)	1 (1.9%)	0	0	0	2 (3.9%)	2 (4.0%)	0	6 (1.3%)	6 (1.0%)
Faeces soft (軟便)											
Yes	1 (5.6%)	0	0	0	0	0	0	0	0	0	1 (0.8%)
No	0	1 (0.9%)	1 (1.9%)	2 (3.7%)	0	0	0	0	1 (2.0%)	5 (1.0%)	5 (0.8%)
Large intestine polyp (大腸ポリープ)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	1 (0.9%)	0	0	2 (3.7%)	0	0	1 (2.0%)	1 (2.0%)	1 (2.0%)	5 (1.0%)	6 (1.0%)
Abdominal pain (腹痛)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	1 (0.9%)	1 (1.9%)	0	0	0	1 (2.0%)	0	1 (2.0%)	4 (0.8%)	4 (0.7%)
Gastritis (胃炎)											
Yes	0	0	0	0	0	0	0	1 (5.0%)	0	1 (1.0%)	1 (0.8%)
No	0	0	0	0	1 (1.8%)	0	0	0	2 (4.0%)	3 (0.6%)	3 (0.5%)
Abdominal distension (腹部膨満)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	0	0	1 (2.0%)	0	2 (4.0%)	3 (0.6%)	3 (0.5%)

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Aphthous ulcer (アフタ性潰瘍)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	1 (0.9%)	0	0	1 (1.9%)	0	0	1 (2.0%)	0	0	2 (0.4%)	3 (0.5%)
Food poisoning (食中毒)											
Yes	0	0	0	0	0	0	0	0	1 (7.7%)	1 (1.0%)	1 (0.8%)
No	1 (0.9%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
Abdominal pain lower (下腹部痛)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	0	0	1 (2.0%)	0	0	1 (0.2%)	1 (0.2%)
Change of bowel habit (便習慣変化)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	0	0	0	1 (2.0%)	0	1 (0.2%)	1 (0.2%)
Colitis (大腸炎)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	1 (0.9%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Colitis ulcerative (潰瘍性大腸炎)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	1 (0.9%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
Diverticulum intestinal (腸憩室)											
Yes	0	0	0	0	0	0	0	0	0	0	0

System Organ Class Preferred Term Hepatic parameter abnormality	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 (0.9%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Enteritis (小腸炎)											
Yes	0	0	0	0	0	0	1 (8.3%)	0	0	1 (1.0%)	1 (0.8%)
No	0	0	0	0	0	0	0	0	0	0	0
Enterocolitis (腸炎)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	0	1 (1.8%)	0	0	0	1 (0.2%)	1 (0.2%)
Enterovesical fistula (腸膀胱瘻)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	0	1 (1.8%)	0	0	0	1 (0.2%)	1 (0.2%)
Epigastric discomfort (心窩部不快感)											
Yes	0	0	0	0	0	0	0	1 (5.0%)	0	1 (1.0%)	1 (0.8%)
No	0	0	0	0	0	0	0	0	0	0	0
Flatulence (鼓腸)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	1 (1.9%)	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Gastric polyps (胃ポリープ)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	0	0	1 (2.0%)	0	0	1 (0.2%)	1 (0.2%)
Gastritis erosive (びらん性胃炎)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	1 (0.9%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)

System Organ Class Preferred Term Hepatic parameter abnormality	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
Gastrointestinal disorder (胃腸障害)											
Yes	0	0	0	0	0	0	0	0	1 (7.7%)	1 (1.0%)	1 (0.8%)
No	0	0	0	0	0	0	0	0	0	0	0
Glossitis (舌炎)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	0	0	0	1 (2.0%)	0	1 (0.2%)	1 (0.2%)
Haematochezia (血便排泄)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	1 (0.9%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Inguinal hernia (鼠径ヘルニア)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	1 (1.9%)	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Irritable bowel syndrome (過敏性腸症候群)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	1 (0.9%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
Lower gastrointestinal haemorrhage (下部消化管出血)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	1 (0.9%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Mouth ulceration (口腔内潰瘍形成)											
Yes	0	0	0	0	0	0	0	0	1 (7.7%)	1 (1.0%)	1 (0.8%)

System Organ Class Preferred Term Hepatic parameter abnormality	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	0	0	0	0	0	0	0	0	0	0
Pancreatic steatosis (膵脂肪変性)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	0	1 (1.8%)	0	0	0	1 (0.2%)	1 (0.2%)
Periodontal disease (歯周病)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	1 (0.9%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Stomatitis (口内炎)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	0	0	0	1 (2.0%)	0	1 (0.2%)	1 (0.2%)
Tooth loss (歯の脱落)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	1 (0.9%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
Toothache (歯痛)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	1 (1.9%)	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Musculoskeletal and connective tissue disorders (筋骨格系および結合組織障害)											
Yes	2 (11.1%)	2 (12.5%)	1 (9.1%)	2 (20.0%)	0	1 (11.1%)	4 (33.3%)	4 (20.0%)	0	14 (14.0%)	16 (13.6%)
No	13 (11.2%)	20 (18.0%)	9 (17.0%)	5 (9.3%)	6 (10.9%)	5 (8.9%)	12 (23.5%)	7 (14.0%)	4 (8.0%)	68 (14.2%)	81 (13.6%)
Back pain (背部痛)											
Yes	0	1 (6.3%)	0	0	0	1 (11.1%)	0	0	0	2 (2.0%)	2 (1.7%)
No	5 (4.3%)	9 (8.1%)	3 (5.7%)	1 (1.9%)	2 (3.6%)	3 (5.4%)	1 (2.0%)	0	0	19 (4.0%)	24 (4.0%)

System Organ Class Preferred Term Hepatic parameter abnormality	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
Arthralgia (関節痛)											
Yes	0	0	0	1 (10.0%)	0	0	0	0	0	1 (1.0%)	1 (0.8%)
No	1 (0.9%)	3 (2.7%)	0	1 (1.9%)	0	2 (3.6%)	2 (3.9%)	2 (4.0%)	1 (2.0%)	11 (2.3%)	12 (2.0%)
Pain in extremity (四肢痛)											
Yes	1 (5.6%)	1 (6.3%)	0	0	0	0	0	0	0	1 (1.0%)	2 (1.7%)
No	0	2 (1.8%)	2 (3.8%)	0	0	0	1 (2.0%)	1 (2.0%)	1 (2.0%)	7 (1.5%)	7 (1.2%)
Myalgia (筋肉痛)											
Yes	1 (5.6%)	0	0	0	0	0	0	0	0	0	1 (0.8%)
No	1 (0.9%)	1 (0.9%)	1 (1.9%)	1 (1.9%)	1 (1.8%)	0	0	0	2 (4.0%)	6 (1.3%)	7 (1.2%)
Spinal osteoarthritis (変形性脊椎症)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	1 (0.9%)	0	0	0	1 (1.8%)	0	4 (7.8%)	1 (2.0%)	1 (2.0%)	7 (1.5%)	8 (1.3%)
Intervertebral disc protrusion (椎間板突出)											
Yes	0	0	0	0	0	0	1 (8.3%)	0	0	1 (1.0%)	1 (0.8%)
No	0	0	1 (1.9%)	0	1 (1.8%)	0	3 (5.9%)	1 (2.0%)	0	6 (1.3%)	6 (1.0%)
Osteoarthritis (変形性関節症)											
Yes	0	0	0	1 (10.0%)	0	0	1 (8.3%)	0	0	2 (2.0%)	2 (1.7%)
No	2 (1.7%)	0	1 (1.9%)	0	0	0	1 (2.0%)	0	0	2 (0.4%)	4 (0.7%)
Periarthritis (関節周囲炎)											
Yes	0	0	0	0	0	0	1 (8.3%)	1 (5.0%)	0	2 (2.0%)	2 (1.7%)
No	1 (0.9%)	1 (0.9%)	1 (1.9%)	0	0	0	0	0	0	2 (0.4%)	3 (0.5%)
Lumbar spinal stenosis (腰部脊柱管狭窄症)											
Yes	0	0	0	0	0	0	0	1 (5.0%)	0	1 (1.0%)	1 (0.8%)

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No	1 (0.9%)	0	0	0	0	0	1 (2.0%)	1 (2.0%)	0	2 (0.4%)	3 (0.5%)
Muscle spasms (筋痙縮)											
Yes	0	0	1 (9.1%)	0	0	0	0	0	0	1 (1.0%)	1 (0.8%)
No	0	1 (0.9%)	1 (1.9%)	0	0	0	1 (2.0%)	0	0	3 (0.6%)	3 (0.5%)
Musculoskeletal stiffness (筋骨格硬直)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	2 (1.8%)	2 (3.8%)	0	0	0	0	0	0	4 (0.8%)	4 (0.7%)
Trigger finger (弾発指)											
Yes	0	0	0	0	0	0	2 (16.7%)	1 (5.0%)	0	3 (3.0%)	3 (2.5%)
No	0	0	0	0	0	0	0	1 (2.0%)	0	1 (0.2%)	1 (0.2%)
Musculoskeletal pain (筋骨格痛)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	2 (1.7%)	0	0	0	0	0	0	0	0	0	2 (0.3%)
Neck pain (頚部痛)											
Yes	0	0	0	0	0	0	0	1 (5.0%)	0	1 (1.0%)	1 (0.8%)
No	0	0	0	0	1 (1.8%)	0	0	0	0	1 (0.2%)	1 (0.2%)
Arthritis (関節炎)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	0	0	0	1 (2.0%)	0	1 (0.2%)	1 (0.2%)
Flank pain (側腹部痛)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	1 (1.9%)	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Joint contracture (関節拘縮)											

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Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	0	0	1 (2.0%)	0	0	1 (0.2%)	1 (0.2%)
Plantar fasciitis (足底筋膜炎)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	1 (1.9%)	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Spondylolisthesis (脊椎すべり症)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	1 (0.9%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
Synovitis (滑膜炎)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	1 (0.9%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Temporomandibular joint syndrome (顎関節症候群)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	1 (1.9%)	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Tendon pain (腱痛)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	1 (0.9%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Metabolism and nutrition disorders (代謝および栄養障害)											
Yes	0	3 (18.8%)	2 (18.2%)	2 (20.0%)	2 (22.2%)	2 (22.2%)	2 (16.7%)	5 (25.0%)	0	18 (18.0%)	18 (15.3%)
No	13 (11.2%)	25 (22.5%)	8 (15.1%)	6 (11.1%)	2 (3.6%)	3 (5.4%)	6 (11.8%)	8 (16.0%)	6 (12.0%)	64 (13.3%)	77 (12.9%)
Hypoglycaemia (低血糖)											
Yes	0	2 (12.5%)	2 (18.2%)	2 (20.0%)	1 (11.1%)	1 (11.1%)	2 (16.7%)	1 (5.0%)	0	11 (11.0%)	11 (9.3%)

System Organ Class Preferred Term Hepatic parameter abnormality	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	5 (4.3%)	19 (17.1%)	7 (13.2%)	4 (7.4%)	1 (1.8%)	1 (1.8%)	3 (5.9%)	1 (2.0%)	4 (8.0%)	40 (8.3%)	45 (7.6%)
Hyperglycaemia (高血糖)											
Yes	0	1 (6.3%)	0	0	0	1 (11.1%)	0	3 (15.0%)	0	5 (5.0%)	5 (4.2%)
No	5 (4.3%)	6 (5.4%)	0	0	1 (1.8%)	0	2 (3.9%)	5 (10.0%)	1 (2.0%)	15 (3.1%)	20 (3.4%)
Decreased appetite (食欲減退)											
Yes	0	0	0	0	0	0	0	1 (5.0%)	0	1 (1.0%)	1 (0.8%)
No	3 (2.6%)	0	0	2 (3.7%)	0	2 (3.6%)	2 (3.9%)	2 (4.0%)	1 (2.0%)	9 (1.9%)	12 (2.0%)
Hyperuricaemia (高尿酸血症)											
Yes	0	1 (6.3%)	0	0	0	0	0	0	0	1 (1.0%)	1 (0.8%)
No	0	1 (0.9%)	0	0	0	0	0	0	1 (2.0%)	2 (0.4%)	2 (0.3%)
Dehydration (脱水)											
Yes	0	0	0	0	1 (11.1%)	0	0	0	0	1 (1.0%)	1 (0.8%)
No	0	0	0	0	0	0	0	0	0	0	0
Dyslipidaemia (脂質異常症)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	1 (0.9%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Gout (痛風)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	1 (1.9%)	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Injury, poisoning and procedural complications (傷害、中毒および処置合併症)											
Yes	2 (11.1%)	1 (6.3%)	1 (9.1%)	2 (20.0%)	0	1 (11.1%)	2 (16.7%)	2 (10.0%)	2 (15.4%)	11 (11.0%)	13 (11.0%)
No	9 (7.8%)	12 (10.8%)	7 (13.2%)	3 (5.6%)	4 (7.3%)	5 (8.9%)	12 (23.5%)	5 (10.0%)	2 (4.0%)	50 (10.4%)	59 (9.9%)
Contusion (挫傷)											

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Yes	2 (11.1%)	1 (6.3%)	0	0	0	0	0	0	0	1 (1.0%)	3 (2.5%)
No	1 (0.9%)	2 (1.8%)	0	2 (3.7%)	0	0	3 (5.9%)	0	0	7 (1.5%)	8 (1.3%)
Ligament sprain (靱帯捻挫)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	1 (0.9%)	1 (0.9%)	2 (3.8%)	0	0	1 (1.8%)	0	1 (2.0%)	0	5 (1.0%)	6 (1.0%)
Thermal burn (熱傷)											
Yes	1 (5.6%)	0	0	1 (10.0%)	0	0	0	1 (5.0%)	0	2 (2.0%)	3 (2.5%)
No	0	0	0	1 (1.9%)	0	0	1 (2.0%)	0	0	2 (0.4%)	2 (0.3%)
Heat illness (熱中症)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	1 (1.9%)	0	1 (1.8%)	0	1 (2.0%)	1 (2.0%)	0	4 (0.8%)	4 (0.7%)
Rib fracture (肋骨骨折)											
Yes	0	0	0	0	0	0	0	0	1 (7.7%)	1 (1.0%)	1 (0.8%)
No	0	2 (1.8%)	0	0	0	0	1 (2.0%)	0	0	3 (0.6%)	3 (0.5%)
Wound (創傷)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	2 (1.7%)	0	0	0	0	1 (1.8%)	0	1 (2.0%)	0	2 (0.4%)	4 (0.7%)
Arthropod bite (節足動物咬傷)											
Yes	0	0	0	0	0	0	0	1 (5.0%)	0	1 (1.0%)	1 (0.8%)
No	0	0	1 (1.9%)	0	0	0	1 (2.0%)	0	0	2 (0.4%)	2 (0.3%)
Arthropod sting (節足動物刺傷)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	1 (1.9%)	1 (1.8%)	0	1 (2.0%)	0	0	3 (0.6%)	3 (0.5%)
Foot fracture (足骨折)											
Yes	0	0	0	0	0	0	0	0	0	0	0

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No	0	0	1 (1.9%)	0	0	0	1 (2.0%)	1 (2.0%)	0	3 (0.6%)	3 (0.5%)
Radius fracture (橈骨骨折)											
Yes	0	0	0	0	0	0	1 (8.3%)	0	0	1 (1.0%)	1 (0.8%)
No	1 (0.9%)	0	0	0	0	0	1 (2.0%)	0	0	1 (0.2%)	2 (0.3%)
Avulsion fracture (剥離骨折)											
Yes	0	0	0	0	0	0	0	0	1 (7.7%)	1 (1.0%)	1 (0.8%)
No	0	0	0	0	0	1 (1.8%)	0	0	0	1 (0.2%)	1 (0.2%)
Hand fracture (手骨折)											
Yes	0	0	1 (9.1%)	0	0	0	0	0	0	1 (1.0%)	1 (0.8%)
No	0	0	0	0	0	0	0	1 (2.0%)	0	1 (0.2%)	1 (0.2%)
Ligament injury (靱帯損傷)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	1 (0.9%)	0	0	0	0	1 (1.8%)	0	0	0	1 (0.2%)	2 (0.3%)
Muscle strain (肉離れ)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	1 (0.9%)	0	0	0	0	0	1 (2.0%)	0	0	1 (0.2%)	2 (0.3%)
Tendon rupture (腱断裂)											
Yes	0	0	1 (9.1%)	0	0	0	0	0	0	1 (1.0%)	1 (0.8%)
No	0	0	1 (1.9%)	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Animal bite (動物咬傷)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	1 (0.9%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
Clavicle fracture (鎖骨骨折)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	1 (0.9%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)

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Closed globe injury (閉鎖性眼球損傷)											
Yes	0	0	0	0	0	1 (11.1%)	0	0	0	1 (1.0%)	1 (0.8%)
No	0	0	0	0	0	0	0	0	0	0	0
Concussion (脳振盪)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	1 (0.9%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Craniocerebral injury (頭蓋脳損傷)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	0	1 (1.8%)	0	0	0	1 (0.2%)	1 (0.2%)
Epicondylitis (上顆炎)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	1 (1.9%)	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Fractured coccyx (尾骨骨折)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	1 (0.9%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Fractured ischium (坐骨骨折)											
Yes	0	0	0	0	0	0	1 (8.3%)	0	0	1 (1.0%)	1 (0.8%)
No	0	0	0	0	0	0	0	0	0	0	0
Heat stroke (熱射病)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	0	0	1 (2.0%)	0	0	1 (0.2%)	1 (0.2%)
Laceration (裂傷)											
Yes	0	0	0	0	0	0	0	0	0	0	0

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No	1 (0.9%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
Lower limb fracture (下肢骨折)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	1 (0.9%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Meniscus injury (半月板損傷)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	0	0	0	0	1 (2.0%)	1 (0.2%)	1 (0.2%)
Multiple fractures (多発骨折)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	0	0	1 (2.0%)	0	0	1 (0.2%)	1 (0.2%)
Nasal injury (鼻部損傷)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	0	0	0	1 (2.0%)	0	1 (0.2%)	1 (0.2%)
Pneumothorax traumatic (外傷性気胸)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	1 (0.9%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Post procedural haemorrhage (処置後出血)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	1 (0.9%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
Post-traumatic neck syndrome (外傷後頚部症候群)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	1 (1.8%)	0	0	0	0	1 (0.2%)	1 (0.2%)

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Procedural pain (処置による疼痛)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	1 (1.8%)	0	0	0	0	1 (0.2%)	1 (0.2%)
Pubis fracture (恥骨骨折)											
Yes	0	0	0	0	0	0	1 (8.3%)	0	0	1 (1.0%)	1 (0.8%)
No	0	0	0	0	0	0	0	0	0	0	0
Skin abrasion (皮膚擦過傷)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	1 (0.9%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Spinal compression fracture (脊椎圧迫骨折)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	1 (0.9%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Spinal fracture (脊椎骨折)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	0	0	0	0	1 (2.0%)	1 (0.2%)	1 (0.2%)
Subarachnoid haemorrhage (くも膜下出血)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	1 (0.9%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
Subdural haematoma (硬膜下血腫)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	1 (0.9%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)

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Tooth fracture (歯牙破折)											
Yes	0	0	0	1 (10.0%)	0	0	0	0	0	1 (1.0%)	1 (0.8%)
No	0	0	0	0	0	0	0	0	0	0	0
Traumatic intracranial haemorrhage (外傷性頭蓋内出血)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	0	0	1 (2.0%)	0	0	1 (0.2%)	1 (0.2%)
Skin and subcutaneous tissue disorders (皮膚および皮下組織障害)											
Yes	1 (5.6%)	1 (6.3%)	0	1 (10.0%)	0	2 (22.2%)	1 (8.3%)	1 (5.0%)	1 (7.7%)	7 (7.0%)	8 (6.8%)
No	3 (2.6%)	9 (8.1%)	6 (11.3%)	2 (3.7%)	0	2 (3.6%)	11 (21.6%)	6 (12.0%)	4 (8.0%)	40 (8.3%)	43 (7.2%)
Eczema (湿疹)											
Yes	0	0	0	0	0	0	1 (8.3%)	0	1 (7.7%)	2 (2.0%)	2 (1.7%)
No	2 (1.7%)	4 (3.6%)	3 (5.7%)	0	0	1 (1.8%)	4 (7.8%)	4 (8.0%)	1 (2.0%)	17 (3.5%)	19 (3.2%)
Acne (ざ瘡)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	1 (0.9%)	2 (3.8%)	1 (1.9%)	0	0	0	0	0	4 (0.8%)	4 (0.7%)
Dermal cyst (皮膚嚢腫)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	1 (0.9%)	1 (1.9%)	0	0	0	1 (2.0%)	0	0	3 (0.6%)	3 (0.5%)
Hyperkeratosis (過角化)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	1 (0.9%)	0	0	0	0	0	0	2 (4.0%)	3 (0.6%)	3 (0.5%)

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Dermatitis (皮膚炎)											
Yes	1 (5.6%)	0	0	0	0	0	0	0	0	0	1 (0.8%)
No	0	0	0	0	0	0	0	0	1 (2.0%)	1 (0.2%)	1 (0.2%)
Drug eruption (薬疹)											
Yes	0	0	0	1 (10.0%)	0	0	0	0	0	1 (1.0%)	1 (0.8%)
No	0	0	0	0	0	0	1 (2.0%)	0	0	1 (0.2%)	1 (0.2%)
Dry skin (皮膚乾燥)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	1 (1.9%)	0	0	0	1 (2.0%)	0	2 (0.4%)	2 (0.3%)
Eczema asteatotic (皮脂欠乏性湿疹)											
Yes	0	1 (6.3%)	0	0	0	0	0	0	0	1 (1.0%)	1 (0.8%)
No	0	1 (0.9%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Rash (発疹)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	1 (0.9%)	0	0	0	0	0	0	1 (2.0%)	0	1 (0.2%)	2 (0.3%)
Asteatosis (皮脂欠乏症)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	0	1 (1.8%)	0	0	0	1 (0.2%)	1 (0.2%)
Dermatitis allergic (アレルギー性皮膚炎)											
Yes	0	0	0	0	0	0	0	1 (5.0%)	0	1 (1.0%)	1 (0.8%)
No	0	0	0	0	0	0	0	0	0	0	0
Dyshidrotic eczema (異汗性湿疹)											

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Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	1 (1.9%)	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Erythema (紅斑)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	0	0	1 (2.0%)	0	0	1 (0.2%)	1 (0.2%)
Haemorrhage subcutaneous (皮下出血)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	0	0	1 (2.0%)	0	0	1 (0.2%)	1 (0.2%)
Leukoderma (白斑)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	0	0	1 (2.0%)	0	0	1 (0.2%)	1 (0.2%)
Miliaria (汗疹)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	1 (0.9%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Nail disorder (爪の障害)											
Yes	0	1 (6.3%)	0	0	0	0	0	0	0	1 (1.0%)	1 (0.8%)
No	0	0	0	0	0	0	0	0	0	0	0
Pruritus (そう痒症)											
Yes	0	0	0	0	0	1 (11.1%)	0	0	0	1 (1.0%)	1 (0.8%)
No	0	0	0	0	0	0	0	0	0	0	0
Seborrhoeic dermatitis (脂漏性皮膚炎)											
Yes	0	0	0	0	0	1 (11.1%)	0	0	0	1 (1.0%)	1 (0.8%)
No	0	0	0	0	0	0	0	0	0	0	0

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Skin mass (皮膚腫瘤)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	0	0	1 (2.0%)	0	0	1 (0.2%)	1 (0.2%)
Urticaria (蕁麻疹)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	0	0	1 (2.0%)	0	0	1 (0.2%)	1 (0.2%)
Respiratory, thoracic and mediastinal disorders (呼吸器、胸郭および縦隔障害)											
Yes	0	0	1 (9.1%)	0	0	1 (11.1%)	1 (8.3%)	1 (5.0%)	3 (23.1%)	7 (7.0%)	7 (5.9%)
No	7 (6.0%)	13 (11.7%)	3 (5.7%)	1 (1.9%)	5 (9.1%)	4 (7.1%)	1 (2.0%)	1 (2.0%)	2 (4.0%)	30 (6.3%)	37 (6.2%)
Upper respiratory tract inflammation (上気道の炎症)											
Yes	0	0	0	0	0	0	1 (8.3%)	0	2 (15.4%)	3 (3.0%)	3 (2.5%)
No	1 (0.9%)	1 (0.9%)	2 (3.8%)	0	1 (1.8%)	2 (3.6%)	1 (2.0%)	0	1 (2.0%)	8 (1.7%)	9 (1.5%)
Cough (咳嗽)											
Yes	0	0	1 (9.1%)	0	0	0	0	1 (5.0%)	0	2 (2.0%)	2 (1.7%)
No	3 (2.6%)	2 (1.8%)	0	1 (1.9%)	0	1 (1.8%)	0	0	0	4 (0.8%)	7 (1.2%)
Oropharyngeal pain (口腔咽頭痛)											
Yes	0	0	0	0	0	0	0	0	1 (7.7%)	1 (1.0%)	1 (0.8%)
No	1 (0.9%)	1 (0.9%)	0	0	0	1 (1.8%)	0	1 (2.0%)	0	3 (0.6%)	4 (0.7%)
Rhinitis allergic (アレルギー性鼻炎)											
Yes	0	0	0	0	0	0	0	0	0	0	0

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No	0	1 (0.9%)	1 (1.9%)	0	1 (1.8%)	1 (1.8%)	1 (2.0%)	0	0	5 (1.0%)	5 (0.8%)
Asthma (喘息)											
Yes	0	0	0	0	0	1 (11.1%)	0	0	0	1 (1.0%)	1 (0.8%)
No	0	1 (0.9%)	0	0	1 (1.8%)	0	0	0	1 (2.0%)	3 (0.6%)	3 (0.5%)
Bronchitis chronic (慢性気管支炎)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	2 (1.8%)	0	0	1 (1.8%)	0	0	0	0	3 (0.6%)	3 (0.5%)
Epistaxis (鼻出血)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	1 (0.9%)	2 (1.8%)	0	0	0	0	0	0	0	2 (0.4%)	3 (0.5%)
Allergic cough (アレルギー性咳嗽)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	1 (0.9%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
Hiccups (しゃっくり)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	1 (1.8%)	0	0	0	0	1 (0.2%)	1 (0.2%)
Nasal congestion (鼻閉)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	1 (1.9%)	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Pleural thickening (胸膜肥厚)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	1 (0.9%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Productive cough (湿性咳嗽)											

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Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	1 (0.9%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Rhinorrhoea (鼻漏)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	1 (0.9%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Eye disorders (眼障害)											
Yes	1 (5.6%)	1 (6.3%)	0	1 (10.0%)	0	2 (22.2%)	0	0	2 (15.4%)	6 (6.0%)	7 (5.9%)
No	4 (3.4%)	6 (5.4%)	8 (15.1%)	1 (1.9%)	0	4 (7.1%)	5 (9.8%)	5 (10.0%)	2 (4.0%)	31 (6.5%)	35 (5.9%)
Diabetic retinopathy (糖尿病網膜症)											
Yes	1 (5.6%)	0	0	0	0	1 (11.1%)	0	0	0	1 (1.0%)	2 (1.7%)
No	1 (0.9%)	1 (0.9%)	1 (1.9%)	0	0	1 (1.8%)	3 (5.9%)	1 (2.0%)	0	7 (1.5%)	8 (1.3%)
Blepharitis (眼瞼炎)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	1 (0.9%)	2 (1.8%)	1 (1.9%)	0	0	0	0	0	1 (2.0%)	4 (0.8%)	5 (0.8%)
Dry eye (眼乾燥)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	1 (0.9%)	1 (0.9%)	1 (1.9%)	0	0	1 (1.8%)	1 (2.0%)	0	0	4 (0.8%)	5 (0.8%)
Asthenopia (眼精疲労)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	1 (0.9%)	2 (3.8%)	0	0	0	0	1 (2.0%)	0	4 (0.8%)	4 (0.7%)
Conjunctivitis allergic (アレルギー性結膜炎)											
Yes	0	0	0	1 (10.0%)	0	0	0	0	1 (7.7%)	2 (2.0%)	2 (1.7%)
No	0	0	1 (1.9%)	0	0	0	0	1 (2.0%)	0	2 (0.4%)	2 (0.3%)

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Cataract (白内障)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	1 (0.9%)	0	1 (1.9%)	0	0	1 (1.8%)	0	0	0	2 (0.4%)	3 (0.5%)
Glaucoma (緑内障)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	1 (1.9%)	0	0	1 (1.8%)	1 (2.0%)	0	0	3 (0.6%)	3 (0.5%)
Ocular hyperaemia (眼充血)											
Yes	0	1 (6.3%)	0	0	0	0	0	0	0	1 (1.0%)	1 (0.8%)
No	0	1 (0.9%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Posterior capsule opacification (後嚢部混濁)											
Yes	0	0	0	0	0	1 (11.1%)	0	0	0	1 (1.0%)	1 (0.8%)
No	0	1 (0.9%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Arteriosclerotic retinopathy (動脈硬化性網膜症)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	1 (1.9%)	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Conjunctival haemorrhage (結膜出血)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	0	0	0	1 (2.0%)	0	1 (0.2%)	1 (0.2%)
Diabetic retinal oedema (糖尿病性網膜浮腫)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	0	0	0	1 (2.0%)	0	1 (0.2%)	1 (0.2%)

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Eye pain (眼痛)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	1 (0.9%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
Macular oedema (黄斑浮腫)											
Yes	0	0	0	0	0	0	0	0	1 (7.7%)	1 (1.0%)	1 (0.8%)
No	0	0	0	0	0	0	0	0	0	0	0
Pingueculitis (瞼裂斑炎)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	0	0	0	0	1 (2.0%)	1 (0.2%)	1 (0.2%)
Retinal haemorrhage (網膜出血)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	1 (1.9%)	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Retinal vein occlusion (網膜静脈閉塞)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	0	1 (1.8%)	0	0	0	1 (0.2%)	1 (0.2%)
Scintillating scotoma (閃輝暗点)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	1 (1.9%)	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Nervous system disorders (神経系障害)											
Yes	2 (11.1%)	0	1 (9.1%)	0	2 (22.2%)	2 (22.2%)	0	0	0	5 (5.0%)	7 (5.9%)

System Organ Class Preferred Term Hepatic parameter abnormality	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	6 (5.2%)	3 (2.7%)	4 (7.5%)	2 (3.7%)	2 (3.6%)	4 (7.1%)	4 (7.8%)	4 (8.0%)	4 (8.0%)	27 (5.6%)	33 (5.5%)
Headache (頭痛)											
Yes	0	0	0	0	1 (11.1%)	0	0	0	0	1 (1.0%)	1 (0.8%)
No	2 (1.7%)	1 (0.9%)	1 (1.9%)	0	0	2 (3.6%)	0	0	1 (2.0%)	5 (1.0%)	7 (1.2%)
Diabetic neuropathy (糖尿病性ニューロパチー)											
Yes	1 (5.6%)	0	0	0	0	0	0	0	0	0	1 (0.8%)
No	0	0	0	0	0	0	2 (3.9%)	2 (4.0%)	1 (2.0%)	5 (1.0%)	5 (0.8%)
Carotid arteriosclerosis (頚動脈硬化症)											
Yes	0	0	0	0	0	1 (11.1%)	0	0	0	1 (1.0%)	1 (0.8%)
No	0	0	1 (1.9%)	1 (1.9%)	0	1 (1.8%)	0	0	0	3 (0.6%)	3 (0.5%)
Cervicobrachial syndrome (頚腕症候群)											
Yes	1 (5.6%)	0	0	0	0	0	0	0	0	0	1 (0.8%)
No	0	0	0	0	2 (3.6%)	0	0	0	0	2 (0.4%)	2 (0.3%)
Dizziness (浮動性めまい)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	2 (1.7%)	0	0	0	0	0	0	0	1 (2.0%)	1 (0.2%)	3 (0.5%)
Intercostal neuralgia (肋間神経痛)											
Yes	0	0	1 (9.1%)	0	0	0	0	0	0	1 (1.0%)	1 (0.8%)
No	0	0	2 (3.8%)	0	0	0	0	0	0	2 (0.4%)	2 (0.3%)
Loss of consciousness (意識消失)											

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Yes	0	0	0	0	1 (11.1%)	1 (11.1%)	0	0	0	2 (2.0%)	2 (1.7%)
No	0	0	0	0	0	0	0	0	0	0	0
Sciatica (坐骨神経痛)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	1 (0.9%)	0	0	0	0	0	1 (2.0%)	0	0	1 (0.2%)	2 (0.3%)
Carotid artery stenosis (頚動脈狭窄)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	0	0	0	1 (2.0%)	0	1 (0.2%)	1 (0.2%)
Carpal tunnel syndrome (手根管症候群)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	0	0	1 (2.0%)	0	0	1 (0.2%)	1 (0.2%)
Cerebral infarction (脳梗塞)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	0	0	0	1 (2.0%)	0	1 (0.2%)	1 (0.2%)
Dysaesthesia (異常感覚)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	0	1 (1.8%)	0	0	0	1 (0.2%)	1 (0.2%)
Hypoaesthesia (感覚鈍麻)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	1 (0.9%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Lacunar infarction (ラクナ梗塞)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	0	0	0	0	1 (2.0%)	1 (0.2%)	1 (0.2%)

System Organ Class Preferred Term Hepatic parameter abnormality	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
Paraesthesia (錯感覚)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	1 (0.9%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Post herpetic neuralgia (ヘルペス後神経痛)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	1 (0.9%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
Presyncope (失神寸前の状態)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	1 (1.9%)	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Syncope (失神)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	0	0	0	0	1 (2.0%)	1 (0.2%)	1 (0.2%)
Investigations (臨床検査)											
Yes	1 (5.6%)	3 (18.8%)	0	0	0	0	3 (25.0%)	0	2 (15.4%)	8 (8.0%)	9 (7.6%)
No	5 (4.3%)	5 (4.5%)	2 (3.8%)	2 (3.7%)	3 (5.5%)	2 (3.6%)	3 (5.9%)	1 (2.0%)	0	18 (3.8%)	23 (3.9%)
Lipase increased (リパーゼ増加)											
Yes	0	0	0	0	0	0	2 (16.7%)	0	0	2 (2.0%)	2 (1.7%)
No	1 (0.9%)	2 (1.8%)	0	0	1 (1.8%)	1 (1.8%)	1 (2.0%)	0	0	5 (1.0%)	6 (1.0%)
Weight decreased (体重減少)											
Yes	1 (5.6%)	0	0	0	0	0	0	0	0	0	1 (0.8%)
No	1 (0.9%)	0	0	1 (1.9%)	1 (1.8%)	0	1 (2.0%)	1 (2.0%)	0	4 (0.8%)	5 (0.8%)

System Organ Class Preferred Term Hepatic parameter abnormality	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
Amylase increased (アミラーゼ増加)											
Yes	0	0	0	0	0	0	1 (8.3%)	0	0	1 (1.0%)	1 (0.8%)
No	0	1 (0.9%)	1 (1.9%)	0	0	1 (1.8%)	0	0	0	3 (0.6%)	3 (0.5%)
Blood creatine phosphokinase increased (血中クレアチンホスホキナーゼ増加)											
Yes	0	0	0	0	0	0	1 (8.3%)	0	0	1 (1.0%)	1 (0.8%)
No	1 (0.9%)	0	0	0	0	1 (1.8%)	0	0	0	1 (0.2%)	2 (0.3%)
Hepatic enzyme increased (肝酵素上昇)											
Yes	0	1 (6.3%)	0	0	0	0	0	0	1 (7.7%)	2 (2.0%)	2 (1.7%)
No	0	1 (0.9%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Blood lactic acid increased (血中乳酸増加)											
Yes	0	1 (6.3%)	0	0	0	0	0	0	0	1 (1.0%)	1 (0.8%)
No	0	1 (0.9%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Gamma-glutamyltransferase increased (γ－グルタミルトランスフェラーゼ増加)											
Yes	0	0	0	0	0	0	0	0	1 (7.7%)	1 (1.0%)	1 (0.8%)
No	0	0	0	0	0	0	1 (2.0%)	0	0	1 (0.2%)	1 (0.2%)
Platelet count decreased (血小板数減少)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	1 (0.9%)	0	0	1 (1.9%)	0	0	0	0	0	1 (0.2%)	2 (0.3%)

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Blood creatinine increased (血中クレアチニン増加)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	1 (1.8%)	0	0	0	0	1 (0.2%)	1 (0.2%)
C-reactive protein increased (C－反応性蛋白増加)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	1 (1.9%)	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Electrocardiogram repolarisation abnormality (心電図再分極異常)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	1 (0.9%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Intraocular pressure increased (眼圧上昇)											
Yes	0	1 (6.3%)	0	0	0	0	0	0	0	1 (1.0%)	1 (0.8%)
No	0	0	0	0	0	0	0	0	0	0	0
Occult blood (便潜血)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	1 (0.9%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Occult blood positive (便潜血陽性)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	1 (0.9%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
White blood cell count increased (白血球数増加)											

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Yes	0	0	0	0	0	0	0	0	0	0	0
No	1 (0.9%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
Vascular disorders (血管障害)											
Yes	1 (5.6%)	2 (12.5%)	0	0	0	0	0	0	1 (7.7%)	3 (3.0%)	4 (3.4%)
No	1 (0.9%)	5 (4.5%)	2 (3.8%)	1 (1.9%)	4 (7.3%)	3 (5.4%)	1 (2.0%)	2 (4.0%)	0	18 (3.8%)	19 (3.2%)
Hypertension (高血圧)											
Yes	0	2 (12.5%)	0	0	0	0	0	0	1 (7.7%)	3 (3.0%)	3 (2.5%)
No	0	5 (4.5%)	2 (3.8%)	1 (1.9%)	3 (5.5%)	3 (5.4%)	1 (2.0%)	2 (4.0%)	0	17 (3.5%)	17 (2.9%)
Orthostatic hypotension (起立性低血圧)											
Yes	1 (5.6%)	0	0	0	0	0	0	0	0	0	1 (0.8%)
No	0	0	1 (1.9%)	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Arteriosclerosis (動脈硬化症)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	1 (1.8%)	0	0	0	0	1 (0.2%)	1 (0.2%)
Hypotension (低血圧)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	1 (0.9%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
Renal and urinary disorders (腎および尿路障害)											
Yes	0	1 (6.3%)	0	0	0	1 (11.1%)	0	0	1 (7.7%)	3 (3.0%)	3 (2.5%)
No	1 (0.9%)	1 (0.9%)	1 (1.9%)	1 (1.9%)	3 (5.5%)	2 (3.6%)	3 (5.9%)	4 (8.0%)	2 (4.0%)	17 (3.5%)	18 (3.0%)
Diabetic nephropathy (糖尿病性腎症)											

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Yes	0	1 (6.3%)	0	0	0	1 (11.1%)	0	0	1 (7.7%)	3 (3.0%)	3 (2.5%)
No	0	0	0	1 (1.9%)	2 (3.6%)	0	1 (2.0%)	0	0	4 (0.8%)	4 (0.7%)
Nephrolithiasis (腎結石症)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	1 (0.9%)	0	0	0	2 (3.6%)	2 (3.6%)	1 (2.0%)	1 (2.0%)	0	6 (1.3%)	7 (1.2%)
Pollakiuria (頻尿)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	0	0	0	2 (4.0%)	1 (2.0%)	3 (0.6%)	3 (0.5%)
Calculus urinary (尿路結石)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	1 (1.9%)	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Haematuria (血尿)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	0	0	1 (2.0%)	0	0	1 (0.2%)	1 (0.2%)
Hypertonic bladder (緊張性膀胱)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	0	0	0	0	1 (2.0%)	1 (0.2%)	1 (0.2%)
Polyuria (多尿)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	1 (0.9%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Renal cyst (腎嚢胞)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	1 (1.8%)	0	0	0	0	1 (0.2%)	1 (0.2%)

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Urinary tract disorder (尿路障害)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	0	0	0	1 (2.0%)	0	1 (0.2%)	1 (0.2%)
Cardiac disorders (心臓障害)											
Yes	0	1 (6.3%)	0	1 (10.0%)	1 (11.1%)	0	0	0	1 (7.7%)	4 (4.0%)	4 (3.4%)
No	2 (1.7%)	2 (1.8%)	0	3 (5.6%)	0	2 (3.6%)	1 (2.0%)	4 (8.0%)	0	12 (2.5%)	14 (2.3%)
Atrial fibrillation (心房細動)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	1 (0.9%)	0	0	0	0	1 (1.8%)	1 (2.0%)	1 (2.0%)	0	3 (0.6%)	4 (0.7%)
Angina unstable (不安定狭心症)											
Yes	0	1 (6.3%)	0	0	1 (11.1%)	0	0	0	0	2 (2.0%)	2 (1.7%)
No	0	0	0	0	0	0	0	0	0	0	0
Coronary artery stenosis (冠動脈狭窄)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	0	0	0	2 (4.0%)	0	2 (0.4%)	2 (0.3%)
Palpitations (動悸)											
Yes	0	0	0	1 (10.0%)	0	0	0	0	0	1 (1.0%)	1 (0.8%)
No	0	0	0	1 (1.9%)	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Sinus bradycardia (洞性徐脈)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	0	2 (3.6%)	0	0	0	2 (0.4%)	2 (0.3%)

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Ventricular extrasystoles (心室性期外収縮)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	1 (0.9%)	0	0	0	0	0	0	1 (2.0%)	0	1 (0.2%)	2 (0.3%)
Acute myocardial infarction (急性心筋梗塞)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	1 (0.9%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Aortic valve incompetence (大動脈弁閉鎖不全症)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	1 (0.9%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Cardiac aneurysm (心臓瘤)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	1 (0.9%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Cardiac failure (心不全)											
Yes	0	0	0	0	0	0	0	0	1 (7.7%)	1 (1.0%)	1 (0.8%)
No	0	0	0	0	0	0	0	0	0	0	0
Extrasystoles (期外収縮)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	0	1 (1.8%)	0	0	0	1 (0.2%)	1 (0.2%)
Myocardial infarction (心筋梗塞)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	1 (1.9%)	0	0	0	0	0	1 (0.2%)	1 (0.2%)

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Myocardial ischaemia (心筋虚血)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	1 (1.9%)	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Sinus tachycardia (洞性頻脈)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	1 (0.9%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
Supraventricular extrasystoles (上室性期外収縮)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	0	1 (1.8%)	0	0	0	1 (0.2%)	1 (0.2%)
General disorders and administration site conditions (一般・全身障害および投与部位の状態)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	4 (3.4%)	1 (0.9%)	1 (1.9%)	2 (3.7%)	0	2 (3.6%)	4 (7.8%)	1 (2.0%)	2 (4.0%)	13 (2.7%)	17 (2.9%)
Fatigue (疲労)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	1 (0.9%)	0	1 (1.9%)	0	0	0	2 (3.9%)	0	1 (2.0%)	4 (0.8%)	5 (0.8%)
Chest pain (胸痛)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	1 (1.9%)	0	0	0	0	1 (2.0%)	2 (0.4%)	2 (0.3%)
Non-cardiac chest pain (非心臓性胸痛)											

System Organ Class Preferred Term Hepatic parameter abnormality	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
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	0	1 (1.8%)	1 (2.0%)	0	0	2 (0.4%)	2 (0.3%)
Pyrexia (発熱)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	1 (0.9%)	0	0	1 (1.9%)	0	0	0	0	0	1 (0.2%)	2 (0.3%)
Chest discomfort (胸部不快感)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	1 (0.9%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
Early satiety (早期満腹)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	1 (0.9%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
Inflammation (炎症)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	0	1 (1.8%)	0	0	0	1 (0.2%)	1 (0.2%)
Malaise (倦怠感)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	0	0	1 (2.0%)	0	0	1 (0.2%)	1 (0.2%)
Oedema peripheral (末梢性浮腫)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	1 (0.9%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Thirst (口渇)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	0	0	0	1 (2.0%)	0	1 (0.2%)	1 (0.2%)
Psychiatric disorders (精神障害)											

System Organ Class Preferred Term Hepatic parameter abnormality	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
Yes	0	0	0	0	0	0	0	1 (5.0%)	0	1 (1.0%)	1 (0.8%)
No	3 (2.6%)	2 (1.8%)	1 (1.9%)	2 (3.7%)	0	1 (1.8%)	3 (5.9%)	1 (2.0%)	1 (2.0%)	11 (2.3%)	14 (2.3%)
Insomnia (不眠症)											
Yes	0	0	0	0	0	0	0	1 (5.0%)	0	1 (1.0%)	1 (0.8%)
No	2 (1.7%)	1 (0.9%)	0	2 (3.7%)	0	1 (1.8%)	3 (5.9%)	0	1 (2.0%)	8 (1.7%)	10 (1.7%)
Apathy (無感情)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	0	0	0	1 (2.0%)	0	1 (0.2%)	1 (0.2%)
Depressed mood (抑うつ気分)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	0	0	1 (2.0%)	0	0	1 (0.2%)	1 (0.2%)
Depression (うつ病)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	1 (0.9%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Mental fatigue (精神疲労)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	1 (1.9%)	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Stress (ストレス)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	1 (0.9%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
Hepatobiliary disorders (肝胆道系障害)											
Yes	0	0	0	0	0	1 (11.1%)	0	2 (10.0%)	1 (7.7%)	4 (4.0%)	4 (3.4%)
No	0	2 (1.8%)	1 (1.9%)	0	2 (3.6%)	2 (3.6%)	0	3 (6.0%)	0	10 (2.1%)	10 (1.7%)
Hepatic steatosis (脂肪肝)											

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Yes	0	0	0	0	0	0	0	1 (5.0%)	0	1 (1.0%)	1 (0.8%)
No	0	1 (0.9%)	1 (1.9%)	0	0	1 (1.8%)	0	1 (2.0%)	0	4 (0.8%)	4 (0.7%)
Alcoholic liver disease (アルコール性肝疾患)											
Yes	0	0	0	0	0	0	0	1 (5.0%)	0	1 (1.0%)	1 (0.8%)
No	0	1 (0.9%)	0	0	0	0	0	1 (2.0%)	0	2 (0.4%)	2 (0.3%)
Cholelithiasis (胆石症)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	1 (1.8%)	0	0	2 (4.0%)	0	3 (0.6%)	3 (0.5%)
Drug-induced liver injury (薬物性肝障害)											
Yes	0	0	0	0	0	0	0	0	1 (7.7%)	1 (1.0%)	1 (0.8%)
No	0	0	0	0	1 (1.8%)	1 (1.8%)	0	0	0	2 (0.4%)	2 (0.3%)
Gallbladder polyp (胆嚢ポリープ)											
Yes	0	0	0	0	0	0	0	1 (5.0%)	0	1 (1.0%)	1 (0.8%)
No	0	0	0	0	0	0	0	1 (2.0%)	0	1 (0.2%)	1 (0.2%)
Cholecystitis (胆嚢炎)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	1 (1.8%)	0	0	0	0	1 (0.2%)	1 (0.2%)
Non-alcoholic steatohepatitis (非アルコール性脂肪性肝炎)											
Yes	0	0	0	0	0	1 (11.1%)	0	0	0	1 (1.0%)	1 (0.8%)
No	0	0	0	0	0	0	0	0	0	0	0

System Organ Class Preferred Term Hepatic parameter abnormality	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
Surgical and medical procedures (外科および内科処置)											
Yes	1 (5.6%)	1 (6.3%)	0	0	1 (11.1%)	0	0	0	0	2 (2.0%)	3 (2.5%)
No	2 (1.7%)	2 (1.8%)	1 (1.9%)	3 (5.6%)	0	0	0	1 (2.0%)	0	7 (1.5%)	9 (1.5%)
Cataract operation (白内障手術)											
Yes	0	1 (6.3%)	0	0	1 (11.1%)	0	0	0	0	2 (2.0%)	2 (1.7%)
No	1 (0.9%)	2 (1.8%)	1 (1.9%)	2 (3.7%)	0	0	0	0	0	5 (1.0%)	6 (1.0%)
Large intestinal polypectomy (大腸ポリープ切除)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	1 (1.9%)	0	0	0	1 (2.0%)	0	2 (0.4%)	2 (0.3%)
Endodontic procedure (歯内療法)											
Yes	1 (5.6%)	0	0	0	0	0	0	0	0	0	1 (0.8%)
No	0	0	0	0	0	0	0	0	0	0	0
Ptosis repair (眼瞼下垂修復)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	1 (0.9%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）)											
Yes	0	0	0	0	0	0	0	0	0	0	0

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No	0	4 (3.6%)	1 (1.9%)	1 (1.9%)	0	1 (1.8%)	1 (2.0%)	2 (4.0%)	1 (2.0%)	11 (2.3%)	11 (1.8%)
Benign neoplasm of spinal cord (脊髄の良性新生物)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	0	1 (1.8%)	0	0	0	1 (0.2%)	1 (0.2%)
Cholangiocarcinoma (胆管細胞癌)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	1 (1.9%)	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Colon adenoma (大腸腺腫)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	0	0	0	0	1 (2.0%)	1 (0.2%)	1 (0.2%)
Colon cancer stage I (結腸癌第1期)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	1 (0.9%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Endometrial cancer stage III (子宮内膜癌第3期)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	0	0	1 (2.0%)	0	0	1 (0.2%)	1 (0.2%)
Haemangioma of liver (肝臓血管腫)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	0	0	0	1 (2.0%)	0	1 (0.2%)	1 (0.2%)
Invasive ductal breast carcinoma (浸潤性乳管癌)											

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Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	0	0	0	1 (2.0%)	0	1 (0.2%)	1 (0.2%)
Rectal cancer (直腸癌)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	1 (0.9%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Skin papilloma (皮膚乳頭腫)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	1 (0.9%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Testis cancer (精巣癌)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	1 (1.9%)	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Thyroid neoplasm (甲状腺新生物)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	0	0	0	1 (2.0%)	0	1 (0.2%)	1 (0.2%)
Uterine leiomyoma (子宮平滑筋腫)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	1 (0.9%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Reproductive system and breast disorders (生殖系および乳房障害)											
Yes	0	0	0	0	0	0	0	1 (5.0%)	0	1 (1.0%)	1 (0.8%)
No	3 (2.6%)	1 (0.9%)	2 (3.8%)	0	1 (1.8%)	0	3 (5.9%)	0	0	7 (1.5%)	10 (1.7%)

System Organ Class Preferred Term Hepatic parameter abnormality	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
Benign prostatic hyperplasia (良性前立腺肥大症)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	1 (0.9%)	0	2 (3.8%)	0	0	0	0	0	0	2 (0.4%)	3 (0.5%)
Dysmenorrhoea (月経困難症)											
Yes	0	0	0	0	0	0	0	1 (5.0%)	0	1 (1.0%)	1 (0.8%)
No	1 (0.9%)	1 (0.9%)	0	0	0	0	0	0	0	1 (0.2%)	2 (0.3%)
Erectile dysfunction (勃起不全)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	0	0	1 (2.0%)	0	0	1 (0.2%)	1 (0.2%)
Genital haemorrhage (性器出血)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	0	0	1 (2.0%)	0	0	1 (0.2%)	1 (0.2%)
Metrorrhagia (不正子宮出血)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	1 (0.9%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
Ovarian cyst (卵巣嚢胞)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	1 (1.8%)	0	0	0	0	1 (0.2%)	1 (0.2%)
Prostatitis (前立腺炎)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	1 (1.9%)	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Uterine polyp (子宮ポリープ)											
Yes	0	0	0	0	0	0	0	0	0	0	0

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No	0	0	0	0	0	0	1 (2.0%)	0	0	1 (0.2%)	1 (0.2%)
Ear and labyrinth disorders (耳および迷路障害)											
Yes	0	0	1 (9.1%)	0	0	0	0	0	0	1 (1.0%)	1 (0.8%)
No	2 (1.7%)	1 (0.9%)	0	3 (5.6%)	0	1 (1.8%)	0	2 (4.0%)	0	7 (1.5%)	9 (1.5%)
Vertigo (回転性めまい)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	1 (0.9%)	0	0	2 (3.7%)	0	0	0	1 (2.0%)	0	3 (0.6%)	4 (0.7%)
Tinnitus (耳鳴)											
Yes	0	0	1 (9.1%)	0	0	0	0	0	0	1 (1.0%)	1 (0.8%)
No	0	0	0	0	0	1 (1.8%)	0	0	0	1 (0.2%)	1 (0.2%)
Deafness transitory (一過性難聴)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	1 (1.9%)	0	0	0	0	0	1 (0.2%)	1 (0.2%)
External ear inflammation (外耳の炎症)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	1 (0.9%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Middle ear inflammation (中耳の炎症)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	1 (0.9%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)

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Sudden hearing loss (突発性難聴)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	1 (0.9%)	0	0	0	0	0	0	0	0	0	1 (0.2%)
Vertigo positional (頭位性回転性めまい)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	0	0	0	1 (2.0%)	0	1 (0.2%)	1 (0.2%)
Immune system disorders (免疫系障害)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	2 (1.7%)	0	1 (1.9%)	1 (1.9%)	0	1 (1.8%)	0	3 (6.0%)	1 (2.0%)	7 (1.5%)	9 (1.5%)
Seasonal allergy (季節性アレルギー)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	1 (0.9%)	0	1 (1.9%)	1 (1.9%)	0	1 (1.8%)	0	1 (2.0%)	1 (2.0%)	5 (1.0%)	6 (1.0%)
Allergy to arthropod sting (節足動物刺傷アレルギー)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	0	0	0	2 (4.0%)	0	2 (0.4%)	2 (0.3%)
Food allergy (食物アレルギー)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	1 (0.9%)	0	0	0	0	0	0	0	0	0	1 (0.2%)

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Blood and lymphatic system disorders (血液およびリンパ系障害)											
Yes	0	0	0	0	0	0	0	0	1 (7.7%)	1 (1.0%)	1 (0.8%)
No	2 (1.7%)	1 (0.9%)	0	1 (1.9%)	0	1 (1.8%)	0	1 (2.0%)	1 (2.0%)	5 (1.0%)	7 (1.2%)
Anaemia (貧血)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	2 (1.7%)	0	0	0	0	0	0	0	0	0	2 (0.3%)
Lymphadenitis (リンパ節炎)											
Yes	0	0	0	0	0	0	0	0	1 (7.7%)	1 (1.0%)	1 (0.8%)
No	0	0	0	0	0	0	0	1 (2.0%)	0	1 (0.2%)	1 (0.2%)
Anaemia macrocytic (大球性貧血)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	0	1 (1.8%)	0	0	0	1 (0.2%)	1 (0.2%)
Anaemia megaloblastic (巨赤芽球性貧血)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	0	0	0	0	1 (2.0%)	1 (0.2%)	1 (0.2%)
Lymphadenopathy (リンパ節症)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	1 (1.9%)	0	0	0	0	0	1 (0.2%)	1 (0.2%)

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Normocytic anaemia (正球性貧血)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	1 (0.9%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Endocrine disorders (内分泌障害)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	1 (0.9%)	0	0	0	2 (3.6%)	0	0	0	3 (0.6%)	3 (0.5%)
Autoimmune thyroiditis (自己免疫性甲状腺炎)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	1 (0.9%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
Hypothyroidism (甲状腺機能低下症)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	0	1 (1.8%)	0	0	0	1 (0.2%)	1 (0.2%)
Inappropriate antidiuretic hormone secretion (抗利尿ホルモン不適合分泌)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	0	1 (1.8%)	0	0	0	1 (0.2%)	1 (0.2%)
Congenital, familial and genetic disorders (先天性、家族性および遺伝性障害)											

System Organ Class Preferred Term Hepatic parameter abnormality	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
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	0	0	0	1 (2.0%)	0	1 (0.2%)	1 (0.2%)
Dermoid cyst (皮様嚢腫)											
Yes	0	0	0	0	0	0	0	0	0	0	0
No	0	0	0	0	0	0	0	1 (2.0%)	0	1 (0.2%)	1 (0.2%)
Product issues (製品の問題)											
Yes	0	1 (6.3%)	0	0	0	0	0	0	0	1 (1.0%)	1 (0.8%)
No	0	0	0	0	0	0	0	0	0	0	0
Device dislocation (医療機器位置異常)											
Yes	0	1 (6.3%)	0	0	0	0	0	0	0	1 (1.0%)	1 (0.8%)
No	0	0	0	0	0	0	0	0	0	0	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
- Hepatic parameter abnormality is defined as any one of following parameter applied: Total Bilirubin >= 1.6 mg/dL; Aspartate aminotransferase (AST) >= 1.25 x Upper Limit of Normal (ULN); AST >= 50 IU; Alanine aminotransferase (ALT) >= 1.25 x ULN; ALT >= 50 IU; Alkaline phosphatase >= 1.25 x ULN; Gamma glutamyl transferase >= 1.5 x ULN.
- "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.
- All adverse events were coded using MedDRA dictionary version 20.1.
- Percentages are based on "Number of patients".

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Table S-170 Subgroup Analysis of Treatment Emergent Adverse Events by Age, System Organ Class and Preferred Term in 16-Week Double-blind Period in Combination with Insulin Therapy (PXL008-020; Safety Population)

System Organ Class Preferred Term Age	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
Number of patients		
< 65 years	76	68
>= 65 years	31	40
< 75 years	104	101
>= 75 years	3	7
Any TEAE		
< 65 years	36 (47.4%)	33 (48.5%)
>= 65 years	15 (48.4%)	24 (60.0%)
< 75 years	49 (47.1%)	52 (51.5%)
>= 75 years	2 (66.7%)	5 (71.4%)
Metabolism and nutrition disorders (代謝および栄養障害)		
< 65 years	13 (17.1%)	12 (17.6%)
>= 65 years	7 (22.6%)	11 (27.5%)
< 75 years	18 (17.3%)	20 (19.8%)
>= 75 years	2 (66.7%)	3 (42.9%)
Hypoglycaemia (低血糖)		
< 65 years	11 (14.5%)	12 (17.6%)
>= 65 years	6 (19.4%)	11 (27.5%)
< 75 years	15 (14.4%)	20 (19.8%)
>= 75 years	2 (66.7%)	3 (42.9%)
Hyperglycaemia (高血糖)		
< 65 years	2 (2.6%)	0
>= 65 years	1 (3.2%)	0
< 75 years	3 (2.9%)	0
>= 75 years	0	0
Infections and infestations (感染症および寄生虫症)		
< 65 years	9 (11.8%)	12 (17.6%)
>= 65 years	6 (19.4%)	12 (30.0%)
< 75 years	14 (13.5%)	22 (21.8%)
>= 75 years	1 (33.3%)	2 (28.6%)
Nasopharyngitis (上咽頭炎)		
< 65 years	6 (7.9%)	7 (10.3%)
>= 65 years	2 (6.5%)	9 (22.5%)
< 75 years	8 (7.7%)	15 (14.9%)
>= 75 years	0	1 (14.3%)
Bronchitis (気管支炎)		
< 65 years	0	2 (2.9%)
>= 65 years	0	1 (2.5%)
< 75 years	0	3 (3.0%)
>= 75 years	0	0
Folliculitis (毛包炎)		
< 65 years	0	1 (1.5%)

System Organ Class Preferred Term Age	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
>= 65 years	0	1 (2.5%)
< 75 years	0	1 (1.0%)
>= 75 years	0	1 (14.3%)
Herpes zoster (帯状疱疹)		
< 65 years	0	0
>= 65 years	0	2 (5.0%)
< 75 years	0	2 (2.0%)
>= 75 years	0	0
Tinea pedis (足部白癬)		
< 65 years	0	1 (1.5%)
>= 65 years	1 (3.2%)	0
< 75 years	1 (1.0%)	1 (1.0%)
>= 75 years	0	0
Asymptomatic bacteriuria (無症候性細菌尿)		
< 65 years	0	0
>= 65 years	0	1 (2.5%)
< 75 years	0	0
>= 75 years	0	1 (14.3%)
Gastroenteritis (胃腸炎)		
< 65 years	1 (1.3%)	0
>= 65 years	0	0
< 75 years	1 (1.0%)	0
>= 75 years	0	0
Gingivitis (歯肉炎)		
< 65 years	0	0
>= 65 years	1 (3.2%)	0
< 75 years	0	0
>= 75 years	1 (33.3%)	0
Oral herpes (口腔ヘルペス)		
< 65 years	1 (1.3%)	0
>= 65 years	0	0
< 75 years	1 (1.0%)	0
>= 75 years	0	0
Otitis externa (外耳炎)		
< 65 years	1 (1.3%)	0
>= 65 years	0	0
< 75 years	1 (1.0%)	0
>= 75 years	0	0
Periodontitis (歯周炎)		
< 65 years	0	1 (1.5%)
>= 65 years	0	0
< 75 years	0	1 (1.0%)
>= 75 years	0	0
Pneumonia (肺炎)		
< 65 years	0	0
>= 65 years	1 (3.2%)	0

System Organ Class Preferred Term Age	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
< 75 years	1 (1.0%)	0
>= 75 years	0	0
Pulpitis dental (歯髄炎)		
< 65 years	0	0
>= 65 years	1 (3.2%)	0
< 75 years	1 (1.0%)	0
>= 75 years	0	0
Gastrointestinal disorders (胃腸障害)		
< 65 years	4 (5.3%)	4 (5.9%)
>= 65 years	3 (9.7%)	6 (15.0%)
< 75 years	7 (6.7%)	9 (8.9%)
>= 75 years	0	1 (14.3%)
Constipation (便秘)		
< 65 years	0	0
>= 65 years	1 (3.2%)	3 (7.5%)
< 75 years	1 (1.0%)	2 (2.0%)
>= 75 years	0	1 (14.3%)
Diarrhoea (下痢)		
< 65 years	2 (2.6%)	0
>= 65 years	0	2 (5.0%)
< 75 years	2 (1.9%)	2 (2.0%)
>= 75 years	0	0
Nausea (悪心)		
< 65 years	2 (2.6%)	0
>= 65 years	0	2 (5.0%)
< 75 years	2 (1.9%)	2 (2.0%)
>= 75 years	0	0
Abdominal discomfort (腹部不快感)		
< 65 years	1 (1.3%)	0
>= 65 years	0	1 (2.5%)
< 75 years	1 (1.0%)	1 (1.0%)
>= 75 years	0	0
Gastrooesophageal reflux disease (胃食道逆流性疾患)		
< 65 years	0	1 (1.5%)
>= 65 years	1 (3.2%)	0
< 75 years	1 (1.0%)	1 (1.0%)
>= 75 years	0	0
Vomiting (嘔吐)		
< 65 years	0	0
>= 65 years	1 (3.2%)	1 (2.5%)
< 75 years	1 (1.0%)	1 (1.0%)
>= 75 years	0	0
Abdominal distension (腹部膨満)		
< 65 years	0	1 (1.5%)
>= 65 years	0	0

System Organ Class Preferred Term Age	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
< 75 years	0	1 (1.0%)
>= 75 years	0	0
Colitis ulcerative (潰瘍性大腸炎)		
< 65 years	0	0
>= 65 years	0	1 (2.5%)
< 75 years	0	1 (1.0%)
>= 75 years	0	0
Dental caries (齲歯)		
< 65 years	0	1 (1.5%)
>= 65 years	0	0
< 75 years	0	1 (1.0%)
>= 75 years	0	0
Periodontal disease (歯周病)		
< 65 years	0	1 (1.5%)
>= 65 years	0	0
< 75 years	0	1 (1.0%)
>= 75 years	0	0
Toothache (歯痛)		
< 65 years	0	0
>= 65 years	0	1 (2.5%)
< 75 years	0	1 (1.0%)
>= 75 years	0	0
Musculoskeletal and connective tissue disorders (筋骨格系および結合組織障害)		
< 65 years	2 (2.6%)	4 (5.9%)
>= 65 years	2 (6.5%)	5 (12.5%)
< 75 years	4 (3.8%)	8 (7.9%)
>= 75 years	0	1 (14.3%)
Muscle spasms (筋痙縮)		
< 65 years	1 (1.3%)	0
>= 65 years	1 (3.2%)	2 (5.0%)
< 75 years	2 (1.9%)	2 (2.0%)
>= 75 years	0	0
Arthralgia (関節痛)		
< 65 years	0	2 (2.9%)
>= 65 years	0	0
< 75 years	0	2 (2.0%)
>= 75 years	0	0
Back pain (背部痛)		
< 65 years	1 (1.3%)	0
>= 65 years	1 (3.2%)	0
< 75 years	2 (1.9%)	0
>= 75 years	0	0
Myofascitis (筋筋膜炎)		
< 65 years	0	0

System Organ Class Preferred Term Age	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
>= 65 years	0	1 (2.5%)
< 75 years	0	0
>= 75 years	0	1 (14.3%)
Neck pain (頚部痛)		
< 65 years	0	1 (1.5%)
>= 65 years	0	0
< 75 years	0	1 (1.0%)
>= 75 years	0	0
Osteoarthritis (変形性関節症)		
< 65 years	0	0
>= 65 years	0	1 (2.5%)
< 75 years	0	1 (1.0%)
>= 75 years	0	0
Pain in extremity (四肢痛)		
< 65 years	0	1 (1.5%)
>= 65 years	0	0
< 75 years	0	1 (1.0%)
>= 75 years	0	0
Spinal osteoarthritis (変形性脊椎症)		
< 65 years	0	0
>= 65 years	0	1 (2.5%)
< 75 years	0	0
>= 75 years	0	1 (14.3%)
Synovial cyst (滑液嚢腫)		
< 65 years	0	0
>= 65 years	0	1 (2.5%)
< 75 years	0	1 (1.0%)
>= 75 years	0	0
Respiratory, thoracic and mediastinal disorders (呼吸器、胸郭および縦隔障害)		
< 65 years	6 (7.9%)	2 (2.9%)
>= 65 years	2 (6.5%)	0
< 75 years	8 (7.7%)	2 (2.0%)
>= 75 years	0	0
Asthma (喘息)		
< 65 years	1 (1.3%)	1 (1.5%)
>= 65 years	1 (3.2%)	0
< 75 years	2 (1.9%)	1 (1.0%)
>= 75 years	0	0
Upper respiratory tract inflammation (上気道の炎症)		
< 65 years	1 (1.3%)	0
>= 65 years	1 (3.2%)	0
< 75 years	2 (1.9%)	0
>= 75 years	0	0
Allergic cough (アレルギー性咳嗽)		

System Organ Class Preferred Term Age	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
< 65 years	1 (1.3%)	0
>= 65 years	0	0
< 75 years	1 (1.0%)	0
>= 75 years	0	0
Cough (咳嗽)		
< 65 years	1 (1.3%)	0
>= 65 years	0	0
< 75 years	1 (1.0%)	0
>= 75 years	0	0
Epistaxis (鼻出血)		
< 65 years	1 (1.3%)	0
>= 65 years	0	0
< 75 years	1 (1.0%)	0
>= 75 years	0	0
Pulmonary embolism (肺塞栓症)		
< 65 years	0	1 (1.5%)
>= 65 years	0	0
< 75 years	0	1 (1.0%)
>= 75 years	0	0
Sleep apnoea syndrome (睡眠時無呼吸症候群)		
< 65 years	1 (1.3%)	0
>= 65 years	0	0
< 75 years	1 (1.0%)	0
>= 75 years	0	0
Nervous system disorders (神経系障害)		
< 65 years	4 (5.3%)	0
>= 65 years	2 (6.5%)	1 (2.5%)
< 75 years	6 (5.8%)	0
>= 75 years	0	1 (14.3%)
Dizziness (浮動性めまい)		
< 65 years	1 (1.3%)	0
>= 65 years	2 (6.5%)	1 (2.5%)
< 75 years	3 (2.9%)	0
>= 75 years	0	1 (14.3%)
Diabetic neuropathy (糖尿病性ニューロパチー)		
< 65 years	1 (1.3%)	0
>= 65 years	0	0
< 75 years	1 (1.0%)	0
>= 75 years	0	0
Guillain-Barre syndrome (ギラン・バレー症候群)		
< 65 years	1 (1.3%)	0
>= 65 years	0	0
< 75 years	1 (1.0%)	0
>= 75 years	0	0
Sciatica (坐骨神経痛)		

System Organ Class Preferred Term Age	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
< 65 years	1 (1.3%)	0
>= 65 years	0	0
< 75 years	1 (1.0%)	0
>= 75 years	0	0
Skin and subcutaneous tissue disorders (皮膚および皮下組織障害)		
< 65 years	2 (2.6%)	1 (1.5%)
>= 65 years	0	2 (5.0%)
< 75 years	2 (1.9%)	2 (2.0%)
>= 75 years	0	1 (14.3%)
Urticaria (蕁麻疹)		
< 65 years	0	1 (1.5%)
>= 65 years	0	1 (2.5%)
< 75 years	0	2 (2.0%)
>= 75 years	0	0
Papule (丘疹)		
< 65 years	1 (1.3%)	0
>= 65 years	0	0
< 75 years	1 (1.0%)	0
>= 75 years	0	0
Pruritus (そう痒症)		
< 65 years	0	0
>= 65 years	0	1 (2.5%)
< 75 years	0	0
>= 75 years	0	1 (14.3%)
Solar dermatitis (日光皮膚炎)		
< 65 years	1 (1.3%)	0
>= 65 years	0	0
< 75 years	1 (1.0%)	0
>= 75 years	0	0
General disorders and administration site conditions (一般・全身障害および投与部位の状態)		
< 65 years	3 (3.9%)	1 (1.5%)
>= 65 years	0	0
< 75 years	3 (2.9%)	1 (1.0%)
>= 75 years	0	0
Pyrexia (発熱)		
< 65 years	3 (3.9%)	1 (1.5%)
>= 65 years	0	0
< 75 years	3 (2.9%)	1 (1.0%)
>= 75 years	0	0
Injury, poisoning and procedural complications (傷害、中毒および処置合併症)		

System Organ Class Preferred Term Age	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
< 65 years	2 (2.6%)	2 (2.9%)
>= 65 years	0	0
< 75 years	2 (1.9%)	2 (2.0%)
>= 75 years	0	0
Contusion (挫傷)		
< 65 years	2 (2.6%)	0
>= 65 years	0	0
< 75 years	2 (1.9%)	0
>= 75 years	0	0
Heat illness (熱中症)		
< 65 years	0	1 (1.5%)
>= 65 years	0	0
< 75 years	0	1 (1.0%)
>= 75 years	0	0
Muscle strain (肉離れ)		
< 65 years	0	1 (1.5%)
>= 65 years	0	0
< 75 years	0	1 (1.0%)
>= 75 years	0	0
Vascular disorders (血管障害)		
< 65 years	0	3 (4.4%)
>= 65 years	0	0
< 75 years	0	3 (3.0%)
>= 75 years	0	0
Hypertension (高血圧)		
< 65 years	0	1 (1.5%)
>= 65 years	0	0
< 75 years	0	1 (1.0%)
>= 75 years	0	0
Peripheral arterial occlusive disease (末梢動脈閉塞性疾患)		
< 65 years	0	1 (1.5%)
>= 65 years	0	0
< 75 years	0	1 (1.0%)
>= 75 years	0	0
Venous thrombosis limb (四肢静脈血栓症)		
< 65 years	0	1 (1.5%)
>= 65 years	0	0
< 75 years	0	1 (1.0%)
>= 75 years	0	0
Eye disorders (眼障害)		
< 65 years	0	2 (2.9%)
>= 65 years	0	0
< 75 years	0	2 (2.0%)
>= 75 years	0	0

System Organ Class Preferred Term Age	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
Angle closure glaucoma (閉塞隅角緑内障)		
< 65 years	0	1 (1.5%)
>= 65 years	0	0
< 75 years	0	1 (1.0%)
>= 75 years	0	0
Vitreous haemorrhage (硝子体出血)		
< 65 years	0	1 (1.5%)
>= 65 years	0	0
< 75 years	0	1 (1.0%)
>= 75 years	0	0
Cardiac disorders (心臓障害)		
< 65 years	1 (1.3%)	0
>= 65 years	0	0
< 75 years	1 (1.0%)	0
>= 75 years	0	0
Bundle branch block right (右脚ブロック)		
< 65 years	1 (1.3%)	0
>= 65 years	0	0
< 75 years	1 (1.0%)	0
>= 75 years	0	0
Ear and labyrinth disorders (耳および迷路障害)		
< 65 years	1 (1.3%)	0
>= 65 years	0	0
< 75 years	1 (1.0%)	0
>= 75 years	0	0
Vertigo positional (頭位性回転性めまい)		
< 65 years	1 (1.3%)	0
>= 65 years	0	0
< 75 years	1 (1.0%)	0
>= 75 years	0	0
Hepatobiliary disorders (肝胆道系障害)		
< 65 years	0	1 (1.5%)
>= 65 years	0	0
< 75 years	0	1 (1.0%)
>= 75 years	0	0
Gallbladder polyp (胆嚢ポリープ)		
< 65 years	0	1 (1.5%)
>= 65 years	0	0
< 75 years	0	1 (1.0%)
>= 75 years	0	0
Investigations (臨床検査)		
< 65 years	0	0

System Organ Class Preferred Term Age	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
>= 65 years	0	1 (2.5%)
< 75 years	0	1 (1.0%)
>= 75 years	0	0
Blood creatine phosphokinase increased (血中クレアチンホスホキナーゼ増加)		
< 65 years	0	0
>= 65 years	0	1 (2.5%)
< 75 years	0	1 (1.0%)
>= 75 years	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）)		
< 65 years	0	1 (1.5%)
>= 65 years	0	0
< 75 years	0	1 (1.0%)
>= 75 years	0	0
Lipoma (脂肪腫)		
< 65 years	0	1 (1.5%)
>= 65 years	0	0
< 75 years	0	1 (1.0%)
>= 75 years	0	0
Renal and urinary disorders (腎および尿路障害)		
< 65 years	0	1 (1.5%)
>= 65 years	0	0
< 75 years	0	1 (1.0%)
>= 75 years	0	0
Haematuria (血尿)		
< 65 years	0	1 (1.5%)
>= 65 years	0	0
< 75 years	0	1 (1.0%)
>= 75 years	0	0
Reproductive system and breast disorders (生殖系および乳房障害)		
< 65 years	1 (1.3%)	0
>= 65 years	0	0
< 75 years	1 (1.0%)	0
>= 75 years	0	0
Amenorrhoea (無月経)		
< 65 years	1 (1.3%)	0
>= 65 years	0	0
< 75 years	1 (1.0%)	0

System Organ Class Preferred Term Age	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
>= 75 years	0	0

- Abbreviations: bid, Twice a day; AE, Adverse event; TEAE, Treatment Emergent AE
- All adverse events were coded using MedDRA dictionary version 20.1.
- Percentages are based on "Number of patients".

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Table S-171 Subgroup Analysis of Treatment Emergent Adverse Events by Sex, System Organ Class and Preferred Term in 16-Week Double-blind Period in Combination with Insulin Therapy (PXL008-020; Safety Population)

System Organ Class Preferred Term Sex	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
Number of patients		
Male	69	66
Female	38	42
Any TEAE		
Male	31 (44.9%)	33 (50.0%)
Female	20 (52.6%)	24 (57.1%)
Metabolism and nutrition disorders (代謝および栄養障害)		
Male	14 (20.3%)	11 (16.7%)
Female	6 (15.8%)	12 (28.6%)
Hypoglycaemia (低血糖)		
Male	11 (15.9%)	11 (16.7%)
Female	6 (15.8%)	12 (28.6%)
Hyperglycaemia (高血糖)		
Male	3 (4.3%)	0
Female	0	0
Infections and infestations (感染症および寄生虫症)		
Male	9 (13.0%)	11 (16.7%)
Female	6 (15.8%)	13 (31.0%)
Nasopharyngitis (上咽頭炎)		
Male	5 (7.2%)	7 (10.6%)
Female	3 (7.9%)	9 (21.4%)
Bronchitis (気管支炎)		
Male	0	1 (1.5%)
Female	0	2 (4.8%)
Folliculitis (毛包炎)		
Male	0	1 (1.5%)
Female	0	1 (2.4%)
Herpes zoster (帯状疱疹)		
Male	0	1 (1.5%)
Female	0	1 (2.4%)
Tinea pedis (足部白癬)		
Male	0	1 (1.5%)
Female	1 (2.6%)	0
Asymptomatic bacteriuria (無症候性細菌尿)		
Male	0	0
Female	0	1 (2.4%)
Gastroenteritis (胃腸炎)		
Male	0	0
Female	1 (2.6%)	0
Gingivitis (歯肉炎)		

System Organ Class Preferred Term Sex	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
Male	1 (1.4%)	0
Female	0	0
Oral herpes (口腔ヘルペス)		
Male	1 (1.4%)	0
Female	0	0
Otitis externa (外耳炎)		
Male	1 (1.4%)	0
Female	0	0
Periodontitis (歯周炎)		
Male	0	0
Female	0	1 (2.4%)
Pneumonia (肺炎)		
Male	0	0
Female	1 (2.6%)	0
Pulpitis dental (歯髄炎)		
Male	1 (1.4%)	0
Female	0	0
Gastrointestinal disorders (胃腸障害)		
Male	4 (5.8%)	6 (9.1%)
Female	3 (7.9%)	4 (9.5%)
Constipation (便秘)		
Male	1 (1.4%)	0
Female	0	3 (7.1%)
Diarrhoea (下痢)		
Male	2 (2.9%)	1 (1.5%)
Female	0	1 (2.4%)
Nausea (悪心)		
Male	0	0
Female	2 (5.3%)	2 (4.8%)
Abdominal discomfort (腹部不快感)		
Male	1 (1.4%)	1 (1.5%)
Female	0	0
Gastrooesophageal reflux disease (胃食道逆流性疾患)		
Male	0	1 (1.5%)
Female	1 (2.6%)	0
Vomiting (嘔吐)		
Male	1 (1.4%)	0
Female	0	1 (2.4%)
Abdominal distension (腹部膨満)		
Male	0	1 (1.5%)
Female	0	0
Colitis ulcerative (潰瘍性大腸炎)		
Male	0	1 (1.5%)

System Organ Class Preferred Term Sex	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
Female	0	0
Dental caries (齲歯)		
Male	0	1 (1.5%)
Female	0	0
Periodontal disease (歯周病)		
Male	0	1 (1.5%)
Female	0	0
Toothache (歯痛)		
Male	0	1 (1.5%)
Female	0	0
Musculoskeletal and connective tissue disorders (筋骨格系および結合組織障害)		
Male	2 (2.9%)	5 (7.6%)
Female	2 (5.3%)	4 (9.5%)
Muscle spasms (筋痙縮)		
Male	1 (1.4%)	1 (1.5%)
Female	1 (2.6%)	1 (2.4%)
Arthralgia (関節痛)		
Male	0	1 (1.5%)
Female	0	1 (2.4%)
Back pain (背部痛)		
Male	1 (1.4%)	0
Female	1 (2.6%)	0
Myofascitis (筋筋膜炎)		
Male	0	0
Female	0	1 (2.4%)
Neck pain (頚部痛)		
Male	0	1 (1.5%)
Female	0	0
Osteoarthritis (変形性関節症)		
Male	0	0
Female	0	1 (2.4%)
Pain in extremity (四肢痛)		
Male	0	1 (1.5%)
Female	0	0
Spinal osteoarthritis (変形性脊椎症)		
Male	0	0
Female	0	1 (2.4%)
Synovial cyst (滑液嚢腫)		
Male	0	1 (1.5%)
Female	0	0

System Organ Class Preferred Term Sex	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
Respiratory, thoracic and mediastinal disorders (呼吸器、胸郭および縦隔障害)		
Male	2 (2.9%)	1 (1.5%)
Female	6 (15.8%)	1 (2.4%)
Asthma (喘息)		
Male	0	0
Female	2 (5.3%)	1 (2.4%)
Upper respiratory tract inflammation (上気道の炎症)		
Male	1 (1.4%)	0
Female	1 (2.6%)	0
Allergic cough (アレルギー性咳嗽)		
Male	0	0
Female	1 (2.6%)	0
Cough (咳嗽)		
Male	0	0
Female	1 (2.6%)	0
Epistaxis (鼻出血)		
Male	0	0
Female	1 (2.6%)	0
Pulmonary embolism (肺塞栓症)		
Male	0	1 (1.5%)
Female	0	0
Sleep apnoea syndrome (睡眠時無呼吸症候群)		
Male	1 (1.4%)	0
Female	0	0
Nervous system disorders (神経系障害)		
Male	4 (5.8%)	0
Female	2 (5.3%)	1 (2.4%)
Dizziness (浮動性めまい)		
Male	2 (2.9%)	0
Female	1 (2.6%)	1 (2.4%)
Diabetic neuropathy (糖尿病性ニューロパチー)		
Male	0	0
Female	1 (2.6%)	0
Guillain-Barre syndrome (ギラン・バレー症候群)		
Male	1 (1.4%)	0
Female	0	0
Sciatica (坐骨神経痛)		
Male	1 (1.4%)	0
Female	0	0
Skin and subcutaneous tissue disorders (皮膚および皮下組織障害)		

System Organ Class Preferred Term Sex	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
Male	2 (2.9%)	2 (3.0%)
Female	0	1 (2.4%)
Urticaria (蕁麻疹)		
Male	0	2 (3.0%)
Female	0	0
Papule (丘疹)		
Male	1 (1.4%)	0
Female	0	0
Pruritus (そう痒症)		
Male	0	0
Female	0	1 (2.4%)
Solar dermatitis (日光皮膚炎)		
Male	1 (1.4%)	0
Female	0	0
General disorders and administration site conditions (一般・全身障害および投与部位の状態)		
Male	3 (4.3%)	1 (1.5%)
Female	0	0
Pyrexia (発熱)		
Male	3 (4.3%)	1 (1.5%)
Female	0	0
Injury, poisoning and procedural complications (傷害、中毒および処置合併症)		
Male	1 (1.4%)	1 (1.5%)
Female	1 (2.6%)	1 (2.4%)
Contusion (挫傷)		
Male	1 (1.4%)	0
Female	1 (2.6%)	0
Heat illness (熱中症)		
Male	0	0
Female	0	1 (2.4%)
Muscle strain (肉離れ)		
Male	0	1 (1.5%)
Female	0	0
Vascular disorders (血管障害)		
Male	0	2 (3.0%)
Female	0	1 (2.4%)
Hypertension (高血圧)		
Male	0	0
Female	0	1 (2.4%)
Peripheral arterial occlusive disease (末梢動脈閉塞性疾患)		

System Organ Class Preferred Term Sex	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
Male	0	1 (1.5%)
Female	0	0
Venous thrombosis limb (四肢静脈血栓症)		
Male	0	1 (1.5%)
Female	0	0
Eye disorders (眼障害)		
Male	0	1 (1.5%)
Female	0	1 (2.4%)
Angle closure glaucoma (閉塞隅角緑内障)		
Male	0	0
Female	0	1 (2.4%)
Vitreous haemorrhage (硝子体出血)		
Male	0	1 (1.5%)
Female	0	0
Cardiac disorders (心臓障害)		
Male	0	0
Female	1 (2.6%)	0
Bundle branch block right (右脚ブロック)		
Male	0	0
Female	1 (2.6%)	0
Ear and labyrinth disorders (耳および迷路障害)		
Male	0	0
Female	1 (2.6%)	0
Vertigo positional (頭位性回転性めまい)		
Male	0	0
Female	1 (2.6%)	0
Hepatobiliary disorders (肝胆道系障害)		
Male	0	0
Female	0	1 (2.4%)
Gallbladder polyp (胆嚢ポリープ)		
Male	0	0
Female	0	1 (2.4%)
Investigations (臨床検査)		
Male	0	1 (1.5%)
Female	0	0
Blood creatine phosphokinase increased (血中クレアチンホスホキナーゼ増加)		
Male	0	1 (1.5%)
Female	0	0

System Organ Class Preferred Term Sex	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）)		
Male	0	1 (1.5%)
Female	0	0
Lipoma (脂肪腫)		
Male	0	1 (1.5%)
Female	0	0
Renal and urinary disorders (腎および尿路障害)		
Male	0	1 (1.5%)
Female	0	0
Haematuria (血尿)		
Male	0	1 (1.5%)
Female	0	0
Reproductive system and breast disorders (生殖系および乳房障害)		
Male	0	0
Female	1 (2.6%)	0
Amenorrhoea (無月経)		
Male	0	0
Female	1 (2.6%)	0

- Abbreviations: bid, Twice a day; AE, Adverse event; TEAE, Treatment Emergent AE
- All adverse events were coded using MedDRA dictionary version 20.1.
- Percentages are based on "Number of patients".

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Table S-172 Subgroup Analysis of Treatment Emergent Adverse Events by Renal Function, System Organ Class and Preferred Term in 16-Week Double-blind Period in Combination with Insulin Therapy (PXL008-020; Safety Population)

System Organ Class Preferred Term Renal function	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
Number of patients		
CKD Stage 1	14	16
CKD Stage 2	93	92
Any TEAE		
CKD Stage 1	7 (50.0%)	9 (56.3%)
CKD Stage 2	44 (47.3%)	48 (52.2%)
Metabolism and nutrition disorders (代謝および栄養障害)		
CKD Stage 1	1 (7.1%)	4 (25.0%)
CKD Stage 2	19 (20.4%)	19 (20.7%)
Hypoglycaemia (低血糖)		
CKD Stage 1	1 (7.1%)	4 (25.0%)
CKD Stage 2	16 (17.2%)	19 (20.7%)
Hyperglycaemia (高血糖)		
CKD Stage 1	0	0
CKD Stage 2	3 (3.2%)	0
Infections and infestations (感染症および寄生虫症)		
CKD Stage 1	3 (21.4%)	4 (25.0%)
CKD Stage 2	12 (12.9%)	20 (21.7%)
Nasopharyngitis (上咽頭炎)		
CKD Stage 1	2 (14.3%)	1 (6.3%)
CKD Stage 2	6 (6.5%)	15 (16.3%)
Bronchitis (気管支炎)		
CKD Stage 1	0	1 (6.3%)
CKD Stage 2	0	2 (2.2%)
Folliculitis (毛包炎)		
CKD Stage 1	0	0
CKD Stage 2	0	2 (2.2%)
Herpes zoster (帯状疱疹)		
CKD Stage 1	0	0
CKD Stage 2	0	2 (2.2%)
Tinea pedis (足部白癬)		
CKD Stage 1	0	1 (6.3%)
CKD Stage 2	1 (1.1%)	0
Asymptomatic bacteriuria (無症候性細菌尿)		
CKD Stage 1	0	0
CKD Stage 2	0	1 (1.1%)
Gastroenteritis (胃腸炎)		
CKD Stage 1	1 (7.1%)	0
CKD Stage 2	0	0
Gingivitis (歯肉炎)		

System Organ Class Preferred Term Renal function	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
CKD Stage 1	0	0
CKD Stage 2	1 (1.1%)	0
Oral herpes (口腔ヘルペス)		
CKD Stage 1	0	0
CKD Stage 2	1 (1.1%)	0
Otitis externa (外耳炎)		
CKD Stage 1	0	0
CKD Stage 2	1 (1.1%)	0
Periodontitis (歯周炎)		
CKD Stage 1	0	1 (6.3%)
CKD Stage 2	0	0
Pneumonia (肺炎)		
CKD Stage 1	0	0
CKD Stage 2	1 (1.1%)	0
Pulpitis dental (歯髄炎)		
CKD Stage 1	0	0
CKD Stage 2	1 (1.1%)	0
Gastrointestinal disorders (胃腸障害)		
CKD Stage 1	1 (7.1%)	4 (25.0%)
CKD Stage 2	6 (6.5%)	6 (6.5%)
Constipation (便秘)		
CKD Stage 1	0	1 (6.3%)
CKD Stage 2	1 (1.1%)	2 (2.2%)
Diarrhoea (下痢)		
CKD Stage 1	0	1 (6.3%)
CKD Stage 2	2 (2.2%)	1 (1.1%)
Nausea (悪心)		
CKD Stage 1	1 (7.1%)	2 (12.5%)
CKD Stage 2	1 (1.1%)	0
Abdominal discomfort (腹部不快感)		
CKD Stage 1	0	0
CKD Stage 2	1 (1.1%)	1 (1.1%)
Gastrooesophageal reflux disease (胃食道逆流性疾患)		
CKD Stage 1	0	1 (6.3%)
CKD Stage 2	1 (1.1%)	0
Vomiting (嘔吐)		
CKD Stage 1	0	1 (6.3%)
CKD Stage 2	1 (1.1%)	0
Abdominal distension (腹部膨満)		
CKD Stage 1	0	0
CKD Stage 2	0	1 (1.1%)
Colitis ulcerative (潰瘍性大腸炎)		
CKD Stage 1	0	0

System Organ Class Preferred Term Renal function	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
CKD Stage 2	0	1 (1.1%)
Dental caries (齲歯)		
CKD Stage 1	0	1 (6.3%)
CKD Stage 2	0	0
Periodontal disease (歯周病)		
CKD Stage 1	0	0
CKD Stage 2	0	1 (1.1%)
Toothache (歯痛)		
CKD Stage 1	0	0
CKD Stage 2	0	1 (1.1%)
Musculoskeletal and connective tissue disorders (筋骨格系および結合組織障害)		
CKD Stage 1	0	1 (6.3%)
CKD Stage 2	4 (4.3%)	8 (8.7%)
Muscle spasms (筋痙縮)		
CKD Stage 1	0	0
CKD Stage 2	2 (2.2%)	2 (2.2%)
Arthralgia (関節痛)		
CKD Stage 1	0	1 (6.3%)
CKD Stage 2	0	1 (1.1%)
Back pain (背部痛)		
CKD Stage 1	0	0
CKD Stage 2	2 (2.2%)	0
Myofascitis (筋筋膜炎)		
CKD Stage 1	0	0
CKD Stage 2	0	1 (1.1%)
Neck pain (頚部痛)		
CKD Stage 1	0	0
CKD Stage 2	0	1 (1.1%)
Osteoarthritis (変形性関節症)		
CKD Stage 1	0	0
CKD Stage 2	0	1 (1.1%)
Pain in extremity (四肢痛)		
CKD Stage 1	0	0
CKD Stage 2	0	1 (1.1%)
Spinal osteoarthritis (変形性脊椎症)		
CKD Stage 1	0	0
CKD Stage 2	0	1 (1.1%)
Synovial cyst (滑液嚢腫)		
CKD Stage 1	0	0
CKD Stage 2	0	1 (1.1%)

System Organ Class Preferred Term Renal function	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
Respiratory, thoracic and mediastinal disorders (呼吸器、胸郭および縦隔障害)		
CKD Stage 1	1 (7.1%)	0
CKD Stage 2	7 (7.5%)	2 (2.2%)
Asthma (喘息)		
CKD Stage 1	0	0
CKD Stage 2	2 (2.2%)	1 (1.1%)
Upper respiratory tract inflammation (上気道の炎症)		
CKD Stage 1	0	0
CKD Stage 2	2 (2.2%)	0
Allergic cough (アレルギー性咳嗽)		
CKD Stage 1	0	0
CKD Stage 2	1 (1.1%)	0
Cough (咳嗽)		
CKD Stage 1	0	0
CKD Stage 2	1 (1.1%)	0
Epistaxis (鼻出血)		
CKD Stage 1	0	0
CKD Stage 2	1 (1.1%)	0
Pulmonary embolism (肺塞栓症)		
CKD Stage 1	0	0
CKD Stage 2	0	1 (1.1%)
Sleep apnoea syndrome (睡眠時無呼吸症候群)		
CKD Stage 1	1 (7.1%)	0
CKD Stage 2	0	0
Nervous system disorders (神経系障害)		
CKD Stage 1	1 (7.1%)	0
CKD Stage 2	5 (5.4%)	1 (1.1%)
Dizziness (浮動性めまい)		
CKD Stage 1	0	0
CKD Stage 2	3 (3.2%)	1 (1.1%)
Diabetic neuropathy (糖尿病性ニューロパチー)		
CKD Stage 1	0	0
CKD Stage 2	1 (1.1%)	0
Guillain-Barre syndrome (ギラン・バレー症候群)		
CKD Stage 1	0	0
CKD Stage 2	1 (1.1%)	0
Sciatica (坐骨神経痛)		
CKD Stage 1	1 (7.1%)	0
CKD Stage 2	0	0
Skin and subcutaneous tissue disorders (皮膚および皮下組織障害)		

System Organ Class Preferred Term Renal function	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
CKD Stage 1	0	0
CKD Stage 2	2 (2.2%)	3 (3.3%)
Urticaria (蕁麻疹)		
CKD Stage 1	0	0
CKD Stage 2	0	2 (2.2%)
Papule (丘疹)		
CKD Stage 1	0	0
CKD Stage 2	1 (1.1%)	0
Pruritus (そう痒症)		
CKD Stage 1	0	0
CKD Stage 2	0	1 (1.1%)
Solar dermatitis (日光皮膚炎)		
CKD Stage 1	0	0
CKD Stage 2	1 (1.1%)	0
General disorders and administration site conditions (一般・全身障害および投与部位の状態)		
CKD Stage 1	1 (7.1%)	0
CKD Stage 2	2 (2.2%)	1 (1.1%)
Pyrexia (発熱)		
CKD Stage 1	1 (7.1%)	0
CKD Stage 2	2 (2.2%)	1 (1.1%)
Injury, poisoning and procedural complications (傷害、中毒および処置合併症)		
CKD Stage 1	1 (7.1%)	0
CKD Stage 2	1 (1.1%)	2 (2.2%)
Contusion (挫傷)		
CKD Stage 1	1 (7.1%)	0
CKD Stage 2	1 (1.1%)	0
Heat illness (熱中症)		
CKD Stage 1	0	0
CKD Stage 2	0	1 (1.1%)
Muscle strain (肉離れ)		
CKD Stage 1	0	0
CKD Stage 2	0	1 (1.1%)
Vascular disorders (血管障害)		
CKD Stage 1	0	1 (6.3%)
CKD Stage 2	0	2 (2.2%)
Hypertension (高血圧)		
CKD Stage 1	0	1 (6.3%)
CKD Stage 2	0	0
Peripheral arterial occlusive disease (末梢動脈閉塞性疾患)		

System Organ Class Preferred Term Renal function	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
CKD Stage 1	0	0
CKD Stage 2	0	1 (1.1%)
Venous thrombosis limb (四肢静脈血栓症)		
CKD Stage 1	0	0
CKD Stage 2	0	1 (1.1%)
Eye disorders (眼障害)		
CKD Stage 1	0	1 (6.3%)
CKD Stage 2	0	1 (1.1%)
Angle closure glaucoma (閉塞隅角緑内障)		
CKD Stage 1	0	1 (6.3%)
CKD Stage 2	0	0
Vitreous haemorrhage (硝子体出血)		
CKD Stage 1	0	0
CKD Stage 2	0	1 (1.1%)
Cardiac disorders (心臓障害)		
CKD Stage 1	0	0
CKD Stage 2	1 (1.1%)	0
Bundle branch block right (右脚ブロック)		
CKD Stage 1	0	0
CKD Stage 2	1 (1.1%)	0
Ear and labyrinth disorders (耳および迷路障害)		
CKD Stage 1	0	0
CKD Stage 2	1 (1.1%)	0
Vertigo positional (頭位性回転性めまい)		
CKD Stage 1	0	0
CKD Stage 2	1 (1.1%)	0
Hepatobiliary disorders (肝胆道系障害)		
CKD Stage 1	0	0
CKD Stage 2	0	1 (1.1%)
Gallbladder polyp (胆嚢ポリープ)		
CKD Stage 1	0	0
CKD Stage 2	0	1 (1.1%)
Investigations (臨床検査)		
CKD Stage 1	0	0
CKD Stage 2	0	1 (1.1%)
Blood creatine phosphokinase increased (血中クレアチンホスホキナーゼ増加)		
CKD Stage 1	0	0
CKD Stage 2	0	1 (1.1%)

System Organ Class Preferred Term Renal function	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）)		
CKD Stage 1	0	0
CKD Stage 2	0	1 (1.1%)
Lipoma (脂肪腫)		
CKD Stage 1	0	0
CKD Stage 2	0	1 (1.1%)
Renal and urinary disorders (腎および尿路障害)		
CKD Stage 1	0	0
CKD Stage 2	0	1 (1.1%)
Haematuria (血尿)		
CKD Stage 1	0	0
CKD Stage 2	0	1 (1.1%)
Reproductive system and breast disorders (生殖系および乳房障害)		
CKD Stage 1	1 (7.1%)	0
CKD Stage 2	0	0
Amenorrhoea (無月経)		
CKD Stage 1	1 (7.1%)	0
CKD Stage 2	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.
- All adverse events were coded using MedDRA dictionary version 20.1.
- Percentages are based on "Number of patients".

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Table S-173 Subgroup Analysis of Treatment Emergent Adverse Events by Hepatic Parameter Abnormality, System Organ Class and Preferred Term in 16-Week Double-blind Period in Combination with Insulin Therapy (PXL008-020; Safety Population)

System Organ Class Preferred Term Hepatic parameter abnormality	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
Number of patients		
Yes	15	17
No	92	91
Any TEAE		
Yes	7 (46.7%)	10 (58.8%)
No	44 (47.8%)	47 (51.6%)
Metabolism and nutrition disorders (代謝および栄養障害)		
Yes	1 (6.7%)	4 (23.5%)
No	19 (20.7%)	19 (20.9%)
Hypoglycaemia (低血糖)		
Yes	1 (6.7%)	4 (23.5%)
No	16 (17.4%)	19 (20.9%)
Hyperglycaemia (高血糖)		
Yes	0	0
No	3 (3.3%)	0
Infections and infestations (感染症および寄生虫症)		
Yes	1 (6.7%)	8 (47.1%)
No	14 (15.2%)	16 (17.6%)
Nasopharyngitis (上咽頭炎)		
Yes	0	6 (35.3%)
No	8 (8.7%)	10 (11.0%)
Bronchitis (気管支炎)		
Yes	0	1 (5.9%)
No	0	2 (2.2%)
Folliculitis (毛包炎)		
Yes	0	1 (5.9%)
No	0	1 (1.1%)
Herpes zoster (帯状疱疹)		
Yes	0	0
No	0	2 (2.2%)
Tinea pedis (足部白癬)		
Yes	0	0
No	1 (1.1%)	1 (1.1%)
Asymptomatic bacteriuria (無症候性細菌尿)		
Yes	0	0
No	0	1 (1.1%)
Gastroenteritis (胃腸炎)		
Yes	0	0
No	1 (1.1%)	0
Gingivitis (歯肉炎)		

System Organ Class Preferred Term Hepatic parameter abnormality	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
Yes	0	0
No	1 (1.1%)	0
Oral herpes (口腔ヘルペス)		
Yes	0	0
No	1 (1.1%)	0
Otitis externa (外耳炎)		
Yes	1 (6.7%)	0
No	0	0
Periodontitis (歯周炎)		
Yes	0	0
No	0	1 (1.1%)
Pneumonia (肺炎)		
Yes	0	0
No	1 (1.1%)	0
Pulpitis dental (歯髄炎)		
Yes	0	0
No	1 (1.1%)	0
Gastrointestinal disorders (胃腸障害)		
Yes	1 (6.7%)	1 (5.9%)
No	6 (6.5%)	9 (9.9%)
Constipation (便秘)		
Yes	0	0
No	1 (1.1%)	3 (3.3%)
Diarrhoea (下痢)		
Yes	1 (6.7%)	0
No	1 (1.1%)	2 (2.2%)
Nausea (悪心)		
Yes	0	1 (5.9%)
No	2 (2.2%)	1 (1.1%)
Abdominal discomfort (腹部不快感)		
Yes	0	0
No	1 (1.1%)	1 (1.1%)
Gastrooesophageal reflux disease (胃食道逆流性疾患)		
Yes	0	0
No	1 (1.1%)	1 (1.1%)
Vomiting (嘔吐)		
Yes	0	0
No	1 (1.1%)	1 (1.1%)
Abdominal distension (腹部膨満)		
Yes	0	0
No	0	1 (1.1%)
Colitis ulcerative (潰瘍性大腸炎)		
Yes	0	0

System Organ Class Preferred Term Hepatic parameter abnormality	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
No	0	1 (1.1%)
Dental caries (齲歯)		
Yes	0	0
No	0	1 (1.1%)
Periodontal disease (歯周病)		
Yes	0	0
No	0	1 (1.1%)
Toothache (歯痛)		
Yes	0	0
No	0	1 (1.1%)
Musculoskeletal and connective tissue disorders (筋骨格系および結合組織障害)		
Yes	1 (6.7%)	3 (17.6%)
No	3 (3.3%)	6 (6.6%)
Muscle spasms (筋痙縮)		
Yes	1 (6.7%)	0
No	1 (1.1%)	2 (2.2%)
Arthralgia (関節痛)		
Yes	0	0
No	0	2 (2.2%)
Back pain (背部痛)		
Yes	0	0
No	2 (2.2%)	0
Myofascitis (筋筋膜炎)		
Yes	0	0
No	0	1 (1.1%)
Neck pain (頚部痛)		
Yes	0	1 (5.9%)
No	0	0
Osteoarthritis (変形性関節症)		
Yes	0	1 (5.9%)
No	0	0
Pain in extremity (四肢痛)		
Yes	0	0
No	0	1 (1.1%)
Spinal osteoarthritis (変形性脊椎症)		
Yes	0	0
No	0	1 (1.1%)
Synovial cyst (滑液嚢腫)		
Yes	0	1 (5.9%)
No	0	0

System Organ Class Preferred Term Hepatic parameter abnormality	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
Respiratory, thoracic and mediastinal disorders (呼吸器、胸郭および縦隔障害)		
Yes	1 (6.7%)	0
No	7 (7.6%)	2 (2.2%)
Asthma (喘息)		
Yes	1 (6.7%)	0
No	1 (1.1%)	1 (1.1%)
Upper respiratory tract inflammation (上気道の炎症)		
Yes	0	0
No	2 (2.2%)	0
Allergic cough (アレルギー性咳嗽)		
Yes	0	0
No	1 (1.1%)	0
Cough (咳嗽)		
Yes	0	0
No	1 (1.1%)	0
Epistaxis (鼻出血)		
Yes	0	0
No	1 (1.1%)	0
Pulmonary embolism (肺塞栓症)		
Yes	0	0
No	0	1 (1.1%)
Sleep apnoea syndrome (睡眠時無呼吸症候群)		
Yes	0	0
No	1 (1.1%)	0
Nervous system disorders (神経系障害)		
Yes	1 (6.7%)	0
No	5 (5.4%)	1 (1.1%)
Dizziness (浮動性めまい)		
Yes	0	0
No	3 (3.3%)	1 (1.1%)
Diabetic neuropathy (糖尿病性ニューロパチー)		
Yes	0	0
No	1 (1.1%)	0
Guillain-Barre syndrome (ギラン・バレー症候群)		
Yes	1 (6.7%)	0
No	0	0
Sciatica (坐骨神経痛)		
Yes	0	0
No	1 (1.1%)	0
Skin and subcutaneous tissue disorders (皮膚および皮下組織障害)		

System Organ Class Preferred Term Hepatic parameter abnormality	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
Yes	0	0
No	2 (2.2%)	3 (3.3%)
Urticaria (蕁麻疹)		
Yes	0	0
No	0	2 (2.2%)
Papule (丘疹)		
Yes	0	0
No	1 (1.1%)	0
Pruritus (そう痒症)		
Yes	0	0
No	0	1 (1.1%)
Solar dermatitis (日光皮膚炎)		
Yes	0	0
No	1 (1.1%)	0
General disorders and administration site conditions (一般・全身障害および投与部位の状態)		
Yes	1 (6.7%)	0
No	2 (2.2%)	1 (1.1%)
Pyrexia (発熱)		
Yes	1 (6.7%)	0
No	2 (2.2%)	1 (1.1%)
Injury, poisoning and procedural complications (傷害、中毒および処置合併症)		
Yes	1 (6.7%)	0
No	1 (1.1%)	2 (2.2%)
Contusion (挫傷)		
Yes	1 (6.7%)	0
No	1 (1.1%)	0
Heat illness (熱中症)		
Yes	0	0
No	0	1 (1.1%)
Muscle strain (肉離れ)		
Yes	0	0
No	0	1 (1.1%)
Vascular disorders (血管障害)		
Yes	0	0
No	0	3 (3.3%)
Hypertension (高血圧)		
Yes	0	0
No	0	1 (1.1%)
Peripheral arterial occlusive disease (末梢動脈閉塞性疾患)		

System Organ Class Preferred Term Hepatic parameter abnormality	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
Yes	0	0
No	0	1 (1.1%)
Venous thrombosis limb (四肢静脈血栓症)		
Yes	0	0
No	0	1 (1.1%)
Eye disorders (眼障害)		
Yes	0	0
No	0	2 (2.2%)
Angle closure glaucoma (閉塞隅角緑内障)		
Yes	0	0
No	0	1 (1.1%)
Vitreous haemorrhage (硝子体出血)		
Yes	0	0
No	0	1 (1.1%)
Cardiac disorders (心臓障害)		
Yes	0	0
No	1 (1.1%)	0
Bundle branch block right (右脚ブロック)		
Yes	0	0
No	1 (1.1%)	0
Ear and labyrinth disorders (耳および迷路障害)		
Yes	0	0
No	1 (1.1%)	0
Vertigo positional (頭位性回転性めまい)		
Yes	0	0
No	1 (1.1%)	0
Hepatobiliary disorders (肝胆道系障害)		
Yes	0	0
No	0	1 (1.1%)
Gallbladder polyp (胆嚢ポリープ)		
Yes	0	0
No	0	1 (1.1%)
Investigations (臨床検査)		
Yes	0	0
No	0	1 (1.1%)
Blood creatine phosphokinase increased (血中クレアチンホスホキナーゼ増加)		
Yes	0	0
No	0	1 (1.1%)

System Organ Class Preferred Term Hepatic parameter abnormality	Placebo + Insulin N = 107	Imeglimin 1000 mg bid + Insulin N = 108
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）)		
Yes	0	1 (5.9%)
No	0	0
Lipoma (脂肪腫)		
Yes	0	1 (5.9%)
No	0	0
Renal and urinary disorders (腎および尿路障害)		
Yes	0	0
No	0	1 (1.1%)
Haematuria (血尿)		
Yes	0	0
No	0	1 (1.1%)
Reproductive system and breast disorders (生殖系および乳房障害)		
Yes	0	0
No	1 (1.1%)	0
Amenorrhoea (無月経)		
Yes	0	0
No	1 (1.1%)	0

- Abbreviations: bid, Twice a day; AE, Adverse event; TEAE, Treatment Emergent AE
- Hepatic parameter abnormality is defined as any one of following parameter applied: Total Bilirubin >= 1.6 mg/dL; Aspartate aminotransferase (AST) >= 1.25 x Upper Limit of Normal (ULN); AST >= 50 IU; Alanine aminotransferase (ALT) >= 1.25 x ULN; ALT >= 50 IU; Alkaline phosphatase >= 1.25 x ULN; Gamma glutamyl transferase >= 1.5 x ULN.
- All adverse events were coded using MedDRA dictionary version 20.1.
- Percentages are based on "Number of patients".

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Table S-174 Subgroup Analysis of Treatment Emergent Adverse Events by Age, System Organ Class and Preferred Term in 52-Week Long-term Period in Combination with Insulin Therapy (PXL008-020; Long-term Safety Population)

System Organ Class Preferred Term Age	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
Number of patients			
< 65 years	72	68	140
>= 65 years	29	40	69
< 75 years	98	101	199
>= 75 years	3	7	10
Any TEAE			
< 65 years	54 (75.0%)	57 (83.8%)	111 (79.3%)
>= 65 years	23 (79.3%)	35 (87.5%)	58 (84.1%)
< 75 years	75 (76.5%)	85 (84.2%)	160 (80.4%)
>= 75 years	2 (66.7%)	7 (100.0%)	9 (90.0%)
Infections and infestations (感染症および寄生虫症)			
< 65 years	22 (30.6%)	31 (45.6%)	53 (37.9%)
>= 65 years	8 (27.6%)	21 (52.5%)	29 (42.0%)
< 75 years	29 (29.6%)	48 (47.5%)	77 (38.7%)
>= 75 years	1 (33.3%)	4 (57.1%)	5 (50.0%)
Nasopharyngitis (上咽頭炎)			
< 65 years	13 (18.1%)	21 (30.9%)	34 (24.3%)
>= 65 years	3 (10.3%)	15 (37.5%)	18 (26.1%)
< 75 years	16 (16.3%)	35 (34.7%)	51 (25.6%)
>= 75 years	0	1 (14.3%)	1 (10.0%)
Bronchitis (気管支炎)			
< 65 years	2 (2.8%)	3 (4.4%)	5 (3.6%)
>= 65 years	3 (10.3%)	1 (2.5%)	4 (5.8%)
< 75 years	4 (4.1%)	4 (4.0%)	8 (4.0%)
>= 75 years	1 (33.3%)	0	1 (10.0%)
Influenza (インフルエンザ)			
< 65 years	3 (4.2%)	3 (4.4%)	6 (4.3%)
>= 65 years	1 (3.4%)	2 (5.0%)	3 (4.3%)
< 75 years	4 (4.1%)	4 (4.0%)	8 (4.0%)
>= 75 years	0	1 (14.3%)	1 (10.0%)
Gastroenteritis (胃腸炎)			
< 65 years	2 (2.8%)	0	2 (1.4%)
>= 65 years	2 (6.9%)	1 (2.5%)	3 (4.3%)
< 75 years	4 (4.1%)	1 (1.0%)	5 (2.5%)
>= 75 years	0	0	0
Cystitis (膀胱炎)			
< 65 years	1 (1.4%)	2 (2.9%)	3 (2.1%)
>= 65 years	0	1 (2.5%)	1 (1.4%)
< 75 years	1 (1.0%)	2 (2.0%)	3 (1.5%)
>= 75 years	0	1 (14.3%)	1 (10.0%)
Herpes zoster (帯状疱疹)			

System Organ Class Preferred Term Age	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
< 65 years	0	0	0
>= 65 years	1 (3.4%)	2 (5.0%)	3 (4.3%)
< 75 years	1 (1.0%)	2 (2.0%)	3 (1.5%)
>= 75 years	0	0	0
Periodontitis (歯周炎)			
< 65 years	1 (1.4%)	1 (1.5%)	2 (1.4%)
>= 65 years	0	1 (2.5%)	1 (1.4%)
< 75 years	1 (1.0%)	2 (2.0%)	3 (1.5%)
>= 75 years	0	0	0
Conjunctivitis (結膜炎)			
< 65 years	2 (2.8%)	0	2 (1.4%)
>= 65 years	0	0	0
< 75 years	2 (2.0%)	0	2 (1.0%)
>= 75 years	0	0	0
Folliculitis (毛包炎)			
< 65 years	0	1 (1.5%)	1 (0.7%)
>= 65 years	0	1 (2.5%)	1 (1.4%)
< 75 years	0	1 (1.0%)	1 (0.5%)
>= 75 years	0	1 (14.3%)	1 (10.0%)
Hordeolum (麦粒腫)			
< 65 years	1 (1.4%)	1 (1.5%)	2 (1.4%)
>= 65 years	0	0	0
< 75 years	1 (1.0%)	1 (1.0%)	2 (1.0%)
>= 75 years	0	0	0
Pharyngitis (咽頭炎)			
< 65 years	1 (1.4%)	1 (1.5%)	2 (1.4%)
>= 65 years	0	0	0
< 75 years	1 (1.0%)	1 (1.0%)	2 (1.0%)
>= 75 years	0	0	0
Urinary tract infection (尿路感染)			
< 65 years	0	2 (2.9%)	2 (1.4%)
>= 65 years	0	0	0
< 75 years	0	2 (2.0%)	2 (1.0%)
>= 75 years	0	0	0
Asymptomatic bacteriuria (無症候性細菌尿)			
< 65 years	0	0	0
>= 65 years	0	1 (2.5%)	1 (1.4%)
< 75 years	0	0	0
>= 75 years	0	1 (14.3%)	1 (10.0%)
Erysipelas (丹毒)			
< 65 years	0	1 (1.5%)	1 (0.7%)
>= 65 years	0	0	0
< 75 years	0	1 (1.0%)	1 (0.5%)
>= 75 years	0	0	0
Furuncle (せつ)			

System Organ Class Preferred Term Age	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
< 65 years	0	1 (1.5%)	1 (0.7%)
>= 65 years	0	0	0
< 75 years	0	1 (1.0%)	1 (0.5%)
>= 75 years	0	0	0
Gastroenteritis viral (ウイルス性胃腸炎)			
< 65 years	0	0	0
>= 65 years	1 (3.4%)	0	1 (1.4%)
< 75 years	1 (1.0%)	0	1 (0.5%)
>= 75 years	0	0	0
Gingivitis (歯肉炎)			
< 65 years	0	1 (1.5%)	1 (0.7%)
>= 65 years	0	0	0
< 75 years	0	1 (1.0%)	1 (0.5%)
>= 75 years	0	0	0
Helicobacter infection (ヘリコバクター感染)			
< 65 years	1 (1.4%)	0	1 (0.7%)
>= 65 years	0	0	0
< 75 years	1 (1.0%)	0	1 (0.5%)
>= 75 years	0	0	0
Herpes simplex (単純ヘルペス)			
< 65 years	0	0	0
>= 65 years	1 (3.4%)	0	1 (1.4%)
< 75 years	1 (1.0%)	0	1 (0.5%)
>= 75 years	0	0	0
Oral herpes (口腔ヘルペス)			
< 65 years	1 (1.4%)	0	1 (0.7%)
>= 65 years	0	0	0
< 75 years	1 (1.0%)	0	1 (0.5%)
>= 75 years	0	0	0
Otitis media acute (急性中耳炎)			
< 65 years	1 (1.4%)	0	1 (0.7%)
>= 65 years	0	0	0
< 75 years	1 (1.0%)	0	1 (0.5%)
>= 75 years	0	0	0
Pneumonia mycoplasmal (マイコプラズマ性肺炎)			
< 65 years	1 (1.4%)	0	1 (0.7%)
>= 65 years	0	0	0
< 75 years	1 (1.0%)	0	1 (0.5%)
>= 75 years	0	0	0
Rhinitis (鼻炎)			
< 65 years	0	0	0
>= 65 years	0	1 (2.5%)	1 (1.4%)
< 75 years	0	1 (1.0%)	1 (0.5%)

System Organ Class Preferred Term Age	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
>= 75 years	0	0	0
Sinusitis (副鼻腔炎)			
< 65 years	0	0	0
>= 65 years	0	1 (2.5%)	1 (1.4%)
< 75 years	0	1 (1.0%)	1 (0.5%)
>= 75 years	0	0	0
Soft tissue infection (軟部組織感染)			
< 65 years	0	1 (1.5%)	1 (0.7%)
>= 65 years	0	0	0
< 75 years	0	1 (1.0%)	1 (0.5%)
>= 75 years	0	0	0
Tinea pedis (足部白癬)			
< 65 years	0	1 (1.5%)	1 (0.7%)
>= 65 years	0	0	0
< 75 years	0	1 (1.0%)	1 (0.5%)
>= 75 years	0	0	0
Tonsillitis (扁桃炎)			
< 65 years	0	1 (1.5%)	1 (0.7%)
>= 65 years	0	0	0
< 75 years	0	1 (1.0%)	1 (0.5%)
>= 75 years	0	0	0
Upper respiratory tract infection (上気道感染)			
< 65 years	1 (1.4%)	0	1 (0.7%)
>= 65 years	0	0	0
< 75 years	1 (1.0%)	0	1 (0.5%)
>= 75 years	0	0	0
Metabolism and nutrition disorders (代謝および栄養障害)			
< 65 years	23 (31.9%)	25 (36.8%)	48 (34.3%)
>= 65 years	14 (48.3%)	17 (42.5%)	31 (44.9%)
< 75 years	35 (35.7%)	37 (36.6%)	72 (36.2%)
>= 75 years	2 (66.7%)	5 (71.4%)	7 (70.0%)
Hypoglycaemia (低血糖)			
< 65 years	23 (31.9%)	23 (33.8%)	46 (32.9%)
>= 65 years	13 (44.8%)	16 (40.0%)	29 (42.0%)
< 75 years	35 (35.7%)	34 (33.7%)	69 (34.7%)
>= 75 years	1 (33.3%)	5 (71.4%)	6 (60.0%)
Dyslipidaemia (脂質異常症)			
< 65 years	1 (1.4%)	1 (1.5%)	2 (1.4%)
>= 65 years	0	0	0
< 75 years	1 (1.0%)	1 (1.0%)	2 (1.0%)
>= 75 years	0	0	0
Hyperglycaemia (高血糖)			
< 65 years	0	1 (1.5%)	1 (0.7%)

System Organ Class Preferred Term Age	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
>= 65 years	0	1 (2.5%)	1 (1.4%)
< 75 years	0	2 (2.0%)	2 (1.0%)
>= 75 years	0	0	0
Hyponatraemia (低ナトリウム血症)			
< 65 years	0	0	0
>= 65 years	1 (3.4%)	0	1 (1.4%)
< 75 years	0	0	0
>= 75 years	1 (33.3%)	0	1 (10.0%)
Musculoskeletal and connective tissue disorders (筋骨格系および結合組織障害)			
< 65 years	8 (11.1%)	14 (20.6%)	22 (15.7%)
>= 65 years	1 (3.4%)	10 (25.0%)	11 (15.9%)
< 75 years	9 (9.2%)	21 (20.8%)	30 (15.1%)
>= 75 years	0	3 (42.9%)	3 (30.0%)
Back pain (背部痛)			
< 65 years	1 (1.4%)	3 (4.4%)	4 (2.9%)
>= 65 years	0	3 (7.5%)	3 (4.3%)
< 75 years	1 (1.0%)	5 (5.0%)	6 (3.0%)
>= 75 years	0	1 (14.3%)	1 (10.0%)
Muscle spasms (筋痙縮)			
< 65 years	1 (1.4%)	1 (1.5%)	2 (1.4%)
>= 65 years	0	3 (7.5%)	3 (4.3%)
< 75 years	1 (1.0%)	4 (4.0%)	5 (2.5%)
>= 75 years	0	0	0
Arthralgia (関節痛)			
< 65 years	1 (1.4%)	3 (4.4%)	4 (2.9%)
>= 65 years	0	0	0
< 75 years	1 (1.0%)	3 (3.0%)	4 (2.0%)
>= 75 years	0	0	0
Spinal osteoarthritis (変形性脊椎症)			
< 65 years	0	1 (1.5%)	1 (0.7%)
>= 65 years	0	3 (7.5%)	3 (4.3%)
< 75 years	0	2 (2.0%)	2 (1.0%)
>= 75 years	0	2 (28.6%)	2 (20.0%)
Musculoskeletal stiffness (筋骨格硬直)			
< 65 years	1 (1.4%)	1 (1.5%)	2 (1.4%)
>= 65 years	0	0	0
< 75 years	1 (1.0%)	1 (1.0%)	2 (1.0%)
>= 75 years	0	0	0
Osteoarthritis (変形性関節症)			
< 65 years	0	0	0
>= 65 years	0	2 (5.0%)	2 (2.9%)
< 75 years	0	2 (2.0%)	2 (1.0%)
>= 75 years	0	0	0

System Organ Class Preferred Term Age	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
Synovial cyst (滑液嚢腫)			
< 65 years	0	0	0
>= 65 years	0	2 (5.0%)	2 (2.9%)
< 75 years	0	2 (2.0%)	2 (1.0%)
>= 75 years	0	0	0
Tenosynovitis (腱鞘炎)			
< 65 years	1 (1.4%)	1 (1.5%)	2 (1.4%)
>= 65 years	0	0	0
< 75 years	1 (1.0%)	1 (1.0%)	2 (1.0%)
>= 75 years	0	0	0
Trigger finger (弾発指)			
< 65 years	1 (1.4%)	1 (1.5%)	2 (1.4%)
>= 65 years	0	0	0
< 75 years	1 (1.0%)	1 (1.0%)	2 (1.0%)
>= 75 years	0	0	0
Chondrocalcinosis pyrophosphate (ピロリン酸カルシウム結晶性軟骨石灰化症)			
< 65 years	0	0	0
>= 65 years	1 (3.4%)	0	1 (1.4%)
< 75 years	1 (1.0%)	0	1 (0.5%)
>= 75 years	0	0	0
Intervertebral disc protrusion (椎間板突出)			
< 65 years	0	1 (1.5%)	1 (0.7%)
>= 65 years	0	0	0
< 75 years	0	1 (1.0%)	1 (0.5%)
>= 75 years	0	0	0
Lumbar spinal stenosis (腰部脊柱管狭窄症)			
< 65 years	0	0	0
>= 65 years	0	1 (2.5%)	1 (1.4%)
< 75 years	0	1 (1.0%)	1 (0.5%)
>= 75 years	0	0	0
Musculoskeletal pain (筋骨格痛)			
< 65 years	1 (1.4%)	0	1 (0.7%)
>= 65 years	0	0	0
< 75 years	1 (1.0%)	0	1 (0.5%)
>= 75 years	0	0	0
Myofascitis (筋筋膜炎)			
< 65 years	0	0	0
>= 65 years	0	1 (2.5%)	1 (1.4%)
< 75 years	0	0	0
>= 75 years	0	1 (14.3%)	1 (10.0%)
Neck pain (頚部痛)			
< 65 years	0	1 (1.5%)	1 (0.7%)
>= 65 years	0	0	0

System Organ Class Preferred Term Age	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
< 75 years	0	1 (1.0%)	1 (0.5%)
>= 75 years	0	0	0
Nodal osteoarthritis (結節性変形性関節症)			
< 65 years	0	0	0
>= 65 years	0	1 (2.5%)	1 (1.4%)
< 75 years	0	1 (1.0%)	1 (0.5%)
>= 75 years	0	0	0
Pain in extremity (四肢痛)			
< 65 years	0	1 (1.5%)	1 (0.7%)
>= 65 years	0	0	0
< 75 years	0	1 (1.0%)	1 (0.5%)
>= 75 years	0	0	0
Synovitis (滑膜炎)			
< 65 years	0	1 (1.5%)	1 (0.7%)
>= 65 years	0	0	0
< 75 years	0	1 (1.0%)	1 (0.5%)
>= 75 years	0	0	0
Temporomandibular joint syndrome (顎関節症候群)			
< 65 years	0	1 (1.5%)	1 (0.7%)
>= 65 years	0	0	0
< 75 years	0	1 (1.0%)	1 (0.5%)
>= 75 years	0	0	0
Tendonitis (腱炎)			
< 65 years	1 (1.4%)	0	1 (0.7%)
>= 65 years	0	0	0
< 75 years	1 (1.0%)	0	1 (0.5%)
>= 75 years	0	0	0
Gastrointestinal disorders (胃腸障害)			
< 65 years	8 (11.1%)	10 (14.7%)	18 (12.9%)
>= 65 years	2 (6.9%)	10 (25.0%)	12 (17.4%)
< 75 years	10 (10.2%)	18 (17.8%)	28 (14.1%)
>= 75 years	0	2 (28.6%)	2 (20.0%)
Constipation (便秘)			
< 65 years	0	0	0
>= 65 years	0	6 (15.0%)	6 (8.7%)
< 75 years	0	4 (4.0%)	4 (2.0%)
>= 75 years	0	2 (28.6%)	2 (20.0%)
Gastrooesophageal reflux disease (胃食道逆流性疾患)			
< 65 years	2 (2.8%)	2 (2.9%)	4 (2.9%)
>= 65 years	0	1 (2.5%)	1 (1.4%)
< 75 years	2 (2.0%)	3 (3.0%)	5 (2.5%)
>= 75 years	0	0	0

System Organ Class Preferred Term Age	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
Nausea (悪心)			
< 65 years	1 (1.4%)	1 (1.5%)	2 (1.4%)
>= 65 years	1 (3.4%)	2 (5.0%)	3 (4.3%)
< 75 years	2 (2.0%)	3 (3.0%)	5 (2.5%)
>= 75 years	0	0	0
Abdominal discomfort (腹部不快感)			
< 65 years	0	2 (2.9%)	2 (1.4%)
>= 65 years	1 (3.4%)	1 (2.5%)	2 (2.9%)
< 75 years	1 (1.0%)	3 (3.0%)	4 (2.0%)
>= 75 years	0	0	0
Diarrhoea (下痢)			
< 65 years	2 (2.8%)	0	2 (1.4%)
>= 65 years	0	2 (5.0%)	2 (2.9%)
< 75 years	2 (2.0%)	2 (2.0%)	4 (2.0%)
>= 75 years	0	0	0
Toothache (歯痛)			
< 65 years	1 (1.4%)	0	1 (0.7%)
>= 65 years	1 (3.4%)	1 (2.5%)	2 (2.9%)
< 75 years	2 (2.0%)	1 (1.0%)	3 (1.5%)
>= 75 years	0	0	0
Abdominal pain upper (上腹部痛)			
< 65 years	0	2 (2.9%)	2 (1.4%)
>= 65 years	0	0	0
< 75 years	0	2 (2.0%)	2 (1.0%)
>= 75 years	0	0	0
Chronic gastritis (慢性胃炎)			
< 65 years	2 (2.8%)	0	2 (1.4%)
>= 65 years	0	0	0
< 75 years	2 (2.0%)	0	2 (1.0%)
>= 75 years	0	0	0
Dental caries (齲歯)			
< 65 years	1 (1.4%)	1 (1.5%)	2 (1.4%)
>= 65 years	0	0	0
< 75 years	1 (1.0%)	1 (1.0%)	2 (1.0%)
>= 75 years	0	0	0
Gastritis (胃炎)			
< 65 years	1 (1.4%)	0	1 (0.7%)
>= 65 years	0	1 (2.5%)	1 (1.4%)
< 75 years	1 (1.0%)	0	1 (0.5%)
>= 75 years	0	1 (14.3%)	1 (10.0%)
Periodontal disease (歯周病)			
< 65 years	0	2 (2.9%)	2 (1.4%)
>= 65 years	0	0	0
< 75 years	0	2 (2.0%)	2 (1.0%)
>= 75 years	0	0	0
Vomiting (嘔吐)			

System Organ Class Preferred Term Age	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
< 65 years	0	0	0
>= 65 years	1 (3.4%)	1 (2.5%)	2 (2.9%)
< 75 years	1 (1.0%)	1 (1.0%)	2 (1.0%)
>= 75 years	0	0	0
Abdominal distension (腹部膨満)			
< 65 years	0	1 (1.5%)	1 (0.7%)
>= 65 years	0	0	0
< 75 years	0	1 (1.0%)	1 (0.5%)
>= 75 years	0	0	0
Colitis ulcerative (潰瘍性大腸炎)			
< 65 years	0	0	0
>= 65 years	0	1 (2.5%)	1 (1.4%)
< 75 years	0	1 (1.0%)	1 (0.5%)
>= 75 years	0	0	0
Large intestine polyp (大腸ポリープ)			
< 65 years	1 (1.4%)	0	1 (0.7%)
>= 65 years	0	0	0
< 75 years	1 (1.0%)	0	1 (0.5%)
>= 75 years	0	0	0
Eye disorders (眼障害)			
< 65 years	4 (5.6%)	6 (8.8%)	10 (7.1%)
>= 65 years	2 (6.9%)	4 (10.0%)	6 (8.7%)
< 75 years	6 (6.1%)	9 (8.9%)	15 (7.5%)
>= 75 years	0	1 (14.3%)	1 (10.0%)
Cataract (白内障)			
< 65 years	1 (1.4%)	2 (2.9%)	3 (2.1%)
>= 65 years	0	0	0
< 75 years	1 (1.0%)	2 (2.0%)	3 (1.5%)
>= 75 years	0	0	0
Diabetic retinopathy (糖尿病網膜症)			
< 65 years	2 (2.8%)	1 (1.5%)	3 (2.1%)
>= 65 years	0	0	0
< 75 years	2 (2.0%)	1 (1.0%)	3 (1.5%)
>= 75 years	0	0	0
Ocular hypertension (高眼圧症)			
< 65 years	0	1 (1.5%)	1 (0.7%)
>= 65 years	0	1 (2.5%)	1 (1.4%)
< 75 years	0	2 (2.0%)	2 (1.0%)
>= 75 years	0	0	0
Vitreous haemorrhage (硝子体出血)			
< 65 years	0	1 (1.5%)	1 (0.7%)
>= 65 years	0	1 (2.5%)	1 (1.4%)
< 75 years	0	2 (2.0%)	2 (1.0%)
>= 75 years	0	0	0
Accommodation disorder (調節障害)			

System Organ Class Preferred Term Age	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
< 65 years	1 (1.4%)	0	1 (0.7%)
>= 65 years	0	0	0
< 75 years	1 (1.0%)	0	1 (0.5%)
>= 75 years	0	0	0
Angle closure glaucoma (閉塞隅角緑内障)			
< 65 years	0	1 (1.5%)	1 (0.7%)
>= 65 years	0	0	0
< 75 years	0	1 (1.0%)	1 (0.5%)
>= 75 years	0	0	0
Conjunctival hyperaemia (結膜充血)			
< 65 years	0	0	0
>= 65 years	1 (3.4%)	0	1 (1.4%)
< 75 years	1 (1.0%)	0	1 (0.5%)
>= 75 years	0	0	0
Conjunctivitis allergic (アレルギー性結膜炎)			
< 65 years	0	0	0
>= 65 years	0	1 (2.5%)	1 (1.4%)
< 75 years	0	1 (1.0%)	1 (0.5%)
>= 75 years	0	0	0
Diabetic retinal oedema (糖尿病性網膜浮腫)			
< 65 years	0	1 (1.5%)	1 (0.7%)
>= 65 years	0	0	0
< 75 years	0	1 (1.0%)	1 (0.5%)
>= 75 years	0	0	0
Dry eye (眼乾燥)			
< 65 years	0	1 (1.5%)	1 (0.7%)
>= 65 years	0	0	0
< 75 years	0	1 (1.0%)	1 (0.5%)
>= 75 years	0	0	0
Glaucoma (緑内障)			
< 65 years	0	0	0
>= 65 years	1 (3.4%)	0	1 (1.4%)
< 75 years	1 (1.0%)	0	1 (0.5%)
>= 75 years	0	0	0
Macular oedema (黄斑浮腫)			
< 65 years	1 (1.4%)	0	1 (0.7%)
>= 65 years	0	0	0
< 75 years	1 (1.0%)	0	1 (0.5%)
>= 75 years	0	0	0
Pingueculitis (瞼裂斑炎)			
< 65 years	1 (1.4%)	0	1 (0.7%)
>= 65 years	0	0	0
< 75 years	1 (1.0%)	0	1 (0.5%)

System Organ Class Preferred Term Age	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
>= 75 years	0	0	0
Retinal detachment (網膜剥離)			
< 65 years	0	1 (1.5%)	1 (0.7%)
>= 65 years	0	0	0
< 75 years	0	1 (1.0%)	1 (0.5%)
>= 75 years	0	0	0
Retinal haemorrhage (網膜出血)			
< 65 years	0	0	0
>= 65 years	0	1 (2.5%)	1 (1.4%)
< 75 years	0	0	0
>= 75 years	0	1 (14.3%)	1 (10.0%)
Trichiasis (睫毛乱生)			
< 65 years	0	0	0
>= 65 years	0	1 (2.5%)	1 (1.4%)
< 75 years	0	1 (1.0%)	1 (0.5%)
>= 75 years	0	0	0
Nervous system disorders (神経系障害)			
< 65 years	1 (1.4%)	5 (7.4%)	6 (4.3%)
>= 65 years	5 (17.2%)	3 (7.5%)	8 (11.6%)
< 75 years	6 (6.1%)	7 (6.9%)	13 (6.5%)
>= 75 years	0	1 (14.3%)	1 (10.0%)
Headache (頭痛)			
< 65 years	0	2 (2.9%)	2 (1.4%)
>= 65 years	3 (10.3%)	1 (2.5%)	4 (5.8%)
< 75 years	3 (3.1%)	3 (3.0%)	6 (3.0%)
>= 75 years	0	0	0
Dizziness (浮動性めまい)			
< 65 years	1 (1.4%)	0	1 (0.7%)
>= 65 years	0	1 (2.5%)	1 (1.4%)
< 75 years	1 (1.0%)	0	1 (0.5%)
>= 75 years	0	1 (14.3%)	1 (10.0%)
Autonomic nervous system imbalance (自律神経失調)			
< 65 years	1 (1.4%)	0	1 (0.7%)
>= 65 years	0	0	0
< 75 years	1 (1.0%)	0	1 (0.5%)
>= 75 years	0	0	0
Carpal tunnel syndrome (手根管症候群)			
< 65 years	0	0	0
>= 65 years	1 (3.4%)	0	1 (1.4%)
< 75 years	1 (1.0%)	0	1 (0.5%)
>= 75 years	0	0	0
Epilepsy (てんかん)			
< 65 years	0	1 (1.5%)	1 (0.7%)

System Organ Class Preferred Term Age	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
>= 65 years	0	0	0
< 75 years	0	1 (1.0%)	1 (0.5%)
>= 75 years	0	0	0
Facial paralysis (顔面麻痺)			
< 65 years	0	1 (1.5%)	1 (0.7%)
>= 65 years	0	0	0
< 75 years	0	1 (1.0%)	1 (0.5%)
>= 75 years	0	0	0
Sciatica (坐骨神経痛)			
< 65 years	0	1 (1.5%)	1 (0.7%)
>= 65 years	0	0	0
< 75 years	0	1 (1.0%)	1 (0.5%)
>= 75 years	0	0	0
Somnolence (傾眠)			
< 65 years	0	0	0
>= 65 years	0	1 (2.5%)	1 (1.4%)
< 75 years	0	1 (1.0%)	1 (0.5%)
>= 75 years	0	0	0
Syncope (失神)			
< 65 years	0	0	0
>= 65 years	1 (3.4%)	0	1 (1.4%)
< 75 years	1 (1.0%)	0	1 (0.5%)
>= 75 years	0	0	0
Skin and subcutaneous tissue disorders (皮膚および皮下組織障害)			
< 65 years	1 (1.4%)	6 (8.8%)	7 (5.0%)
>= 65 years	1 (3.4%)	5 (12.5%)	6 (8.7%)
< 75 years	2 (2.0%)	10 (9.9%)	12 (6.0%)
>= 75 years	0	1 (14.3%)	1 (10.0%)
Dermatitis (皮膚炎)			
< 65 years	0	0	0
>= 65 years	1 (3.4%)	2 (5.0%)	3 (4.3%)
< 75 years	1 (1.0%)	2 (2.0%)	3 (1.5%)
>= 75 years	0	0	0
Eczema (湿疹)			
< 65 years	0	2 (2.9%)	2 (1.4%)
>= 65 years	0	0	0
< 75 years	0	2 (2.0%)	2 (1.0%)
>= 75 years	0	0	0
Urticaria (蕁麻疹)			
< 65 years	0	1 (1.5%)	1 (0.7%)
>= 65 years	0	1 (2.5%)	1 (1.4%)
< 75 years	0	2 (2.0%)	2 (1.0%)
>= 75 years	0	0	0
Acne (ざ瘡)			

System Organ Class Preferred Term Age	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
< 65 years	0	1 (1.5%)	1 (0.7%)
>= 65 years	0	0	0
< 75 years	0	1 (1.0%)	1 (0.5%)
>= 75 years	0	0	0
Cold sweat (冷汗)			
< 65 years	0	1 (1.5%)	1 (0.7%)
>= 65 years	0	0	0
< 75 years	0	1 (1.0%)	1 (0.5%)
>= 75 years	0	0	0
Drug eruption (薬疹)			
< 65 years	0	1 (1.5%)	1 (0.7%)
>= 65 years	0	0	0
< 75 years	0	1 (1.0%)	1 (0.5%)
>= 75 years	0	0	0
Hand dermatitis (手皮膚炎)			
< 65 years	1 (1.4%)	0	1 (0.7%)
>= 65 years	0	0	0
< 75 years	1 (1.0%)	0	1 (0.5%)
>= 75 years	0	0	0
Hyperkeratosis (過角化)			
< 65 years	0	0	0
>= 65 years	0	1 (2.5%)	1 (1.4%)
< 75 years	0	1 (1.0%)	1 (0.5%)
>= 75 years	0	0	0
Miliaria (汗疹)			
< 65 years	0	1 (1.5%)	1 (0.7%)
>= 65 years	0	0	0
< 75 years	0	1 (1.0%)	1 (0.5%)
>= 75 years	0	0	0
Pruritus (そう痒症)			
< 65 years	0	0	0
>= 65 years	0	1 (2.5%)	1 (1.4%)
< 75 years	0	0	0
>= 75 years	0	1 (14.3%)	1 (10.0%)
Respiratory, thoracic and mediastinal disorders (呼吸器、胸郭および縦隔障害)			
< 65 years	3 (4.2%)	3 (4.4%)	6 (4.3%)
>= 65 years	4 (13.8%)	1 (2.5%)	5 (7.2%)
< 75 years	7 (7.1%)	4 (4.0%)	11 (5.5%)
>= 75 years	0	0	0
Upper respiratory tract inflammation (上気道の炎症)			
< 65 years	1 (1.4%)	1 (1.5%)	2 (1.4%)
>= 65 years	2 (6.9%)	0	2 (2.9%)
< 75 years	3 (3.1%)	1 (1.0%)	4 (2.0%)
>= 75 years	0	0	0

System Organ Class Preferred Term Age	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
Asthma (喘息)			
< 65 years	0	1 (1.5%)	1 (0.7%)
>= 65 years	1 (3.4%)	0	1 (1.4%)
< 75 years	1 (1.0%)	1 (1.0%)	2 (1.0%)
>= 75 years	0	0	0
Cough (咳嗽)			
< 65 years	1 (1.4%)	0	1 (0.7%)
>= 65 years	0	1 (2.5%)	1 (1.4%)
< 75 years	1 (1.0%)	1 (1.0%)	2 (1.0%)
>= 75 years	0	0	0
Sputum increased (喀痰増加)			
< 65 years	1 (1.4%)	0	1 (0.7%)
>= 65 years	1 (3.4%)	0	1 (1.4%)
< 75 years	2 (2.0%)	0	2 (1.0%)
>= 75 years	0	0	0
Pulmonary embolism (肺塞栓症)			
< 65 years	0	1 (1.5%)	1 (0.7%)
>= 65 years	0	0	0
< 75 years	0	1 (1.0%)	1 (0.5%)
>= 75 years	0	0	0
Rhinitis allergic (アレルギー性鼻炎)			
< 65 years	0	0	0
>= 65 years	1 (3.4%)	0	1 (1.4%)
< 75 years	1 (1.0%)	0	1 (0.5%)
>= 75 years	0	0	0
Injury, poisoning and procedural complications (傷害、中毒および処置合併症)			
< 65 years	1 (1.4%)	7 (10.3%)	8 (5.7%)
>= 65 years	1 (3.4%)	1 (2.5%)	2 (2.9%)
< 75 years	2 (2.0%)	8 (7.9%)	10 (5.0%)
>= 75 years	0	0	0
Contusion (挫傷)			
< 65 years	0	2 (2.9%)	2 (1.4%)
>= 65 years	0	1 (2.5%)	1 (1.4%)
< 75 years	0	3 (3.0%)	3 (1.5%)
>= 75 years	0	0	0
Stress fracture (ストレス骨折)			
< 65 years	0	2 (2.9%)	2 (1.4%)
>= 65 years	0	0	0
< 75 years	0	2 (2.0%)	2 (1.0%)
>= 75 years	0	0	0
Clavicle fracture (鎖骨骨折)			
< 65 years	0	0	0
>= 65 years	1 (3.4%)	0	1 (1.4%)

System Organ Class Preferred Term Age	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
< 75 years	1 (1.0%)	0	1 (0.5%)
>= 75 years	0	0	0
Hand fracture (手骨折)			
< 65 years	0	1 (1.5%)	1 (0.7%)
>= 65 years	0	0	0
< 75 years	0	1 (1.0%)	1 (0.5%)
>= 75 years	0	0	0
Heat illness (熱中症)			
< 65 years	0	1 (1.5%)	1 (0.7%)
>= 65 years	0	0	0
< 75 years	0	1 (1.0%)	1 (0.5%)
>= 75 years	0	0	0
Ligament sprain (靱帯捻挫)			
< 65 years	0	1 (1.5%)	1 (0.7%)
>= 65 years	0	0	0
< 75 years	0	1 (1.0%)	1 (0.5%)
>= 75 years	0	0	0
Muscle strain (肉離れ)			
< 65 years	0	1 (1.5%)	1 (0.7%)
>= 65 years	0	0	0
< 75 years	0	1 (1.0%)	1 (0.5%)
>= 75 years	0	0	0
Scratch (引っかき傷)			
< 65 years	1 (1.4%)	0	1 (0.7%)
>= 65 years	0	0	0
< 75 years	1 (1.0%)	0	1 (0.5%)
>= 75 years	0	0	0
Vascular disorders (血管障害)			
< 65 years	1 (1.4%)	5 (7.4%)	6 (4.3%)
>= 65 years	1 (3.4%)	2 (5.0%)	3 (4.3%)
< 75 years	2 (2.0%)	7 (6.9%)	9 (4.5%)
>= 75 years	0	0	0
Hypertension (高血圧)			
< 65 years	1 (1.4%)	3 (4.4%)	4 (2.9%)
>= 65 years	1 (3.4%)	2 (5.0%)	3 (4.3%)
< 75 years	2 (2.0%)	5 (5.0%)	7 (3.5%)
>= 75 years	0	0	0
Peripheral arterial occlusive disease (末梢動脈閉塞性疾患)			
< 65 years	0	1 (1.5%)	1 (0.7%)
>= 65 years	0	0	0
< 75 years	0	1 (1.0%)	1 (0.5%)
>= 75 years	0	0	0
Venous thrombosis limb (四肢静脈血栓症)			

System Organ Class Preferred Term Age	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
< 65 years	0	1 (1.5%)	1 (0.7%)
>= 65 years	0	0	0
< 75 years	0	1 (1.0%)	1 (0.5%)
>= 75 years	0	0	0
Investigations (臨床検査)			
< 65 years	1 (1.4%)	4 (5.9%)	5 (3.6%)
>= 65 years	0	2 (5.0%)	2 (2.9%)
< 75 years	1 (1.0%)	6 (5.9%)	7 (3.5%)
>= 75 years	0	0	0
Blood creatine phosphokinase increased (血中クレアチンホスホキナーゼ増加)			
< 65 years	1 (1.4%)	1 (1.5%)	2 (1.4%)
>= 65 years	0	1 (2.5%)	1 (1.4%)
< 75 years	1 (1.0%)	2 (2.0%)	3 (1.5%)
>= 75 years	0	0	0
Aspartate aminotransferase increased (アスパラギン酸アミノトランスフェラーゼ増加)			
< 65 years	0	0	0
>= 65 years	0	1 (2.5%)	1 (1.4%)
< 75 years	0	1 (1.0%)	1 (0.5%)
>= 75 years	0	0	0
Blood alkaline phosphatase increased (血中アルカリホスファターゼ増加)			
< 65 years	0	1 (1.5%)	1 (0.7%)
>= 65 years	0	0	0
< 75 years	0	1 (1.0%)	1 (0.5%)
>= 75 years	0	0	0
Blood glucose abnormal (血中ブドウ糖異常)			
< 65 years	0	1 (1.5%)	1 (0.7%)
>= 65 years	0	0	0
< 75 years	0	1 (1.0%)	1 (0.5%)
>= 75 years	0	0	0
Blood lactic acid increased (血中乳酸増加)			
< 65 years	0	1 (1.5%)	1 (0.7%)
>= 65 years	0	0	0
< 75 years	0	1 (1.0%)	1 (0.5%)
>= 75 years	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）)			
< 65 years	2 (2.8%)	2 (2.9%)	4 (2.9%)

System Organ Class Preferred Term Age	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
>= 65 years	2 (6.9%)	1 (2.5%)	3 (4.3%)
< 75 years	4 (4.1%)	2 (2.0%)	6 (3.0%)
>= 75 years	0	1 (14.3%)	1 (10.0%)
Papillary thyroid cancer (乳頭様甲状腺癌)			
< 65 years	1 (1.4%)	0	1 (0.7%)
>= 65 years	1 (3.4%)	0	1 (1.4%)
< 75 years	2 (2.0%)	0	2 (1.0%)
>= 75 years	0	0	0
Benign neoplasm of thyroid gland (甲状腺の良性新生物)			
< 65 years	0	0	0
>= 65 years	0	1 (2.5%)	1 (1.4%)
< 75 years	0	0	0
>= 75 years	0	1 (14.3%)	1 (10.0%)
Intraductal papillary mucinous neoplasm (膵管内乳頭粘液性腫瘍)			
< 65 years	1 (1.4%)	0	1 (0.7%)
>= 65 years	0	0	0
< 75 years	1 (1.0%)	0	1 (0.5%)
>= 75 years	0	0	0
Lipoma (脂肪腫)			
< 65 years	0	1 (1.5%)	1 (0.7%)
>= 65 years	0	0	0
< 75 years	0	1 (1.0%)	1 (0.5%)
>= 75 years	0	0	0
Pancreatic carcinoma (膵癌)			
< 65 years	0	0	0
>= 65 years	1 (3.4%)	0	1 (1.4%)
< 75 years	1 (1.0%)	0	1 (0.5%)
>= 75 years	0	0	0
Uterine leiomyoma (子宮平滑筋腫)			
< 65 years	0	1 (1.5%)	1 (0.7%)
>= 65 years	0	0	0
< 75 years	0	1 (1.0%)	1 (0.5%)
>= 75 years	0	0	0
General disorders and administration site conditions (一般・全身障害および投与部位の状態)			
< 65 years	0	3 (4.4%)	3 (2.1%)
>= 65 years	3 (10.3%)	0	3 (4.3%)
< 75 years	3 (3.1%)	3 (3.0%)	6 (3.0%)
>= 75 years	0	0	0
Pyrexia (発熱)			
< 65 years	0	2 (2.9%)	2 (1.4%)

System Organ Class Preferred Term Age	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
>= 65 years	2 (6.9%)	0	2 (2.9%)
< 75 years	2 (2.0%)	2 (2.0%)	4 (2.0%)
>= 75 years	0	0	0
Oedema peripheral (末梢性浮腫)			
< 65 years	0	1 (1.5%)	1 (0.7%)
>= 65 years	0	0	0
< 75 years	0	1 (1.0%)	1 (0.5%)
>= 75 years	0	0	0
Sudden death (突然死)			
< 65 years	0	0	0
>= 65 years	1 (3.4%)	0	1 (1.4%)
< 75 years	1 (1.0%)	0	1 (0.5%)
>= 75 years	0	0	0
Hepatobiliary disorders (肝胆道系障害)			
< 65 years	2 (2.8%)	2 (2.9%)	4 (2.9%)
>= 65 years	1 (3.4%)	0	1 (1.4%)
< 75 years	2 (2.0%)	2 (2.0%)	4 (2.0%)
>= 75 years	1 (33.3%)	0	1 (10.0%)
Hepatic steatosis (脂肪肝)			
< 65 years	1 (1.4%)	1 (1.5%)	2 (1.4%)
>= 65 years	0	0	0
< 75 years	1 (1.0%)	1 (1.0%)	2 (1.0%)
>= 75 years	0	0	0
Gallbladder polyp (胆嚢ポリープ)			
< 65 years	0	1 (1.5%)	1 (0.7%)
>= 65 years	0	0	0
< 75 years	0	1 (1.0%)	1 (0.5%)
>= 75 years	0	0	0
Hepatic function abnormal (肝機能異常)			
< 65 years	0	0	0
>= 65 years	1 (3.4%)	0	1 (1.4%)
< 75 years	0	0	0
>= 75 years	1 (33.3%)	0	1 (10.0%)
Hyperplastic cholecystopathy (過形成性胆嚢症)			
< 65 years	1 (1.4%)	0	1 (0.7%)
>= 65 years	0	0	0
< 75 years	1 (1.0%)	0	1 (0.5%)
>= 75 years	0	0	0
Immune system disorders (免疫系障害)			
< 65 years	0	3 (4.4%)	3 (2.1%)
>= 65 years	1 (3.4%)	1 (2.5%)	2 (2.9%)
< 75 years	1 (1.0%)	4 (4.0%)	5 (2.5%)

System Organ Class Preferred Term Age	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
>= 75 years	0	0	0
Seasonal allergy (季節性アレルギー)			
< 65 years	0	3 (4.4%)	3 (2.1%)
>= 65 years	1 (3.4%)	1 (2.5%)	2 (2.9%)
< 75 years	1 (1.0%)	4 (4.0%)	5 (2.5%)
>= 75 years	0	0	0
Ear and labyrinth disorders (耳および迷路障害)			
< 65 years	1 (1.4%)	1 (1.5%)	2 (1.4%)
>= 65 years	0	2 (5.0%)	2 (2.9%)
< 75 years	1 (1.0%)	3 (3.0%)	4 (2.0%)
>= 75 years	0	0	0
Meniere's disease (メニエール病)			
< 65 years	1 (1.4%)	0	1 (0.7%)
>= 65 years	0	0	0
< 75 years	1 (1.0%)	0	1 (0.5%)
>= 75 years	0	0	0
Tinnitus (耳鳴)			
< 65 years	0	1 (1.5%)	1 (0.7%)
>= 65 years	0	0	0
< 75 years	0	1 (1.0%)	1 (0.5%)
>= 75 years	0	0	0
Vertigo (回転性めまい)			
< 65 years	0	0	0
>= 65 years	0	1 (2.5%)	1 (1.4%)
< 75 years	0	1 (1.0%)	1 (0.5%)
>= 75 years	0	0	0
Vertigo positional (頭位性回転性めまい)			
< 65 years	0	0	0
>= 65 years	0	1 (2.5%)	1 (1.4%)
< 75 years	0	1 (1.0%)	1 (0.5%)
>= 75 years	0	0	0
Cardiac disorders (心臓障害)			
< 65 years	1 (1.4%)	1 (1.5%)	2 (1.4%)
>= 65 years	1 (3.4%)	0	1 (1.4%)
< 75 years	1 (1.0%)	1 (1.0%)	2 (1.0%)
>= 75 years	1 (33.3%)	0	1 (10.0%)
Atrial fibrillation (心房細動)			
< 65 years	0	0	0
>= 65 years	1 (3.4%)	0	1 (1.4%)
< 75 years	0	0	0
>= 75 years	1 (33.3%)	0	1 (10.0%)

System Organ Class Preferred Term Age	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
Cardiac failure congestive (うっ血性心不全)			
< 65 years	0	0	0
>= 65 years	1 (3.4%)	0	1 (1.4%)
< 75 years	0	0	0
>= 75 years	1 (33.3%)	0	1 (10.0%)
Coronary artery stenosis (冠動脈狭窄)			
< 65 years	0	1 (1.5%)	1 (0.7%)
>= 65 years	0	0	0
< 75 years	0	1 (1.0%)	1 (0.5%)
>= 75 years	0	0	0
Extrasystoles (期外収縮)			
< 65 years	1 (1.4%)	0	1 (0.7%)
>= 65 years	0	0	0
< 75 years	1 (1.0%)	0	1 (0.5%)
>= 75 years	0	0	0
Reproductive system and breast disorders (生殖系および乳房障害)			
< 65 years	0	0	0
>= 65 years	2 (6.9%)	1 (2.5%)	3 (4.3%)
< 75 years	2 (2.0%)	0	2 (1.0%)
>= 75 years	0	1 (14.3%)	1 (10.0%)
Benign prostatic hyperplasia (良性前立腺肥大症)			
< 65 years	0	0	0
>= 65 years	1 (3.4%)	1 (2.5%)	2 (2.9%)
< 75 years	1 (1.0%)	0	1 (0.5%)
>= 75 years	0	1 (14.3%)	1 (10.0%)
Prostatomegaly (前立腺腫大)			
< 65 years	0	0	0
>= 65 years	1 (3.4%)	0	1 (1.4%)
< 75 years	1 (1.0%)	0	1 (0.5%)
>= 75 years	0	0	0
Psychiatric disorders (精神障害)			
< 65 years	1 (1.4%)	0	1 (0.7%)
>= 65 years	0	1 (2.5%)	1 (1.4%)
< 75 years	1 (1.0%)	1 (1.0%)	2 (1.0%)
>= 75 years	0	0	0
Depressive symptom (抑うつ症状)			
< 65 years	1 (1.4%)	0	1 (0.7%)
>= 65 years	0	0	0
< 75 years	1 (1.0%)	0	1 (0.5%)
>= 75 years	0	0	0
Insomnia (不眠症)			

System Organ Class Preferred Term Age	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
< 65 years	0	0	0
>= 65 years	0	1 (2.5%)	1 (1.4%)
< 75 years	0	1 (1.0%)	1 (0.5%)
>= 75 years	0	0	0
Renal and urinary disorders (腎および尿路障害)			
< 65 years	0	1 (1.5%)	1 (0.7%)
>= 65 years	1 (3.4%)	0	1 (1.4%)
< 75 years	1 (1.0%)	1 (1.0%)	2 (1.0%)
>= 75 years	0	0	0
Haematuria (血尿)			
< 65 years	0	1 (1.5%)	1 (0.7%)
>= 65 years	0	0	0
< 75 years	0	1 (1.0%)	1 (0.5%)
>= 75 years	0	0	0
Renal cyst (腎嚢胞)			
< 65 years	0	0	0
>= 65 years	1 (3.4%)	0	1 (1.4%)
< 75 years	1 (1.0%)	0	1 (0.5%)
>= 75 years	0	0	0
Blood and lymphatic system disorders (血液およびリンパ系障害)			
< 65 years	0	0	0
>= 65 years	1 (3.4%)	0	1 (1.4%)
< 75 years	1 (1.0%)	0	1 (0.5%)
>= 75 years	0	0	0
Iron deficiency anaemia (鉄欠乏性貧血)			
< 65 years	0	0	0
>= 65 years	1 (3.4%)	0	1 (1.4%)
< 75 years	1 (1.0%)	0	1 (0.5%)
>= 75 years	0	0	0

- 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.
- All adverse events were coded using MedDRA dictionary version 20.1.
- Percentages are based on "Number of patients".

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Table S-175 Subgroup Analysis of Treatment Emergent Adverse Events by Sex, System Organ Class and Preferred Term in 52-Week Long-term Period in Combination with Insulin Therapy (PXL008-020; Long-term Safety Population)

System Organ Class Preferred Term Sex	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
Number of patients			
Male	64	66	130
Female	37	42	79
Any TEAE			
Male	50 (78.1%)	53 (80.3%)	103 (79.2%)
Female	27 (73.0%)	39 (92.9%)	66 (83.5%)
Infections and infestations (感染症および寄生虫症)			
Male	20 (31.3%)	26 (39.4%)	46 (35.4%)
Female	10 (27.0%)	26 (61.9%)	36 (45.6%)
Nasopharyngitis (上咽頭炎)			
Male	11 (17.2%)	20 (30.3%)	31 (23.8%)
Female	5 (13.5%)	16 (38.1%)	21 (26.6%)
Bronchitis (気管支炎)			
Male	2 (3.1%)	1 (1.5%)	3 (2.3%)
Female	3 (8.1%)	3 (7.1%)	6 (7.6%)
Influenza (インフルエンザ)			
Male	4 (6.3%)	1 (1.5%)	5 (3.8%)
Female	0	4 (9.5%)	4 (5.1%)
Gastroenteritis (胃腸炎)			
Male	1 (1.6%)	0	1 (0.8%)
Female	3 (8.1%)	1 (2.4%)	4 (5.1%)
Cystitis (膀胱炎)			
Male	0	0	0
Female	1 (2.7%)	3 (7.1%)	4 (5.1%)
Herpes zoster (帯状疱疹)			
Male	0	1 (1.5%)	1 (0.8%)
Female	1 (2.7%)	1 (2.4%)	2 (2.5%)
Periodontitis (歯周炎)			
Male	1 (1.6%)	0	1 (0.8%)
Female	0	2 (4.8%)	2 (2.5%)
Conjunctivitis (結膜炎)			
Male	2 (3.1%)	0	2 (1.5%)
Female	0	0	0
Folliculitis (毛包炎)			
Male	0	1 (1.5%)	1 (0.8%)
Female	0	1 (2.4%)	1 (1.3%)
Hordeolum (麦粒腫)			
Male	1 (1.6%)	0	1 (0.8%)
Female	0	1 (2.4%)	1 (1.3%)

System Organ Class Preferred Term Sex	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
Pharyngitis (咽頭炎)			
Male	1 (1.6%)	1 (1.5%)	2 (1.5%)
Female	0	0	0
Urinary tract infection (尿路感染)			
Male	0	1 (1.5%)	1 (0.8%)
Female	0	1 (2.4%)	1 (1.3%)
Asymptomatic bacteriuria (無症候性細菌尿)			
Male	0	0	0
Female	0	1 (2.4%)	1 (1.3%)
Erysipelas (丹毒)			
Male	0	1 (1.5%)	1 (0.8%)
Female	0	0	0
Furuncle (せつ)			
Male	0	1 (1.5%)	1 (0.8%)
Female	0	0	0
Gastroenteritis viral (ウイルス性胃腸炎)			
Male	0	0	0
Female	1 (2.7%)	0	1 (1.3%)
Gingivitis (歯肉炎)			
Male	0	1 (1.5%)	1 (0.8%)
Female	0	0	0
Helicobacter infection (ヘリコバクター感染)			
Male	1 (1.6%)	0	1 (0.8%)
Female	0	0	0
Herpes simplex (単純ヘルペス)			
Male	1 (1.6%)	0	1 (0.8%)
Female	0	0	0
Oral herpes (口腔ヘルペス)			
Male	1 (1.6%)	0	1 (0.8%)
Female	0	0	0
Otitis media acute (急性中耳炎)			
Male	1 (1.6%)	0	1 (0.8%)
Female	0	0	0
Pneumonia mycoplasmal (マイコプラズマ性肺炎)			
Male	1 (1.6%)	0	1 (0.8%)
Female	0	0	0
Rhinitis (鼻炎)			
Male	0	1 (1.5%)	1 (0.8%)
Female	0	0	0

System Organ Class Preferred Term Sex	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
Sinusitis (副鼻腔炎)			
Male	0	0	0
Female	0	1 (2.4%)	1 (1.3%)
Soft tissue infection (軟部組織感染)			
Male	0	1 (1.5%)	1 (0.8%)
Female	0	0	0
Tinea pedis (足部白癬)			
Male	0	1 (1.5%)	1 (0.8%)
Female	0	0	0
Tonsillitis (扁桃炎)			
Male	0	1 (1.5%)	1 (0.8%)
Female	0	0	0
Upper respiratory tract infection (上気道感染)			
Male	0	0	0
Female	1 (2.7%)	0	1 (1.3%)
Metabolism and nutrition disorders (代謝および栄養障害)			
Male	24 (37.5%)	24 (36.4%)	48 (36.9%)
Female	13 (35.1%)	18 (42.9%)	31 (39.2%)
Hypoglycaemia (低血糖)			
Male	24 (37.5%)	22 (33.3%)	46 (35.4%)
Female	12 (32.4%)	17 (40.5%)	29 (36.7%)
Dyslipidaemia (脂質異常症)			
Male	0	1 (1.5%)	1 (0.8%)
Female	1 (2.7%)	0	1 (1.3%)
Hyperglycaemia (高血糖)			
Male	0	1 (1.5%)	1 (0.8%)
Female	0	1 (2.4%)	1 (1.3%)
Hyponatraemia (低ナトリウム血症)			
Male	0	0	0
Female	1 (2.7%)	0	1 (1.3%)
Musculoskeletal and connective tissue disorders (筋骨格系および結合組織障害)			
Male	5 (7.8%)	13 (19.7%)	18 (13.8%)
Female	4 (10.8%)	11 (26.2%)	15 (19.0%)
Back pain (背部痛)			
Male	0	2 (3.0%)	2 (1.5%)
Female	1 (2.7%)	4 (9.5%)	5 (6.3%)
Muscle spasms (筋痙縮)			
Male	1 (1.6%)	3 (4.5%)	4 (3.1%)

System Organ Class Preferred Term Sex	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
Female	0	1 (2.4%)	1 (1.3%)
Arthralgia (関節痛)			
Male	1 (1.6%)	2 (3.0%)	3 (2.3%)
Female	0	1 (2.4%)	1 (1.3%)
Spinal osteoarthritis (変形性脊椎症)			
Male	0	1 (1.5%)	1 (0.8%)
Female	0	3 (7.1%)	3 (3.8%)
Musculoskeletal stiffness (筋骨格硬直)			
Male	0	1 (1.5%)	1 (0.8%)
Female	1 (2.7%)	0	1 (1.3%)
Osteoarthritis (変形性関節症)			
Male	0	0	0
Female	0	2 (4.8%)	2 (2.5%)
Synovial cyst (滑液嚢腫)			
Male	0	1 (1.5%)	1 (0.8%)
Female	0	1 (2.4%)	1 (1.3%)
Tenosynovitis (腱鞘炎)			
Male	0	0	0
Female	1 (2.7%)	1 (2.4%)	2 (2.5%)
Trigger finger (弾発指)			
Male	1 (1.6%)	0	1 (0.8%)
Female	0	1 (2.4%)	1 (1.3%)
Chondrocalcinosis pyrophosphate (ピロリン酸カルシウム結晶性軟骨石灰化症)			
Male	0	0	0
Female	1 (2.7%)	0	1 (1.3%)
Intervertebral disc protrusion (椎間板突出)			
Male	0	1 (1.5%)	1 (0.8%)
Female	0	0	0
Lumbar spinal stenosis (腰部脊柱管狭窄症)			
Male	0	1 (1.5%)	1 (0.8%)
Female	0	0	0
Musculoskeletal pain (筋骨格痛)			
Male	1 (1.6%)	0	1 (0.8%)
Female	0	0	0
Myofascitis (筋筋膜炎)			
Male	0	0	0
Female	0	1 (2.4%)	1 (1.3%)
Neck pain (頚部痛)			
Male	0	1 (1.5%)	1 (0.8%)
Female	0	0	0

System Organ Class Preferred Term Sex	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
Nodal osteoarthritis (結節性変形性関節症)			
Male	0	0	0
Female	0	1 (2.4%)	1 (1.3%)
Pain in extremity (四肢痛)			
Male	0	1 (1.5%)	1 (0.8%)
Female	0	0	0
Synovitis (滑膜炎)			
Male	0	1 (1.5%)	1 (0.8%)
Female	0	0	0
Temporomandibular joint syndrome (顎関節症候群)			
Male	0	1 (1.5%)	1 (0.8%)
Female	0	0	0
Tendonitis (腱炎)			
Male	1 (1.6%)	0	1 (0.8%)
Female	0	0	0
Gastrointestinal disorders (胃腸障害)			
Male	5 (7.8%)	10 (15.2%)	15 (11.5%)
Female	5 (13.5%)	10 (23.8%)	15 (19.0%)
Constipation (便秘)			
Male	0	0	0
Female	0	6 (14.3%)	6 (7.6%)
Gastrooesophageal reflux disease (胃食道逆流性疾患)			
Male	1 (1.6%)	3 (4.5%)	4 (3.1%)
Female	1 (2.7%)	0	1 (1.3%)
Nausea (悪心)			
Male	1 (1.6%)	0	1 (0.8%)
Female	1 (2.7%)	3 (7.1%)	4 (5.1%)
Abdominal discomfort (腹部不快感)			
Male	0	2 (3.0%)	2 (1.5%)
Female	1 (2.7%)	1 (2.4%)	2 (2.5%)
Diarrhoea (下痢)			
Male	1 (1.6%)	1 (1.5%)	2 (1.5%)
Female	1 (2.7%)	1 (2.4%)	2 (2.5%)
Toothache (歯痛)			
Male	1 (1.6%)	1 (1.5%)	2 (1.5%)
Female	1 (2.7%)	0	1 (1.3%)
Abdominal pain upper (上腹部痛)			
Male	0	1 (1.5%)	1 (0.8%)
Female	0	1 (2.4%)	1 (1.3%)
Chronic gastritis (慢性胃炎)			

System Organ Class Preferred Term Sex	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
Male	1 (1.6%)	0	1 (0.8%)
Female	1 (2.7%)	0	1 (1.3%)
Dental caries (齲歯)			
Male	1 (1.6%)	1 (1.5%)	2 (1.5%)
Female	0	0	0
Gastritis (胃炎)			
Male	0	0	0
Female	1 (2.7%)	1 (2.4%)	2 (2.5%)
Periodontal disease (歯周病)			
Male	0	1 (1.5%)	1 (0.8%)
Female	0	1 (2.4%)	1 (1.3%)
Vomiting (嘔吐)			
Male	0	0	0
Female	1 (2.7%)	1 (2.4%)	2 (2.5%)
Abdominal distension (腹部膨満)			
Male	0	1 (1.5%)	1 (0.8%)
Female	0	0	0
Colitis ulcerative (潰瘍性大腸炎)			
Male	0	1 (1.5%)	1 (0.8%)
Female	0	0	0
Large intestine polyp (大腸ポリープ)			
Male	1 (1.6%)	0	1 (0.8%)
Female	0	0	0
Eye disorders (眼障害)			
Male	3 (4.7%)	4 (6.1%)	7 (5.4%)
Female	3 (8.1%)	6 (14.3%)	9 (11.4%)
Cataract (白内障)			
Male	1 (1.6%)	1 (1.5%)	2 (1.5%)
Female	0	1 (2.4%)	1 (1.3%)
Diabetic retinopathy (糖尿病網膜症)			
Male	1 (1.6%)	1 (1.5%)	2 (1.5%)
Female	1 (2.7%)	0	1 (1.3%)
Ocular hypertension (高眼圧症)			
Male	0	2 (3.0%)	2 (1.5%)
Female	0	0	0
Vitreous haemorrhage (硝子体出血)			
Male	0	1 (1.5%)	1 (0.8%)
Female	0	1 (2.4%)	1 (1.3%)
Accommodation disorder (調節障害)			
Male	1 (1.6%)	0	1 (0.8%)
Female	0	0	0
Angle closure glaucoma (閉塞隅角緑内障)			

System Organ Class Preferred Term Sex	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
Male	0	0	0
Female	0	1 (2.4%)	1 (1.3%)
Conjunctival hyperaemia (結膜充血)			
Male	0	0	0
Female	1 (2.7%)	0	1 (1.3%)
Conjunctivitis allergic (アレルギー性結膜炎)			
Male	0	0	0
Female	0	1 (2.4%)	1 (1.3%)
Diabetic retinal oedema (糖尿病性網膜浮腫)			
Male	0	1 (1.5%)	1 (0.8%)
Female	0	0	0
Dry eye (眼乾燥)			
Male	0	0	0
Female	0	1 (2.4%)	1 (1.3%)
Glaucoma (緑内障)			
Male	1 (1.6%)	0	1 (0.8%)
Female	0	0	0
Macular oedema (黄斑浮腫)			
Male	0	0	0
Female	1 (2.7%)	0	1 (1.3%)
Pingueculitis (瞼裂斑炎)			
Male	1 (1.6%)	0	1 (0.8%)
Female	0	0	0
Retinal detachment (網膜剥離)			
Male	0	1 (1.5%)	1 (0.8%)
Female	0	0	0
Retinal haemorrhage (網膜出血)			
Male	0	0	0
Female	0	1 (2.4%)	1 (1.3%)
Trichiasis (睫毛乱生)			
Male	0	1 (1.5%)	1 (0.8%)
Female	0	0	0
Nervous system disorders (神経系障害)			
Male	3 (4.7%)	3 (4.5%)	6 (4.6%)
Female	3 (8.1%)	5 (11.9%)	8 (10.1%)
Headache (頭痛)			
Male	1 (1.6%)	1 (1.5%)	2 (1.5%)
Female	2 (5.4%)	2 (4.8%)	4 (5.1%)
Dizziness (浮動性めまい)			
Male	1 (1.6%)	0	1 (0.8%)
Female	0	1 (2.4%)	1 (1.3%)

System Organ Class Preferred Term Sex	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
Autonomic nervous system imbalance (自律神経失調)			
Male	1 (1.6%)	0	1 (0.8%)
Female	0	0	0
Carpal tunnel syndrome (手根管症候群)			
Male	1 (1.6%)	0	1 (0.8%)
Female	0	0	0
Epilepsy (てんかん)			
Male	0	1 (1.5%)	1 (0.8%)
Female	0	0	0
Facial paralysis (顔面麻痺)			
Male	0	0	0
Female	0	1 (2.4%)	1 (1.3%)
Sciatica (坐骨神経痛)			
Male	0	1 (1.5%)	1 (0.8%)
Female	0	0	0
Somnolence (傾眠)			
Male	0	0	0
Female	0	1 (2.4%)	1 (1.3%)
Syncope (失神)			
Male	0	0	0
Female	1 (2.7%)	0	1 (1.3%)
Skin and subcutaneous tissue disorders (皮膚および皮下組織障害)			
Male	2 (3.1%)	7 (10.6%)	9 (6.9%)
Female	0	4 (9.5%)	4 (5.1%)
Dermatitis (皮膚炎)			
Male	1 (1.6%)	2 (3.0%)	3 (2.3%)
Female	0	0	0
Eczema (湿疹)			
Male	0	1 (1.5%)	1 (0.8%)
Female	0	1 (2.4%)	1 (1.3%)
Urticaria (蕁麻疹)			
Male	0	2 (3.0%)	2 (1.5%)
Female	0	0	0
Acne (ざ瘡)			
Male	0	0	0
Female	0	1 (2.4%)	1 (1.3%)
Cold sweat (冷汗)			
Male	0	1 (1.5%)	1 (0.8%)
Female	0	0	0
Drug eruption (薬疹)			

System Organ Class Preferred Term Sex	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
Male	0	0	0
Female	0	1 (2.4%)	1 (1.3%)
Hand dermatitis (手皮膚炎)			
Male	1 (1.6%)	0	1 (0.8%)
Female	0	0	0
Hyperkeratosis (過角化)			
Male	0	0	0
Female	0	1 (2.4%)	1 (1.3%)
Miliaria (汗疹)			
Male	0	1 (1.5%)	1 (0.8%)
Female	0	0	0
Pruritus (そう痒症)			
Male	0	0	0
Female	0	1 (2.4%)	1 (1.3%)
Respiratory, thoracic and mediastinal disorders (呼吸器、胸郭および縦隔障害)			
Male	3 (4.7%)	1 (1.5%)	4 (3.1%)
Female	4 (10.8%)	3 (7.1%)	7 (8.9%)
Upper respiratory tract inflammation (上気道の炎症)			
Male	2 (3.1%)	0	2 (1.5%)
Female	1 (2.7%)	1 (2.4%)	2 (2.5%)
Asthma (喘息)			
Male	0	0	0
Female	1 (2.7%)	1 (2.4%)	2 (2.5%)
Cough (咳嗽)			
Male	0	0	0
Female	1 (2.7%)	1 (2.4%)	2 (2.5%)
Sputum increased (喀痰増加)			
Male	1 (1.6%)	0	1 (0.8%)
Female	1 (2.7%)	0	1 (1.3%)
Pulmonary embolism (肺塞栓症)			
Male	0	1 (1.5%)	1 (0.8%)
Female	0	0	0
Rhinitis allergic (アレルギー性鼻炎)			
Male	0	0	0
Female	1 (2.7%)	0	1 (1.3%)
Injury, poisoning and procedural complications (傷害、中毒および処置合併症)			
Male	2 (3.1%)	4 (6.1%)	6 (4.6%)
Female	0	4 (9.5%)	4 (5.1%)
Contusion (挫傷)			

System Organ Class Preferred Term Sex	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
Male	0	1 (1.5%)	1 (0.8%)
Female	0	2 (4.8%)	2 (2.5%)
Stress fracture (ストレス骨折)			
Male	0	1 (1.5%)	1 (0.8%)
Female	0	1 (2.4%)	1 (1.3%)
Clavicle fracture (鎖骨骨折)			
Male	1 (1.6%)	0	1 (0.8%)
Female	0	0	0
Hand fracture (手骨折)			
Male	0	1 (1.5%)	1 (0.8%)
Female	0	0	0
Heat illness (熱中症)			
Male	0	0	0
Female	0	1 (2.4%)	1 (1.3%)
Ligament sprain (靱帯捻挫)			
Male	0	1 (1.5%)	1 (0.8%)
Female	0	0	0
Muscle strain (肉離れ)			
Male	0	1 (1.5%)	1 (0.8%)
Female	0	0	0
Scratch (引っかき傷)			
Male	1 (1.6%)	0	1 (0.8%)
Female	0	0	0
Vascular disorders (血管障害)			
Male	2 (3.1%)	5 (7.6%)	7 (5.4%)
Female	0	2 (4.8%)	2 (2.5%)
Hypertension (高血圧)			
Male	2 (3.1%)	3 (4.5%)	5 (3.8%)
Female	0	2 (4.8%)	2 (2.5%)
Peripheral arterial occlusive disease (末梢動脈閉塞性疾患)			
Male	0	1 (1.5%)	1 (0.8%)
Female	0	0	0
Venous thrombosis limb (四肢静脈血栓症)			
Male	0	1 (1.5%)	1 (0.8%)
Female	0	0	0
Investigations (臨床検査)			
Male	1 (1.6%)	4 (6.1%)	5 (3.8%)
Female	0	2 (4.8%)	2 (2.5%)
Blood creatine phosphokinase increased (血中クレアチンホスホキナーゼ増加)			

System Organ Class Preferred Term Sex	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
Male	1 (1.6%)	2 (3.0%)	3 (2.3%)
Female	0	0	0
Aspartate aminotransferase increased (アスパラギン酸アミノトランスフェラーゼ増加)			
Male	0	0	0
Female	0	1 (2.4%)	1 (1.3%)
Blood alkaline phosphatase increased (血中アルカリホスファターゼ増加)			
Male	0	1 (1.5%)	1 (0.8%)
Female	0	0	0
Blood glucose abnormal (血中ブドウ糖異常)			
Male	0	0	0
Female	0	1 (2.4%)	1 (1.3%)
Blood lactic acid increased (血中乳酸増加)			
Male	0	1 (1.5%)	1 (0.8%)
Female	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）)			
Male	2 (3.1%)	1 (1.5%)	3 (2.3%)
Female	2 (5.4%)	2 (4.8%)	4 (5.1%)
Papillary thyroid cancer (乳頭様甲状腺癌)			
Male	0	0	0
Female	2 (5.4%)	0	2 (2.5%)
Benign neoplasm of thyroid gland (甲状腺の良性新生物)			
Male	0	0	0
Female	0	1 (2.4%)	1 (1.3%)
Intraductal papillary mucinous neoplasm (膵管内乳頭粘液性腫瘍)			
Male	1 (1.6%)	0	1 (0.8%)
Female	0	0	0
Lipoma (脂肪腫)			
Male	0	1 (1.5%)	1 (0.8%)
Female	0	0	0
Pancreatic carcinoma (膵癌)			
Male	1 (1.6%)	0	1 (0.8%)
Female	0	0	0
Uterine leiomyoma (子宮平滑筋腫)			

System Organ Class Preferred Term Sex	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
Male	0	0	0
Female	0	1 (2.4%)	1 (1.3%)
General disorders and administration site conditions (一般・全身障害および投与部位の状態)			
Male	2 (3.1%)	1 (1.5%)	3 (2.3%)
Female	1 (2.7%)	2 (4.8%)	3 (3.8%)
Pyrexia (発熱)			
Male	1 (1.6%)	1 (1.5%)	2 (1.5%)
Female	1 (2.7%)	1 (2.4%)	2 (2.5%)
Oedema peripheral (末梢性浮腫)			
Male	0	0	0
Female	0	1 (2.4%)	1 (1.3%)
Sudden death (突然死)			
Male	1 (1.6%)	0	1 (0.8%)
Female	0	0	0
Hepatobiliary disorders (肝胆道系障害)			
Male	2 (3.1%)	1 (1.5%)	3 (2.3%)
Female	1 (2.7%)	1 (2.4%)	2 (2.5%)
Hepatic steatosis (脂肪肝)			
Male	1 (1.6%)	1 (1.5%)	2 (1.5%)
Female	0	0	0
Gallbladder polyp (胆嚢ポリープ)			
Male	0	0	0
Female	0	1 (2.4%)	1 (1.3%)
Hepatic function abnormal (肝機能異常)			
Male	0	0	0
Female	1 (2.7%)	0	1 (1.3%)
Hyperplastic cholecystopathy (過形成性胆嚢症)			
Male	1 (1.6%)	0	1 (0.8%)
Female	0	0	0
Immune system disorders (免疫系障害)			
Male	1 (1.6%)	1 (1.5%)	2 (1.5%)
Female	0	3 (7.1%)	3 (3.8%)
Seasonal allergy (季節性アレルギー)			
Male	1 (1.6%)	1 (1.5%)	2 (1.5%)
Female	0	3 (7.1%)	3 (3.8%)

System Organ Class Preferred Term Sex	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
Ear and labyrinth disorders (耳および迷路障害)			
Male	1 (1.6%)	1 (1.5%)	2 (1.5%)
Female	0	2 (4.8%)	2 (2.5%)
Meniere's disease (メニエール病)			
Male	1 (1.6%)	0	1 (0.8%)
Female	0	0	0
Tinnitus (耳鳴)			
Male	0	1 (1.5%)	1 (0.8%)
Female	0	0	0
Vertigo (回転性めまい)			
Male	0	0	0
Female	0	1 (2.4%)	1 (1.3%)
Vertigo positional (頭位性回転性めまい)			
Male	0	0	0
Female	0	1 (2.4%)	1 (1.3%)
Cardiac disorders (心臓障害)			
Male	0	1 (1.5%)	1 (0.8%)
Female	2 (5.4%)	0	2 (2.5%)
Atrial fibrillation (心房細動)			
Male	0	0	0
Female	1 (2.7%)	0	1 (1.3%)
Cardiac failure congestive (うっ血性心不全)			
Male	0	0	0
Female	1 (2.7%)	0	1 (1.3%)
Coronary artery stenosis (冠動脈狭窄)			
Male	0	1 (1.5%)	1 (0.8%)
Female	0	0	0
Extrasystoles (期外収縮)			
Male	0	0	0
Female	1 (2.7%)	0	1 (1.3%)
Reproductive system and breast disorders (生殖系および乳房障害)			
Male	2 (3.1%)	1 (1.5%)	3 (2.3%)
Female	0	0	0
Benign prostatic hyperplasia (良性前立腺肥大症)			
Male	1 (1.6%)	1 (1.5%)	2 (1.5%)
Female	0	0	0
Prostatomegaly (前立腺腫大)			

System Organ Class Preferred Term Sex	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
Male	1 (1.6%)	0	1 (0.8%)
Female	0	0	0
Psychiatric disorders (精神障害)			
Male	0	1 (1.5%)	1 (0.8%)
Female	1 (2.7%)	0	1 (1.3%)
Depressive symptom (抑うつ症状)			
Male	0	0	0
Female	1 (2.7%)	0	1 (1.3%)
Insomnia (不眠症)			
Male	0	1 (1.5%)	1 (0.8%)
Female	0	0	0
Renal and urinary disorders (腎および尿路障害)			
Male	1 (1.6%)	1 (1.5%)	2 (1.5%)
Female	0	0	0
Haematuria (血尿)			
Male	0	1 (1.5%)	1 (0.8%)
Female	0	0	0
Renal cyst (腎嚢胞)			
Male	1 (1.6%)	0	1 (0.8%)
Female	0	0	0
Blood and lymphatic system disorders (血液およびリンパ系障害)			
Male	1 (1.6%)	0	1 (0.8%)
Female	0	0	0
Iron deficiency anaemia (鉄欠乏性貧血)			
Male	1 (1.6%)	0	1 (0.8%)
Female	0	0	0

- 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.
- All adverse events were coded using MedDRA dictionary version 20.1.
- Percentages are based on "Number of patients".

Control No:<<t-s-175-subae-020lt.sas, 2020-03-06T00:12:45>>

Table S-176 Subgroup Analysis of Treatment Emergent Adverse Events by Renal Function, System Organ Class and Preferred Term in 52-Week Long-term Period in Combination with Insulin Therapy (PXL008-020; Long-term Safety Population)

System Organ Class Preferred Term Renal function	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
Number of patients			
CKD Stage 1	13	16	29
CKD Stage 2	88	92	180
Any TEAE			
CKD Stage 1	11 (84.6%)	13 (81.3%)	24 (82.8%)
CKD Stage 2	66 (75.0%)	79 (85.9%)	145 (80.6%)
Infections and infestations (感染症および寄生虫症)			
CKD Stage 1	2 (15.4%)	7 (43.8%)	9 (31.0%)
CKD Stage 2	28 (31.8%)	45 (48.9%)	73 (40.6%)
Nasopharyngitis (上咽頭炎)			
CKD Stage 1	2 (15.4%)	3 (18.8%)	5 (17.2%)
CKD Stage 2	14 (15.9%)	33 (35.9%)	47 (26.1%)
Bronchitis (気管支炎)			
CKD Stage 1	0	1 (6.3%)	1 (3.4%)
CKD Stage 2	5 (5.7%)	3 (3.3%)	8 (4.4%)
Influenza (インフルエンザ)			
CKD Stage 1	1 (7.7%)	0	1 (3.4%)
CKD Stage 2	3 (3.4%)	5 (5.4%)	8 (4.4%)
Gastroenteritis (胃腸炎)			
CKD Stage 1	0	0	0
CKD Stage 2	4 (4.5%)	1 (1.1%)	5 (2.8%)
Cystitis (膀胱炎)			
CKD Stage 1	0	0	0
CKD Stage 2	1 (1.1%)	3 (3.3%)	4 (2.2%)
Herpes zoster (帯状疱疹)			
CKD Stage 1	0	0	0
CKD Stage 2	1 (1.1%)	2 (2.2%)	3 (1.7%)
Periodontitis (歯周炎)			
CKD Stage 1	0	1 (6.3%)	1 (3.4%)
CKD Stage 2	1 (1.1%)	1 (1.1%)	2 (1.1%)
Conjunctivitis (結膜炎)			
CKD Stage 1	0	0	0
CKD Stage 2	2 (2.3%)	0	2 (1.1%)
Folliculitis (毛包炎)			
CKD Stage 1	0	0	0
CKD Stage 2	0	2 (2.2%)	2 (1.1%)
Hordeolum (麦粒腫)			
CKD Stage 1	0	0	0
CKD Stage 2	1 (1.1%)	1 (1.1%)	2 (1.1%)

System Organ Class Preferred Term Renal function	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
Pharyngitis (咽頭炎)			
CKD Stage 1	0	0	0
CKD Stage 2	1 (1.1%)	1 (1.1%)	2 (1.1%)
Urinary tract infection (尿路感染)			
CKD Stage 1	0	0	0
CKD Stage 2	0	2 (2.2%)	2 (1.1%)
Asymptomatic bacteriuria (無症候性細菌尿)			
CKD Stage 1	0	0	0
CKD Stage 2	0	1 (1.1%)	1 (0.6%)
Erysipelas (丹毒)			
CKD Stage 1	0	1 (6.3%)	1 (3.4%)
CKD Stage 2	0	0	0
Furuncle (せつ)			
CKD Stage 1	0	1 (6.3%)	1 (3.4%)
CKD Stage 2	0	0	0
Gastroenteritis viral (ウイルス性胃腸炎)			
CKD Stage 1	0	0	0
CKD Stage 2	1 (1.1%)	0	1 (0.6%)
Gingivitis (歯肉炎)			
CKD Stage 1	0	0	0
CKD Stage 2	0	1 (1.1%)	1 (0.6%)
Helicobacter infection (ヘリコバクター感染)			
CKD Stage 1	0	0	0
CKD Stage 2	1 (1.1%)	0	1 (0.6%)
Herpes simplex (単純ヘルペス)			
CKD Stage 1	0	0	0
CKD Stage 2	1 (1.1%)	0	1 (0.6%)
Oral herpes (口腔ヘルペス)			
CKD Stage 1	0	0	0
CKD Stage 2	1 (1.1%)	0	1 (0.6%)
Otitis media acute (急性中耳炎)			
CKD Stage 1	0	0	0
CKD Stage 2	1 (1.1%)	0	1 (0.6%)
Pneumonia mycoplasmal (マイコプラズマ性肺炎)			
CKD Stage 1	0	0	0
CKD Stage 2	1 (1.1%)	0	1 (0.6%)
Rhinitis (鼻炎)			
CKD Stage 1	0	0	0
CKD Stage 2	0	1 (1.1%)	1 (0.6%)

System Organ Class Preferred Term Renal function	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
Sinusitis (副鼻腔炎)			
CKD Stage 1	0	0	0
CKD Stage 2	0	1 (1.1%)	1 (0.6%)
Soft tissue infection (軟部組織感染)			
CKD Stage 1	0	1 (6.3%)	1 (3.4%)
CKD Stage 2	0	0	0
Tinea pedis (足部白癬)			
CKD Stage 1	0	1 (6.3%)	1 (3.4%)
CKD Stage 2	0	0	0
Tonsillitis (扁桃炎)			
CKD Stage 1	0	0	0
CKD Stage 2	0	1 (1.1%)	1 (0.6%)
Upper respiratory tract infection (上気道感染)			
CKD Stage 1	0	0	0
CKD Stage 2	1 (1.1%)	0	1 (0.6%)
Metabolism and nutrition disorders (代謝および栄養障害)			
CKD Stage 1	7 (53.8%)	7 (43.8%)	14 (48.3%)
CKD Stage 2	30 (34.1%)	35 (38.0%)	65 (36.1%)
Hypoglycaemia (低血糖)			
CKD Stage 1	7 (53.8%)	6 (37.5%)	13 (44.8%)
CKD Stage 2	29 (33.0%)	33 (35.9%)	62 (34.4%)
Dyslipidaemia (脂質異常症)			
CKD Stage 1	0	1 (6.3%)	1 (3.4%)
CKD Stage 2	1 (1.1%)	0	1 (0.6%)
Hyperglycaemia (高血糖)			
CKD Stage 1	0	0	0
CKD Stage 2	0	2 (2.2%)	2 (1.1%)
Hyponatraemia (低ナトリウム血症)			
CKD Stage 1	0	0	0
CKD Stage 2	1 (1.1%)	0	1 (0.6%)
Musculoskeletal and connective tissue disorders (筋骨格系および結合組織障害)			
CKD Stage 1	2 (15.4%)	2 (12.5%)	4 (13.8%)
CKD Stage 2	7 (8.0%)	22 (23.9%)	29 (16.1%)
Back pain (背部痛)			
CKD Stage 1	0	0	0
CKD Stage 2	1 (1.1%)	6 (6.5%)	7 (3.9%)
Muscle spasms (筋痙縮)			
CKD Stage 1	1 (7.7%)	0	1 (3.4%)

System Organ Class Preferred Term Renal function	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
CKD Stage 2	0	4 (4.3%)	4 (2.2%)
Arthralgia (関節痛)			
CKD Stage 1	0	2 (12.5%)	2 (6.9%)
CKD Stage 2	1 (1.1%)	1 (1.1%)	2 (1.1%)
Spinal osteoarthritis (変形性脊椎症)			
CKD Stage 1	0	0	0
CKD Stage 2	0	4 (4.3%)	4 (2.2%)
Musculoskeletal stiffness (筋骨格硬直)			
CKD Stage 1	0	0	0
CKD Stage 2	1 (1.1%)	1 (1.1%)	2 (1.1%)
Osteoarthritis (変形性関節症)			
CKD Stage 1	0	0	0
CKD Stage 2	0	2 (2.2%)	2 (1.1%)
Synovial cyst (滑液嚢腫)			
CKD Stage 1	0	0	0
CKD Stage 2	0	2 (2.2%)	2 (1.1%)
Tenosynovitis (腱鞘炎)			
CKD Stage 1	0	0	0
CKD Stage 2	1 (1.1%)	1 (1.1%)	2 (1.1%)
Trigger finger (弾発指)			
CKD Stage 1	0	0	0
CKD Stage 2	1 (1.1%)	1 (1.1%)	2 (1.1%)
Chondrocalcinosis pyrophosphate (ピロリン酸カルシウム結晶性軟骨石灰化症)			
CKD Stage 1	0	0	0
CKD Stage 2	1 (1.1%)	0	1 (0.6%)
Intervertebral disc protrusion (椎間板突出)			
CKD Stage 1	0	0	0
CKD Stage 2	0	1 (1.1%)	1 (0.6%)
Lumbar spinal stenosis (腰部脊柱管狭窄症)			
CKD Stage 1	0	0	0
CKD Stage 2	0	1 (1.1%)	1 (0.6%)
Musculoskeletal pain (筋骨格痛)			
CKD Stage 1	0	0	0
CKD Stage 2	1 (1.1%)	0	1 (0.6%)
Myofascitis (筋筋膜炎)			
CKD Stage 1	0	0	0
CKD Stage 2	0	1 (1.1%)	1 (0.6%)
Neck pain (頚部痛)			
CKD Stage 1	0	0	0
CKD Stage 2	0	1 (1.1%)	1 (0.6%)

System Organ Class Preferred Term Renal function	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
Nodal osteoarthritis (結節性変形性関節症)			
CKD Stage 1	0	0	0
CKD Stage 2	0	1 (1.1%)	1 (0.6%)
Pain in extremity (四肢痛)			
CKD Stage 1	0	0	0
CKD Stage 2	0	1 (1.1%)	1 (0.6%)
Synovitis (滑膜炎)			
CKD Stage 1	0	0	0
CKD Stage 2	0	1 (1.1%)	1 (0.6%)
Temporomandibular joint syndrome (顎関節症候群)			
CKD Stage 1	0	0	0
CKD Stage 2	0	1 (1.1%)	1 (0.6%)
Tendonitis (腱炎)			
CKD Stage 1	1 (7.7%)	0	1 (3.4%)
CKD Stage 2	0	0	0
Gastrointestinal disorders (胃腸障害)			
CKD Stage 1	2 (15.4%)	5 (31.3%)	7 (24.1%)
CKD Stage 2	8 (9.1%)	15 (16.3%)	23 (12.8%)
Constipation (便秘)			
CKD Stage 1	0	1 (6.3%)	1 (3.4%)
CKD Stage 2	0	5 (5.4%)	5 (2.8%)
Gastrooesophageal reflux disease (胃食道逆流性疾患)			
CKD Stage 1	2 (15.4%)	2 (12.5%)	4 (13.8%)
CKD Stage 2	0	1 (1.1%)	1 (0.6%)
Nausea (悪心)			
CKD Stage 1	0	2 (12.5%)	2 (6.9%)
CKD Stage 2	2 (2.3%)	1 (1.1%)	3 (1.7%)
Abdominal discomfort (腹部不快感)			
CKD Stage 1	0	0	0
CKD Stage 2	1 (1.1%)	3 (3.3%)	4 (2.2%)
Diarrhoea (下痢)			
CKD Stage 1	0	1 (6.3%)	1 (3.4%)
CKD Stage 2	2 (2.3%)	1 (1.1%)	3 (1.7%)
Toothache (歯痛)			
CKD Stage 1	0	0	0
CKD Stage 2	2 (2.3%)	1 (1.1%)	3 (1.7%)
Abdominal pain upper (上腹部痛)			
CKD Stage 1	0	0	0
CKD Stage 2	0	2 (2.2%)	2 (1.1%)
Chronic gastritis (慢性胃炎)			

System Organ Class Preferred Term Renal function	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
CKD Stage 1	1 (7.7%)	0	1 (3.4%)
CKD Stage 2	1 (1.1%)	0	1 (0.6%)
Dental caries (齲歯)			
CKD Stage 1	0	1 (6.3%)	1 (3.4%)
CKD Stage 2	1 (1.1%)	0	1 (0.6%)
Gastritis (胃炎)			
CKD Stage 1	0	0	0
CKD Stage 2	1 (1.1%)	1 (1.1%)	2 (1.1%)
Periodontal disease (歯周病)			
CKD Stage 1	0	0	0
CKD Stage 2	0	2 (2.2%)	2 (1.1%)
Vomiting (嘔吐)			
CKD Stage 1	0	1 (6.3%)	1 (3.4%)
CKD Stage 2	1 (1.1%)	0	1 (0.6%)
Abdominal distension (腹部膨満)			
CKD Stage 1	0	0	0
CKD Stage 2	0	1 (1.1%)	1 (0.6%)
Colitis ulcerative (潰瘍性大腸炎)			
CKD Stage 1	0	0	0
CKD Stage 2	0	1 (1.1%)	1 (0.6%)
Large intestine polyp (大腸ポリープ)			
CKD Stage 1	0	0	0
CKD Stage 2	1 (1.1%)	0	1 (0.6%)
Eye disorders (眼障害)			
CKD Stage 1	1 (7.7%)	1 (6.3%)	2 (6.9%)
CKD Stage 2	5 (5.7%)	9 (9.8%)	14 (7.8%)
Cataract (白内障)			
CKD Stage 1	0	0	0
CKD Stage 2	1 (1.1%)	2 (2.2%)	3 (1.7%)
Diabetic retinopathy (糖尿病網膜症)			
CKD Stage 1	0	0	0
CKD Stage 2	2 (2.3%)	1 (1.1%)	3 (1.7%)
Ocular hypertension (高眼圧症)			
CKD Stage 1	0	0	0
CKD Stage 2	0	2 (2.2%)	2 (1.1%)
Vitreous haemorrhage (硝子体出血)			
CKD Stage 1	0	0	0
CKD Stage 2	0	2 (2.2%)	2 (1.1%)
Accommodation disorder (調節障害)			
CKD Stage 1	1 (7.7%)	0	1 (3.4%)
CKD Stage 2	0	0	0
Angle closure glaucoma (閉塞隅角緑内障)			

System Organ Class Preferred Term Renal function	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
CKD Stage 1	0	1 (6.3%)	1 (3.4%)
CKD Stage 2	0	0	0
Conjunctival hyperaemia (結膜充血)			
CKD Stage 1	0	0	0
CKD Stage 2	1 (1.1%)	0	1 (0.6%)
Conjunctivitis allergic (アレルギー性結膜炎)			
CKD Stage 1	0	0	0
CKD Stage 2	0	1 (1.1%)	1 (0.6%)
Diabetic retinal oedema (糖尿病性網膜浮腫)			
CKD Stage 1	0	0	0
CKD Stage 2	0	1 (1.1%)	1 (0.6%)
Dry eye (眼乾燥)			
CKD Stage 1	0	0	0
CKD Stage 2	0	1 (1.1%)	1 (0.6%)
Glaucoma (緑内障)			
CKD Stage 1	0	0	0
CKD Stage 2	1 (1.1%)	0	1 (0.6%)
Macular oedema (黄斑浮腫)			
CKD Stage 1	0	0	0
CKD Stage 2	1 (1.1%)	0	1 (0.6%)
Pingueculitis (瞼裂斑炎)			
CKD Stage 1	1 (7.7%)	0	1 (3.4%)
CKD Stage 2	0	0	0
Retinal detachment (網膜剥離)			
CKD Stage 1	0	0	0
CKD Stage 2	0	1 (1.1%)	1 (0.6%)
Retinal haemorrhage (網膜出血)			
CKD Stage 1	0	0	0
CKD Stage 2	0	1 (1.1%)	1 (0.6%)
Trichiasis (睫毛乱生)			
CKD Stage 1	0	0	0
CKD Stage 2	0	1 (1.1%)	1 (0.6%)
Nervous system disorders (神経系障害)			
CKD Stage 1	0	2 (12.5%)	2 (6.9%)
CKD Stage 2	6 (6.8%)	6 (6.5%)	12 (6.7%)
Headache (頭痛)			
CKD Stage 1	0	0	0
CKD Stage 2	3 (3.4%)	3 (3.3%)	6 (3.3%)
Dizziness (浮動性めまい)			
CKD Stage 1	0	0	0
CKD Stage 2	1 (1.1%)	1 (1.1%)	2 (1.1%)

System Organ Class Preferred Term Renal function	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
Autonomic nervous system imbalance (自律神経失調)			
CKD Stage 1	0	0	0
CKD Stage 2	1 (1.1%)	0	1 (0.6%)
Carpal tunnel syndrome (手根管症候群)			
CKD Stage 1	0	0	0
CKD Stage 2	1 (1.1%)	0	1 (0.6%)
Epilepsy (てんかん)			
CKD Stage 1	0	0	0
CKD Stage 2	0	1 (1.1%)	1 (0.6%)
Facial paralysis (顔面麻痺)			
CKD Stage 1	0	1 (6.3%)	1 (3.4%)
CKD Stage 2	0	0	0
Sciatica (坐骨神経痛)			
CKD Stage 1	0	1 (6.3%)	1 (3.4%)
CKD Stage 2	0	0	0
Somnolence (傾眠)			
CKD Stage 1	0	0	0
CKD Stage 2	0	1 (1.1%)	1 (0.6%)
Syncope (失神)			
CKD Stage 1	0	0	0
CKD Stage 2	1 (1.1%)	0	1 (0.6%)
Skin and subcutaneous tissue disorders (皮膚および皮下組織障害)			
CKD Stage 1	1 (7.7%)	1 (6.3%)	2 (6.9%)
CKD Stage 2	1 (1.1%)	10 (10.9%)	11 (6.1%)
Dermatitis (皮膚炎)			
CKD Stage 1	0	0	0
CKD Stage 2	1 (1.1%)	2 (2.2%)	3 (1.7%)
Eczema (湿疹)			
CKD Stage 1	0	0	0
CKD Stage 2	0	2 (2.2%)	2 (1.1%)
Urticaria (蕁麻疹)			
CKD Stage 1	0	0	0
CKD Stage 2	0	2 (2.2%)	2 (1.1%)
Acne (ざ瘡)			
CKD Stage 1	0	0	0
CKD Stage 2	0	1 (1.1%)	1 (0.6%)
Cold sweat (冷汗)			
CKD Stage 1	0	1 (6.3%)	1 (3.4%)
CKD Stage 2	0	0	0
Drug eruption (薬疹)			

System Organ Class Preferred Term Renal function	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
CKD Stage 1	0	0	0
CKD Stage 2	0	1 (1.1%)	1 (0.6%)
Hand dermatitis (手皮膚炎)			
CKD Stage 1	1 (7.7%)	0	1 (3.4%)
CKD Stage 2	0	0	0
Hyperkeratosis (過角化)			
CKD Stage 1	0	0	0
CKD Stage 2	0	1 (1.1%)	1 (0.6%)
Miliaria (汗疹)			
CKD Stage 1	0	0	0
CKD Stage 2	0	1 (1.1%)	1 (0.6%)
Pruritus (そう痒症)			
CKD Stage 1	0	0	0
CKD Stage 2	0	1 (1.1%)	1 (0.6%)
Respiratory, thoracic and mediastinal disorders (呼吸器、胸郭および縦隔障害)			
CKD Stage 1	0	1 (6.3%)	1 (3.4%)
CKD Stage 2	7 (8.0%)	3 (3.3%)	10 (5.6%)
Upper respiratory tract inflammation (上気道の炎症)			
CKD Stage 1	0	0	0
CKD Stage 2	3 (3.4%)	1 (1.1%)	4 (2.2%)
Asthma (喘息)			
CKD Stage 1	0	0	0
CKD Stage 2	1 (1.1%)	1 (1.1%)	2 (1.1%)
Cough (咳嗽)			
CKD Stage 1	0	1 (6.3%)	1 (3.4%)
CKD Stage 2	1 (1.1%)	0	1 (0.6%)
Sputum increased (喀痰増加)			
CKD Stage 1	0	0	0
CKD Stage 2	2 (2.3%)	0	2 (1.1%)
Pulmonary embolism (肺塞栓症)			
CKD Stage 1	0	0	0
CKD Stage 2	0	1 (1.1%)	1 (0.6%)
Rhinitis allergic (アレルギー性鼻炎)			
CKD Stage 1	0	0	0
CKD Stage 2	1 (1.1%)	0	1 (0.6%)
Injury, poisoning and procedural complications (傷害、中毒および処置合併症)			
CKD Stage 1	0	0	0
CKD Stage 2	2 (2.3%)	8 (8.7%)	10 (5.6%)
Contusion (挫傷)			

System Organ Class Preferred Term Renal function	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
CKD Stage 1	0	0	0
CKD Stage 2	0	3 (3.3%)	3 (1.7%)
Stress fracture (ストレス骨折)			
CKD Stage 1	0	0	0
CKD Stage 2	0	2 (2.2%)	2 (1.1%)
Clavicle fracture (鎖骨骨折)			
CKD Stage 1	0	0	0
CKD Stage 2	1 (1.1%)	0	1 (0.6%)
Hand fracture (手骨折)			
CKD Stage 1	0	0	0
CKD Stage 2	0	1 (1.1%)	1 (0.6%)
Heat illness (熱中症)			
CKD Stage 1	0	0	0
CKD Stage 2	0	1 (1.1%)	1 (0.6%)
Ligament sprain (靱帯捻挫)			
CKD Stage 1	0	0	0
CKD Stage 2	0	1 (1.1%)	1 (0.6%)
Muscle strain (肉離れ)			
CKD Stage 1	0	0	0
CKD Stage 2	0	1 (1.1%)	1 (0.6%)
Scratch (引っかき傷)			
CKD Stage 1	0	0	0
CKD Stage 2	1 (1.1%)	0	1 (0.6%)
Vascular disorders (血管障害)			
CKD Stage 1	1 (7.7%)	2 (12.5%)	3 (10.3%)
CKD Stage 2	1 (1.1%)	5 (5.4%)	6 (3.3%)
Hypertension (高血圧)			
CKD Stage 1	1 (7.7%)	2 (12.5%)	3 (10.3%)
CKD Stage 2	1 (1.1%)	3 (3.3%)	4 (2.2%)
Peripheral arterial occlusive disease (末梢動脈閉塞性疾患)			
CKD Stage 1	0	0	0
CKD Stage 2	0	1 (1.1%)	1 (0.6%)
Venous thrombosis limb (四肢静脈血栓症)			
CKD Stage 1	0	0	0
CKD Stage 2	0	1 (1.1%)	1 (0.6%)
Investigations (臨床検査)			
CKD Stage 1	1 (7.7%)	1 (6.3%)	2 (6.9%)
CKD Stage 2	0	5 (5.4%)	5 (2.8%)
Blood creatine phosphokinase increased (血中クレアチンホスホキナーゼ増加)			

System Organ Class Preferred Term Renal function	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
CKD Stage 1	1 (7.7%)	0	1 (3.4%)
CKD Stage 2	0	2 (2.2%)	2 (1.1%)
Aspartate aminotransferase increased (アスパラギン酸アミノトランスフェラーゼ増加)			
CKD Stage 1	0	1 (6.3%)	1 (3.4%)
CKD Stage 2	0	0	0
Blood alkaline phosphatase increased (血中アルカリホスファターゼ増加)			
CKD Stage 1	0	0	0
CKD Stage 2	0	1 (1.1%)	1 (0.6%)
Blood glucose abnormal (血中ブドウ糖異常)			
CKD Stage 1	0	0	0
CKD Stage 2	0	1 (1.1%)	1 (0.6%)
Blood lactic acid increased (血中乳酸増加)			
CKD Stage 1	0	0	0
CKD Stage 2	0	1 (1.1%)	1 (0.6%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）)			
CKD Stage 1	0	1 (6.3%)	1 (3.4%)
CKD Stage 2	4 (4.5%)	2 (2.2%)	6 (3.3%)
Papillary thyroid cancer (乳頭様甲状腺癌)			
CKD Stage 1	0	0	0
CKD Stage 2	2 (2.3%)	0	2 (1.1%)
Benign neoplasm of thyroid gland (甲状腺の良性新生物)			
CKD Stage 1	0	0	0
CKD Stage 2	0	1 (1.1%)	1 (0.6%)
Intraductal papillary mucinous neoplasm (膵管内乳頭粘液性腫瘍)			
CKD Stage 1	0	0	0
CKD Stage 2	1 (1.1%)	0	1 (0.6%)
Lipoma (脂肪腫)			
CKD Stage 1	0	0	0
CKD Stage 2	0	1 (1.1%)	1 (0.6%)
Pancreatic carcinoma (膵癌)			
CKD Stage 1	0	0	0
CKD Stage 2	1 (1.1%)	0	1 (0.6%)
Uterine leiomyoma (子宮平滑筋腫)			

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CKD Stage 1	0	1 (6.3%)	1 (3.4%)
CKD Stage 2	0	0	0
General disorders and administration site conditions (一般・全身障害および投与部位の状態)			
CKD Stage 1	0	1 (6.3%)	1 (3.4%)
CKD Stage 2	3 (3.4%)	2 (2.2%)	5 (2.8%)
Pyrexia (発熱)			
CKD Stage 1	0	0	0
CKD Stage 2	2 (2.3%)	2 (2.2%)	4 (2.2%)
Oedema peripheral (末梢性浮腫)			
CKD Stage 1	0	1 (6.3%)	1 (3.4%)
CKD Stage 2	0	0	0
Sudden death (突然死)			
CKD Stage 1	0	0	0
CKD Stage 2	1 (1.1%)	0	1 (0.6%)
Hepatobiliary disorders (肝胆道系障害)			
CKD Stage 1	0	1 (6.3%)	1 (3.4%)
CKD Stage 2	3 (3.4%)	1 (1.1%)	4 (2.2%)
Hepatic steatosis (脂肪肝)			
CKD Stage 1	0	1 (6.3%)	1 (3.4%)
CKD Stage 2	1 (1.1%)	0	1 (0.6%)
Gallbladder polyp (胆嚢ポリープ)			
CKD Stage 1	0	0	0
CKD Stage 2	0	1 (1.1%)	1 (0.6%)
Hepatic function abnormal (肝機能異常)			
CKD Stage 1	0	0	0
CKD Stage 2	1 (1.1%)	0	1 (0.6%)
Hyperplastic cholecystopathy (過形成性胆嚢症)			
CKD Stage 1	0	0	0
CKD Stage 2	1 (1.1%)	0	1 (0.6%)
Immune system disorders (免疫系障害)			
CKD Stage 1	0	0	0
CKD Stage 2	1 (1.1%)	4 (4.3%)	5 (2.8%)
Seasonal allergy (季節性アレルギー)			
CKD Stage 1	0	0	0
CKD Stage 2	1 (1.1%)	4 (4.3%)	5 (2.8%)

System Organ Class Preferred Term Renal function	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
Ear and labyrinth disorders (耳および迷路障害)			
CKD Stage 1	1 (7.7%)	1 (6.3%)	2 (6.9%)
CKD Stage 2	0	2 (2.2%)	2 (1.1%)
Meniere's disease (メニエール病)			
CKD Stage 1	1 (7.7%)	0	1 (3.4%)
CKD Stage 2	0	0	0
Tinnitus (耳鳴)			
CKD Stage 1	0	0	0
CKD Stage 2	0	1 (1.1%)	1 (0.6%)
Vertigo (回転性めまい)			
CKD Stage 1	0	0	0
CKD Stage 2	0	1 (1.1%)	1 (0.6%)
Vertigo positional (頭位性回転性めまい)			
CKD Stage 1	0	1 (6.3%)	1 (3.4%)
CKD Stage 2	0	0	0
Cardiac disorders (心臓障害)			
CKD Stage 1	0	0	0
CKD Stage 2	2 (2.3%)	1 (1.1%)	3 (1.7%)
Atrial fibrillation (心房細動)			
CKD Stage 1	0	0	0
CKD Stage 2	1 (1.1%)	0	1 (0.6%)
Cardiac failure congestive (うっ血性心不全)			
CKD Stage 1	0	0	0
CKD Stage 2	1 (1.1%)	0	1 (0.6%)
Coronary artery stenosis (冠動脈狭窄)			
CKD Stage 1	0	0	0
CKD Stage 2	0	1 (1.1%)	1 (0.6%)
Extrasystoles (期外収縮)			
CKD Stage 1	0	0	0
CKD Stage 2	1 (1.1%)	0	1 (0.6%)
Reproductive system and breast disorders (生殖系および乳房障害)			
CKD Stage 1	0	0	0
CKD Stage 2	2 (2.3%)	1 (1.1%)	3 (1.7%)
Benign prostatic hyperplasia (良性前立腺肥大症)			
CKD Stage 1	0	0	0
CKD Stage 2	1 (1.1%)	1 (1.1%)	2 (1.1%)
Prostatomegaly (前立腺腫大)			

System Organ Class Preferred Term Renal function	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
CKD Stage 1	0	0	0
CKD Stage 2	1 (1.1%)	0	1 (0.6%)
Psychiatric disorders (精神障害)			
CKD Stage 1	0	0	0
CKD Stage 2	1 (1.1%)	1 (1.1%)	2 (1.1%)
Depressive symptom (抑うつ症状)			
CKD Stage 1	0	0	0
CKD Stage 2	1 (1.1%)	0	1 (0.6%)
Insomnia (不眠症)			
CKD Stage 1	0	0	0
CKD Stage 2	0	1 (1.1%)	1 (0.6%)
Renal and urinary disorders (腎および尿路障害)			
CKD Stage 1	0	0	0
CKD Stage 2	1 (1.1%)	1 (1.1%)	2 (1.1%)
Haematuria (血尿)			
CKD Stage 1	0	0	0
CKD Stage 2	0	1 (1.1%)	1 (0.6%)
Renal cyst (腎嚢胞)			
CKD Stage 1	0	0	0
CKD Stage 2	1 (1.1%)	0	1 (0.6%)
Blood and lymphatic system disorders (血液およびリンパ系障害)			
CKD Stage 1	0	0	0
CKD Stage 2	1 (1.1%)	0	1 (0.6%)
Iron deficiency anaemia (鉄欠乏性貧血)			
CKD Stage 1	0	0	0
CKD Stage 2	1 (1.1%)	0	1 (0.6%)

- Abbreviations: 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.
- "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.
- All adverse events were coded using MedDRA dictionary version 20.1.
- Percentages are based on "Number of patients".

Control No:<<t-s-176-subae-020lt.sas, 2020-03-06T00:12:49>>

Table S-177 Subgroup Analysis of Treatment Emergent Adverse Events by Hepatic Parameter Abnormality, System Organ Class and Preferred Term in 52-Week Long-term Period in Combination with Insulin Therapy (PXL008-020; Long-term Safety Population)

System Organ Class Preferred Term Hepatic parameter abnormality	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
Number of patients			
Yes	14	17	31
No	87	91	178
Any TEAE			
Yes	12 (85.7%)	14 (82.4%)	26 (83.9%)
No	65 (74.7%)	78 (85.7%)	143 (80.3%)
Infections and infestations (感染症および寄生虫症)			
Yes	3 (21.4%)	11 (64.7%)	14 (45.2%)
No	27 (31.0%)	41 (45.1%)	68 (38.2%)
Nasopharyngitis (上咽頭炎)			
Yes	2 (14.3%)	7 (41.2%)	9 (29.0%)
No	14 (16.1%)	29 (31.9%)	43 (24.2%)
Bronchitis (気管支炎)			
Yes	0	1 (5.9%)	1 (3.2%)
No	5 (5.7%)	3 (3.3%)	8 (4.5%)
Influenza (インフルエンザ)			
Yes	1 (7.1%)	1 (5.9%)	2 (6.5%)
No	3 (3.4%)	4 (4.4%)	7 (3.9%)
Gastroenteritis (胃腸炎)			
Yes	1 (7.1%)	0	1 (3.2%)
No	3 (3.4%)	1 (1.1%)	4 (2.2%)
Cystitis (膀胱炎)			
Yes	1 (7.1%)	1 (5.9%)	2 (6.5%)
No	0	2 (2.2%)	2 (1.1%)
Herpes zoster (帯状疱疹)			
Yes	0	0	0
No	1 (1.1%)	2 (2.2%)	3 (1.7%)
Periodontitis (歯周炎)			
Yes	0	0	0
No	1 (1.1%)	2 (2.2%)	3 (1.7%)
Conjunctivitis (結膜炎)			
Yes	0	0	0
No	2 (2.3%)	0	2 (1.1%)
Folliculitis (毛包炎)			
Yes	0	1 (5.9%)	1 (3.2%)
No	0	1 (1.1%)	1 (0.6%)
Hordeolum (麦粒腫)			
Yes	0	0	0
No	1 (1.1%)	1 (1.1%)	2 (1.1%)

System Organ Class Preferred Term Hepatic parameter abnormality	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
Pharyngitis (咽頭炎)			
Yes	0	1 (5.9%)	1 (3.2%)
No	1 (1.1%)	0	1 (0.6%)
Urinary tract infection (尿路感染)			
Yes	0	0	0
No	0	2 (2.2%)	2 (1.1%)
Asymptomatic bacteriuria (無症候性細菌尿)			
Yes	0	0	0
No	0	1 (1.1%)	1 (0.6%)
Erysipelas (丹毒)			
Yes	0	0	0
No	0	1 (1.1%)	1 (0.6%)
Furuncle (せつ)			
Yes	0	1 (5.9%)	1 (3.2%)
No	0	0	0
Gastroenteritis viral (ウイルス性胃腸炎)			
Yes	0	0	0
No	1 (1.1%)	0	1 (0.6%)
Gingivitis (歯肉炎)			
Yes	0	1 (5.9%)	1 (3.2%)
No	0	0	0
Helicobacter infection (ヘリコバクター感染)			
Yes	0	0	0
No	1 (1.1%)	0	1 (0.6%)
Herpes simplex (単純ヘルペス)			
Yes	0	0	0
No	1 (1.1%)	0	1 (0.6%)
Oral herpes (口腔ヘルペス)			
Yes	0	0	0
No	1 (1.1%)	0	1 (0.6%)
Otitis media acute (急性中耳炎)			
Yes	0	0	0
No	1 (1.1%)	0	1 (0.6%)
Pneumonia mycoplasmal (マイコプラズマ性肺炎)			
Yes	0	0	0
No	1 (1.1%)	0	1 (0.6%)
Rhinitis (鼻炎)			
Yes	0	1 (5.9%)	1 (3.2%)
No	0	0	0

System Organ Class Preferred Term Hepatic parameter abnormality	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
Sinusitis (副鼻腔炎)			
Yes	0	0	0
No	0	1 (1.1%)	1 (0.6%)
Soft tissue infection (軟部組織感染)			
Yes	0	0	0
No	0	1 (1.1%)	1 (0.6%)
Tinea pedis (足部白癬)			
Yes	0	0	0
No	0	1 (1.1%)	1 (0.6%)
Tonsillitis (扁桃炎)			
Yes	0	0	0
No	0	1 (1.1%)	1 (0.6%)
Upper respiratory tract infection (上気道感染)			
Yes	1 (7.1%)	0	1 (3.2%)
No	0	0	0
Metabolism and nutrition disorders (代謝および栄養障害)			
Yes	7 (50.0%)	6 (35.3%)	13 (41.9%)
No	30 (34.5%)	36 (39.6%)	66 (37.1%)
Hypoglycaemia (低血糖)			
Yes	7 (50.0%)	5 (29.4%)	12 (38.7%)
No	29 (33.3%)	34 (37.4%)	63 (35.4%)
Dyslipidaemia (脂質異常症)			
Yes	0	0	0
No	1 (1.1%)	1 (1.1%)	2 (1.1%)
Hyperglycaemia (高血糖)			
Yes	0	1 (5.9%)	1 (3.2%)
No	0	1 (1.1%)	1 (0.6%)
Hyponatraemia (低ナトリウム血症)			
Yes	0	0	0
No	1 (1.1%)	0	1 (0.6%)
Musculoskeletal and connective tissue disorders (筋骨格系および結合組織障害)			
Yes	1 (7.1%)	6 (35.3%)	7 (22.6%)
No	8 (9.2%)	18 (19.8%)	26 (14.6%)
Back pain (背部痛)			
Yes	0	1 (5.9%)	1 (3.2%)
No	1 (1.1%)	5 (5.5%)	6 (3.4%)
Muscle spasms (筋痙縮)			
Yes	0	2 (11.8%)	2 (6.5%)

System Organ Class Preferred Term Hepatic parameter abnormality	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
No	1 (1.1%)	2 (2.2%)	3 (1.7%)
Arthralgia (関節痛)			
Yes	0	1 (5.9%)	1 (3.2%)
No	1 (1.1%)	2 (2.2%)	3 (1.7%)
Spinal osteoarthritis (変形性脊椎症)			
Yes	0	0	0
No	0	4 (4.4%)	4 (2.2%)
Musculoskeletal stiffness (筋骨格硬直)			
Yes	0	0	0
No	1 (1.1%)	1 (1.1%)	2 (1.1%)
Osteoarthritis (変形性関節症)			
Yes	0	1 (5.9%)	1 (3.2%)
No	0	1 (1.1%)	1 (0.6%)
Synovial cyst (滑液嚢腫)			
Yes	0	1 (5.9%)	1 (3.2%)
No	0	1 (1.1%)	1 (0.6%)
Tenosynovitis (腱鞘炎)			
Yes	0	0	0
No	1 (1.1%)	1 (1.1%)	2 (1.1%)
Trigger finger (弾発指)			
Yes	1 (7.1%)	0	1 (3.2%)
No	0	1 (1.1%)	1 (0.6%)
Chondrocalcinosis pyrophosphate (ピロリン酸カルシウム結晶性軟骨石灰化症)			
Yes	0	0	0
No	1 (1.1%)	0	1 (0.6%)
Intervertebral disc protrusion (椎間板突出)			
Yes	0	0	0
No	0	1 (1.1%)	1 (0.6%)
Lumbar spinal stenosis (腰部脊柱管狭窄症)			
Yes	0	0	0
No	0	1 (1.1%)	1 (0.6%)
Musculoskeletal pain (筋骨格痛)			
Yes	0	0	0
No	1 (1.1%)	0	1 (0.6%)
Myofascitis (筋筋膜炎)			
Yes	0	0	0
No	0	1 (1.1%)	1 (0.6%)
Neck pain (頚部痛)			
Yes	0	1 (5.9%)	1 (3.2%)
No	0	0	0

System Organ Class Preferred Term Hepatic parameter abnormality	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
Nodal osteoarthritis (結節性変形性関節症)			
Yes	0	0	0
No	0	1 (1.1%)	1 (0.6%)
Pain in extremity (四肢痛)			
Yes	0	0	0
No	0	1 (1.1%)	1 (0.6%)
Synovitis (滑膜炎)			
Yes	0	0	0
No	0	1 (1.1%)	1 (0.6%)
Temporomandibular joint syndrome (顎関節症候群)			
Yes	0	0	0
No	0	1 (1.1%)	1 (0.6%)
Tendonitis (腱炎)			
Yes	0	0	0
No	1 (1.1%)	0	1 (0.6%)
Gastrointestinal disorders (胃腸障害)			
Yes	0	2 (11.8%)	2 (6.5%)
No	10 (11.5%)	18 (19.8%)	28 (15.7%)
Constipation (便秘)			
Yes	0	1 (5.9%)	1 (3.2%)
No	0	5 (5.5%)	5 (2.8%)
Gastrooesophageal reflux disease (胃食道逆流性疾患)			
Yes	0	0	0
No	2 (2.3%)	3 (3.3%)	5 (2.8%)
Nausea (悪心)			
Yes	0	1 (5.9%)	1 (3.2%)
No	2 (2.3%)	2 (2.2%)	4 (2.2%)
Abdominal discomfort (腹部不快感)			
Yes	0	0	0
No	1 (1.1%)	3 (3.3%)	4 (2.2%)
Diarrhoea (下痢)			
Yes	0	0	0
No	2 (2.3%)	2 (2.2%)	4 (2.2%)
Toothache (歯痛)			
Yes	0	0	0
No	2 (2.3%)	1 (1.1%)	3 (1.7%)
Abdominal pain upper (上腹部痛)			
Yes	0	0	0
No	0	2 (2.2%)	2 (1.1%)
Chronic gastritis (慢性胃炎)			

System Organ Class Preferred Term Hepatic parameter abnormality	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
Yes	0	0	0
No	2 (2.3%)	0	2 (1.1%)
Dental caries (齲歯)			
Yes	0	0	0
No	1 (1.1%)	1 (1.1%)	2 (1.1%)
Gastritis (胃炎)			
Yes	0	0	0
No	1 (1.1%)	1 (1.1%)	2 (1.1%)
Periodontal disease (歯周病)			
Yes	0	0	0
No	0	2 (2.2%)	2 (1.1%)
Vomiting (嘔吐)			
Yes	0	0	0
No	1 (1.1%)	1 (1.1%)	2 (1.1%)
Abdominal distension (腹部膨満)			
Yes	0	0	0
No	0	1 (1.1%)	1 (0.6%)
Colitis ulcerative (潰瘍性大腸炎)			
Yes	0	0	0
No	0	1 (1.1%)	1 (0.6%)
Large intestine polyp (大腸ポリープ)			
Yes	0	0	0
No	1 (1.1%)	0	1 (0.6%)
Eye disorders (眼障害)			
Yes	1 (7.1%)	0	1 (3.2%)
No	5 (5.7%)	10 (11.0%)	15 (8.4%)
Cataract (白内障)			
Yes	0	0	0
No	1 (1.1%)	2 (2.2%)	3 (1.7%)
Diabetic retinopathy (糖尿病網膜症)			
Yes	0	0	0
No	2 (2.3%)	1 (1.1%)	3 (1.7%)
Ocular hypertension (高眼圧症)			
Yes	0	0	0
No	0	2 (2.2%)	2 (1.1%)
Vitreous haemorrhage (硝子体出血)			
Yes	0	0	0
No	0	2 (2.2%)	2 (1.1%)
Accommodation disorder (調節障害)			
Yes	0	0	0
No	1 (1.1%)	0	1 (0.6%)
Angle closure glaucoma (閉塞隅角緑内障)			

System Organ Class Preferred Term Hepatic parameter abnormality	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
Yes	0	0	0
No	0	1 (1.1%)	1 (0.6%)
Conjunctival hyperaemia (結膜充血)			
Yes	0	0	0
No	1 (1.1%)	0	1 (0.6%)
Conjunctivitis allergic (アレルギー性結膜炎)			
Yes	0	0	0
No	0	1 (1.1%)	1 (0.6%)
Diabetic retinal oedema (糖尿病性網膜浮腫)			
Yes	0	0	0
No	0	1 (1.1%)	1 (0.6%)
Dry eye (眼乾燥)			
Yes	0	0	0
No	0	1 (1.1%)	1 (0.6%)
Glaucoma (緑内障)			
Yes	0	0	0
No	1 (1.1%)	0	1 (0.6%)
Macular oedema (黄斑浮腫)			
Yes	1 (7.1%)	0	1 (3.2%)
No	0	0	0
Pingueculitis (瞼裂斑炎)			
Yes	0	0	0
No	1 (1.1%)	0	1 (0.6%)
Retinal detachment (網膜剥離)			
Yes	0	0	0
No	0	1 (1.1%)	1 (0.6%)
Retinal haemorrhage (網膜出血)			
Yes	0	0	0
No	0	1 (1.1%)	1 (0.6%)
Trichiasis (睫毛乱生)			
Yes	0	0	0
No	0	1 (1.1%)	1 (0.6%)
Nervous system disorders (神経系障害)			
Yes	0	2 (11.8%)	2 (6.5%)
No	6 (6.9%)	6 (6.6%)	12 (6.7%)
Headache (頭痛)			
Yes	0	1 (5.9%)	1 (3.2%)
No	3 (3.4%)	2 (2.2%)	5 (2.8%)
Dizziness (浮動性めまい)			
Yes	0	0	0
No	1 (1.1%)	1 (1.1%)	2 (1.1%)

System Organ Class Preferred Term Hepatic parameter abnormality	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
Autonomic nervous system imbalance (自律神経失調)			
Yes	0	0	0
No	1 (1.1%)	0	1 (0.6%)
Carpal tunnel syndrome (手根管症候群)			
Yes	0	0	0
No	1 (1.1%)	0	1 (0.6%)
Epilepsy (てんかん)			
Yes	0	1 (5.9%)	1 (3.2%)
No	0	0	0
Facial paralysis (顔面麻痺)			
Yes	0	0	0
No	0	1 (1.1%)	1 (0.6%)
Sciatica (坐骨神経痛)			
Yes	0	0	0
No	0	1 (1.1%)	1 (0.6%)
Somnolence (傾眠)			
Yes	0	0	0
No	0	1 (1.1%)	1 (0.6%)
Syncope (失神)			
Yes	0	0	0
No	1 (1.1%)	0	1 (0.6%)
Skin and subcutaneous tissue disorders (皮膚および皮下組織障害)			
Yes	0	3 (17.6%)	3 (9.7%)
No	2 (2.3%)	8 (8.8%)	10 (5.6%)
Dermatitis (皮膚炎)			
Yes	0	0	0
No	1 (1.1%)	2 (2.2%)	3 (1.7%)
Eczema (湿疹)			
Yes	0	1 (5.9%)	1 (3.2%)
No	0	1 (1.1%)	1 (0.6%)
Urticaria (蕁麻疹)			
Yes	0	0	0
No	0	2 (2.2%)	2 (1.1%)
Acne (ざ瘡)			
Yes	0	0	0
No	0	1 (1.1%)	1 (0.6%)
Cold sweat (冷汗)			
Yes	0	1 (5.9%)	1 (3.2%)
No	0	0	0
Drug eruption (薬疹)			

System Organ Class Preferred Term Hepatic parameter abnormality	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
Yes	0	0	0
No	0	1 (1.1%)	1 (0.6%)
Hand dermatitis (手皮膚炎)			
Yes	0	0	0
No	1 (1.1%)	0	1 (0.6%)
Hyperkeratosis (過角化)			
Yes	0	0	0
No	0	1 (1.1%)	1 (0.6%)
Miliaria (汗疹)			
Yes	0	1 (5.9%)	1 (3.2%)
No	0	0	0
Pruritus (そう痒症)			
Yes	0	0	0
No	0	1 (1.1%)	1 (0.6%)
Respiratory, thoracic and mediastinal disorders (呼吸器、胸郭および縦隔障害)			
Yes	0	2 (11.8%)	2 (6.5%)
No	7 (8.0%)	2 (2.2%)	9 (5.1%)
Upper respiratory tract inflammation (上気道の炎症)			
Yes	0	1 (5.9%)	1 (3.2%)
No	3 (3.4%)	0	3 (1.7%)
Asthma (喘息)			
Yes	0	0	0
No	1 (1.1%)	1 (1.1%)	2 (1.1%)
Cough (咳嗽)			
Yes	0	1 (5.9%)	1 (3.2%)
No	1 (1.1%)	0	1 (0.6%)
Sputum increased (喀痰増加)			
Yes	0	0	0
No	2 (2.3%)	0	2 (1.1%)
Pulmonary embolism (肺塞栓症)			
Yes	0	0	0
No	0	1 (1.1%)	1 (0.6%)
Rhinitis allergic (アレルギー性鼻炎)			
Yes	0	0	0
No	1 (1.1%)	0	1 (0.6%)
Injury, poisoning and procedural complications (傷害、中毒および処置合併症)			
Yes	0	1 (5.9%)	1 (3.2%)
No	2 (2.3%)	7 (7.7%)	9 (5.1%)
Contusion (挫傷)			

System Organ Class Preferred Term Hepatic parameter abnormality	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
Yes	0	1 (5.9%)	1 (3.2%)
No	0	2 (2.2%)	2 (1.1%)
Stress fracture (ストレス骨折)			
Yes	0	0	0
No	0	2 (2.2%)	2 (1.1%)
Clavicle fracture (鎖骨骨折)			
Yes	0	0	0
No	1 (1.1%)	0	1 (0.6%)
Hand fracture (手骨折)			
Yes	0	0	0
No	0	1 (1.1%)	1 (0.6%)
Heat illness (熱中症)			
Yes	0	0	0
No	0	1 (1.1%)	1 (0.6%)
Ligament sprain (靱帯捻挫)			
Yes	0	0	0
No	0	1 (1.1%)	1 (0.6%)
Muscle strain (肉離れ)			
Yes	0	0	0
No	0	1 (1.1%)	1 (0.6%)
Scratch (引っかき傷)			
Yes	0	0	0
No	1 (1.1%)	0	1 (0.6%)
Vascular disorders (血管障害)			
Yes	0	0	0
No	2 (2.3%)	7 (7.7%)	9 (5.1%)
Hypertension (高血圧)			
Yes	0	0	0
No	2 (2.3%)	5 (5.5%)	7 (3.9%)
Peripheral arterial occlusive disease (末梢動脈閉塞性疾患)			
Yes	0	0	0
No	0	1 (1.1%)	1 (0.6%)
Venous thrombosis limb (四肢静脈血栓症)			
Yes	0	0	0
No	0	1 (1.1%)	1 (0.6%)
Investigations (臨床検査)			
Yes	0	2 (11.8%)	2 (6.5%)
No	1 (1.1%)	4 (4.4%)	5 (2.8%)
Blood creatine phosphokinase increased (血中クレアチンホスホキナーゼ増加)			

System Organ Class Preferred Term Hepatic parameter abnormality	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
Yes	0	0	0
No	1 (1.1%)	2 (2.2%)	3 (1.7%)
Aspartate aminotransferase increased (アスパラギン酸アミノトランスフェラーゼ増加)			
Yes	0	1 (5.9%)	1 (3.2%)
No	0	0	0
Blood alkaline phosphatase increased (血中アルカリホスファターゼ増加)			
Yes	0	0	0
No	0	1 (1.1%)	1 (0.6%)
Blood glucose abnormal (血中ブドウ糖異常)			
Yes	0	0	0
No	0	1 (1.1%)	1 (0.6%)
Blood lactic acid increased (血中乳酸増加)			
Yes	0	1 (5.9%)	1 (3.2%)
No	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）)			
Yes	1 (7.1%)	1 (5.9%)	2 (6.5%)
No	3 (3.4%)	2 (2.2%)	5 (2.8%)
Papillary thyroid cancer (乳頭様甲状腺癌)			
Yes	0	0	0
No	2 (2.3%)	0	2 (1.1%)
Benign neoplasm of thyroid gland (甲状腺の良性新生物)			
Yes	0	0	0
No	0	1 (1.1%)	1 (0.6%)
Intraductal papillary mucinous neoplasm (膵管内乳頭粘液性腫瘍)			
Yes	0	0	0
No	1 (1.1%)	0	1 (0.6%)
Lipoma (脂肪腫)			
Yes	0	1 (5.9%)	1 (3.2%)
No	0	0	0
Pancreatic carcinoma (膵癌)			
Yes	1 (7.1%)	0	1 (3.2%)
No	0	0	0
Uterine leiomyoma (子宮平滑筋腫)			

System Organ Class Preferred Term Hepatic parameter abnormality	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
Yes	0	0	0
No	0	1 (1.1%)	1 (0.6%)
General disorders and administration site conditions (一般・全身障害および投与部位の状態)			
Yes	0	1 (5.9%)	1 (3.2%)
No	3 (3.4%)	2 (2.2%)	5 (2.8%)
Pyrexia (発熱)			
Yes	0	1 (5.9%)	1 (3.2%)
No	2 (2.3%)	1 (1.1%)	3 (1.7%)
Oedema peripheral (末梢性浮腫)			
Yes	0	0	0
No	0	1 (1.1%)	1 (0.6%)
Sudden death (突然死)			
Yes	0	0	0
No	1 (1.1%)	0	1 (0.6%)
Hepatobiliary disorders (肝胆道系障害)			
Yes	0	0	0
No	3 (3.4%)	2 (2.2%)	5 (2.8%)
Hepatic steatosis (脂肪肝)			
Yes	0	0	0
No	1 (1.1%)	1 (1.1%)	2 (1.1%)
Gallbladder polyp (胆嚢ポリープ)			
Yes	0	0	0
No	0	1 (1.1%)	1 (0.6%)
Hepatic function abnormal (肝機能異常)			
Yes	0	0	0
No	1 (1.1%)	0	1 (0.6%)
Hyperplastic cholecystopathy (過形成性胆嚢症)			
Yes	0	0	0
No	1 (1.1%)	0	1 (0.6%)
Immune system disorders (免疫系障害)			
Yes	0	0	0
No	1 (1.1%)	4 (4.4%)	5 (2.8%)
Seasonal allergy (季節性アレルギー)			
Yes	0	0	0
No	1 (1.1%)	4 (4.4%)	5 (2.8%)

System Organ Class Preferred Term Hepatic parameter abnormality	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
Ear and labyrinth disorders (耳および迷路障害)			
Yes	0	1 (5.9%)	1 (3.2%)
No	1 (1.1%)	2 (2.2%)	3 (1.7%)
Meniere's disease (メニエール病)			
Yes	0	0	0
No	1 (1.1%)	0	1 (0.6%)
Tinnitus (耳鳴)			
Yes	0	0	0
No	0	1 (1.1%)	1 (0.6%)
Vertigo (回転性めまい)			
Yes	0	0	0
No	0	1 (1.1%)	1 (0.6%)
Vertigo positional (頭位性回転性めまい)			
Yes	0	1 (5.9%)	1 (3.2%)
No	0	0	0
Cardiac disorders (心臓障害)			
Yes	1 (7.1%)	0	1 (3.2%)
No	1 (1.1%)	1 (1.1%)	2 (1.1%)
Atrial fibrillation (心房細動)			
Yes	0	0	0
No	1 (1.1%)	0	1 (0.6%)
Cardiac failure congestive (うっ血性心不全)			
Yes	0	0	0
No	1 (1.1%)	0	1 (0.6%)
Coronary artery stenosis (冠動脈狭窄)			
Yes	0	0	0
No	0	1 (1.1%)	1 (0.6%)
Extrasystoles (期外収縮)			
Yes	1 (7.1%)	0	1 (3.2%)
No	0	0	0
Reproductive system and breast disorders (生殖系および乳房障害)			
Yes	0	0	0
No	2 (2.3%)	1 (1.1%)	3 (1.7%)
Benign prostatic hyperplasia (良性前立腺肥大症)			
Yes	0	0	0
No	1 (1.1%)	1 (1.1%)	2 (1.1%)
Prostatomegaly (前立腺腫大)			

System Organ Class Preferred Term Hepatic parameter abnormality	Placebo/Imeglimin + Insulin N = 101	Imeglimin/Imeglimin + Insulin N = 108	Imeglimin + Insulin Total N = 209
Yes	0	0	0
No	1 (1.1%)	0	1 (0.6%)
Psychiatric disorders (精神障害)			
Yes	0	0	0
No	1 (1.1%)	1 (1.1%)	2 (1.1%)
Depressive symptom (抑うつ症状)			
Yes	0	0	0
No	1 (1.1%)	0	1 (0.6%)
Insomnia (不眠症)			
Yes	0	0	0
No	0	1 (1.1%)	1 (0.6%)
Renal and urinary disorders (腎および尿路障害)			
Yes	0	0	0
No	1 (1.1%)	1 (1.1%)	2 (1.1%)
Haematuria (血尿)			
Yes	0	0	0
No	0	1 (1.1%)	1 (0.6%)
Renal cyst (腎嚢胞)			
Yes	0	0	0
No	1 (1.1%)	0	1 (0.6%)
Blood and lymphatic system disorders (血液およびリンパ系障害)			
Yes	0	0	0
No	1 (1.1%)	0	1 (0.6%)
Iron deficiency anaemia (鉄欠乏性貧血)			
Yes	0	0	0
No	1 (1.1%)	0	1 (0.6%)

- Abbreviations: AE, Adverse event; TEAE, Treatment Emergent AE
- Hepatic parameter abnormality is defined as any one of following parameter applied: Total Bilirubin >= 1.6 mg/dL; Aspartate aminotransferase (AST) >= 1.25 x Upper Limit of Normal (ULN); AST >= 50 IU; Alanine aminotransferase (ALT) >= 1.25 x ULN; ALT >= 50 IU; Alkaline phosphatase >= 1.25 x ULN; Gamma glutamyl transferase >= 1.5 x ULN.
- "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.
- All adverse events were coded using MedDRA dictionary version 20.1.
- Percentages are based on "Number of patients".

Control No:<<t-s-177-subae-020lt.sas, 2020-03-06T00:12:54>>

Table S-178 Shift of Laboratory Findings of Hematology in 24-Week Double-blind Period with Monotherapy (PXL008-014, PXL008-018; Safety Population)

Parameter Week	Baseline	Post-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
Basophils (10^9/L)							
Week 2	m		74	75	73	71	219
	Normal	Normal	74 (100.0%)	75 (100.0%)	73 (100.0%)	71 (100.0%)	219 (100.0%)
Week 4	m		179	75	178	70	323
	Normal	Normal	179 (100.0%)	75 (100.0%)	178 (100.0%)	70 (100.0%)	323 (100.0%)
Week 8	m		176	72	175	67	314
	Normal	Normal	175 (99.4%)	72 (100.0%)	175 (100.0%)	67 (100.0%)	314 (100.0%)
		High	1 (0.6%)	0	0	0	0
Week 12	m		169	72	172	68	312
	Normal	Normal	169 (100.0%)	72 (100.0%)	172 (100.0%)	68 (100.0%)	312 (100.0%)
Week 16	m		168	71	171	68	310
	Normal	Normal	168 (100.0%)	71 (100.0%)	171 (100.0%)	68 (100.0%)	310 (100.0%)
Week 20	m		167	70	169	66	305
	Normal	Normal	167 (100.0%)	70 (100.0%)	169 (100.0%)	66 (100.0%)	305 (100.0%)
Week 24	m		166	69	168	66	303
	Normal	Normal	166 (100.0%)	69 (100.0%)	168 (100.0%)	66 (100.0%)	303 (100.0%)
LOCF Endpoint	m		181	75	180	75	330
	Normal	Normal	181 (100.0%)	75 (100.0%)	180 (100.0%)	75 (100.0%)	330 (100.0%)
Basophils/Leukocytes (%)							
Week 2	m		74	75	73	71	219
	Normal	Normal	74 (100.0%)	75 (100.0%)	73 (100.0%)	71 (100.0%)	219 (100.0%)

Parameter Week	Baseline	Post-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
Week 4	m		179	75	178	70	323
	Normal	Normal	178 (99.4%)	75 (100.0%)	177 (99.4%)	70 (100.0%)	322 (99.7%)
	High	Normal	1 (0.6%)	0	1 (0.6%)	0	1 (0.3%)
Week 8	m		176	72	175	67	314
	Normal	Normal	174 (98.9%)	72 (100.0%)	174 (99.4%)	67 (100.0%)	313 (99.7%)
		High	1 (0.6%)	0	0	0	0
	High	Normal	1 (0.6%)	0	1 (0.6%)	0	1 (0.3%)
Week 12	m		169	72	172	68	312
	Normal	Normal	168 (99.4%)	72 (100.0%)	171 (99.4%)	68 (100.0%)	311 (99.7%)
	High	Normal	1 (0.6%)	0	1 (0.6%)	0	1 (0.3%)
Week 16	m		168	71	171	68	310
	Normal	Normal	168 (100.0%)	71 (100.0%)	170 (99.4%)	68 (100.0%)	309 (99.7%)
	High	Normal	0	0	1 (0.6%)	0	1 (0.3%)
Week 20	m		167	70	169	66	305
	Normal	Normal	166 (99.4%)	70 (100.0%)	168 (99.4%)	66 (100.0%)	304 (99.7%)
		High	1 (0.6%)	0	0	0	0
	High	Normal	0	0	1 (0.6%)	0	1 (0.3%)
Week 24	m		166	69	168	66	303
	Normal	Normal	166 (100.0%)	69 (100.0%)	167 (99.4%)	66 (100.0%)	302 (99.7%)
	High	Normal	0	0	1 (0.6%)	0	1 (0.3%)
LOCF Endpoint	m		181	75	180	75	330
	Normal	Normal	180 (99.4%)	75 (100.0%)	179 (99.4%)	75 (100.0%)	329 (99.7%)
	High	Normal	1 (0.6%)	0	1 (0.6%)	0	1 (0.3%)

Parameter Week	Baseline	Post-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
Eosinophils (10^9/L)							
Week 2	m		74	75	73	71	219
	Normal	Normal	74 (100.0%)	74 (98.7%)	72 (98.6%)	71 (100.0%)	217 (99.1%)
		High	0	1 (1.3%)	1 (1.4%)	0	2 (0.9%)
Week 4	m		179	75	178	70	323
	Normal	Normal	178 (99.4%)	75 (100.0%)	176 (98.9%)	69 (98.6%)	320 (99.1%)
		High	1 (0.6%)	0	2 (1.1%)	1 (1.4%)	3 (0.9%)
Week 8	m		176	72	175	67	314
	Normal	Normal	175 (99.4%)	72 (100.0%)	174 (99.4%)	66 (98.5%)	312 (99.4%)
		High	1 (0.6%)	0	1 (0.6%)	1 (1.5%)	2 (0.6%)
Week 12	m		169	72	172	68	312
	Normal	Normal	169 (100.0%)	72 (100.0%)	171 (99.4%)	68 (100.0%)	311 (99.7%)
		High	0	0	1 (0.6%)	0	1 (0.3%)
Week 16	m		168	71	171	68	310
	Normal	Normal	167 (99.4%)	71 (100.0%)	169 (98.8%)	68 (100.0%)	308 (99.4%)
		High	1 (0.6%)	0	2 (1.2%)	0	2 (0.6%)
Week 20	m		167	70	169	66	305
	Normal	Normal	167 (100.0%)	70 (100.0%)	166 (98.2%)	66 (100.0%)	302 (99.0%)
		High	0	0	3 (1.8%)	0	3 (1.0%)
Week 24	m		166	69	168	66	303
	Normal	Normal	166 (100.0%)	69 (100.0%)	166 (98.8%)	64 (97.0%)	299 (98.7%)
		High	0	0	2 (1.2%)	2 (3.0%)	4 (1.3%)
LOCF Endpoint	m		181	75	180	75	330
	Normal	Normal	181 (100.0%)	75 (100.0%)	178 (98.9%)	73 (97.3%)	326 (98.8%)

Parameter Week	Baseline	Post-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
		High	0	0	2 (1.1%)	2 (2.7%)	4 (1.2%)
Eosinophils/Leukocytes (%)							
Week 2	m		74	75	73	71	219
	Normal	Normal	71 (95.9%)	73 (97.3%)	71 (97.3%)	70 (98.6%)	214 (97.7%)
		High	1 (1.4%)	2 (2.7%)	2 (2.7%)	1 (1.4%)	5 (2.3%)
	High	Normal	2 (2.7%)	0	0	0	0
Week 4	m		179	75	178	70	323
	Normal	Normal	173 (96.6%)	75 (100.0%)	170 (95.5%)	68 (97.1%)	313 (96.9%)
		High	2 (1.1%)	0	3 (1.7%)	2 (2.9%)	5 (1.5%)
	High	Normal	3 (1.7%)	0	2 (1.1%)	0	2 (0.6%)
		High	1 (0.6%)	0	3 (1.7%)	0	3 (0.9%)
Week 8	m		176	72	175	67	314
	Normal	Normal	171 (97.2%)	72 (100.0%)	168 (96.0%)	65 (97.0%)	305 (97.1%)
		High	1 (0.6%)	0	2 (1.1%)	2 (3.0%)	4 (1.3%)
	High	Normal	3 (1.7%)	0	2 (1.1%)	0	2 (0.6%)
		High	1 (0.6%)	0	3 (1.7%)	0	3 (1.0%)
Week 12	m		169	72	172	68	312
	Normal	Normal	162 (95.9%)	72 (100.0%)	165 (95.9%)	68 (100.0%)	305 (97.8%)
		High	3 (1.8%)	0	2 (1.2%)	0	2 (0.6%)
	High	Normal	2 (1.2%)	0	2 (1.2%)	0	2 (0.6%)
		High	2 (1.2%)	0	3 (1.7%)	0	3 (1.0%)
Week 16	m		168	71	171	68	310
	Normal	Normal	162 (96.4%)	69 (97.2%)	164 (95.9%)	67 (98.5%)	300 (96.8%)
		High	2 (1.2%)	2 (2.8%)	2 (1.2%)	1 (1.5%)	5 (1.6%)
	High	Normal	3 (1.8%)	0	3 (1.8%)	0	3 (1.0%)
		High	1 (0.6%)	0	2 (1.2%)	0	2 (0.6%)

Parameter Week	Baseline	Post-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
Week 20	m		167	70	169	66	305
	Normal	Normal	163 (97.6%)	70 (100.0%)	157 (92.9%)	64 (97.0%)	291 (95.4%)
		High	0	0	7 (4.1%)	2 (3.0%)	9 (3.0%)
	High	Normal	3 (1.8%)	0	3 (1.8%)	0	3 (1.0%)
		High	1 (0.6%)	0	2 (1.2%)	0	2 (0.7%)
Week 24	m		166	69	168	66	303
	Normal	Normal	158 (95.2%)	65 (94.2%)	158 (94.0%)	63 (95.5%)	286 (94.4%)
		High	4 (2.4%)	4 (5.8%)	5 (3.0%)	3 (4.5%)	12 (4.0%)
	High	Normal	4 (2.4%)	0	2 (1.2%)	0	2 (0.7%)
		High	0	0	3 (1.8%)	0	3 (1.0%)
LOCF Endpoint	m		181	75	180	75	330
	Normal	Normal	173 (95.6%)	71 (94.7%)	170 (94.4%)	72 (96.0%)	313 (94.8%)
		High	4 (2.2%)	4 (5.3%)	5 (2.8%)	3 (4.0%)	12 (3.6%)
	High	Normal	4 (2.2%)	0	2 (1.1%)	0	2 (0.6%)
		High	0	0	3 (1.7%)	0	3 (0.9%)
Ery. Mean Corpuscular Hemoglobin (pg)							
Week 2	m		74	75	73	71	219
	Low	Low	4 (5.4%)	1 (1.3%)	1 (1.4%)	2 (2.8%)	4 (1.8%)
	Normal	Normal	70 (94.6%)	73 (97.3%)	70 (95.9%)	69 (97.2%)	212 (96.8%)
		High	0	0	1 (1.4%)	0	1 (0.5%)
	High	High	0	1 (1.3%)	1 (1.4%)	0	2 (0.9%)
Week 4	m		179	75	178	70	323
	Low	Low	3 (1.7%)	1 (1.3%)	1 (0.6%)	2 (2.9%)	4 (1.2%)
		Normal	1 (0.6%)	0	0	0	0
	Normal	Low	1 (0.6%)	1 (1.3%)	0	0	1 (0.3%)

Parameter Week	Baseline	Post-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
		Normal	172 (96.1%)	72 (96.0%)	173 (97.2%)	68 (97.1%)	313 (96.9%)
	High	Normal	0	0	3 (1.7%)	0	3 (0.9%)
		High	2 (1.1%)	1 (1.3%)	1 (0.6%)	0	2 (0.6%)
Week 8	m		176	72	175	67	314
	Low	Low	3 (1.7%)	1 (1.4%)	0	2 (3.0%)	3 (1.0%)
	Normal	Low	0	1 (1.4%)	0	0	1 (0.3%)
		Normal	171 (97.2%)	69 (95.8%)	169 (96.6%)	65 (97.0%)	303 (96.5%)
		High	0	0	2 (1.1%)	0	2 (0.6%)
	High	Normal	0	0	3 (1.7%)	0	3 (1.0%)
		High	2 (1.1%)	1 (1.4%)	1 (0.6%)	0	2 (0.6%)
Week 12	m		169	72	172	68	312
	Low	Low	2 (1.2%)	1 (1.4%)	0	2 (2.9%)	3 (1.0%)
		Normal	1 (0.6%)	0	0	0	0
	Normal	Low	0	1 (1.4%)	0	0	1 (0.3%)
		Normal	164 (97.0%)	69 (95.8%)	168 (97.7%)	66 (97.1%)	303 (97.1%)
	High	Normal	0	0	2 (1.2%)	0	2 (0.6%)
		High	2 (1.2%)	1 (1.4%)	2 (1.2%)	0	3 (1.0%)
Week 16	m		168	71	171	68	310
	Low	Low	3 (1.8%)	1 (1.4%)	0	2 (2.9%)	3 (1.0%)
	Normal	Low	0	2 (2.8%)	0	0	2 (0.6%)
		Normal	161 (95.8%)	67 (94.4%)	165 (96.5%)	66 (97.1%)	298 (96.1%)
		High	2 (1.2%)	0	2 (1.2%)	0	2 (0.6%)
	High	Normal	0	0	2 (1.2%)	0	2 (0.6%)
		High	2 (1.2%)	1 (1.4%)	2 (1.2%)	0	3 (1.0%)
Week 20	m		167	70	169	66	305
	Low	Low	2 (1.2%)	1 (1.4%)	0	2 (3.0%)	3 (1.0%)
		Normal	1 (0.6%)	0	0	0	0

Parameter Week	Baseline	Post-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
	Normal	Low	0	2 (2.9%)	0	0	2 (0.7%)
		Normal	159 (95.2%)	65 (92.9%)	163 (96.4%)	63 (95.5%)	291 (95.4%)
		High	3 (1.8%)	1 (1.4%)	2 (1.2%)	1 (1.5%)	4 (1.3%)
	High	High	2 (1.2%)	1 (1.4%)	4 (2.4%)	0	5 (1.6%)
Week 24	m		166	69	168	66	303
	Low	Low	2 (1.2%)	1 (1.4%)	0	2 (3.0%)	3 (1.0%)
		Normal	1 (0.6%)	0	0	0	0
	Normal	Low	0	2 (2.9%)	0	0	2 (0.7%)
		Normal	159 (95.8%)	65 (94.2%)	162 (96.4%)	63 (95.5%)	290 (95.7%)
		High	2 (1.2%)	0	2 (1.2%)	1 (1.5%)	3 (1.0%)
	High	Normal	0	0	2 (1.2%)	0	2 (0.7%)
		High	2 (1.2%)	1 (1.4%)	2 (1.2%)	0	3 (1.0%)
LOCF Endpoint	m		181	75	180	75	330
	Low	Low	3 (1.7%)	1 (1.3%)	1 (0.6%)	3 (4.0%)	5 (1.5%)
		Normal	1 (0.6%)	0	0	0	0
	Normal	Low	0	2 (2.7%)	0	0	2 (0.6%)
		Normal	173 (95.6%)	71 (94.7%)	172 (95.6%)	71 (94.7%)	314 (95.2%)
		High	2 (1.1%)	0	3 (1.7%)	1 (1.3%)	4 (1.2%)
	High	Normal	0	0	2 (1.1%)	0	2 (0.6%)
		High	2 (1.1%)	1 (1.3%)	2 (1.1%)	0	3 (0.9%)
Ery. Mean Corpuscular HGB Concentration (g/L)							
Week 2	m		74	75	73	71	219
	Low	Low	34 (45.9%)	32 (42.7%)	28 (38.4%)	25 (35.2%)	85 (38.8%)
		Normal	7 (9.5%)	7 (9.3%)	8 (11.0%)	8 (11.3%)	23 (10.5%)
	Normal	Low	12 (16.2%)	14 (18.7%)	10 (13.7%)	15 (21.1%)	39 (17.8%)
		Normal	21 (28.4%)	22 (29.3%)	27 (37.0%)	23 (32.4%)	72 (32.9%)

Parameter Week	Baseline	Post-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
Week 4	m		179	75	178	70	323
	Low	Low	36 (20.1%)	33 (44.0%)	28 (15.7%)	30 (42.9%)	91 (28.2%)
		Normal	5 (2.8%)	6 (8.0%)	8 (4.5%)	2 (2.9%)	16 (5.0%)
	Normal	Low	11 (6.1%)	15 (20.0%)	22 (12.4%)	22 (31.4%)	59 (18.3%)
		Normal	127 (70.9%)	21 (28.0%)	120 (67.4%)	16 (22.9%)	157 (48.6%)
Week 8	m		176	72	175	67	314
	Low	Low	34 (19.3%)	36 (50.0%)	30 (17.1%)	25 (37.3%)	91 (29.0%)
		Normal	5 (2.8%)	2 (2.8%)	4 (2.3%)	5 (7.5%)	11 (3.5%)
	Normal	Low	13 (7.4%)	15 (20.8%)	21 (12.0%)	18 (26.9%)	54 (17.2%)
		Normal	124 (70.5%)	19 (26.4%)	120 (68.6%)	19 (28.4%)	158 (50.3%)
Week 12	m		169	72	172	68	312
	Low	Low	30 (17.8%)	26 (36.1%)	19 (11.0%)	20 (29.4%)	65 (20.8%)
		Normal	7 (4.1%)	12 (16.7%)	14 (8.1%)	11 (16.2%)	37 (11.9%)
	Normal	Low	12 (7.1%)	20 (27.8%)	20 (11.6%)	20 (29.4%)	60 (19.2%)
		Normal	120 (71.0%)	14 (19.4%)	119 (69.2%)	17 (25.0%)	150 (48.1%)
Week 16	m		168	71	171	68	310
	Low	Low	20 (11.9%)	18 (25.4%)	13 (7.6%)	12 (17.6%)	43 (13.9%)
		Normal	17 (10.1%)	20 (28.2%)	20 (11.7%)	19 (27.9%)	59 (19.0%)
	Normal	Low	9 (5.4%)	14 (19.7%)	14 (8.2%)	15 (22.1%)	43 (13.9%)
		Normal	122 (72.6%)	19 (26.8%)	124 (72.5%)	22 (32.4%)	165 (53.2%)
Week 20	m		167	70	169	66	305
	Low	Low	13 (7.8%)	10 (14.3%)	9 (5.3%)	6 (9.1%)	25 (8.2%)
		Normal	23 (13.8%)	27 (38.6%)	24 (14.2%)	25 (37.9%)	76 (24.9%)
	Normal	Low	7 (4.2%)	13 (18.6%)	13 (7.7%)	15 (22.7%)	41 (13.4%)
		Normal	124 (74.3%)	20 (28.6%)	123 (72.8%)	20 (30.3%)	163 (53.4%)
Week 24	m		166	69	168	66	303

Parameter Week	Baseline	Post-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
	Low	Low	11 (6.6%)	4 (5.8%)	1 (0.6%)	5 (7.6%)	10 (3.3%)
		Normal	26 (15.7%)	32 (46.4%)	32 (19.0%)	25 (37.9%)	89 (29.4%)
	Normal	Low	6 (3.6%)	7 (10.1%)	6 (3.6%)	6 (9.1%)	19 (6.3%)
		Normal	123 (74.1%)	26 (37.7%)	129 (76.8%)	30 (45.5%)	185 (61.1%)
LOCF Endpoint	m		181	75	180	75	330
	Low	Low	16 (8.8%)	5 (6.7%)	4 (2.2%)	8 (10.7%)	17 (5.2%)
		Normal	26 (14.4%)	34 (45.3%)	32 (17.8%)	26 (34.7%)	92 (27.9%)
	Normal	Low	8 (4.4%)	7 (9.3%)	9 (5.0%)	9 (12.0%)	25 (7.6%)
		Normal	131 (72.4%)	29 (38.7%)	135 (75.0%)	32 (42.7%)	196 (59.4%)
Ery. Mean Corpuscular Volume (fL)							
Week 2	m		74	75	73	71	219
	Low	Low	2 (2.7%)	0	0	1 (1.4%)	1 (0.5%)
		Normal	1 (1.4%)	0	0	0	0
	Normal	Normal	51 (68.9%)	55 (73.3%)	50 (68.5%)	42 (59.2%)	147 (67.1%)
		High	3 (4.1%)	3 (4.0%)	1 (1.4%)	8 (11.3%)	12 (5.5%)
	High	Normal	2 (2.7%)	2 (2.7%)	1 (1.4%)	1 (1.4%)	4 (1.8%)
		High	15 (20.3%)	15 (20.0%)	21 (28.8%)	19 (26.8%)	55 (25.1%)
Week 4	m		179	75	178	70	323
	Low	Low	3 (1.7%)	0	0	1 (1.4%)	1 (0.3%)
		Normal	1 (0.6%)	0	0	0	0
	Normal	Normal	148 (82.7%)	54 (72.0%)	149 (83.7%)	41 (58.6%)	244 (75.5%)
		High	6 (3.4%)	4 (5.3%)	4 (2.2%)	8 (11.4%)	16 (5.0%)
	High	Normal	4 (2.2%)	0	2 (1.1%)	1 (1.4%)	3 (0.9%)
		High	17 (9.5%)	17 (22.7%)	23 (12.9%)	19 (27.1%)	59 (18.3%)
Week 8	m		176	72	175	67	314
	Low	Low	1 (0.6%)	0	0	1 (1.5%)	1 (0.3%)

Parameter Week	Baseline	Post-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
		Normal	2 (1.1%)	0	0	0	0
	Normal	Normal	147 (83.5%)	48 (66.7%)	141 (80.6%)	39 (58.2%)	228 (72.6%)
		High	7 (4.0%)	7 (9.7%)	11 (6.3%)	8 (11.9%)	26 (8.3%)
	High	Normal	3 (1.7%)	0	0	3 (4.5%)	3 (1.0%)
		High	16 (9.1%)	17 (23.6%)	23 (13.1%)	16 (23.9%)	56 (17.8%)
Week 12	m		169	72	172	68	312
	Low	Low	1 (0.6%)	0	0	1 (1.5%)	1 (0.3%)
		Normal	2 (1.2%)	0	0	0	0
	Normal	Low	0	1 (1.4%)	0	0	1 (0.3%)
		Normal	140 (82.8%)	46 (63.9%)	134 (77.9%)	37 (54.4%)	217 (69.6%)
		High	8 (4.7%)	8 (11.1%)	16 (9.3%)	11 (16.2%)	35 (11.2%)
	High	Normal	4 (2.4%)	2 (2.8%)	1 (0.6%)	5 (7.4%)	8 (2.6%)
		High	14 (8.3%)	15 (20.8%)	21 (12.2%)	14 (20.6%)	50 (16.0%)
Week 16	m		168	71	171	68	310
	Low	Low	1 (0.6%)	0	0	0	0
		Normal	2 (1.2%)	0	0	1 (1.5%)	1 (0.3%)
	Normal	Low	0	1 (1.4%)	0	1 (1.5%)	2 (0.6%)
		Normal	135 (80.4%)	43 (60.6%)	133 (77.8%)	38 (55.9%)	214 (69.0%)
		High	12 (7.1%)	10 (14.1%)	16 (9.4%)	9 (13.2%)	35 (11.3%)
	High	Normal	5 (3.0%)	3 (4.2%)	2 (1.2%)	7 (10.3%)	12 (3.9%)
		High	13 (7.7%)	14 (19.7%)	20 (11.7%)	12 (17.6%)	46 (14.8%)
Week 20	m		167	70	169	66	305
	Low	Low	1 (0.6%)	0	0	0	0
		Normal	2 (1.2%)	0	0	1 (1.5%)	1 (0.3%)
	Normal	Low	1 (0.6%)	1 (1.4%)	0	1 (1.5%)	2 (0.7%)
		Normal	136 (81.4%)	46 (65.7%)	127 (75.1%)	39 (59.1%)	212 (69.5%)
		High	9 (5.4%)	7 (10.0%)	20 (11.8%)	7 (10.6%)	34 (11.1%)
	High	Normal	9 (5.4%)	5 (7.1%)	1 (0.6%)	8 (12.1%)	14 (4.6%)

Parameter Week	Baseline	Post-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
		High	9 (5.4%)	11 (15.7%)	21 (12.4%)	10 (15.2%)	42 (13.8%)
Week 24	m		166	69	168	66	303
	Low	Low	1 (0.6%)	0	0	0	0
		Normal	2 (1.2%)	0	0	1 (1.5%)	1 (0.3%)
	Normal	Low	1 (0.6%)	2 (2.9%)	0	1 (1.5%)	3 (1.0%)
		Normal	135 (81.3%)	46 (66.7%)	132 (78.6%)	38 (57.6%)	216 (71.3%)
		High	10 (6.0%)	5 (7.2%)	14 (8.3%)	7 (10.6%)	26 (8.6%)
	High	Normal	8 (4.8%)	5 (7.2%)	4 (2.4%)	7 (10.6%)	16 (5.3%)
		High	9 (5.4%)	11 (15.9%)	18 (10.7%)	12 (18.2%)	41 (13.5%)
LOCF Endpoint	m		181	75	180	75	330
	Low	Low	2 (1.1%)	0	0	1 (1.3%)	1 (0.3%)
		Normal	2 (1.1%)	0	0	1 (1.3%)	1 (0.3%)
	Normal	Low	1 (0.6%)	2 (2.7%)	0	1 (1.3%)	3 (0.9%)
		Normal	144 (79.6%)	50 (66.7%)	139 (77.2%)	45 (60.0%)	234 (70.9%)
		High	11 (6.1%)	6 (8.0%)	16 (8.9%)	7 (9.3%)	29 (8.8%)
	High	Normal	9 (5.0%)	5 (6.7%)	4 (2.2%)	8 (10.7%)	17 (5.2%)
		High	12 (6.6%)	12 (16.0%)	21 (11.7%)	12 (16.0%)	45 (13.6%)
Erythrocytes (10^12/L)							
Week 2	m		74	75	73	71	219
	Low	Low	4 (5.4%)	5 (6.7%)	9 (12.3%)	8 (11.3%)	22 (10.0%)
		Normal	1 (1.4%)	1 (1.3%)	1 (1.4%)	2 (2.8%)	4 (1.8%)
	Normal	Low	2 (2.7%)	5 (6.7%)	4 (5.5%)	4 (5.6%)	13 (5.9%)
		Normal	67 (90.5%)	64 (85.3%)	59 (80.8%)	57 (80.3%)	180 (82.2%)
Week 4	m		179	75	178	70	323
	Low	Low	8 (4.5%)	5 (6.7%)	15 (8.4%)	8 (11.4%)	28 (8.7%)
		Normal	2 (1.1%)	1 (1.3%)	6 (3.4%)	2 (2.9%)	9 (2.8%)
	Normal	Low	7 (3.9%)	4 (5.3%)	15 (8.4%)	2 (2.9%)	21 (6.5%)

Parameter Week	Baseline	Post-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
		Normal	160 (89.4%)	65 (86.7%)	142 (79.8%)	58 (82.9%)	265 (82.0%)
		High	2 (1.1%)	0	0	0	0
Week 8	m		176	72	175	67	314
	Low	Low	9 (5.1%)	4 (5.6%)	16 (9.1%)	9 (13.4%)	29 (9.2%)
		Normal	1 (0.6%)	2 (2.8%)	5 (2.9%)	1 (1.5%)	8 (2.5%)
	Normal	Low	7 (4.0%)	4 (5.6%)	20 (11.4%)	5 (7.5%)	29 (9.2%)
		Normal	158 (89.8%)	62 (86.1%)	134 (76.6%)	52 (77.6%)	248 (79.0%)
		High	1 (0.6%)	0	0	0	0
Week 12	m		169	72	172	68	312
	Low	Low	7 (4.1%)	3 (4.2%)	17 (9.9%)	8 (11.8%)	28 (9.0%)
		Normal	3 (1.8%)	3 (4.2%)	3 (1.7%)	2 (2.9%)	8 (2.6%)
	Normal	Low	8 (4.7%)	3 (4.2%)	18 (10.5%)	6 (8.8%)	27 (8.7%)
		Normal	151 (89.3%)	63 (87.5%)	134 (77.9%)	52 (76.5%)	249 (79.8%)
Week 16	m		168	71	171	68	310
	Low	Low	7 (4.2%)	4 (5.6%)	16 (9.4%)	9 (13.2%)	29 (9.4%)
		Normal	3 (1.8%)	2 (2.8%)	3 (1.8%)	1 (1.5%)	6 (1.9%)
	Normal	Low	3 (1.8%)	5 (7.0%)	14 (8.2%)	3 (4.4%)	22 (7.1%)
		Normal	155 (92.3%)	60 (84.5%)	138 (80.7%)	55 (80.9%)	253 (81.6%)
Week 20	m		167	70	169	66	305
	Low	Low	7 (4.2%)	3 (4.3%)	14 (8.3%)	9 (13.6%)	26 (8.5%)
		Normal	3 (1.8%)	2 (2.9%)	5 (3.0%)	1 (1.5%)	8 (2.6%)
	Normal	Low	2 (1.2%)	5 (7.1%)	12 (7.1%)	5 (7.6%)	22 (7.2%)
		Normal	155 (92.8%)	60 (85.7%)	138 (81.7%)	51 (77.3%)	249 (81.6%)
Week 24	m		166	69	168	66	303
	Low	Low	8 (4.8%)	2 (2.9%)	15 (8.9%)	9 (13.6%)	26 (8.6%)
		Normal	2 (1.2%)	3 (4.3%)	4 (2.4%)	1 (1.5%)	8 (2.6%)

Parameter Week	Baseline	Post-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
	Normal	Low	1 (0.6%)	5 (7.2%)	10 (6.0%)	8 (12.1%)	23 (7.6%)
		Normal	155 (93.4%)	59 (85.5%)	139 (82.7%)	48 (72.7%)	246 (81.2%)
LOCF Endpoint	m		181	75	180	75	330
	Low	Low	8 (4.4%)	2 (2.7%)	16 (8.9%)	9 (12.0%)	27 (8.2%)
		Normal	2 (1.1%)	4 (5.3%)	5 (2.8%)	1 (1.3%)	10 (3.0%)
	Normal	Low	2 (1.1%)	6 (8.0%)	11 (6.1%)	10 (13.3%)	27 (8.2%)
		Normal	169 (93.4%)	63 (84.0%)	148 (82.2%)	55 (73.3%)	266 (80.6%)
Hematocrit (fraction of 1)							
Week 2	m		74	75	73	71	219
	Low	Low	3 (4.1%)	0	2 (2.7%)	3 (4.2%)	5 (2.3%)
		Normal	0	0	1 (1.4%)	3 (4.2%)	4 (1.8%)
	Normal	Low	0	1 (1.3%)	2 (2.7%)	1 (1.4%)	4 (1.8%)
		Normal	67 (90.5%)	66 (88.0%)	63 (86.3%)	60 (84.5%)	189 (86.3%)
		High	0	3 (4.0%)	0	0	3 (1.4%)
	High	Normal	1 (1.4%)	2 (2.7%)	3 (4.1%)	0	5 (2.3%)
		High	3 (4.1%)	3 (4.0%)	2 (2.7%)	4 (5.6%)	9 (4.1%)
Week 4	m		179	75	178	70	323
	Low	Low	5 (2.8%)	0	6 (3.4%)	4 (5.7%)	10 (3.1%)
		Normal	2 (1.1%)	0	2 (1.1%)	2 (2.9%)	4 (1.2%)
	Normal	Low	1 (0.6%)	0	4 (2.2%)	1 (1.4%)	5 (1.5%)
		Normal	166 (92.7%)	68 (90.7%)	161 (90.4%)	59 (84.3%)	288 (89.2%)
		High	1 (0.6%)	2 (2.7%)	0	0	2 (0.6%)
	High	Normal	2 (1.1%)	3 (4.0%)	3 (1.7%)	3 (4.3%)	9 (2.8%)
		High	2 (1.1%)	2 (2.7%)	2 (1.1%)	1 (1.4%)	5 (1.5%)
Week 8	m		176	72	175	67	314
	Low	Low	3 (1.7%)	0	7 (4.0%)	3 (4.5%)	10 (3.2%)
		Normal	4 (2.3%)	0	1 (0.6%)	3 (4.5%)	4 (1.3%)

Parameter Week	Baseline	Post-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
	Normal	Low	2 (1.1%)	1 (1.4%)	6 (3.4%)	1 (1.5%)	8 (2.5%)
		Normal	161 (91.5%)	62 (86.1%)	158 (90.3%)	55 (82.1%)	275 (87.6%)
		High	2 (1.1%)	4 (5.6%)	0	1 (1.5%)	5 (1.6%)
	High	Normal	1 (0.6%)	3 (4.2%)	3 (1.7%)	2 (3.0%)	8 (2.5%)
		High	3 (1.7%)	2 (2.8%)	0	2 (3.0%)	4 (1.3%)
Week 12	m		169	72	172	68	312
	Low	Low	6 (3.6%)	0	4 (2.3%)	3 (4.4%)	7 (2.2%)
		Normal	1 (0.6%)	0	4 (2.3%)	3 (4.4%)	7 (2.2%)
	Normal	Low	3 (1.8%)	1 (1.4%)	4 (2.3%)	4 (5.9%)	9 (2.9%)
		Normal	154 (91.1%)	64 (88.9%)	157 (91.3%)	54 (79.4%)	275 (88.1%)
		High	2 (1.2%)	2 (2.8%)	0	0	2 (0.6%)
	High	Normal	0	3 (4.2%)	3 (1.7%)	2 (2.9%)	8 (2.6%)
		High	3 (1.8%)	2 (2.8%)	0	2 (2.9%)	4 (1.3%)
Week 16	m		168	71	171	68	310
	Low	Low	3 (1.8%)	0	3 (1.8%)	2 (2.9%)	5 (1.6%)
		Normal	4 (2.4%)	0	5 (2.9%)	4 (5.9%)	9 (2.9%)
	Normal	Low	2 (1.2%)	0	5 (2.9%)	3 (4.4%)	8 (2.6%)
		Normal	155 (92.3%)	64 (90.1%)	155 (90.6%)	54 (79.4%)	273 (88.1%)
		High	1 (0.6%)	2 (2.8%)	0	1 (1.5%)	3 (1.0%)
	High	Normal	3 (1.8%)	5 (7.0%)	3 (1.8%)	2 (2.9%)	10 (3.2%)
		High	0	0	0	2 (2.9%)	2 (0.6%)
Week 20	m		167	70	169	66	305
	Low	Low	4 (2.4%)	0	4 (2.4%)	5 (7.6%)	9 (3.0%)
		Normal	3 (1.8%)	0	4 (2.4%)	1 (1.5%)	5 (1.6%)
	Normal	Low	2 (1.2%)	2 (2.9%)	2 (1.2%)	5 (7.6%)	9 (3.0%)
		Normal	154 (92.2%)	62 (88.6%)	154 (91.1%)	51 (77.3%)	267 (87.5%)
		High	1 (0.6%)	1 (1.4%)	2 (1.2%)	0	3 (1.0%)
	High	Normal	3 (1.8%)	5 (7.1%)	3 (1.8%)	2 (3.0%)	10 (3.3%)

Parameter Week	Baseline	Post-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
		High	0	0	0	2 (3.0%)	2 (0.7%)
Week 24	m		166	69	168	66	303
	Low	Low	3 (1.8%)	0	3 (1.8%)	6 (9.1%)	9 (3.0%)
		Normal	4 (2.4%)	0	5 (3.0%)	0	5 (1.7%)
	Normal	Low	1 (0.6%)	1 (1.4%)	2 (1.2%)	4 (6.1%)	7 (2.3%)
		Normal	153 (92.2%)	64 (92.8%)	155 (92.3%)	52 (78.8%)	271 (89.4%)
		High	2 (1.2%)	0	0	0	0
	High	Normal	2 (1.2%)	3 (4.3%)	3 (1.8%)	1 (1.5%)	7 (2.3%)
		High	1 (0.6%)	1 (1.4%)	0	3 (4.5%)	4 (1.3%)
LOCF Endpoint	m		181	75	180	75	330
	Low	Low	3 (1.7%)	0	3 (1.7%)	7 (9.3%)	10 (3.0%)
		Normal	4 (2.2%)	0	6 (3.3%)	0	6 (1.8%)
	Normal	Low	1 (0.6%)	1 (1.3%)	3 (1.7%)	5 (6.7%)	9 (2.7%)
		Normal	167 (92.3%)	69 (92.0%)	163 (90.6%)	59 (78.7%)	291 (88.2%)
		High	2 (1.1%)	0	0	0	0
	High	Normal	3 (1.7%)	4 (5.3%)	4 (2.2%)	1 (1.3%)	9 (2.7%)
		High	1 (0.6%)	1 (1.3%)	1 (0.6%)	3 (4.0%)	5 (1.5%)
Hemoglobin (g/L)							
Week 2	m		74	75	73	71	219
	Low	Low	7 (9.5%)	6 (8.0%)	6 (8.2%)	12 (16.9%)	24 (11.0%)
		Normal	3 (4.1%)	0	2 (2.7%)	1 (1.4%)	3 (1.4%)
	Normal	Low	5 (6.8%)	4 (5.3%)	8 (11.0%)	8 (11.3%)	20 (9.1%)
		Normal	59 (79.7%)	65 (86.7%)	57 (78.1%)	50 (70.4%)	172 (78.5%)
Week 4	m		179	75	178	70	323
	Low	Low	9 (5.0%)	6 (8.0%)	11 (6.2%)	12 (17.1%)	29 (9.0%)
		Normal	6 (3.4%)	0	2 (1.1%)	1 (1.4%)	3 (0.9%)
	Normal	Low	7 (3.9%)	4 (5.3%)	9 (5.1%)	3 (4.3%)	16 (5.0%)

Parameter Week	Baseline	Post-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
		Normal	156 (87.2%)	65 (86.7%)	154 (86.5%)	54 (77.1%)	273 (84.5%)
		High	0	0	1 (0.6%)	0	1 (0.3%)
	High	Normal	0	0	1 (0.6%)	0	1 (0.3%)
		High	1 (0.6%)	0	0	0	0
Week 8	m		176	72	175	67	314
	Low	Low	8 (4.5%)	5 (6.9%)	9 (5.1%)	10 (14.9%)	24 (7.6%)
		Normal	6 (3.4%)	1 (1.4%)	3 (1.7%)	3 (4.5%)	7 (2.2%)
	Normal	Low	8 (4.5%)	6 (8.3%)	11 (6.3%)	7 (10.4%)	24 (7.6%)
		Normal	152 (86.4%)	60 (83.3%)	151 (86.3%)	47 (70.1%)	258 (82.2%)
		High	1 (0.6%)	0	0	0	0
	High	Normal	0	0	1 (0.6%)	0	1 (0.3%)
		High	1 (0.6%)	0	0	0	0
Week 12	m		169	72	172	68	312
	Low	Low	10 (5.9%)	5 (6.9%)	8 (4.7%)	11 (16.2%)	24 (7.7%)
		Normal	4 (2.4%)	1 (1.4%)	3 (1.7%)	2 (2.9%)	6 (1.9%)
	Normal	Low	2 (1.2%)	7 (9.7%)	12 (7.0%)	3 (4.4%)	22 (7.1%)
		Normal	152 (89.9%)	59 (81.9%)	148 (86.0%)	52 (76.5%)	259 (83.0%)
	High	Normal	0	0	1 (0.6%)	0	1 (0.3%)
		High	1 (0.6%)	0	0	0	0
Week 16	m		168	71	171	68	310
	Low	Low	6 (3.6%)	5 (7.0%)	9 (5.3%)	11 (16.2%)	25 (8.1%)
		Normal	8 (4.8%)	0	2 (1.2%)	2 (2.9%)	4 (1.3%)
	Normal	Low	2 (1.2%)	5 (7.0%)	9 (5.3%)	4 (5.9%)	18 (5.8%)
		Normal	151 (89.9%)	61 (85.9%)	149 (87.1%)	51 (75.0%)	261 (84.2%)
		High	0	0	1 (0.6%)	0	1 (0.3%)
	High	Normal	0	0	1 (0.6%)	0	1 (0.3%)
		High	1 (0.6%)	0	0	0	0

Parameter Week	Baseline	Post-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
Week 20	m		167	70	169	66	305
	Low	Low	7 (4.2%)	3 (4.3%)	9 (5.3%)	11 (16.7%)	23 (7.5%)
		Normal	7 (4.2%)	1 (1.4%)	2 (1.2%)	1 (1.5%)	4 (1.3%)
	Normal	Low	2 (1.2%)	7 (10.0%)	10 (5.9%)	6 (9.1%)	23 (7.5%)
		Normal	150 (89.8%)	59 (84.3%)	146 (86.4%)	48 (72.7%)	253 (83.0%)
		High	0	0	1 (0.6%)	0	1 (0.3%)
	High	Normal	0	0	1 (0.6%)	0	1 (0.3%)
		High	1 (0.6%)	0	0	0	0
Week 24	m		166	69	168	66	303
	Low	Low	7 (4.2%)	2 (2.9%)	9 (5.4%)	10 (15.2%)	21 (6.9%)
		Normal	7 (4.2%)	2 (2.9%)	2 (1.2%)	2 (3.0%)	6 (2.0%)
	Normal	Low	2 (1.2%)	4 (5.8%)	5 (3.0%)	3 (4.5%)	12 (4.0%)
		Normal	149 (89.8%)	61 (88.4%)	150 (89.3%)	51 (77.3%)	262 (86.5%)
		High	0	0	1 (0.6%)	0	1 (0.3%)
	High	Normal	0	0	1 (0.6%)	0	1 (0.3%)
		High	1 (0.6%)	0	0	0	0
LOCF Endpoint	m		181	75	180	75	330
	Low	Low	7 (3.9%)	3 (4.0%)	12 (6.7%)	12 (16.0%)	27 (8.2%)
		Normal	9 (5.0%)	3 (4.0%)	2 (1.1%)	2 (2.7%)	7 (2.1%)
	Normal	Low	3 (1.7%)	5 (6.7%)	5 (2.8%)	5 (6.7%)	15 (4.5%)
		Normal	161 (89.0%)	64 (85.3%)	159 (88.3%)	56 (74.7%)	279 (84.5%)
		High	0	0	1 (0.6%)	0	1 (0.3%)
	High	Normal	0	0	1 (0.6%)	0	1 (0.3%)
		High	1 (0.6%)	0	0	0	0
Leukocytes (10^9/L)							
Week 2	m		74	75	73	71	219
	Low	Low	1 (1.4%)	2 (2.7%)	0	0	2 (0.9%)
		Normal	5 (6.8%)	2 (2.7%)	3 (4.1%)	1 (1.4%)	6 (2.7%)

Parameter Week	Baseline	Post-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
		High	0	0	1 (1.4%)	0	1 (0.5%)
	Normal	Low	1 (1.4%)	2 (2.7%)	1 (1.4%)	0	3 (1.4%)
		Normal	67 (90.5%)	68 (90.7%)	67 (91.8%)	69 (97.2%)	204 (93.2%)
		High	0	1 (1.3%)	0	1 (1.4%)	2 (0.9%)
	High	Normal	0	0	1 (1.4%)	0	1 (0.5%)
Week 4	m		179	75	178	70	323
	Low	Low	7 (3.9%)	1 (1.3%)	4 (2.2%)	0	5 (1.5%)
		Normal	7 (3.9%)	3 (4.0%)	13 (7.3%)	1 (1.4%)	17 (5.3%)
	Normal	Low	5 (2.8%)	1 (1.3%)	1 (0.6%)	0	2 (0.6%)
		Normal	157 (87.7%)	68 (90.7%)	157 (88.2%)	69 (98.6%)	294 (91.0%)
		High	1 (0.6%)	2 (2.7%)	1 (0.6%)	0	3 (0.9%)
	High	Normal	2 (1.1%)	0	2 (1.1%)	0	2 (0.6%)
Week 8	m		176	72	175	67	314
	Low	Low	7 (4.0%)	1 (1.4%)	6 (3.4%)	0	7 (2.2%)
		Normal	7 (4.0%)	3 (4.2%)	11 (6.3%)	1 (1.5%)	15 (4.8%)
	Normal	Low	3 (1.7%)	2 (2.8%)	4 (2.3%)	0	6 (1.9%)
		Normal	154 (87.5%)	66 (91.7%)	152 (86.9%)	65 (97.0%)	283 (90.1%)
		High	3 (1.7%)	0	0	1 (1.5%)	1 (0.3%)
	High	Normal	2 (1.1%)	0	2 (1.1%)	0	2 (0.6%)
Week 12	m		169	72	172	68	312
	Low	Low	9 (5.3%)	1 (1.4%)	8 (4.7%)	0	9 (2.9%)
		Normal	5 (3.0%)	3 (4.2%)	9 (5.2%)	1 (1.5%)	13 (4.2%)
	Normal	Low	7 (4.1%)	3 (4.2%)	1 (0.6%)	0	4 (1.3%)
		Normal	145 (85.8%)	64 (88.9%)	152 (88.4%)	67 (98.5%)	283 (90.7%)
		High	1 (0.6%)	1 (1.4%)	0	0	1 (0.3%)
	High	Normal	2 (1.2%)	0	2 (1.2%)	0	2 (0.6%)
Week 16	m		168	71	171	68	310

Parameter Week	Baseline	Post-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
	Low	Low	6 (3.6%)	2 (2.8%)	7 (4.1%)	0	9 (2.9%)
		Normal	8 (4.8%)	2 (2.8%)	10 (5.8%)	1 (1.5%)	13 (4.2%)
	Normal	Low	3 (1.8%)	0	5 (2.9%)	0	5 (1.6%)
		Normal	148 (88.1%)	67 (94.4%)	147 (86.0%)	66 (97.1%)	280 (90.3%)
		High	1 (0.6%)	0	0	1 (1.5%)	1 (0.3%)
	High	Normal	1 (0.6%)	0	2 (1.2%)	0	2 (0.6%)
		High	1 (0.6%)	0	0	0	0
Week 20	m		167	70	169	66	305
	Low	Low	7 (4.2%)	2 (2.9%)	7 (4.1%)	0	9 (3.0%)
		Normal	7 (4.2%)	2 (2.9%)	10 (5.9%)	1 (1.5%)	13 (4.3%)
	Normal	Low	5 (3.0%)	2 (2.9%)	6 (3.6%)	1 (1.5%)	9 (3.0%)
		Normal	146 (87.4%)	64 (91.4%)	144 (85.2%)	63 (95.5%)	271 (88.9%)
		High	0	0	0	1 (1.5%)	1 (0.3%)
	High	Normal	1 (0.6%)	0	2 (1.2%)	0	2 (0.7%)
		High	1 (0.6%)	0	0	0	0
Week 24	m		166	69	168	66	303
	Low	Low	6 (3.6%)	1 (1.4%)	7 (4.2%)	0	8 (2.6%)
		Normal	7 (4.2%)	3 (4.3%)	10 (6.0%)	1 (1.5%)	14 (4.6%)
	Normal	Low	5 (3.0%)	5 (7.2%)	7 (4.2%)	1 (1.5%)	13 (4.3%)
		Normal	146 (88.0%)	59 (85.5%)	142 (84.5%)	63 (95.5%)	264 (87.1%)
		High	0	1 (1.4%)	0	1 (1.5%)	2 (0.7%)
	High	Normal	2 (1.2%)	0	2 (1.2%)	0	2 (0.7%)
LOCF Endpoint	m		181	75	180	75	330
	Low	Low	7 (3.9%)	1 (1.3%)	7 (3.9%)	0	8 (2.4%)
		Normal	7 (3.9%)	3 (4.0%)	10 (5.6%)	1 (1.3%)	14 (4.2%)
	Normal	Low	5 (2.8%)	5 (6.7%)	7 (3.9%)	2 (2.7%)	14 (4.2%)
		Normal	160 (88.4%)	65 (86.7%)	154 (85.6%)	71 (94.7%)	290 (87.9%)
		High	0	1 (1.3%)	0	1 (1.3%)	2 (0.6%)

Parameter Week	Baseline	Post-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
	High	Normal	2 (1.1%)	0	2 (1.1%)	0	2 (0.6%)
Lymphocytes (10^9/L)							
Week 2	m		74	75	73	71	219
	Low	Low	0	1 (1.3%)	2 (2.7%)	0	3 (1.4%)
	Normal	Low	1 (1.4%)	2 (2.7%)	0	2 (2.8%)	4 (1.8%)
		Normal	73 (98.6%)	72 (96.0%)	71 (97.3%)	69 (97.2%)	212 (96.8%)
Week 4	m		179	75	178	70	323
	Low	Low	1 (0.6%)	0	1 (0.6%)	0	1 (0.3%)
		Normal	1 (0.6%)	1 (1.3%)	3 (1.7%)	0	4 (1.2%)
	Normal	Low	3 (1.7%)	1 (1.3%)	1 (0.6%)	2 (2.9%)	4 (1.2%)
		Normal	170 (95.0%)	73 (97.3%)	172 (96.6%)	68 (97.1%)	313 (96.9%)
		High	3 (1.7%)	0	0	0	0
	High	Normal	1 (0.6%)	0	0	0	0
		High	0	0	1 (0.6%)	0	1 (0.3%)
Week 8	m		176	72	175	67	314
	Low	Low	2 (1.1%)	0	2 (1.1%)	0	2 (0.6%)
		Normal	0	1 (1.4%)	2 (1.1%)	0	3 (1.0%)
	Normal	Low	2 (1.1%)	0	0	0	0
		Normal	169 (96.0%)	71 (98.6%)	170 (97.1%)	67 (100.0%)	308 (98.1%)
		High	2 (1.1%)	0	0	0	0
	High	Normal	1 (0.6%)	0	0	0	0
		High	0	0	1 (0.6%)	0	1 (0.3%)
Week 12	m		169	72	172	68	312
	Low	Low	1 (0.6%)	0	1 (0.6%)	0	1 (0.3%)
		Normal	1 (0.6%)	1 (1.4%)	3 (1.7%)	0	4 (1.3%)
	Normal	Low	2 (1.2%)	0	1 (0.6%)	1 (1.5%)	2 (0.6%)
		Normal	164 (97.0%)	71 (98.6%)	166 (96.5%)	67 (98.5%)	304 (97.4%)

Parameter Week	Baseline	Post-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
	High	Normal	1 (0.6%)	0	0	0	0
		High	0	0	1 (0.6%)	0	1 (0.3%)
Week 16	m		168	71	171	68	310
	Low	Low	2 (1.2%)	0	2 (1.2%)	0	2 (0.6%)
		Normal	0	1 (1.4%)	2 (1.2%)	0	3 (1.0%)
	Normal	Low	1 (0.6%)	0	0	0	0
		Normal	164 (97.6%)	70 (98.6%)	166 (97.1%)	68 (100.0%)	304 (98.1%)
	High	Normal	1 (0.6%)	0	0	0	0
		High	0	0	1 (0.6%)	0	1 (0.3%)
Week 20	m		167	70	169	66	305
	Low	Low	2 (1.2%)	0	2 (1.2%)	0	2 (0.7%)
		Normal	0	1 (1.4%)	2 (1.2%)	0	3 (1.0%)
	Normal	Low	1 (0.6%)	1 (1.4%)	1 (0.6%)	1 (1.5%)	3 (1.0%)
		Normal	161 (96.4%)	68 (97.1%)	163 (96.4%)	64 (97.0%)	295 (96.7%)
		High	2 (1.2%)	0	0	1 (1.5%)	1 (0.3%)
	High	Normal	1 (0.6%)	0	1 (0.6%)	0	1 (0.3%)
Week 24	m		166	69	168	66	303
	Low	Low	1 (0.6%)	1 (1.4%)	2 (1.2%)	0	3 (1.0%)
		Normal	1 (0.6%)	0	2 (1.2%)	0	2 (0.7%)
	Normal	Low	2 (1.2%)	1 (1.4%)	2 (1.2%)	1 (1.5%)	4 (1.3%)
		Normal	161 (97.0%)	67 (97.1%)	161 (95.8%)	64 (97.0%)	292 (96.4%)
		High	0	0	0	1 (1.5%)	1 (0.3%)
	High	Normal	0	0	1 (0.6%)	0	1 (0.3%)
		High	1 (0.6%)	0	0	0	0
LOCF Endpoint	m		181	75	180	75	330
	Low	Low	1 (0.6%)	1 (1.3%)	2 (1.1%)	0	3 (0.9%)
		Normal	1 (0.6%)	0	2 (1.1%)	0	2 (0.6%)

Parameter Week	Baseline	Post-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
	Normal	Low	2 (1.1%)	1 (1.3%)	2 (1.1%)	2 (2.7%)	5 (1.5%)
		Normal	176 (97.2%)	73 (97.3%)	173 (96.1%)	72 (96.0%)	318 (96.4%)
		High	0	0	0	1 (1.3%)	1 (0.3%)
	High	Normal	0	0	1 (0.6%)	0	1 (0.3%)
		High	1 (0.6%)	0	0	0	0
Lymphocytes/Leukocytes (%)							
Week 2	m		74	75	73	71	219
	Low	Normal	0	1 (1.3%)	1 (1.4%)	0	2 (0.9%)
	Normal	Low	1 (1.4%)	1 (1.3%)	0	0	1 (0.5%)
		Normal	60 (81.1%)	59 (78.7%)	60 (82.2%)	59 (83.1%)	178 (81.3%)
		High	5 (6.8%)	5 (6.7%)	4 (5.5%)	3 (4.2%)	12 (5.5%)
	High	Low	0	1 (1.3%)	1 (1.4%)	0	2 (0.9%)
		Normal	5 (6.8%)	5 (6.7%)	5 (6.8%)	5 (7.0%)	15 (6.8%)
		High	3 (4.1%)	3 (4.0%)	2 (2.7%)	4 (5.6%)	9 (4.1%)
Week 4	m		179	75	178	70	323
	Low	Low	0	1 (1.3%)	1 (0.6%)	0	2 (0.6%)
		Normal	1 (0.6%)	0	2 (1.1%)	0	2 (0.6%)
	Normal	Low	0	0	2 (1.1%)	0	2 (0.6%)
		Normal	162 (90.5%)	56 (74.7%)	155 (87.1%)	60 (85.7%)	271 (83.9%)
		High	7 (3.9%)	9 (12.0%)	4 (2.2%)	1 (1.4%)	14 (4.3%)
	High	Normal	3 (1.7%)	6 (8.0%)	8 (4.5%)	8 (11.4%)	22 (6.8%)
		High	6 (3.4%)	3 (4.0%)	6 (3.4%)	1 (1.4%)	10 (3.1%)
Week 8	m		176	72	175	67	314
	Low	Low	0	1 (1.4%)	0	0	1 (0.3%)
		Normal	1 (0.6%)	0	3 (1.7%)	0	3 (1.0%)
	Normal	Low	1 (0.6%)	0	2 (1.1%)	0	2 (0.6%)
		Normal	159 (90.3%)	57 (79.2%)	153 (87.4%)	57 (85.1%)	267 (85.0%)
		High	7 (4.0%)	5 (6.9%)	3 (1.7%)	1 (1.5%)	9 (2.9%)

Parameter Week	Baseline	Post-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
	High	Normal	4 (2.3%)	5 (6.9%)	9 (5.1%)	6 (9.0%)	20 (6.4%)
		High	4 (2.3%)	4 (5.6%)	5 (2.9%)	3 (4.5%)	12 (3.8%)
Week 12	m		169	72	172	68	312
	Low	Low	1 (0.6%)	0	1 (0.6%)	0	1 (0.3%)
		Normal	0	1 (1.4%)	2 (1.2%)	0	3 (1.0%)
	Normal	Low	0	0	0	1 (1.5%)	1 (0.3%)
		Normal	155 (91.7%)	59 (81.9%)	151 (87.8%)	57 (83.8%)	267 (85.6%)
		High	5 (3.0%)	3 (4.2%)	5 (2.9%)	1 (1.5%)	9 (2.9%)
	High	Normal	4 (2.4%)	4 (5.6%)	9 (5.2%)	8 (11.8%)	21 (6.7%)
		High	4 (2.4%)	5 (6.9%)	4 (2.3%)	1 (1.5%)	10 (3.2%)
Week 16	m		168	71	171	68	310
	Low	Normal	1 (0.6%)	1 (1.4%)	3 (1.8%)	0	4 (1.3%)
	Normal	Normal	151 (89.9%)	57 (80.3%)	148 (86.5%)	58 (85.3%)	263 (84.8%)
		High	8 (4.8%)	4 (5.6%)	7 (4.1%)	1 (1.5%)	12 (3.9%)
	High	Normal	3 (1.8%)	5 (7.0%)	9 (5.3%)	6 (8.8%)	20 (6.5%)
		High	5 (3.0%)	4 (5.6%)	4 (2.3%)	3 (4.4%)	11 (3.5%)
Week 20	m		167	70	169	66	305
	Low	Low	1 (0.6%)	0	1 (0.6%)	0	1 (0.3%)
		Normal	0	1 (1.4%)	2 (1.2%)	0	3 (1.0%)
	Normal	Low	3 (1.8%)	0	0	0	0
		Normal	148 (88.6%)	51 (72.9%)	145 (85.8%)	51 (77.3%)	247 (81.0%)
		High	7 (4.2%)	9 (12.9%)	8 (4.7%)	6 (9.1%)	23 (7.5%)
	High	Normal	4 (2.4%)	7 (10.0%)	9 (5.3%)	5 (7.6%)	21 (6.9%)
		High	4 (2.4%)	2 (2.9%)	4 (2.4%)	4 (6.1%)	10 (3.3%)
Week 24	m		166	69	168	66	303
	Low	Low	0	0	2 (1.2%)	0	2 (0.7%)
		Normal	1 (0.6%)	1 (1.4%)	1 (0.6%)	0	2 (0.7%)

Parameter Week	Baseline	Post-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
	Normal	Low	0	0	2 (1.2%)	0	2 (0.7%)
		Normal	152 (91.6%)	45 (65.2%)	140 (83.3%)	49 (74.2%)	234 (77.2%)
		High	6 (3.6%)	14 (20.3%)	10 (6.0%)	8 (12.1%)	32 (10.6%)
	High	Normal	2 (1.2%)	7 (10.1%)	9 (5.4%)	4 (6.1%)	20 (6.6%)
		High	5 (3.0%)	2 (2.9%)	4 (2.4%)	5 (7.6%)	11 (3.6%)
LOCF Endpoint	m		181	75	180	75	330
	Low	Low	0	0	2 (1.1%)	0	2 (0.6%)
		Normal	1 (0.6%)	1 (1.3%)	1 (0.6%)	0	2 (0.6%)
	Normal	Low	0	0	2 (1.1%)	1 (1.3%)	3 (0.9%)
		Normal	165 (91.2%)	51 (68.0%)	151 (83.9%)	56 (74.7%)	258 (78.2%)
		High	5 (2.8%)	14 (18.7%)	10 (5.6%)	9 (12.0%)	33 (10.0%)
	High	Normal	2 (1.1%)	7 (9.3%)	9 (5.0%)	4 (5.3%)	20 (6.1%)
		High	8 (4.4%)	2 (2.7%)	5 (2.8%)	5 (6.7%)	12 (3.6%)
Monocytes (10^9/L)							
Week 2	m		74	75	73	71	219
	Normal	Normal	74 (100.0%)	75 (100.0%)	72 (98.6%)	71 (100.0%)	218 (99.5%)
		High	0	0	1 (1.4%)	0	1 (0.5%)
Week 4	m		179	75	178	70	323
	Low	Normal	0	0	1 (0.6%)	0	1 (0.3%)
	Normal	Normal	179 (100.0%)	75 (100.0%)	177 (99.4%)	70 (100.0%)	322 (99.7%)
Week 8	m		176	72	175	67	314
	Low	Normal	0	0	1 (0.6%)	0	1 (0.3%)
	Normal	Normal	176 (100.0%)	72 (100.0%)	174 (99.4%)	67 (100.0%)	313 (99.7%)
Week 12	m		169	72	172	68	312
	Low	Normal	0	0	1 (0.6%)	0	1 (0.3%)
	Normal	Low	3 (1.8%)	0	0	0	0

Parameter Week	Baseline	Post-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
		Normal	166 (98.2%)	72 (100.0%)	171 (99.4%)	68 (100.0%)	311 (99.7%)
Week 16	m		168	71	171	68	310
	Low	Normal	0	0	1 (0.6%)	0	1 (0.3%)
	Normal	Low	1 (0.6%)	0	0	0	0
		Normal	167 (99.4%)	71 (100.0%)	170 (99.4%)	68 (100.0%)	309 (99.7%)
Week 20	m		167	70	169	66	305
	Low	Normal	0	0	1 (0.6%)	0	1 (0.3%)
	Normal	Normal	167 (100.0%)	70 (100.0%)	168 (99.4%)	66 (100.0%)	304 (99.7%)
Week 24	m		166	69	168	66	303
	Low	Normal	0	0	1 (0.6%)	0	1 (0.3%)
	Normal	Normal	166 (100.0%)	69 (100.0%)	166 (98.8%)	66 (100.0%)	301 (99.3%)
		High	0	0	1 (0.6%)	0	1 (0.3%)
LOCF Endpoint	m		181	75	180	75	330
	Low	Normal	0	0	1 (0.6%)	0	1 (0.3%)
	Normal	Normal	181 (100.0%)	75 (100.0%)	178 (98.9%)	75 (100.0%)	328 (99.4%)
		High	0	0	1 (0.6%)	0	1 (0.3%)
Monocytes/Leukocytes (%)							
Week 2	m		74	75	73	71	219
	Normal	Normal	73 (98.6%)	72 (96.0%)	72 (98.6%)	68 (95.8%)	212 (96.8%)
		High	1 (1.4%)	2 (2.7%)	0	2 (2.8%)	4 (1.8%)
	High	Normal	0	1 (1.3%)	1 (1.4%)	1 (1.4%)	3 (1.4%)
Week 4	m		179	75	178	70	323
	Normal	Normal	177 (98.9%)	74 (98.7%)	175 (98.3%)	69 (98.6%)	318 (98.5%)
		High	1 (0.6%)	0	0	0	0
	High	Normal	0	1 (1.3%)	3 (1.7%)	1 (1.4%)	5 (1.5%)

Parameter Week	Baseline	Post-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
		High	1 (0.6%)	0	0	0	0
Week 8	m		176	72	175	67	314
	Normal	Low	0	0	1 (0.6%)	0	1 (0.3%)
		Normal	173 (98.3%)	71 (98.6%)	171 (97.7%)	66 (98.5%)	308 (98.1%)
		High	2 (1.1%)	0	0	0	0
	High	Normal	0	1 (1.4%)	3 (1.7%)	1 (1.5%)	5 (1.6%)
		High	1 (0.6%)	0	0	0	0
Week 12	m		169	72	172	68	312
	Normal	Low	3 (1.8%)	0	0	0	0
		Normal	164 (97.0%)	71 (98.6%)	169 (98.3%)	67 (98.5%)	307 (98.4%)
		High	1 (0.6%)	0	0	0	0
	High	Normal	0	1 (1.4%)	3 (1.7%)	1 (1.5%)	5 (1.6%)
		High	1 (0.6%)	0	0	0	0
Week 16	m		168	71	171	68	310
	Normal	Normal	167 (99.4%)	69 (97.2%)	167 (97.7%)	67 (98.5%)	303 (97.7%)
		High	0	1 (1.4%)	1 (0.6%)	0	2 (0.6%)
	High	Normal	0	1 (1.4%)	3 (1.8%)	1 (1.5%)	5 (1.6%)
		High	1 (0.6%)	0	0	0	0
Week 20	m		167	70	169	66	305
	Normal	Normal	164 (98.2%)	67 (95.7%)	165 (97.6%)	63 (95.5%)	295 (96.7%)
		High	2 (1.2%)	2 (2.9%)	1 (0.6%)	2 (3.0%)	5 (1.6%)
	High	Normal	1 (0.6%)	1 (1.4%)	3 (1.8%)	1 (1.5%)	5 (1.6%)
Week 24	m		166	69	168	66	303
	Normal	Low	0	0	1 (0.6%)	0	1 (0.3%)
		Normal	162 (97.6%)	65 (94.2%)	159 (94.6%)	62 (93.9%)	286 (94.4%)
		High	3 (1.8%)	3 (4.3%)	5 (3.0%)	3 (4.5%)	11 (3.6%)

Parameter Week	Baseline	Post-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
	High	Normal	1 (0.6%)	1 (1.4%)	2 (1.2%)	1 (1.5%)	4 (1.3%)
		High	0	0	1 (0.6%)	0	1 (0.3%)
LOCF Endpoint	m		181	75	180	75	330
	Normal	Low	0	0	1 (0.6%)	0	1 (0.3%)
		Normal	177 (97.8%)	71 (94.7%)	171 (95.0%)	70 (93.3%)	312 (94.5%)
		High	3 (1.7%)	3 (4.0%)	5 (2.8%)	4 (5.3%)	12 (3.6%)
	High	Normal	1 (0.6%)	1 (1.3%)	2 (1.1%)	1 (1.3%)	4 (1.2%)
		High	0	0	1 (0.6%)	0	1 (0.3%)
Neutrophils (10^9/L)							
Week 2	m		74	75	73	71	219
	Low	Normal	0	1 (1.3%)	2 (2.7%)	1 (1.4%)	4 (1.8%)
	Normal	Low	1 (1.4%)	0	1 (1.4%)	1 (1.4%)	2 (0.9%)
		Normal	73 (98.6%)	73 (97.3%)	68 (93.2%)	69 (97.2%)	210 (95.9%)
		High	0	1 (1.3%)	1 (1.4%)	0	2 (0.9%)
	High	High	0	0	1 (1.4%)	0	1 (0.5%)
Week 4	m		179	75	178	70	323
	Low	Low	2 (1.1%)	0	7 (3.9%)	0	7 (2.2%)
		Normal	5 (2.8%)	1 (1.3%)	5 (2.8%)	1 (1.4%)	7 (2.2%)
	Normal	Low	5 (2.8%)	0	1 (0.6%)	0	1 (0.3%)
		Normal	164 (91.6%)	73 (97.3%)	162 (91.0%)	69 (98.6%)	304 (94.1%)
		High	1 (0.6%)	1 (1.3%)	1 (0.6%)	0	2 (0.6%)
	High	Normal	2 (1.1%)	0	2 (1.1%)	0	2 (0.6%)
Week 8	m		176	72	175	67	314
	Low	Low	4 (2.3%)	0	5 (2.9%)	0	5 (1.6%)
		Normal	3 (1.7%)	1 (1.4%)	7 (4.0%)	1 (1.5%)	9 (2.9%)
	Normal	Low	5 (2.8%)	0	3 (1.7%)	0	3 (1.0%)
		Normal	160 (90.9%)	71 (98.6%)	156 (89.1%)	66 (98.5%)	293 (93.3%)

Parameter Week	Baseline	Post-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
		High	2 (1.1%)	0	2 (1.1%)	0	2 (0.6%)
	High	Normal	2 (1.1%)	0	2 (1.1%)	0	2 (0.6%)
Week 12	m		169	72	172	68	312
	Low	Low	4 (2.4%)	0	6 (3.5%)	0	6 (1.9%)
		Normal	3 (1.8%)	1 (1.4%)	6 (3.5%)	1 (1.5%)	8 (2.6%)
	Normal	Low	5 (3.0%)	0	1 (0.6%)	0	1 (0.3%)
		Normal	155 (91.7%)	71 (98.6%)	157 (91.3%)	67 (98.5%)	295 (94.6%)
	High	Normal	1 (0.6%)	0	2 (1.2%)	0	2 (0.6%)
		High	1 (0.6%)	0	0	0	0
Week 16	m		168	71	171	68	310
	Low	Low	3 (1.8%)	0	4 (2.3%)	0	4 (1.3%)
		Normal	4 (2.4%)	1 (1.4%)	8 (4.7%)	1 (1.5%)	10 (3.2%)
	Normal	Low	5 (3.0%)	1 (1.4%)	5 (2.9%)	0	6 (1.9%)
		Normal	153 (91.1%)	69 (97.2%)	151 (88.3%)	67 (98.5%)	287 (92.6%)
		High	1 (0.6%)	0	1 (0.6%)	0	1 (0.3%)
	High	Normal	1 (0.6%)	0	2 (1.2%)	0	2 (0.6%)
		High	1 (0.6%)	0	0	0	0
Week 20	m		167	70	169	66	305
	Low	Low	2 (1.2%)	0	4 (2.4%)	0	4 (1.3%)
		Normal	5 (3.0%)	1 (1.4%)	8 (4.7%)	1 (1.5%)	10 (3.3%)
	Normal	Low	4 (2.4%)	0	4 (2.4%)	1 (1.5%)	5 (1.6%)
		Normal	153 (91.6%)	69 (98.6%)	150 (88.8%)	64 (97.0%)	283 (92.8%)
		High	1 (0.6%)	0	1 (0.6%)	0	1 (0.3%)
	High	Normal	1 (0.6%)	0	2 (1.2%)	0	2 (0.7%)
		High	1 (0.6%)	0	0	0	0
Week 24	m		166	69	168	66	303
	Low	Low	2 (1.2%)	0	4 (2.4%)	0	4 (1.3%)

Parameter Week	Baseline	Post-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
		Normal	5 (3.0%)	1 (1.4%)	8 (4.8%)	1 (1.5%)	10 (3.3%)
	Normal	Low	3 (1.8%)	5 (7.2%)	5 (3.0%)	1 (1.5%)	11 (3.6%)
		Normal	154 (92.8%)	62 (89.9%)	148 (88.1%)	64 (97.0%)	274 (90.4%)
		High	0	1 (1.4%)	1 (0.6%)	0	2 (0.7%)
	High	Normal	2 (1.2%)	0	2 (1.2%)	0	2 (0.7%)
LOCF Endpoint	m		181	75	180	75	330
	Low	Low	2 (1.1%)	0	4 (2.2%)	0	4 (1.2%)
		Normal	5 (2.8%)	1 (1.3%)	8 (4.4%)	1 (1.3%)	10 (3.0%)
	Normal	Low	2 (1.1%)	5 (6.7%)	5 (2.8%)	1 (1.3%)	11 (3.3%)
		Normal	170 (93.9%)	68 (90.7%)	160 (88.9%)	73 (97.3%)	301 (91.2%)
		High	0	1 (1.3%)	1 (0.6%)	0	2 (0.6%)
	High	Normal	2 (1.1%)	0	2 (1.1%)	0	2 (0.6%)
Neutrophils/Leukocytes (%)							
Week 2	m		74	75	73	71	219
	Low	Low	0	0	0	2 (2.8%)	2 (0.9%)
		Normal	3 (4.1%)	2 (2.7%)	2 (2.7%)	4 (5.6%)	8 (3.7%)
		High	0	1 (1.3%)	0	0	1 (0.5%)
	Normal	Low	1 (1.4%)	1 (1.3%)	1 (1.4%)	1 (1.4%)	3 (1.4%)
		Normal	69 (93.2%)	69 (92.0%)	68 (93.2%)	64 (90.1%)	201 (91.8%)
		High	1 (1.4%)	1 (1.3%)	1 (1.4%)	0	2 (0.9%)
	High	Normal	0	1 (1.3%)	0	0	1 (0.5%)
		High	0	0	1 (1.4%)	0	1 (0.5%)
Week 4	m		179	75	178	70	323
	Low	Low	3 (1.7%)	1 (1.3%)	1 (0.6%)	1 (1.4%)	3 (0.9%)
		Normal	1 (0.6%)	2 (2.7%)	4 (2.2%)	5 (7.1%)	11 (3.4%)
	Normal	Low	2 (1.1%)	2 (2.7%)	3 (1.7%)	1 (1.4%)	6 (1.9%)
		Normal	171 (95.5%)	68 (90.7%)	165 (92.7%)	63 (90.0%)	296 (91.6%)
		High	1 (0.6%)	1 (1.3%)	2 (1.1%)	0	3 (0.9%)

Parameter Week	Baseline	Post-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
	High	Normal	1 (0.6%)	0	3 (1.7%)	0	3 (0.9%)
		High	0	1 (1.3%)	0	0	1 (0.3%)
Week 8	m		176	72	175	67	314
	Low	Low	1 (0.6%)	0	1 (0.6%)	2 (3.0%)	3 (1.0%)
		Normal	3 (1.7%)	3 (4.2%)	4 (2.3%)	4 (6.0%)	11 (3.5%)
	Normal	Low	4 (2.3%)	1 (1.4%)	2 (1.1%)	0	3 (1.0%)
		Normal	166 (94.3%)	67 (93.1%)	163 (93.1%)	61 (91.0%)	291 (92.7%)
		High	1 (0.6%)	0	2 (1.1%)	0	2 (0.6%)
	High	Normal	1 (0.6%)	0	3 (1.7%)	0	3 (1.0%)
		High	0	1 (1.4%)	0	0	1 (0.3%)
Week 12	m		169	72	172	68	312
	Low	Low	1 (0.6%)	0	1 (0.6%)	0	1 (0.3%)
		Normal	3 (1.8%)	3 (4.2%)	4 (2.3%)	6 (8.8%)	13 (4.2%)
	Normal	Low	4 (2.4%)	3 (4.2%)	4 (2.3%)	0	7 (2.2%)
		Normal	160 (94.7%)	65 (90.3%)	159 (92.4%)	62 (91.2%)	286 (91.7%)
		High	0	0	1 (0.6%)	0	1 (0.3%)
	High	Normal	0	1 (1.4%)	2 (1.2%)	0	3 (1.0%)
		High	1 (0.6%)	0	1 (0.6%)	0	1 (0.3%)
Week 16	m		168	71	171	68	310
	Low	Low	2 (1.2%)	0	1 (0.6%)	0	1 (0.3%)
		Normal	2 (1.2%)	3 (4.2%)	4 (2.3%)	6 (8.8%)	13 (4.2%)
	Normal	Low	2 (1.2%)	5 (7.0%)	4 (2.3%)	2 (2.9%)	11 (3.5%)
		Normal	160 (95.2%)	62 (87.3%)	158 (92.4%)	60 (88.2%)	280 (90.3%)
		High	1 (0.6%)	0	1 (0.6%)	0	1 (0.3%)
	High	Normal	0	1 (1.4%)	2 (1.2%)	0	3 (1.0%)
		High	1 (0.6%)	0	1 (0.6%)	0	1 (0.3%)
Week 20	m		167	70	169	66	305

Parameter Week	Baseline	Post-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
	Low	Low	1 (0.6%)	0	2 (1.2%)	0	2 (0.7%)
		Normal	3 (1.8%)	2 (2.9%)	3 (1.8%)	6 (9.1%)	11 (3.6%)
	Normal	Low	5 (3.0%)	3 (4.3%)	7 (4.1%)	5 (7.6%)	15 (4.9%)
		Normal	154 (92.2%)	64 (91.4%)	154 (91.1%)	55 (83.3%)	273 (89.5%)
		High	3 (1.8%)	0	0	0	0
	High	Normal	1 (0.6%)	1 (1.4%)	2 (1.2%)	0	3 (1.0%)
		High	0	0	1 (0.6%)	0	1 (0.3%)
Week 24	m		166	69	168	66	303
	Low	Low	2 (1.2%)	0	1 (0.6%)	0	1 (0.3%)
		Normal	1 (0.6%)	2 (2.9%)	4 (2.4%)	6 (9.1%)	12 (4.0%)
	Normal	Low	7 (4.2%)	13 (18.8%)	9 (5.4%)	9 (13.6%)	31 (10.2%)
		Normal	154 (92.8%)	53 (76.8%)	147 (87.5%)	51 (77.3%)	251 (82.8%)
		High	1 (0.6%)	0	4 (2.4%)	0	4 (1.3%)
	High	Normal	1 (0.6%)	1 (1.4%)	2 (1.2%)	0	3 (1.0%)
		High	0	0	1 (0.6%)	0	1 (0.3%)
LOCF Endpoint	m		181	75	180	75	330
	Low	Low	2 (1.1%)	0	1 (0.6%)	0	1 (0.3%)
		Normal	2 (1.1%)	3 (4.0%)	4 (2.2%)	6 (8.0%)	13 (3.9%)
	Normal	Low	6 (3.3%)	13 (17.3%)	9 (5.0%)	9 (12.0%)	31 (9.4%)
		Normal	169 (93.4%)	58 (77.3%)	159 (88.3%)	60 (80.0%)	277 (83.9%)
		High	1 (0.6%)	0	4 (2.2%)	0	4 (1.2%)
	High	Normal	1 (0.6%)	1 (1.3%)	2 (1.1%)	0	3 (0.9%)
		High	0	0	1 (0.6%)	0	1 (0.3%)
Platelets (10^9/L)							
Week 2	m		74	75	73	71	219
	Low	Low	4 (5.4%)	3 (4.0%)	0	2 (2.8%)	5 (2.3%)
		Normal	1 (1.4%)	0	2 (2.7%)	2 (2.8%)	4 (1.8%)
	Normal	Low	3 (4.1%)	3 (4.0%)	0	0	3 (1.4%)

Parameter Week	Baseline	Post-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
		Normal	65 (87.8%)	69 (92.0%)	71 (97.3%)	66 (93.0%)	206 (94.1%)
		High	1 (1.4%)	0	0	0	0
	High	Normal	0	0	0	1 (1.4%)	1 (0.5%)
Week 4	m		179	75	177	70	322
	Low	Low	6 (3.4%)	3 (4.0%)	6 (3.4%)	3 (4.3%)	12 (3.7%)
		Normal	3 (1.7%)	0	1 (0.6%)	1 (1.4%)	2 (0.6%)
	Normal	Low	4 (2.2%)	1 (1.3%)	2 (1.1%)	0	3 (0.9%)
		Normal	166 (92.7%)	70 (93.3%)	168 (94.9%)	65 (92.9%)	303 (94.1%)
		High	0	1 (1.3%)	0	0	1 (0.3%)
	High	High	0	0	0	1 (1.4%)	1 (0.3%)
Week 8	m		176	72	175	67	314
	Low	Low	7 (4.0%)	2 (2.8%)	5 (2.9%)	2 (3.0%)	9 (2.9%)
		Normal	1 (0.6%)	1 (1.4%)	2 (1.1%)	2 (3.0%)	5 (1.6%)
	Normal	Low	2 (1.1%)	1 (1.4%)	1 (0.6%)	0	2 (0.6%)
		Normal	166 (94.3%)	68 (94.4%)	167 (95.4%)	62 (92.5%)	297 (94.6%)
	High	High	0	0	0	1 (1.5%)	1 (0.3%)
Week 12	m		169	72	171	68	311
	Low	Low	7 (4.1%)	3 (4.2%)	4 (2.3%)	2 (2.9%)	9 (2.9%)
		Normal	1 (0.6%)	0	2 (1.2%)	2 (2.9%)	4 (1.3%)
	Normal	Low	4 (2.4%)	2 (2.8%)	1 (0.6%)	0	3 (1.0%)
		Normal	157 (92.9%)	67 (93.1%)	163 (95.3%)	62 (91.2%)	292 (93.9%)
		High	0	0	1 (0.6%)	1 (1.5%)	2 (0.6%)
	High	High	0	0	0	1 (1.5%)	1 (0.3%)
Week 16	m		168	71	171	68	310
	Low	Low	6 (3.6%)	2 (2.8%)	5 (2.9%)	3 (4.4%)	10 (3.2%)
		Normal	2 (1.2%)	1 (1.4%)	1 (0.6%)	1 (1.5%)	3 (1.0%)
	Normal	Low	5 (3.0%)	1 (1.4%)	2 (1.2%)	0	3 (1.0%)

Parameter Week	Baseline	Post-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
		Normal	155 (92.3%)	67 (94.4%)	163 (95.3%)	62 (91.2%)	292 (94.2%)
		High	0	0	0	1 (1.5%)	1 (0.3%)
	High	High	0	0	0	1 (1.5%)	1 (0.3%)
Week 20	m		167	70	169	66	305
	Low	Low	5 (3.0%)	2 (2.9%)	2 (1.2%)	3 (4.5%)	7 (2.3%)
		Normal	3 (1.8%)	1 (1.4%)	4 (2.4%)	1 (1.5%)	6 (2.0%)
	Normal	Low	3 (1.8%)	3 (4.3%)	2 (1.2%)	1 (1.5%)	6 (2.0%)
		Normal	156 (93.4%)	63 (90.0%)	161 (95.3%)	59 (89.4%)	283 (92.8%)
		High	0	1 (1.4%)	0	1 (1.5%)	2 (0.7%)
	High	High	0	0	0	1 (1.5%)	1 (0.3%)
Week 24	m		166	69	168	66	303
	Low	Low	5 (3.0%)	3 (4.3%)	2 (1.2%)	2 (3.0%)	7 (2.3%)
		Normal	2 (1.2%)	0	4 (2.4%)	2 (3.0%)	6 (2.0%)
	Normal	Low	3 (1.8%)	2 (2.9%)	2 (1.2%)	0	4 (1.3%)
		Normal	155 (93.4%)	63 (91.3%)	160 (95.2%)	59 (89.4%)	282 (93.1%)
		High	1 (0.6%)	1 (1.4%)	0	2 (3.0%)	3 (1.0%)
	High	High	0	0	0	1 (1.5%)	1 (0.3%)
LOCF Endpoint	m		181	75	180	75	330
	Low	Low	6 (3.3%)	3 (4.0%)	2 (1.1%)	3 (4.0%)	8 (2.4%)
		Normal	4 (2.2%)	0	5 (2.8%)	2 (2.7%)	7 (2.1%)
	Normal	Low	4 (2.2%)	2 (2.7%)	2 (1.1%)	0	4 (1.2%)
		Normal	166 (91.7%)	69 (92.0%)	171 (95.0%)	66 (88.0%)	306 (92.7%)
		High	1 (0.6%)	1 (1.3%)	0	3 (4.0%)	4 (1.2%)
	High	High	0	0	0	1 (1.3%)	1 (0.3%)

- 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.

Table S-179 Shift of Laboratory Findings of Biochemistry in 24-Week Double-blind Period with Monotherapy (PXL008-014, PXL008-018; Safety Population)

Parameter Week	Baseline	Post-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
Alanine Aminotransferase (U/L)							
Week 2	m		74	75	73	71	219
	Normal	Normal	62 (83.8%)	63 (84.0%)	63 (86.3%)	59 (83.1%)	185 (84.5%)
		High	0	1 (1.3%)	0	0	1 (0.5%)
	High	Normal	1 (1.4%)	2 (2.7%)	4 (5.5%)	5 (7.0%)	11 (5.0%)
		High	11 (14.9%)	9 (12.0%)	6 (8.2%)	7 (9.9%)	22 (10.0%)
Week 4	m		179	75	178	70	323
	Normal	Normal	149 (83.2%)	63 (84.0%)	151 (84.8%)	57 (81.4%)	271 (83.9%)
		High	3 (1.7%)	1 (1.3%)	5 (2.8%)	2 (2.9%)	8 (2.5%)
	High	Normal	5 (2.8%)	2 (2.7%)	7 (3.9%)	7 (10.0%)	16 (5.0%)
		High	22 (12.3%)	9 (12.0%)	15 (8.4%)	4 (5.7%)	28 (8.7%)
Week 8	m		176	72	175	68	315
	Normal	Normal	142 (80.7%)	62 (86.1%)	148 (84.6%)	55 (80.9%)	265 (84.1%)
		High	8 (4.5%)	0	5 (2.9%)	2 (2.9%)	7 (2.2%)
	High	Normal	6 (3.4%)	5 (6.9%)	7 (4.0%)	5 (7.4%)	17 (5.4%)
		High	20 (11.4%)	5 (6.9%)	15 (8.6%)	6 (8.8%)	26 (8.3%)
Week 12	m		169	72	172	68	312
	Normal	Normal	136 (80.5%)	62 (86.1%)	147 (85.5%)	53 (77.9%)	262 (84.0%)
		High	7 (4.1%)	0	3 (1.7%)	4 (5.9%)	7 (2.2%)
	High	Normal	6 (3.6%)	5 (6.9%)	8 (4.7%)	7 (10.3%)	20 (6.4%)
		High	20 (11.8%)	5 (6.9%)	14 (8.1%)	4 (5.9%)	23 (7.4%)
Week 16	m		168	71	171	68	310
	Normal	Low	0	1 (1.4%)	0	0	1 (0.3%)
		Normal	131 (78.0%)	59 (83.1%)	145 (84.8%)	54 (79.4%)	258 (83.2%)

Parameter Week	Baseline	Post-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
		High	12 (7.1%)	1 (1.4%)	5 (2.9%)	3 (4.4%)	9 (2.9%)
	High	Normal	6 (3.6%)	5 (7.0%)	9 (5.3%)	6 (8.8%)	20 (6.5%)
		High	19 (11.3%)	5 (7.0%)	12 (7.0%)	5 (7.4%)	22 (7.1%)
Week 20	m		168	70	169	67	306
	Normal	Normal	131 (78.0%)	60 (85.7%)	145 (85.8%)	52 (77.6%)	257 (84.0%)
		High	12 (7.1%)	0	3 (1.8%)	4 (6.0%)	7 (2.3%)
	High	Normal	6 (3.6%)	3 (4.3%)	8 (4.7%)	6 (9.0%)	17 (5.6%)
		High	19 (11.3%)	7 (10.0%)	13 (7.7%)	5 (7.5%)	25 (8.2%)
Week 24	m		167	70	168	67	305
	Normal	Normal	131 (78.4%)	59 (84.3%)	140 (83.3%)	51 (76.1%)	250 (82.0%)
		High	11 (6.6%)	1 (1.4%)	7 (4.2%)	5 (7.5%)	13 (4.3%)
	High	Normal	7 (4.2%)	4 (5.7%)	9 (5.4%)	5 (7.5%)	18 (5.9%)
		High	18 (10.8%)	6 (8.6%)	12 (7.1%)	6 (9.0%)	24 (7.9%)
LOCF Endpoint	m		181	75	180	75	330
	Normal	Normal	143 (79.0%)	63 (84.0%)	150 (83.3%)	58 (77.3%)	271 (82.1%)
		High	11 (6.1%)	1 (1.3%)	7 (3.9%)	5 (6.7%)	13 (3.9%)
	High	Normal	8 (4.4%)	4 (5.3%)	10 (5.6%)	6 (8.0%)	20 (6.1%)
		High	19 (10.5%)	7 (9.3%)	13 (7.2%)	6 (8.0%)	26 (7.9%)
Albumin (g/L)							
Week 2	m		74	75	73	71	219
	Normal	Normal	74 (100.0%)	75 (100.0%)	73 (100.0%)	71 (100.0%)	219 (100.0%)
Week 4	m		179	75	178	70	323
	Normal	Normal	176 (98.3%)	75 (100.0%)	165 (92.7%)	70 (100.0%)	310 (96.0%)
		High	1 (0.6%)	0	8 (4.5%)	0	8 (2.5%)
	High	Normal	2 (1.1%)	0	3 (1.7%)	0	3 (0.9%)
		High	0	0	2 (1.1%)	0	2 (0.6%)

Parameter Week	Baseline	Post-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
Week 8	m		176	72	175	68	315
	Normal	Normal	170 (96.6%)	72 (100.0%)	162 (92.6%)	68 (100.0%)	302 (95.9%)
		High	4 (2.3%)	0	8 (4.6%)	0	8 (2.5%)
	High	Normal	2 (1.1%)	0	3 (1.7%)	0	3 (1.0%)
		High	0	0	2 (1.1%)	0	2 (0.6%)
Week 12	m		169	72	172	68	312
	Normal	Normal	163 (96.4%)	72 (100.0%)	158 (91.9%)	68 (100.0%)	298 (95.5%)
		High	4 (2.4%)	0	9 (5.2%)	0	9 (2.9%)
	High	Normal	0	0	3 (1.7%)	0	3 (1.0%)
		High	2 (1.2%)	0	2 (1.2%)	0	2 (0.6%)
Week 16	m		168	71	171	68	310
	Normal	Normal	161 (95.8%)	71 (100.0%)	158 (92.4%)	68 (100.0%)	297 (95.8%)
		High	5 (3.0%)	0	8 (4.7%)	0	8 (2.6%)
	High	Normal	2 (1.2%)	0	2 (1.2%)	0	2 (0.6%)
		High	0	0	3 (1.8%)	0	3 (1.0%)
Week 20	m		168	70	169	67	306
	Normal	Normal	160 (95.2%)	70 (100.0%)	156 (92.3%)	67 (100.0%)	293 (95.8%)
		High	6 (3.6%)	0	8 (4.7%)	0	8 (2.6%)
	High	Normal	2 (1.2%)	0	2 (1.2%)	0	2 (0.7%)
		High	0	0	3 (1.8%)	0	3 (1.0%)
Week 24	m		167	70	168	67	305
	Normal	Normal	156 (93.4%)	70 (100.0%)	151 (89.9%)	67 (100.0%)	288 (94.4%)
		High	9 (5.4%)	0	12 (7.1%)	0	12 (3.9%)
	High	Normal	2 (1.2%)	0	2 (1.2%)	0	2 (0.7%)
		High	0	0	3 (1.8%)	0	3 (1.0%)

Parameter Week	Baseline	Post-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
LOCF Endpoint	m		181	75	180	75	330
	Normal	Normal	170 (93.9%)	75 (100.0%)	163 (90.6%)	75 (100.0%)	313 (94.8%)
		High	9 (5.0%)	0	12 (6.7%)	0	12 (3.6%)
	High	Normal	2 (1.1%)	0	2 (1.1%)	0	2 (0.6%)
		High	0	0	3 (1.7%)	0	3 (0.9%)
Alkaline Phosphatase (U/L)							
Week 2	m		74	75	73	71	219
	Low	Low	2 (2.7%)	3 (4.0%)	5 (6.8%)	2 (2.8%)	10 (4.6%)
		Normal	6 (8.1%)	1 (1.3%)	1 (1.4%)	0	2 (0.9%)
	Normal	Low	3 (4.1%)	1 (1.3%)	5 (6.8%)	6 (8.5%)	12 (5.5%)
		Normal	62 (83.8%)	69 (92.0%)	62 (84.9%)	62 (87.3%)	193 (88.1%)
		High	0	1 (1.3%)	0	0	1 (0.5%)
	High	Normal	0	0	0	1 (1.4%)	1 (0.5%)
		High	1 (1.4%)	0	0	0	0
Week 4	m		179	75	178	70	323
	Low	Low	6 (3.4%)	3 (4.0%)	8 (4.5%)	2 (2.9%)	13 (4.0%)
		Normal	3 (1.7%)	1 (1.3%)	2 (1.1%)	0	3 (0.9%)
	Normal	Low	1 (0.6%)	1 (1.3%)	4 (2.2%)	5 (7.1%)	10 (3.1%)
		Normal	168 (93.9%)	69 (92.0%)	162 (91.0%)	62 (88.6%)	293 (90.7%)
		High	0	1 (1.3%)	0	0	1 (0.3%)
	High	Normal	1 (0.6%)	0	1 (0.6%)	1 (1.4%)	2 (0.6%)
		High	0	0	1 (0.6%)	0	1 (0.3%)
Week 8	m		176	72	175	68	315
	Low	Low	4 (2.3%)	2 (2.8%)	8 (4.6%)	2 (2.9%)	12 (3.8%)
		Normal	5 (2.8%)	2 (2.8%)	2 (1.1%)	0	4 (1.3%)
	Normal	Low	1 (0.6%)	2 (2.8%)	8 (4.6%)	5 (7.4%)	15 (4.8%)
		Normal	165 (93.8%)	66 (91.7%)	155 (88.6%)	60 (88.2%)	281 (89.2%)
	High	Normal	1 (0.6%)	0	1 (0.6%)	1 (1.5%)	2 (0.6%)

Parameter Week	Baseline	Post-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
		High	0	0	1 (0.6%)	0	1 (0.3%)
Week 12	m		169	72	172	68	312
	Low	Low	5 (3.0%)	2 (2.8%)	7 (4.1%)	2 (2.9%)	11 (3.5%)
		Normal	4 (2.4%)	2 (2.8%)	2 (1.2%)	0	4 (1.3%)
	Normal	Low	1 (0.6%)	2 (2.8%)	5 (2.9%)	4 (5.9%)	11 (3.5%)
		Normal	158 (93.5%)	66 (91.7%)	156 (90.7%)	61 (89.7%)	283 (90.7%)
	High	Normal	0	0	1 (0.6%)	1 (1.5%)	2 (0.6%)
		High	1 (0.6%)	0	1 (0.6%)	0	1 (0.3%)
Week 16	m		168	71	171	68	310
	Low	Low	4 (2.4%)	3 (4.2%)	7 (4.1%)	2 (2.9%)	12 (3.9%)
		Normal	5 (3.0%)	1 (1.4%)	2 (1.2%)	0	3 (1.0%)
	Normal	Low	0	1 (1.4%)	5 (2.9%)	6 (8.8%)	12 (3.9%)
		Normal	158 (94.0%)	65 (91.5%)	155 (90.6%)	59 (86.8%)	279 (90.0%)
		High	0	1 (1.4%)	0	0	1 (0.3%)
	High	Normal	0	0	1 (0.6%)	0	1 (0.3%)
		High	1 (0.6%)	0	1 (0.6%)	1 (1.5%)	2 (0.6%)
Week 20	m		168	70	169	67	306
	Low	Low	3 (1.8%)	2 (2.9%)	7 (4.1%)	2 (3.0%)	11 (3.6%)
		Normal	6 (3.6%)	2 (2.9%)	2 (1.2%)	0	4 (1.3%)
	Normal	Low	0	2 (2.9%)	2 (1.2%)	4 (6.0%)	8 (2.6%)
		Normal	156 (92.9%)	64 (91.4%)	155 (91.7%)	60 (89.6%)	279 (91.2%)
		High	2 (1.2%)	0	1 (0.6%)	0	1 (0.3%)
	High	Normal	1 (0.6%)	0	1 (0.6%)	1 (1.5%)	2 (0.7%)
		High	0	0	1 (0.6%)	0	1 (0.3%)
Week 24	m		167	70	168	67	305
	Low	Low	4 (2.4%)	1 (1.4%)	4 (2.4%)	2 (3.0%)	7 (2.3%)
		Normal	5 (3.0%)	3 (4.3%)	5 (3.0%)	0	8 (2.6%)

Parameter Week	Baseline	Post-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
	Normal	Low	0	0	3 (1.8%)	1 (1.5%)	4 (1.3%)
		Normal	157 (94.0%)	65 (92.9%)	154 (91.7%)	63 (94.0%)	282 (92.5%)
		High	0	1 (1.4%)	0	0	1 (0.3%)
	High	Normal	0	0	1 (0.6%)	0	1 (0.3%)
		High	1 (0.6%)	0	1 (0.6%)	1 (1.5%)	2 (0.7%)
LOCF Endpoint	m		181	75	180	75	330
	Low	Low	4 (2.2%)	1 (1.3%)	5 (2.8%)	2 (2.7%)	8 (2.4%)
		Normal	5 (2.8%)	3 (4.0%)	5 (2.8%)	1 (1.3%)	9 (2.7%)
	Normal	Low	0	0	3 (1.7%)	1 (1.3%)	4 (1.2%)
		Normal	171 (94.5%)	70 (93.3%)	165 (91.7%)	70 (93.3%)	305 (92.4%)
		High	0	1 (1.3%)	0	0	1 (0.3%)
	High	Normal	0	0	1 (0.6%)	0	1 (0.3%)
		High	1 (0.6%)	0	1 (0.6%)	1 (1.3%)	2 (0.6%)
Amylase (U/L)							
Week 2	m		74	75	73	71	219
	Low	Low	0	0	1 (1.4%)	0	1 (0.5%)
		Normal	0	0	1 (1.4%)	1 (1.4%)	2 (0.9%)
	Normal	Low	1 (1.4%)	0	0	0	0
		Normal	73 (98.6%)	75 (100.0%)	71 (97.3%)	68 (95.8%)	214 (97.7%)
		High	0	0	0	1 (1.4%)	1 (0.5%)
	High	High	0	0	0	1 (1.4%)	1 (0.5%)
Week 4	m		179	75	178	70	323
	Low	Low	3 (1.7%)	0	3 (1.7%)	0	3 (0.9%)
		Normal	0	0	5 (2.8%)	1 (1.4%)	6 (1.9%)
	Normal	Low	4 (2.2%)	0	0	0	0
		Normal	171 (95.5%)	75 (100.0%)	167 (93.8%)	68 (97.1%)	310 (96.0%)
		High	1 (0.6%)	0	1 (0.6%)	0	1 (0.3%)
	High	Normal	0	0	1 (0.6%)	0	1 (0.3%)

Parameter Week	Baseline	Post-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
		High	0	0	1 (0.6%)	1 (1.4%)	2 (0.6%)
Week 8	m		176	72	175	68	315
	Low	Low	3 (1.7%)	0	6 (3.4%)	0	6 (1.9%)
		Normal	0	0	2 (1.1%)	1 (1.5%)	3 (1.0%)
	Normal	Low	5 (2.8%)	0	1 (0.6%)	0	1 (0.3%)
		Normal	168 (95.5%)	72 (100.0%)	164 (93.7%)	66 (97.1%)	302 (95.9%)
	High	Normal	0	0	2 (1.1%)	0	2 (0.6%)
		High	0	0	0	1 (1.5%)	1 (0.3%)
Week 12	m		169	72	172	68	312
	Low	Low	3 (1.8%)	0	5 (2.9%)	0	5 (1.6%)
		Normal	0	0	2 (1.2%)	1 (1.5%)	3 (1.0%)
	Normal	Low	5 (3.0%)	0	2 (1.2%)	1 (1.5%)	3 (1.0%)
		Normal	161 (95.3%)	72 (100.0%)	161 (93.6%)	65 (95.6%)	298 (95.5%)
	High	Normal	0	0	2 (1.2%)	0	2 (0.6%)
		High	0	0	0	1 (1.5%)	1 (0.3%)
Week 16	m		168	71	171	68	310
	Low	Low	3 (1.8%)	0	4 (2.3%)	0	4 (1.3%)
		Normal	0	0	3 (1.8%)	1 (1.5%)	4 (1.3%)
	Normal	Low	6 (3.6%)	0	1 (0.6%)	0	1 (0.3%)
		Normal	159 (94.6%)	71 (100.0%)	161 (94.2%)	65 (95.6%)	297 (95.8%)
		High	0	0	0	1 (1.5%)	1 (0.3%)
	High	Normal	0	0	2 (1.2%)	0	2 (0.6%)
		High	0	0	0	1 (1.5%)	1 (0.3%)
Week 20	m		168	70	169	67	306
	Low	Low	3 (1.8%)	0	3 (1.8%)	0	3 (1.0%)
		Normal	0	0	4 (2.4%)	1 (1.5%)	5 (1.6%)
	Normal	Low	4 (2.4%)	0	1 (0.6%)	0	1 (0.3%)

Parameter Week	Baseline	Post-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
		Normal	161 (95.8%)	70 (100.0%)	159 (94.1%)	65 (97.0%)	294 (96.1%)
	High	Normal	0	0	1 (0.6%)	0	1 (0.3%)
		High	0	0	1 (0.6%)	1 (1.5%)	2 (0.7%)
Week 24	m		167	70	168	67	305
	Low	Low	3 (1.8%)	0	3 (1.8%)	0	3 (1.0%)
		Normal	0	0	3 (1.8%)	1 (1.5%)	4 (1.3%)
	Normal	Low	2 (1.2%)	0	0	0	0
		Normal	162 (97.0%)	69 (98.6%)	160 (95.2%)	64 (95.5%)	293 (96.1%)
		High	0	1 (1.4%)	0	1 (1.5%)	2 (0.7%)
	High	Normal	0	0	2 (1.2%)	0	2 (0.7%)
		High	0	0	0	1 (1.5%)	1 (0.3%)
LOCF Endpoint	m		181	75	180	75	330
	Low	Low	3 (1.7%)	0	5 (2.8%)	0	5 (1.5%)
		Normal	0	0	3 (1.7%)	1 (1.3%)	4 (1.2%)
	Normal	Low	2 (1.1%)	0	0	0	0
		Normal	176 (97.2%)	74 (98.7%)	170 (94.4%)	72 (96.0%)	316 (95.8%)
		High	0	1 (1.3%)	0	1 (1.3%)	2 (0.6%)
	High	Normal	0	0	2 (1.1%)	0	2 (0.6%)
		High	0	0	0	1 (1.3%)	1 (0.3%)
Aspartate Aminotransferase (U/L)							
Week 2	m		74	75	73	71	219
	Normal	Normal	65 (87.8%)	68 (90.7%)	68 (93.2%)	64 (90.1%)	200 (91.3%)
		High	3 (4.1%)	1 (1.3%)	1 (1.4%)	1 (1.4%)	3 (1.4%)
	High	Normal	0	2 (2.7%)	1 (1.4%)	4 (5.6%)	7 (3.2%)
		High	6 (8.1%)	4 (5.3%)	3 (4.1%)	2 (2.8%)	9 (4.1%)
Week 4	m		179	75	178	70	323

Parameter Week	Baseline	Post-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
	Normal	Low	0	0	1 (0.6%)	0	1 (0.3%)
		Normal	156 (87.2%)	69 (92.0%)	164 (92.1%)	64 (91.4%)	297 (92.0%)
		High	6 (3.4%)	0	3 (1.7%)	1 (1.4%)	4 (1.2%)
	High	Normal	6 (3.4%)	4 (5.3%)	3 (1.7%)	4 (5.7%)	11 (3.4%)
		High	11 (6.1%)	2 (2.7%)	7 (3.9%)	1 (1.4%)	10 (3.1%)
Week 8	m		176	72	175	68	315
	Normal	Low	0	0	1 (0.6%)	0	1 (0.3%)
		Normal	152 (86.4%)	66 (91.7%)	161 (92.0%)	61 (89.7%)	288 (91.4%)
		High	8 (4.5%)	0	3 (1.7%)	2 (2.9%)	5 (1.6%)
	High	Normal	7 (4.0%)	3 (4.2%)	4 (2.3%)	2 (2.9%)	9 (2.9%)
		High	9 (5.1%)	3 (4.2%)	6 (3.4%)	3 (4.4%)	12 (3.8%)
Week 12	m		168	72	170	68	310
	Normal	Low	0	0	1 (0.6%)	0	1 (0.3%)
		Normal	142 (84.5%)	64 (88.9%)	153 (90.0%)	60 (88.2%)	277 (89.4%)
		High	10 (6.0%)	2 (2.8%)	7 (4.1%)	3 (4.4%)	12 (3.9%)
	High	Normal	5 (3.0%)	5 (6.9%)	3 (1.8%)	3 (4.4%)	11 (3.5%)
		High	11 (6.5%)	1 (1.4%)	6 (3.5%)	2 (2.9%)	9 (2.9%)
Week 16	m		168	71	171	68	310
	Normal	Normal	141 (83.9%)	65 (91.5%)	155 (90.6%)	59 (86.8%)	279 (90.0%)
		High	11 (6.5%)	0	6 (3.5%)	4 (5.9%)	10 (3.2%)
	High	Normal	8 (4.8%)	5 (7.0%)	4 (2.3%)	3 (4.4%)	12 (3.9%)
		High	8 (4.8%)	1 (1.4%)	6 (3.5%)	2 (2.9%)	9 (2.9%)
Week 20	m		168	70	169	67	306
	Normal	Low	0	0	1 (0.6%)	0	1 (0.3%)
		Normal	142 (84.5%)	62 (88.6%)	155 (91.7%)	58 (86.6%)	275 (89.9%)
		High	10 (6.0%)	2 (2.9%)	3 (1.8%)	4 (6.0%)	9 (2.9%)
	High	Normal	6 (3.6%)	4 (5.7%)	2 (1.2%)	3 (4.5%)	9 (2.9%)

Parameter Week	Baseline	Post-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
		High	10 (6.0%)	2 (2.9%)	8 (4.7%)	2 (3.0%)	12 (3.9%)
Week 24	m		165	70	168	67	305
	Normal	Normal	143 (86.7%)	63 (90.0%)	153 (91.1%)	58 (86.6%)	274 (89.8%)
		High	6 (3.6%)	1 (1.4%)	5 (3.0%)	4 (6.0%)	10 (3.3%)
	High	Normal	9 (5.5%)	4 (5.7%)	2 (1.2%)	2 (3.0%)	8 (2.6%)
		High	7 (4.2%)	2 (2.9%)	8 (4.8%)	3 (4.5%)	13 (4.3%)
LOCF Endpoint	m		181	75	180	75	330
	Normal	Normal	158 (87.3%)	68 (90.7%)	164 (91.1%)	64 (85.3%)	296 (89.7%)
		High	6 (3.3%)	1 (1.3%)	6 (3.3%)	5 (6.7%)	12 (3.6%)
	High	Normal	9 (5.0%)	4 (5.3%)	2 (1.1%)	3 (4.0%)	9 (2.7%)
		High	8 (4.4%)	2 (2.7%)	8 (4.4%)	3 (4.0%)	13 (3.9%)
Bicarbonate (mmol/L)							
Week 2	m		74	75	73	71	219
	Low	Low	1 (1.4%)	0	0	0	0
	Normal	Low	1 (1.4%)	2 (2.7%)	2 (2.7%)	1 (1.4%)	5 (2.3%)
		Normal	72 (97.3%)	71 (94.7%)	71 (97.3%)	70 (98.6%)	212 (96.8%)
	High	Normal	0	2 (2.7%)	0	0	2 (0.9%)
Week 4	m		179	75	178	70	323
	Low	Normal	1 (0.6%)	0	0	0	0
	Normal	Low	1 (0.6%)	2 (2.7%)	1 (0.6%)	2 (2.9%)	5 (1.5%)
		Normal	177 (98.9%)	71 (94.7%)	177 (99.4%)	68 (97.1%)	316 (97.8%)
	High	Normal	0	2 (2.7%)	0	0	2 (0.6%)
Week 8	m		176	72	175	68	315
	Low	Normal	1 (0.6%)	0	0	0	0
	Normal	Low	0	0	1 (0.6%)	3 (4.4%)	4 (1.3%)
		Normal	175 (99.4%)	70 (97.2%)	174 (99.4%)	64 (94.1%)	308 (97.8%)

Parameter Week	Baseline	Post-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
		High	0	0	0	1 (1.5%)	1 (0.3%)
	High	Normal	0	2 (2.8%)	0	0	2 (0.6%)
Week 12	m		169	72	172	68	312
	Normal	Low	1 (0.6%)	0	1 (0.6%)	0	1 (0.3%)
		Normal	168 (99.4%)	70 (97.2%)	171 (99.4%)	68 (100.0%)	309 (99.0%)
	High	Normal	0	2 (2.8%)	0	0	2 (0.6%)
Week 16	m		168	71	171	68	310
	Normal	Normal	168 (100.0%)	68 (95.8%)	170 (99.4%)	68 (100.0%)	306 (98.7%)
		High	0	1 (1.4%)	1 (0.6%)	0	2 (0.6%)
	High	Normal	0	1 (1.4%)	0	0	1 (0.3%)
		High	0	1 (1.4%)	0	0	1 (0.3%)
Week 20	m		168	70	169	67	306
	Normal	Normal	168 (100.0%)	68 (97.1%)	169 (100.0%)	67 (100.0%)	304 (99.3%)
	High	Normal	0	2 (2.9%)	0	0	2 (0.7%)
Week 24	m		167	70	168	67	305
	Normal	Normal	167 (100.0%)	67 (95.7%)	168 (100.0%)	67 (100.0%)	302 (99.0%)
		High	0	1 (1.4%)	0	0	1 (0.3%)
	High	Normal	0	2 (2.9%)	0	0	2 (0.7%)
LOCF Endpoint	m		181	75	180	75	330
	Low	Normal	1 (0.6%)	0	0	0	0
	Normal	Low	0	0	1 (0.6%)	2 (2.7%)	3 (0.9%)
		Normal	180 (99.4%)	72 (96.0%)	179 (99.4%)	73 (97.3%)	324 (98.2%)
		High	0	1 (1.3%)	0	0	1 (0.3%)
	High	Normal	0	2 (2.7%)	0	0	2 (0.6%)

Bilirubin (umol/L)

Parameter Week	Baseline	Post-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
Week 2	m		74	75	73	71	219
	Normal	Normal	61 (82.4%)	55 (73.3%)	55 (75.3%)	59 (83.1%)	169 (77.2%)
		High	6 (8.1%)	6 (8.0%)	1 (1.4%)	3 (4.2%)	10 (4.6%)
	High	Normal	3 (4.1%)	9 (12.0%)	6 (8.2%)	1 (1.4%)	16 (7.3%)
		High	4 (5.4%)	5 (6.7%)	11 (15.1%)	8 (11.3%)	24 (11.0%)
Week 4	m		179	75	178	70	323
	Low	Normal	1 (0.6%)	0	1 (0.6%)	0	1 (0.3%)
	Normal	Normal	164 (91.6%)	57 (76.0%)	153 (86.0%)	60 (85.7%)	270 (83.6%)
		High	5 (2.8%)	4 (5.3%)	4 (2.2%)	1 (1.4%)	9 (2.8%)
	High	Normal	2 (1.1%)	8 (10.7%)	11 (6.2%)	6 (8.6%)	25 (7.7%)
		High	7 (3.9%)	6 (8.0%)	9 (5.1%)	3 (4.3%)	18 (5.6%)
Week 8	m		175	72	175	68	315
	Low	Normal	1 (0.6%)	0	1 (0.6%)	0	1 (0.3%)
	Normal	Low	0	0	1 (0.6%)	0	1 (0.3%)
		Normal	156 (89.1%)	53 (73.6%)	150 (85.7%)	56 (82.4%)	259 (82.2%)
		High	9 (5.1%)	5 (6.9%)	5 (2.9%)	3 (4.4%)	13 (4.1%)
	High	Normal	3 (1.7%)	7 (9.7%)	9 (5.1%)	3 (4.4%)	19 (6.0%)
		High	6 (3.4%)	7 (9.7%)	9 (5.1%)	6 (8.8%)	22 (7.0%)
Week 12	m		169	72	172	68	312
	Low	Normal	1 (0.6%)	0	1 (0.6%)	0	1 (0.3%)
	Normal	Normal	153 (90.5%)	55 (76.4%)	149 (86.6%)	54 (79.4%)	258 (82.7%)
		High	7 (4.1%)	3 (4.2%)	4 (2.3%)	5 (7.4%)	12 (3.8%)
	High	Normal	4 (2.4%)	7 (9.7%)	9 (5.2%)	4 (5.9%)	20 (6.4%)
		High	4 (2.4%)	7 (9.7%)	9 (5.2%)	5 (7.4%)	21 (6.7%)
Week 16	m		168	71	171	68	310
	Low	Low	0	0	1 (0.6%)	0	1 (0.3%)
		Normal	1 (0.6%)	0	0	0	0

Parameter Week	Baseline	Post-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
	Normal	Low	1 (0.6%)	0	0	0	0
		Normal	149 (88.7%)	54 (76.1%)	147 (86.0%)	58 (85.3%)	259 (83.5%)
		High	9 (5.4%)	3 (4.2%)	5 (2.9%)	1 (1.5%)	9 (2.9%)
	High	Normal	3 (1.8%)	9 (12.7%)	11 (6.4%)	4 (5.9%)	24 (7.7%)
		High	5 (3.0%)	5 (7.0%)	7 (4.1%)	5 (7.4%)	17 (5.5%)
Week 20	m		168	70	169	67	306
	Low	Normal	1 (0.6%)	0	1 (0.6%)	0	1 (0.3%)
	Normal	Normal	149 (88.7%)	56 (80.0%)	147 (87.0%)	57 (85.1%)	260 (85.0%)
		High	10 (6.0%)	0	4 (2.4%)	1 (1.5%)	5 (1.6%)
	High	Normal	3 (1.8%)	8 (11.4%)	11 (6.5%)	1 (1.5%)	20 (6.5%)
		High	5 (3.0%)	6 (8.6%)	6 (3.6%)	8 (11.9%)	20 (6.5%)
Week 24	m		167	70	168	67	305
	Low	Normal	1 (0.6%)	0	1 (0.6%)	0	1 (0.3%)
	Normal	Low	1 (0.6%)	0	0	0	0
		Normal	146 (87.4%)	52 (74.3%)	144 (85.7%)	56 (83.6%)	252 (82.6%)
		High	11 (6.6%)	4 (5.7%)	6 (3.6%)	2 (3.0%)	12 (3.9%)
	High	Normal	3 (1.8%)	10 (14.3%)	8 (4.8%)	4 (6.0%)	22 (7.2%)
		High	5 (3.0%)	4 (5.7%)	9 (5.4%)	5 (7.5%)	18 (5.9%)
LOCF Endpoint	m		181	75	180	75	330
	Low	Normal	1 (0.6%)	0	1 (0.6%)	0	1 (0.3%)
	Normal	Low	1 (0.6%)	0	0	0	0
		Normal	158 (87.3%)	56 (74.7%)	152 (84.4%)	62 (82.7%)	270 (81.8%)
		High	11 (6.1%)	5 (6.7%)	6 (3.3%)	2 (2.7%)	13 (3.9%)
	High	Normal	3 (1.7%)	10 (13.3%)	10 (5.6%)	6 (8.0%)	26 (7.9%)
		High	7 (3.9%)	4 (5.3%)	11 (6.1%)	5 (6.7%)	20 (6.1%)
Calcium (mmol/L)							
Week 2	m		74	75	73	71	219

Parameter Week	Baseline	Post-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
	Low	Low	1 (1.4%)	0	2 (2.7%)	2 (2.8%)	4 (1.8%)
		Normal	5 (6.8%)	3 (4.0%)	3 (4.1%)	2 (2.8%)	8 (3.7%)
	Normal	Low	4 (5.4%)	6 (8.0%)	5 (6.8%)	7 (9.9%)	18 (8.2%)
		Normal	64 (86.5%)	66 (88.0%)	63 (86.3%)	60 (84.5%)	189 (86.3%)
Week 4	m		179	75	178	70	323
	Low	Low	0	1 (1.3%)	3 (1.7%)	0	4 (1.2%)
		Normal	5 (2.8%)	2 (2.7%)	4 (2.2%)	4 (5.7%)	10 (3.1%)
	Normal	Low	3 (1.7%)	5 (6.7%)	6 (3.4%)	7 (10.0%)	18 (5.6%)
		Normal	171 (95.5%)	67 (89.3%)	165 (92.7%)	59 (84.3%)	291 (90.1%)
Week 8	m		176	72	175	68	315
	Low	Low	3 (1.7%)	0	2 (1.1%)	1 (1.5%)	3 (1.0%)
		Normal	2 (1.1%)	3 (4.2%)	5 (2.9%)	3 (4.4%)	11 (3.5%)
	Normal	Low	2 (1.1%)	4 (5.6%)	5 (2.9%)	3 (4.4%)	12 (3.8%)
		Normal	169 (96.0%)	65 (90.3%)	163 (93.1%)	61 (89.7%)	289 (91.7%)
Week 12	m		169	72	172	68	312
	Low	Low	1 (0.6%)	0	0	0	0
		Normal	4 (2.4%)	3 (4.2%)	6 (3.5%)	4 (5.9%)	13 (4.2%)
	Normal	Low	1 (0.6%)	5 (6.9%)	3 (1.7%)	2 (2.9%)	10 (3.2%)
		Normal	163 (96.4%)	64 (88.9%)	163 (94.8%)	62 (91.2%)	289 (92.6%)
Week 16	m		168	71	171	68	310
	Low	Low	1 (0.6%)	0	0	0	0
		Normal	4 (2.4%)	3 (4.2%)	6 (3.5%)	4 (5.9%)	13 (4.2%)
	Normal	Low	1 (0.6%)	2 (2.8%)	0	0	2 (0.6%)
		Normal	162 (96.4%)	66 (93.0%)	165 (96.5%)	64 (94.1%)	295 (95.2%)
Week 20	m		168	70	169	67	306
	Low	Low	1 (0.6%)	0	0	0	0

Parameter Week	Baseline	Post-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
		Normal	4 (2.4%)	3 (4.3%)	6 (3.6%)	4 (6.0%)	13 (4.2%)
	Normal	Low	0	2 (2.9%)	0	0	2 (0.7%)
		Normal	163 (97.0%)	65 (92.9%)	163 (96.4%)	63 (94.0%)	291 (95.1%)
Week 24	m		167	70	168	67	305
	Low	Normal	5 (3.0%)	3 (4.3%)	6 (3.6%)	4 (6.0%)	13 (4.3%)
	Normal	Low	3 (1.8%)	1 (1.4%)	0	1 (1.5%)	2 (0.7%)
		Normal	159 (95.2%)	66 (94.3%)	162 (96.4%)	62 (92.5%)	290 (95.1%)
LOCF Endpoint	m		181	75	180	75	330
	Low	Low	1 (0.6%)	0	0	0	0
		Normal	5 (2.8%)	3 (4.0%)	7 (3.9%)	4 (5.3%)	14 (4.2%)
	Normal	Low	3 (1.7%)	1 (1.3%)	1 (0.6%)	1 (1.3%)	3 (0.9%)
		Normal	172 (95.0%)	71 (94.7%)	172 (95.6%)	70 (93.3%)	313 (94.8%)
Chloride (mmol/L)							
Week 2	m		74	75	73	71	219
	Low	Normal	0	0	0	1 (1.4%)	1 (0.5%)
	Normal	Normal	74 (100.0%)	75 (100.0%)	73 (100.0%)	70 (98.6%)	218 (99.5%)
Week 4	m		179	75	178	70	323
	Low	Normal	1 (0.6%)	0	1 (0.6%)	1 (1.4%)	2 (0.6%)
	Normal	Normal	178 (99.4%)	75 (100.0%)	177 (99.4%)	69 (98.6%)	321 (99.4%)
Week 8	m		176	72	175	68	315
	Low	Normal	1 (0.6%)	0	1 (0.6%)	1 (1.5%)	2 (0.6%)
	Normal	Normal	175 (99.4%)	72 (100.0%)	174 (99.4%)	67 (98.5%)	313 (99.4%)
Week 12	m		169	72	172	68	312
	Low	Low	0	0	0	1 (1.5%)	1 (0.3%)
		Normal	1 (0.6%)	0	1 (0.6%)	0	1 (0.3%)

Parameter Week	Baseline	Post-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
	Normal	Normal	168 (99.4%)	72 (100.0%)	171 (99.4%)	67 (98.5%)	310 (99.4%)
Week 16	m		168	71	171	68	310
	Low	Low	0	0	0	1 (1.5%)	1 (0.3%)
		Normal	1 (0.6%)	0	1 (0.6%)	0	1 (0.3%)
	Normal	Normal	167 (99.4%)	71 (100.0%)	170 (99.4%)	67 (98.5%)	308 (99.4%)
Week 20	m		168	70	169	67	306
	Low	Low	0	0	0	1 (1.5%)	1 (0.3%)
		Normal	1 (0.6%)	0	1 (0.6%)	0	1 (0.3%)
	Normal	Normal	167 (99.4%)	70 (100.0%)	168 (99.4%)	66 (98.5%)	304 (99.3%)
Week 24	m		167	70	168	67	305
	Low	Low	0	0	0	1 (1.5%)	1 (0.3%)
		Normal	1 (0.6%)	0	1 (0.6%)	0	1 (0.3%)
	Normal	Normal	166 (99.4%)	70 (100.0%)	167 (99.4%)	66 (98.5%)	303 (99.3%)
LOCF Endpoint	m		181	75	180	75	330
	Low	Low	0	0	0	1 (1.3%)	1 (0.3%)
		Normal	1 (0.6%)	0	1 (0.6%)	0	1 (0.3%)
	Normal	Low	0	0	0	1 (1.3%)	1 (0.3%)
		Normal	180 (99.4%)	75 (100.0%)	179 (99.4%)	73 (97.3%)	327 (99.1%)
Creatine Kinase (U/L)							
Week 2	m		74	75	73	71	219
	Normal	Normal	67 (90.5%)	70 (93.3%)	70 (95.9%)	64 (90.1%)	204 (93.2%)
		High	2 (2.7%)	2 (2.7%)	1 (1.4%)	3 (4.2%)	6 (2.7%)
	High	Normal	2 (2.7%)	2 (2.7%)	0	1 (1.4%)	3 (1.4%)
		High	3 (4.1%)	1 (1.3%)	2 (2.7%)	3 (4.2%)	6 (2.7%)
Week 4	m		179	75	178	70	323

Parameter Week	Baseline	Post-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
	Low	Normal	1 (0.6%)	0	0	0	0
	Normal	Low	0	0	1 (0.6%)	0	1 (0.3%)
		Normal	161 (89.9%)	70 (93.3%)	165 (92.7%)	63 (90.0%)	298 (92.3%)
		High	8 (4.5%)	2 (2.7%)	7 (3.9%)	3 (4.3%)	12 (3.7%)
	High	Normal	7 (3.9%)	2 (2.7%)	3 (1.7%)	1 (1.4%)	6 (1.9%)
		High	2 (1.1%)	1 (1.3%)	2 (1.1%)	3 (4.3%)	6 (1.9%)
Week 8	m		176	72	175	68	315
	Low	Normal	1 (0.6%)	0	0	0	0
	Normal	Low	0	0	1 (0.6%)	0	1 (0.3%)
		Normal	160 (90.9%)	67 (93.1%)	168 (96.0%)	62 (91.2%)	297 (94.3%)
		High	6 (3.4%)	2 (2.8%)	1 (0.6%)	2 (2.9%)	5 (1.6%)
	High	Normal	7 (4.0%)	1 (1.4%)	3 (1.7%)	1 (1.5%)	5 (1.6%)
		High	2 (1.1%)	2 (2.8%)	2 (1.1%)	3 (4.4%)	7 (2.2%)
Week 12	m		169	72	172	68	312
	Low	Low	1 (0.6%)	0	0	0	0
	Normal	Low	1 (0.6%)	0	0	0	0
		Normal	152 (89.9%)	68 (94.4%)	160 (93.0%)	64 (94.1%)	292 (93.6%)
		High	7 (4.1%)	1 (1.4%)	7 (4.1%)	0	8 (2.6%)
	High	Normal	4 (2.4%)	1 (1.4%)	3 (1.7%)	2 (2.9%)	6 (1.9%)
		High	4 (2.4%)	2 (2.8%)	2 (1.2%)	2 (2.9%)	6 (1.9%)
Week 16	m		168	71	171	68	310
	Low	Low	1 (0.6%)	0	0	0	0
	Normal	Low	0	0	2 (1.2%)	0	2 (0.6%)
		Normal	152 (90.5%)	66 (93.0%)	158 (92.4%)	62 (91.2%)	286 (92.3%)
		High	7 (4.2%)	2 (2.8%)	6 (3.5%)	2 (2.9%)	10 (3.2%)
	High	Normal	6 (3.6%)	2 (2.8%)	4 (2.3%)	1 (1.5%)	7 (2.3%)
		High	2 (1.2%)	1 (1.4%)	1 (0.6%)	3 (4.4%)	5 (1.6%)

Parameter Week	Baseline	Post-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
Week 20	m		168	70	169	67	306
	Low	Normal	1 (0.6%)	0	0	0	0
	Normal	Normal	154 (91.7%)	66 (94.3%)	158 (93.5%)	60 (89.6%)	284 (92.8%)
		High	5 (3.0%)	1 (1.4%)	6 (3.6%)	3 (4.5%)	10 (3.3%)
	High	Normal	6 (3.6%)	1 (1.4%)	3 (1.8%)	2 (3.0%)	6 (2.0%)
		High	2 (1.2%)	2 (2.9%)	2 (1.2%)	2 (3.0%)	6 (2.0%)
Week 24	m		167	70	168	67	305
	Low	Normal	1 (0.6%)	0	0	0	0
	Normal	Low	0	0	1 (0.6%)	0	1 (0.3%)
		Normal	151 (90.4%)	64 (91.4%)	156 (92.9%)	61 (91.0%)	281 (92.1%)
		High	7 (4.2%)	3 (4.3%)	6 (3.6%)	2 (3.0%)	11 (3.6%)
	High	Normal	6 (3.6%)	1 (1.4%)	3 (1.8%)	1 (1.5%)	5 (1.6%)
		High	2 (1.2%)	2 (2.9%)	2 (1.2%)	3 (4.5%)	7 (2.3%)
LOCF Endpoint	m		181	75	180	75	330
	Low	Normal	1 (0.6%)	0	0	0	0
	Normal	Low	0	0	1 (0.6%)	0	1 (0.3%)
		Normal	164 (90.6%)	69 (92.0%)	168 (93.3%)	69 (92.0%)	306 (92.7%)
		High	7 (3.9%)	3 (4.0%)	6 (3.3%)	2 (2.7%)	11 (3.3%)
	High	Normal	7 (3.9%)	1 (1.3%)	3 (1.7%)	1 (1.3%)	5 (1.5%)
		High	2 (1.1%)	2 (2.7%)	2 (1.1%)	3 (4.0%)	7 (2.1%)
Creatinine (umol/L)							
Week 2	m		74	75	73	71	219
	Low	Low	2 (2.7%)	1 (1.3%)	1 (1.4%)	3 (4.2%)	5 (2.3%)
		Normal	0	2 (2.7%)	2 (2.7%)	0	4 (1.8%)
	Normal	Low	2 (2.7%)	0	1 (1.4%)	2 (2.8%)	3 (1.4%)
		Normal	70 (94.6%)	72 (96.0%)	69 (94.5%)	66 (93.0%)	207 (94.5%)
Week 4	m		179	75	178	70	323

Parameter Week	Baseline	Post-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
	Low	Low	1 (0.6%)	1 (1.3%)	1 (0.6%)	1 (1.4%)	3 (0.9%)
		Normal	1 (0.6%)	2 (2.7%)	2 (1.1%)	2 (2.9%)	6 (1.9%)
	Normal	Low	1 (0.6%)	3 (4.0%)	2 (1.1%)	2 (2.9%)	7 (2.2%)
		Normal	176 (98.3%)	69 (92.0%)	172 (96.6%)	65 (92.9%)	306 (94.7%)
		High	0	0	1 (0.6%)	0	1 (0.3%)
Week 8	m		176	72	175	68	315
	Low	Low	2 (1.1%)	1 (1.4%)	0	1 (1.5%)	2 (0.6%)
		Normal	0	2 (2.8%)	3 (1.7%)	2 (2.9%)	7 (2.2%)
	Normal	Low	2 (1.1%)	1 (1.4%)	1 (0.6%)	2 (2.9%)	4 (1.3%)
		Normal	172 (97.7%)	68 (94.4%)	171 (97.7%)	63 (92.6%)	302 (95.9%)
Week 12	m		169	72	172	68	312
	Low	Low	0	1 (1.4%)	0	1 (1.5%)	2 (0.6%)
		Normal	2 (1.2%)	2 (2.8%)	3 (1.7%)	2 (2.9%)	7 (2.2%)
	Normal	Low	1 (0.6%)	1 (1.4%)	1 (0.6%)	4 (5.9%)	6 (1.9%)
		Normal	166 (98.2%)	68 (94.4%)	167 (97.1%)	61 (89.7%)	296 (94.9%)
		High	0	0	1 (0.6%)	0	1 (0.3%)
Week 16	m		168	71	171	68	310
	Low	Low	1 (0.6%)	0	0	2 (2.9%)	2 (0.6%)
		Normal	1 (0.6%)	3 (4.2%)	3 (1.8%)	1 (1.5%)	7 (2.3%)
	Normal	Low	1 (0.6%)	0	1 (0.6%)	1 (1.5%)	2 (0.6%)
		Normal	165 (98.2%)	68 (95.8%)	166 (97.1%)	64 (94.1%)	298 (96.1%)
		High	0	0	1 (0.6%)	0	1 (0.3%)
Week 20	m		168	70	169	67	306
	Low	Low	2 (1.2%)	0	0	1 (1.5%)	1 (0.3%)
		Normal	0	3 (4.3%)	3 (1.8%)	2 (3.0%)	8 (2.6%)
	Normal	Low	1 (0.6%)	0	2 (1.2%)	2 (3.0%)	4 (1.3%)
		Normal	165 (98.2%)	67 (95.7%)	163 (96.4%)	62 (92.5%)	292 (95.4%)

Parameter Week	Baseline	Post-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
		High	0	0	1 (0.6%)	0	1 (0.3%)
Week 24	m		167	70	168	67	305
	Low	Low	1 (0.6%)	0	1 (0.6%)	1 (1.5%)	2 (0.7%)
		Normal	1 (0.6%)	3 (4.3%)	2 (1.2%)	2 (3.0%)	7 (2.3%)
	Normal	Low	0	0	1 (0.6%)	2 (3.0%)	3 (1.0%)
		Normal	165 (98.8%)	67 (95.7%)	163 (97.0%)	62 (92.5%)	292 (95.7%)
		High	0	0	1 (0.6%)	0	1 (0.3%)
LOCF Endpoint	m		181	75	180	75	330
	Low	Low	1 (0.6%)	0	1 (0.6%)	1 (1.3%)	2 (0.6%)
		Normal	1 (0.6%)	3 (4.0%)	2 (1.1%)	4 (5.3%)	9 (2.7%)
	Normal	Low	0	1 (1.3%)	1 (0.6%)	2 (2.7%)	4 (1.2%)
		Normal	179 (98.9%)	71 (94.7%)	175 (97.2%)	68 (90.7%)	314 (95.2%)
		High	0	0	1 (0.6%)	0	1 (0.3%)
Gamma Glutamyl Transferase (U/L)							
Week 2	m		74	75	73	71	219
	Low	Low	1 (1.4%)	1 (1.3%)	0	1 (1.4%)	2 (0.9%)
	Normal	Low	0	1 (1.3%)	0	0	1 (0.5%)
		Normal	52 (70.3%)	57 (76.0%)	60 (82.2%)	56 (78.9%)	173 (79.0%)
		High	2 (2.7%)	2 (2.7%)	0	1 (1.4%)	3 (1.4%)
	High	Normal	1 (1.4%)	1 (1.3%)	2 (2.7%)	3 (4.2%)	6 (2.7%)
		High	18 (24.3%)	13 (17.3%)	11 (15.1%)	10 (14.1%)	34 (15.5%)
Week 4	m		179	75	178	70	323
	Low	Low	1 (0.6%)	1 (1.3%)	1 (0.6%)	1 (1.4%)	3 (0.9%)
		Normal	1 (0.6%)	0	0	0	0
	Normal	Low	0	1 (1.3%)	0	2 (2.9%)	3 (0.9%)
		Normal	134 (74.9%)	59 (78.7%)	149 (83.7%)	53 (75.7%)	261 (80.8%)

Parameter Week	Baseline	Post-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
		High	6 (3.4%)	0	0	1 (1.4%)	1 (0.3%)
	High	Normal	2 (1.1%)	0	7 (3.9%)	4 (5.7%)	11 (3.4%)
		High	35 (19.6%)	14 (18.7%)	21 (11.8%)	9 (12.9%)	44 (13.6%)
Week 8	m		176	72	175	68	315
	Low	Low	1 (0.6%)	1 (1.4%)	1 (0.6%)	1 (1.5%)	3 (1.0%)
		Normal	1 (0.6%)	0	0	0	0
	Normal	Low	1 (0.6%)	2 (2.8%)	0	0	2 (0.6%)
		Normal	129 (73.3%)	55 (76.4%)	144 (82.3%)	53 (77.9%)	252 (80.0%)
		High	8 (4.5%)	1 (1.4%)	3 (1.7%)	2 (2.9%)	6 (1.9%)
	High	Normal	4 (2.3%)	0	6 (3.4%)	6 (8.8%)	12 (3.8%)
		High	32 (18.2%)	13 (18.1%)	21 (12.0%)	6 (8.8%)	40 (12.7%)
Week 12	m		169	72	172	68	312
	Low	Low	1 (0.6%)	1 (1.4%)	0	1 (1.5%)	2 (0.6%)
		Normal	1 (0.6%)	0	1 (0.6%)	0	1 (0.3%)
	Normal	Low	0	1 (1.4%)	2 (1.2%)	1 (1.5%)	4 (1.3%)
		Normal	124 (73.4%)	54 (75.0%)	138 (80.2%)	52 (76.5%)	244 (78.2%)
		High	9 (5.3%)	3 (4.2%)	4 (2.3%)	2 (2.9%)	9 (2.9%)
	High	Normal	6 (3.6%)	1 (1.4%)	6 (3.5%)	4 (5.9%)	11 (3.5%)
		High	28 (16.6%)	12 (16.7%)	21 (12.2%)	8 (11.8%)	41 (13.1%)
Week 16	m		168	71	171	68	310
	Low	Low	1 (0.6%)	1 (1.4%)	1 (0.6%)	1 (1.5%)	3 (1.0%)
		Normal	1 (0.6%)	0	0	0	0
	Normal	Low	0	1 (1.4%)	1 (0.6%)	0	2 (0.6%)
		Normal	125 (74.4%)	54 (76.1%)	140 (81.9%)	52 (76.5%)	246 (79.4%)
		High	8 (4.8%)	2 (2.8%)	3 (1.8%)	3 (4.4%)	8 (2.6%)
	High	Normal	4 (2.4%)	0	8 (4.7%)	4 (5.9%)	12 (3.9%)
		High	29 (17.3%)	13 (18.3%)	18 (10.5%)	8 (11.8%)	39 (12.6%)

Parameter Week	Baseline	Post-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
Week 20	m		168	70	169	67	306
	Low	Low	1 (0.6%)	1 (1.4%)	1 (0.6%)	1 (1.5%)	3 (1.0%)
		Normal	1 (0.6%)	0	0	0	0
	Normal	Low	0	0	1 (0.6%)	1 (1.5%)	2 (0.7%)
		Normal	122 (72.6%)	53 (75.7%)	135 (79.9%)	49 (73.1%)	237 (77.5%)
		High	11 (6.5%)	4 (5.7%)	6 (3.6%)	4 (6.0%)	14 (4.6%)
	High	Normal	2 (1.2%)	1 (1.4%)	7 (4.1%)	4 (6.0%)	12 (3.9%)
		High	31 (18.5%)	11 (15.7%)	19 (11.2%)	8 (11.9%)	38 (12.4%)
Week 24	m		167	70	168	67	305
	Low	Low	0	1 (1.4%)	1 (0.6%)	1 (1.5%)	3 (1.0%)
		Normal	2 (1.2%)	0	0	0	0
	Normal	Low	1 (0.6%)	1 (1.4%)	2 (1.2%)	1 (1.5%)	4 (1.3%)
		Normal	122 (73.1%)	50 (71.4%)	136 (81.0%)	48 (71.6%)	234 (76.7%)
		High	9 (5.4%)	6 (8.6%)	3 (1.8%)	5 (7.5%)	14 (4.6%)
	High	Normal	5 (3.0%)	1 (1.4%)	5 (3.0%)	2 (3.0%)	8 (2.6%)
		High	28 (16.8%)	11 (15.7%)	21 (12.5%)	10 (14.9%)	42 (13.8%)
LOCF Endpoint	m		181	75	180	75	330
	Low	Low	0	1 (1.3%)	1 (0.6%)	1 (1.3%)	3 (0.9%)
		Normal	2 (1.1%)	0	0	0	0
	Normal	Low	1 (0.6%)	1 (1.3%)	2 (1.1%)	1 (1.3%)	4 (1.2%)
		Normal	131 (72.4%)	53 (70.7%)	146 (81.1%)	54 (72.0%)	253 (76.7%)
		High	10 (5.5%)	6 (8.0%)	3 (1.7%)	6 (8.0%)	15 (4.5%)
	High	Normal	6 (3.3%)	1 (1.3%)	5 (2.8%)	2 (2.7%)	8 (2.4%)
		High	31 (17.1%)	13 (17.3%)	23 (12.8%)	11 (14.7%)	47 (14.2%)
Lipase (U/L)							
Week 2	m		74	75	73	71	219
	Low	Low	5 (6.8%)	4 (5.3%)	5 (6.8%)	5 (7.0%)	14 (6.4%)
		Normal	2 (2.7%)	1 (1.3%)	6 (8.2%)	3 (4.2%)	10 (4.6%)

Parameter Week	Baseline	Post-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
	Normal	Low	3 (4.1%)	1 (1.3%)	1 (1.4%)	0	2 (0.9%)
		Normal	61 (82.4%)	68 (90.7%)	60 (82.2%)	60 (84.5%)	188 (85.8%)
		High	0	1 (1.3%)	0	1 (1.4%)	2 (0.9%)
	High	Normal	1 (1.4%)	0	1 (1.4%)	2 (2.8%)	3 (1.4%)
		High	2 (2.7%)	0	0	0	0
Week 4	m		179	75	178	70	323
	Low	Low	5 (2.8%)	4 (5.3%)	5 (2.8%)	4 (5.7%)	13 (4.0%)
		Normal	2 (1.1%)	1 (1.3%)	6 (3.4%)	4 (5.7%)	11 (3.4%)
	Normal	Low	2 (1.1%)	2 (2.7%)	3 (1.7%)	0	5 (1.5%)
		Normal	165 (92.2%)	67 (89.3%)	161 (90.4%)	60 (85.7%)	288 (89.2%)
		High	0	1 (1.3%)	1 (0.6%)	0	2 (0.6%)
	High	Normal	5 (2.8%)	0	1 (0.6%)	2 (2.9%)	3 (0.9%)
		High	0	0	1 (0.6%)	0	1 (0.3%)
Week 8	m		176	72	175	68	315
	Low	Low	6 (3.4%)	5 (6.9%)	8 (4.6%)	4 (5.9%)	17 (5.4%)
		Normal	1 (0.6%)	0	3 (1.7%)	4 (5.9%)	7 (2.2%)
	Normal	Low	2 (1.1%)	4 (5.6%)	1 (0.6%)	2 (2.9%)	7 (2.2%)
		Normal	160 (90.9%)	62 (86.1%)	159 (90.9%)	56 (82.4%)	277 (87.9%)
		High	2 (1.1%)	1 (1.4%)	2 (1.1%)	0	3 (1.0%)
	High	Normal	5 (2.8%)	0	2 (1.1%)	2 (2.9%)	4 (1.3%)
Week 12	m		169	72	172	68	312
	Low	Low	6 (3.6%)	2 (2.8%)	7 (4.1%)	3 (4.4%)	12 (3.8%)
		Normal	1 (0.6%)	3 (4.2%)	4 (2.3%)	5 (7.4%)	12 (3.8%)
	Normal	Low	3 (1.8%)	1 (1.4%)	2 (1.2%)	1 (1.5%)	4 (1.3%)
		Normal	153 (90.5%)	66 (91.7%)	155 (90.1%)	57 (83.8%)	278 (89.1%)
		High	1 (0.6%)	0	2 (1.2%)	0	2 (0.6%)
	High	Normal	4 (2.4%)	0	1 (0.6%)	2 (2.9%)	3 (1.0%)
		High	1 (0.6%)	0	1 (0.6%)	0	1 (0.3%)

Parameter Week	Baseline	Post-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
Week 16	m		168	71	171	68	310
	Low	Low	3 (1.8%)	4 (5.6%)	7 (4.1%)	3 (4.4%)	14 (4.5%)
		Normal	4 (2.4%)	1 (1.4%)	4 (2.3%)	5 (7.4%)	10 (3.2%)
	Normal	Low	4 (2.4%)	2 (2.8%)	3 (1.8%)	2 (2.9%)	7 (2.3%)
		Normal	152 (90.5%)	63 (88.7%)	153 (89.5%)	55 (80.9%)	271 (87.4%)
		High	0	1 (1.4%)	2 (1.2%)	1 (1.5%)	4 (1.3%)
	High	Normal	3 (1.8%)	0	1 (0.6%)	1 (1.5%)	2 (0.6%)
		High	2 (1.2%)	0	1 (0.6%)	1 (1.5%)	2 (0.6%)
Week 20	m		168	70	169	67	306
	Low	Low	3 (1.8%)	3 (4.3%)	6 (3.6%)	4 (6.0%)	13 (4.2%)
		Normal	4 (2.4%)	2 (2.9%)	5 (3.0%)	4 (6.0%)	11 (3.6%)
	Normal	Low	1 (0.6%)	3 (4.3%)	2 (1.2%)	1 (1.5%)	6 (2.0%)
		Normal	153 (91.1%)	61 (87.1%)	152 (89.9%)	56 (83.6%)	269 (87.9%)
		High	2 (1.2%)	1 (1.4%)	2 (1.2%)	0	3 (1.0%)
	High	Normal	5 (3.0%)	0	1 (0.6%)	2 (3.0%)	3 (1.0%)
		High	0	0	1 (0.6%)	0	1 (0.3%)
Week 24	m		167	70	168	67	305
	Low	Low	5 (3.0%)	3 (4.3%)	7 (4.2%)	3 (4.5%)	13 (4.3%)
		Normal	2 (1.2%)	2 (2.9%)	4 (2.4%)	5 (7.5%)	11 (3.6%)
	Normal	Low	2 (1.2%)	1 (1.4%)	2 (1.2%)	0	3 (1.0%)
		Normal	151 (90.4%)	63 (90.0%)	149 (88.7%)	57 (85.1%)	269 (88.2%)
		High	2 (1.2%)	1 (1.4%)	4 (2.4%)	0	5 (1.6%)
	High	Normal	4 (2.4%)	0	1 (0.6%)	2 (3.0%)	3 (1.0%)
		High	1 (0.6%)	0	1 (0.6%)	0	1 (0.3%)
LOCF Endpoint	m		181	75	180	75	330
	Low	Low	5 (2.8%)	3 (4.0%)	7 (3.9%)	3 (4.0%)	13 (3.9%)
		Normal	2 (1.1%)	2 (2.7%)	4 (2.2%)	6 (8.0%)	12 (3.6%)

Parameter Week	Baseline	Post-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
	Normal	Low	2 (1.1%)	1 (1.3%)	2 (1.1%)	0	3 (0.9%)
		Normal	165 (91.2%)	68 (90.7%)	161 (89.4%)	64 (85.3%)	293 (88.8%)
		High	2 (1.1%)	1 (1.3%)	4 (2.2%)	0	5 (1.5%)
	High	Normal	4 (2.2%)	0	1 (0.6%)	2 (2.7%)	3 (0.9%)
		High	1 (0.6%)	0	1 (0.6%)	0	1 (0.3%)
Phosphate (mmol/L)							
Week 2	m		74	74	73	71	218
	Normal	Low	0	1 (1.4%)	0	0	1 (0.5%)
		Normal	71 (95.9%)	70 (94.6%)	72 (98.6%)	70 (98.6%)	212 (97.2%)
		High	0	3 (4.1%)	1 (1.4%)	1 (1.4%)	5 (2.3%)
	High	Normal	3 (4.1%)	0	0	0	0
Week 4	m		179	75	178	70	323
	Normal	Normal	176 (98.3%)	74 (98.7%)	177 (99.4%)	70 (100.0%)	321 (99.4%)
		High	0	1 (1.3%)	1 (0.6%)	0	2 (0.6%)
	High	Normal	3 (1.7%)	0	0	0	0
Week 8	m		176	72	175	68	315
	Normal	Low	1 (0.6%)	1 (1.4%)	0	1 (1.5%)	2 (0.6%)
		Normal	172 (97.7%)	69 (95.8%)	173 (98.9%)	66 (97.1%)	308 (97.8%)
		High	0	2 (2.8%)	2 (1.1%)	1 (1.5%)	5 (1.6%)
	High	Normal	3 (1.7%)	0	0	0	0
Week 12	m		169	72	172	68	312
	Normal	Low	1 (0.6%)	0	0	0	0
		Normal	165 (97.6%)	72 (100.0%)	171 (99.4%)	68 (100.0%)	311 (99.7%)
		High	0	0	1 (0.6%)	0	1 (0.3%)
	High	Normal	3 (1.8%)	0	0	0	0
Week 16	m		168	71	171	68	310

Parameter Week	Baseline	Post-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
	Normal	Low	2 (1.2%)	2 (2.8%)	1 (0.6%)	1 (1.5%)	4 (1.3%)
		Normal	163 (97.0%)	67 (94.4%)	170 (99.4%)	67 (98.5%)	304 (98.1%)
		High	0	2 (2.8%)	0	0	2 (0.6%)
	High	Normal	3 (1.8%)	0	0	0	0
Week 20	m		168	70	169	67	306
	Normal	Low	2 (1.2%)	0	1 (0.6%)	0	1 (0.3%)
		Normal	163 (97.0%)	69 (98.6%)	168 (99.4%)	67 (100.0%)	304 (99.3%)
		High	0	1 (1.4%)	0	0	1 (0.3%)
	High	Normal	3 (1.8%)	0	0	0	0
Week 24	m		167	70	168	67	305
	Normal	Low	3 (1.8%)	2 (2.9%)	0	1 (1.5%)	3 (1.0%)
		Normal	161 (96.4%)	67 (95.7%)	168 (100.0%)	66 (98.5%)	301 (98.7%)
		High	0	1 (1.4%)	0	0	1 (0.3%)
	High	Normal	3 (1.8%)	0	0	0	0
LOCF Endpoint	m		181	75	180	75	330
	Normal	Low	3 (1.7%)	2 (2.7%)	0	1 (1.3%)	3 (0.9%)
		Normal	175 (96.7%)	72 (96.0%)	180 (100.0%)	74 (98.7%)	326 (98.8%)
		High	0	1 (1.3%)	0	0	1 (0.3%)
	High	Normal	3 (1.7%)	0	0	0	0
Potassium (mmol/L)							
Week 2	m		73	72	72	68	212
	Low	Low	1 (1.4%)	0	0	0	0
		Normal	0	1 (1.4%)	1 (1.4%)	0	2 (0.9%)
	Normal	Normal	71 (97.3%)	71 (98.6%)	70 (97.2%)	67 (98.5%)	208 (98.1%)
		High	1 (1.4%)	0	1 (1.4%)	1 (1.5%)	2 (0.9%)
Week 4	m		179	74	178	68	320

Parameter Week	Baseline	Post-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
	Low	Low	0	1 (1.4%)	0	0	1 (0.3%)
		Normal	1 (0.6%)	0	2 (1.1%)	0	2 (0.6%)
	Normal	Normal	176 (98.3%)	71 (95.9%)	175 (98.3%)	67 (98.5%)	313 (97.8%)
		High	1 (0.6%)	2 (2.7%)	0	1 (1.5%)	3 (0.9%)
	High	Normal	1 (0.6%)	0	1 (0.6%)	0	1 (0.3%)
Week 8	m		176	70	175	67	312
	Low	Low	0	1 (1.4%)	1 (0.6%)	0	2 (0.6%)
		Normal	1 (0.6%)	0	1 (0.6%)	0	1 (0.3%)
	Normal	Low	0	0	0	1 (1.5%)	1 (0.3%)
		Normal	174 (98.9%)	67 (95.7%)	170 (97.1%)	65 (97.0%)	302 (96.8%)
		High	0	2 (2.9%)	2 (1.1%)	1 (1.5%)	5 (1.6%)
	High	Normal	1 (0.6%)	0	1 (0.6%)	0	1 (0.3%)
Week 12	m		169	72	170	67	309
	Low	Low	0	0	1 (0.6%)	0	1 (0.3%)
		Normal	0	1 (1.4%)	1 (0.6%)	0	2 (0.6%)
	Normal	Low	1 (0.6%)	0	0	0	0
		Normal	167 (98.8%)	71 (98.6%)	166 (97.6%)	66 (98.5%)	303 (98.1%)
		High	0	0	1 (0.6%)	1 (1.5%)	2 (0.6%)
	High	Normal	1 (0.6%)	0	1 (0.6%)	0	1 (0.3%)
Week 16	m		167	69	171	68	308
	Low	Low	0	1 (1.4%)	1 (0.6%)	0	2 (0.6%)
		Normal	0	0	1 (0.6%)	0	1 (0.3%)
	Normal	Low	0	2 (2.9%)	1 (0.6%)	0	3 (1.0%)
		Normal	165 (98.8%)	65 (94.2%)	167 (97.7%)	68 (100.0%)	300 (97.4%)
		High	1 (0.6%)	1 (1.4%)	0	0	1 (0.3%)
	High	Normal	1 (0.6%)	0	1 (0.6%)	0	1 (0.3%)
Week 20	m		168	68	169	67	304

Parameter Week	Baseline	Post-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
	Low	Low	0	0	1 (0.6%)	0	1 (0.3%)
		Normal	0	1 (1.5%)	1 (0.6%)	0	2 (0.7%)
	Normal	Low	1 (0.6%)	0	0	0	0
		Normal	165 (98.2%)	65 (95.6%)	166 (98.2%)	66 (98.5%)	297 (97.7%)
		High	1 (0.6%)	2 (2.9%)	0	1 (1.5%)	3 (1.0%)
	High	Normal	1 (0.6%)	0	1 (0.6%)	0	1 (0.3%)
Week 24	m		164	69	168	67	304
	Low	Low	0	1 (1.4%)	1 (0.6%)	0	2 (0.7%)
		Normal	0	0	1 (0.6%)	0	1 (0.3%)
	Normal	Low	1 (0.6%)	0	0	0	0
		Normal	161 (98.2%)	67 (97.1%)	164 (97.6%)	66 (98.5%)	297 (97.7%)
		High	1 (0.6%)	1 (1.4%)	1 (0.6%)	1 (1.5%)	3 (1.0%)
	High	Normal	1 (0.6%)	0	1 (0.6%)	0	1 (0.3%)
LOCF Endpoint	m		181	75	180	75	330
	Low	Low	0	1 (1.3%)	1 (0.6%)	0	2 (0.6%)
		Normal	1 (0.6%)	0	1 (0.6%)	0	1 (0.3%)
	Normal	Low	1 (0.6%)	0	0	0	0
		Normal	177 (97.8%)	72 (96.0%)	176 (97.8%)	74 (98.7%)	322 (97.6%)
		High	1 (0.6%)	2 (2.7%)	1 (0.6%)	1 (1.3%)	4 (1.2%)
	High	Normal	1 (0.6%)	0	1 (0.6%)	0	1 (0.3%)
Protein (g/L)							
Week 2	m		74	75	73	71	219
	Low	Normal	0	1 (1.3%)	0	0	1 (0.5%)
	Normal	Normal	72 (97.3%)	72 (96.0%)	70 (95.9%)	66 (93.0%)	208 (95.0%)
		High	1 (1.4%)	0	0	0	0
	High	Normal	1 (1.4%)	1 (1.3%)	2 (2.7%)	3 (4.2%)	6 (2.7%)
		High	0	1 (1.3%)	1 (1.4%)	2 (2.8%)	4 (1.8%)

Parameter Week	Baseline	Post-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
Week 4	m		179	75	178	70	323
	Low	Normal	0	1 (1.3%)	0	0	1 (0.3%)
	Normal	Low	0	1 (1.3%)	0	1 (1.4%)	2 (0.6%)
		Normal	177 (98.9%)	71 (94.7%)	170 (95.5%)	64 (91.4%)	305 (94.4%)
		High	1 (0.6%)	0	4 (2.2%)	0	4 (1.2%)
	High	Normal	1 (0.6%)	2 (2.7%)	3 (1.7%)	4 (5.7%)	9 (2.8%)
		High	0	0	1 (0.6%)	1 (1.4%)	2 (0.6%)
Week 8	m		176	72	175	68	315
	Low	Normal	0	1 (1.4%)	0	0	1 (0.3%)
	Normal	Low	0	1 (1.4%)	0	0	1 (0.3%)
		Normal	174 (98.9%)	67 (93.1%)	166 (94.9%)	62 (91.2%)	295 (93.7%)
		High	1 (0.6%)	1 (1.4%)	5 (2.9%)	1 (1.5%)	7 (2.2%)
	High	Normal	1 (0.6%)	1 (1.4%)	3 (1.7%)	4 (5.9%)	8 (2.5%)
		High	0	1 (1.4%)	1 (0.6%)	1 (1.5%)	3 (1.0%)
Week 12	m		169	72	172	68	312
	Low	Normal	0	1 (1.4%)	0	0	1 (0.3%)
	Normal	Low	0	1 (1.4%)	0	0	1 (0.3%)
		Normal	166 (98.2%)	67 (93.1%)	163 (94.8%)	62 (91.2%)	292 (93.6%)
		High	2 (1.2%)	1 (1.4%)	5 (2.9%)	1 (1.5%)	7 (2.2%)
	High	Normal	1 (0.6%)	0	2 (1.2%)	3 (4.4%)	5 (1.6%)
		High	0	2 (2.8%)	2 (1.2%)	2 (2.9%)	6 (1.9%)
Week 16	m		168	71	171	68	310
	Low	Normal	0	1 (1.4%)	0	0	1 (0.3%)
	Normal	Low	0	0	1 (0.6%)	0	1 (0.3%)
		Normal	165 (98.2%)	67 (94.4%)	163 (95.3%)	63 (92.6%)	293 (94.5%)
		High	2 (1.2%)	1 (1.4%)	3 (1.8%)	0	4 (1.3%)
	High	Normal	1 (0.6%)	1 (1.4%)	3 (1.8%)	5 (7.4%)	9 (2.9%)
		High	0	1 (1.4%)	1 (0.6%)	0	2 (0.6%)

Parameter Week	Baseline	Post-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
Week 20	m		168	70	169	67	306
	Low	Normal	0	1 (1.4%)	0	0	1 (0.3%)
	Normal	Low	0	0	1 (0.6%)	0	1 (0.3%)
		Normal	166 (98.8%)	66 (94.3%)	160 (94.7%)	62 (92.5%)	288 (94.1%)
		High	1 (0.6%)	1 (1.4%)	4 (2.4%)	0	5 (1.6%)
	High	Normal	1 (0.6%)	2 (2.9%)	3 (1.8%)	4 (6.0%)	9 (2.9%)
		High	0	0	1 (0.6%)	1 (1.5%)	2 (0.7%)
Week 24	m		167	70	168	67	305
	Low	Normal	0	1 (1.4%)	0	0	1 (0.3%)
	Normal	Normal	160 (95.8%)	66 (94.3%)	155 (92.3%)	58 (86.6%)	279 (91.5%)
		High	6 (3.6%)	1 (1.4%)	9 (5.4%)	4 (6.0%)	14 (4.6%)
	High	Normal	1 (0.6%)	0	2 (1.2%)	4 (6.0%)	6 (2.0%)
		High	0	2 (2.9%)	2 (1.2%)	1 (1.5%)	5 (1.6%)
LOCF Endpoint	m		181	75	180	75	330
	Low	Normal	0	1 (1.3%)	0	0	1 (0.3%)
	Normal	Normal	173 (95.6%)	71 (94.7%)	166 (92.2%)	66 (88.0%)	303 (91.8%)
		High	7 (3.9%)	1 (1.3%)	10 (5.6%)	4 (5.3%)	15 (4.5%)
	High	Normal	1 (0.6%)	0	2 (1.1%)	4 (5.3%)	6 (1.8%)
		High	0	2 (2.7%)	2 (1.1%)	1 (1.3%)	5 (1.5%)
Sodium (mmol/L)							
Week 2	m		74	75	73	71	219
	Low	Low	0	0	0	1 (1.4%)	1 (0.5%)
		Normal	1 (1.4%)	0	0	1 (1.4%)	1 (0.5%)
	Normal	Low	0	3 (4.0%)	0	0	3 (1.4%)
		Normal	73 (98.6%)	72 (96.0%)	73 (100.0%)	69 (97.2%)	214 (97.7%)
Week 4	m		179	75	178	70	323

Parameter Week	Baseline	Post-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
	Low	Low	0	0	0	1 (1.4%)	1 (0.3%)
		Normal	2 (1.1%)	0	0	1 (1.4%)	1 (0.3%)
	Normal	Normal	177 (98.9%)	75 (100.0%)	178 (100.0%)	68 (97.1%)	321 (99.4%)
Week 8	m		176	72	175	68	315
	Low	Low	0	0	0	1 (1.5%)	1 (0.3%)
		Normal	2 (1.1%)	0	0	1 (1.5%)	1 (0.3%)
	Normal	Low	0	0	2 (1.1%)	2 (2.9%)	4 (1.3%)
		Normal	174 (98.9%)	72 (100.0%)	173 (98.9%)	63 (92.6%)	308 (97.8%)
		High	0	0	0	1 (1.5%)	1 (0.3%)
Week 12	m		169	72	172	68	312
	Low	Low	0	0	0	1 (1.5%)	1 (0.3%)
		Normal	2 (1.2%)	0	0	1 (1.5%)	1 (0.3%)
	Normal	Normal	167 (98.8%)	72 (100.0%)	172 (100.0%)	66 (97.1%)	310 (99.4%)
Week 16	m		168	71	171	68	310
	Low	Low	0	0	0	1 (1.5%)	1 (0.3%)
		Normal	2 (1.2%)	0	0	1 (1.5%)	1 (0.3%)
	Normal	Normal	165 (98.2%)	71 (100.0%)	171 (100.0%)	66 (97.1%)	308 (99.4%)
		High	1 (0.6%)	0	0	0	0
Week 20	m		168	70	169	67	306
	Low	Low	0	0	0	1 (1.5%)	1 (0.3%)
		Normal	2 (1.2%)	0	0	1 (1.5%)	1 (0.3%)
	Normal	Normal	166 (98.8%)	70 (100.0%)	169 (100.0%)	65 (97.0%)	304 (99.3%)
Week 24	m		167	70	168	67	305
	Low	Low	0	0	0	1 (1.5%)	1 (0.3%)
		Normal	2 (1.2%)	0	0	1 (1.5%)	1 (0.3%)
	Normal	Low	1 (0.6%)	0	0	0	0

Parameter Week	Baseline	Post-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
		Normal	164 (98.2%)	70 (100.0%)	168 (100.0%)	65 (97.0%)	303 (99.3%)
LOCF Endpoint	m		181	75	180	75	330
	Low	Low	0	0	0	1 (1.3%)	1 (0.3%)
		Normal	2 (1.1%)	0	0	1 (1.3%)	1 (0.3%)
	Normal	Low	2 (1.1%)	0	0	1 (1.3%)	1 (0.3%)
		Normal	177 (97.8%)	75 (100.0%)	180 (100.0%)	72 (96.0%)	327 (99.1%)
Urate (umol/L)							
Week 2	m		74	75	73	71	219
	Low	Low	4 (5.4%)	2 (2.7%)	4 (5.5%)	3 (4.2%)	9 (4.1%)
		Normal	4 (5.4%)	3 (4.0%)	4 (5.5%)	3 (4.2%)	10 (4.6%)
	Normal	Low	0	1 (1.3%)	1 (1.4%)	1 (1.4%)	3 (1.4%)
		Normal	64 (86.5%)	67 (89.3%)	60 (82.2%)	60 (84.5%)	187 (85.4%)
		High	0	0	1 (1.4%)	0	1 (0.5%)
	High	Normal	0	0	1 (1.4%)	2 (2.8%)	3 (1.4%)
		High	2 (2.7%)	2 (2.7%)	2 (2.7%)	2 (2.8%)	6 (2.7%)
Week 4	m		179	75	178	70	323
	Low	Low	3 (1.7%)	3 (4.0%)	3 (1.7%)	3 (4.3%)	9 (2.8%)
		Normal	4 (2.2%)	2 (2.7%)	5 (2.8%)	3 (4.3%)	10 (3.1%)
	Normal	Low	5 (2.8%)	3 (4.0%)	1 (0.6%)	0	4 (1.2%)
		Normal	163 (91.1%)	64 (85.3%)	165 (92.7%)	59 (84.3%)	288 (89.2%)
		High	1 (0.6%)	1 (1.3%)	0	1 (1.4%)	2 (0.6%)
	High	Normal	2 (1.1%)	1 (1.3%)	2 (1.1%)	2 (2.9%)	5 (1.5%)
		High	1 (0.6%)	1 (1.3%)	2 (1.1%)	2 (2.9%)	5 (1.5%)
Week 8	m		176	72	175	68	315
	Low	Low	5 (2.8%)	4 (5.6%)	3 (1.7%)	3 (4.4%)	10 (3.2%)
		Normal	1 (0.6%)	1 (1.4%)	5 (2.9%)	3 (4.4%)	9 (2.9%)
	Normal	Low	4 (2.3%)	4 (5.6%)	2 (1.1%)	1 (1.5%)	7 (2.2%)

Parameter Week	Baseline	Post-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
		Normal	163 (92.6%)	61 (84.7%)	162 (92.6%)	57 (83.8%)	280 (88.9%)
		High	0	0	0	1 (1.5%)	1 (0.3%)
	High	Normal	1 (0.6%)	0	1 (0.6%)	1 (1.5%)	2 (0.6%)
		High	2 (1.1%)	2 (2.8%)	2 (1.1%)	2 (2.9%)	6 (1.9%)
Week 12	m		169	72	172	68	312
	Low	Low	2 (1.2%)	1 (1.4%)	2 (1.2%)	3 (4.4%)	6 (1.9%)
		Normal	3 (1.8%)	4 (5.6%)	5 (2.9%)	3 (4.4%)	12 (3.8%)
	Normal	Low	3 (1.8%)	1 (1.4%)	0	1 (1.5%)	2 (0.6%)
		Normal	157 (92.9%)	64 (88.9%)	161 (93.6%)	56 (82.4%)	281 (90.1%)
		High	1 (0.6%)	0	1 (0.6%)	2 (2.9%)	3 (1.0%)
	High	Normal	2 (1.2%)	0	1 (0.6%)	1 (1.5%)	2 (0.6%)
		High	1 (0.6%)	2 (2.8%)	2 (1.2%)	2 (2.9%)	6 (1.9%)
Week 16	m		168	71	171	68	310
	Low	Low	2 (1.2%)	3 (4.2%)	3 (1.8%)	4 (5.9%)	10 (3.2%)
		Normal	3 (1.8%)	2 (2.8%)	4 (2.3%)	2 (2.9%)	8 (2.6%)
	Normal	Low	0	4 (5.6%)	3 (1.8%)	0	7 (2.3%)
		Normal	159 (94.6%)	60 (84.5%)	157 (91.8%)	59 (86.8%)	276 (89.0%)
		High	1 (0.6%)	0	1 (0.6%)	0	1 (0.3%)
	High	Normal	1 (0.6%)	1 (1.4%)	1 (0.6%)	1 (1.5%)	3 (1.0%)
		High	2 (1.2%)	1 (1.4%)	2 (1.2%)	2 (2.9%)	5 (1.6%)
Week 20	m		168	70	169	67	306
	Low	Low	2 (1.2%)	3 (4.3%)	2 (1.2%)	2 (3.0%)	7 (2.3%)
		Normal	3 (1.8%)	2 (2.9%)	5 (3.0%)	3 (4.5%)	10 (3.3%)
	Normal	Low	0	3 (4.3%)	0	0	3 (1.0%)
		Normal	159 (94.6%)	59 (84.3%)	157 (92.9%)	58 (86.6%)	274 (89.5%)
		High	1 (0.6%)	1 (1.4%)	2 (1.2%)	1 (1.5%)	4 (1.3%)
	High	Normal	2 (1.2%)	1 (1.4%)	1 (0.6%)	1 (1.5%)	3 (1.0%)
		High	1 (0.6%)	1 (1.4%)	2 (1.2%)	2 (3.0%)	5 (1.6%)

Parameter Week	Baseline	Post-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
Week 24	m		167	70	168	67	305
	Low	Low	2 (1.2%)	3 (4.3%)	4 (2.4%)	2 (3.0%)	9 (3.0%)
		Normal	3 (1.8%)	2 (2.9%)	3 (1.8%)	3 (4.5%)	8 (2.6%)
	Normal	Low	4 (2.4%)	3 (4.3%)	0	2 (3.0%)	5 (1.6%)
		Normal	154 (92.2%)	59 (84.3%)	157 (93.5%)	57 (85.1%)	273 (89.5%)
		High	1 (0.6%)	1 (1.4%)	1 (0.6%)	0	2 (0.7%)
	High	Normal	3 (1.8%)	1 (1.4%)	1 (0.6%)	1 (1.5%)	3 (1.0%)
		High	0	1 (1.4%)	2 (1.2%)	2 (3.0%)	5 (1.6%)
LOCF Endpoint	m		181	75	180	75	330
	Low	Low	5 (2.8%)	3 (4.0%)	4 (2.2%)	4 (5.3%)	11 (3.3%)
		Normal	4 (2.2%)	2 (2.7%)	4 (2.2%)	3 (4.0%)	9 (2.7%)
	Normal	Low	6 (3.3%)	4 (5.3%)	1 (0.6%)	2 (2.7%)	7 (2.1%)
		Normal	162 (89.5%)	63 (84.0%)	165 (91.7%)	62 (82.7%)	290 (87.9%)
		High	1 (0.6%)	1 (1.3%)	2 (1.1%)	0	3 (0.9%)
	High	Normal	3 (1.7%)	1 (1.3%)	2 (1.1%)	1 (1.3%)	4 (1.2%)
		High	0	1 (1.3%)	2 (1.1%)	3 (4.0%)	6 (1.8%)
Urea Nitrogen (mmol/L)							
Week 2	m		74	75	73	71	219
	Normal	Normal	73 (98.6%)	73 (97.3%)	71 (97.3%)	67 (94.4%)	211 (96.3%)
		High	1 (1.4%)	0	1 (1.4%)	2 (2.8%)	3 (1.4%)
	High	Normal	0	1 (1.3%)	1 (1.4%)	1 (1.4%)	3 (1.4%)
		High	0	1 (1.3%)	0	1 (1.4%)	2 (0.9%)
Week 4	m		179	75	178	70	323
	Normal	Normal	176 (98.3%)	72 (96.0%)	173 (97.2%)	67 (95.7%)	312 (96.6%)
		High	3 (1.7%)	1 (1.3%)	4 (2.2%)	1 (1.4%)	6 (1.9%)
	High	Normal	0	1 (1.3%)	1 (0.6%)	1 (1.4%)	3 (0.9%)
		High	0	1 (1.3%)	0	1 (1.4%)	2 (0.6%)

Parameter Week	Baseline	Post-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
Week 8	m		176	72	175	68	315
	Normal	Normal	176 (100.0%)	70 (97.2%)	173 (98.9%)	65 (95.6%)	308 (97.8%)
		High	0	0	1 (0.6%)	1 (1.5%)	2 (0.6%)
	High	Normal	0	1 (1.4%)	0	1 (1.5%)	2 (0.6%)
		High	0	1 (1.4%)	1 (0.6%)	1 (1.5%)	3 (1.0%)
Week 12	m		169	72	172	68	312
	Normal	Normal	167 (98.8%)	70 (97.2%)	170 (98.8%)	66 (97.1%)	306 (98.1%)
		High	2 (1.2%)	0	1 (0.6%)	0	1 (0.3%)
	High	Normal	0	1 (1.4%)	1 (0.6%)	1 (1.5%)	3 (1.0%)
		High	0	1 (1.4%)	0	1 (1.5%)	2 (0.6%)
Week 16	m		168	71	171	68	310
	Normal	Normal	167 (99.4%)	69 (97.2%)	170 (99.4%)	64 (94.1%)	303 (97.7%)
		High	1 (0.6%)	0	0	2 (2.9%)	2 (0.6%)
	High	Normal	0	1 (1.4%)	1 (0.6%)	1 (1.5%)	3 (1.0%)
		High	0	1 (1.4%)	0	1 (1.5%)	2 (0.6%)
Week 20	m		168	70	169	67	306
	Normal	Normal	166 (98.8%)	68 (97.1%)	167 (98.8%)	64 (95.5%)	299 (97.7%)
		High	2 (1.2%)	0	1 (0.6%)	1 (1.5%)	2 (0.7%)
	High	Normal	0	1 (1.4%)	1 (0.6%)	1 (1.5%)	3 (1.0%)
		High	0	1 (1.4%)	0	1 (1.5%)	2 (0.7%)
Week 24	m		167	70	168	67	305
	Normal	Normal	165 (98.8%)	66 (94.3%)	167 (99.4%)	63 (94.0%)	296 (97.0%)
		High	2 (1.2%)	2 (2.9%)	0	2 (3.0%)	4 (1.3%)
	High	Normal	0	1 (1.4%)	1 (0.6%)	1 (1.5%)	3 (1.0%)
		High	0	1 (1.4%)	0	1 (1.5%)	2 (0.7%)

Parameter Week	Baseline	Post-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
LOCF Endpoint	m		181	75	180	75	330
	Normal	Normal	179 (98.9%)	70 (93.3%)	179 (99.4%)	70 (93.3%)	319 (96.7%)
		High	2 (1.1%)	3 (4.0%)	0	3 (4.0%)	6 (1.8%)
	High	Normal	0	1 (1.3%)	1 (0.6%)	1 (1.3%)	3 (0.9%)
		High	0	1 (1.3%)	0	1 (1.3%)	2 (0.6%)

- 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-179-labot-24wdb.sas, 2020-03-06T00:14:27>>

Table S-180 Shift of Laboratory Findings of Urinalysis in 24-Week Double-blind Period with Monotherapy (PXL008-014, PXL008-018; Safety Population)

Parameter Week	Baseline	Post-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
Ketones							
Week 4	m		106	0	106	0	106
	Negative	Negative	93 (87.7%)	.	97 (91.5%)	.	97 (91.5%)
		Trace	3 (2.8%)	.	1 (0.9%)	.	1 (0.9%)
		Positive	1 (0.9%)	.	3 (2.8%)	.	3 (2.8%)
	Trace	Negative	6 (5.7%)	.	2 (1.9%)	.	2 (1.9%)
	Positive	Negative	1 (0.9%)	.	2 (1.9%)	.	2 (1.9%)
		Trace	0	.	1 (0.9%)	.	1 (0.9%)
		Positive	2 (1.9%)	.	0	.	0
Week 8	m		176	72	175	68	315
	Negative	Negative	160 (90.9%)	64 (88.9%)	162 (92.6%)	59 (86.8%)	285 (90.5%)
		Trace	4 (2.3%)	2 (2.8%)	3 (1.7%)	3 (4.4%)	8 (2.5%)
		Positive	1 (0.6%)	0	2 (1.1%)	0	2 (0.6%)
	Trace	Negative	7 (4.0%)	5 (6.9%)	3 (1.7%)	5 (7.4%)	13 (4.1%)
		Trace	0	0	1 (0.6%)	0	1 (0.3%)
		Positive	0	0	0	1 (1.5%)	1 (0.3%)
	Positive	Negative	4 (2.3%)	1 (1.4%)	4 (2.3%)	0	5 (1.6%)
Week 12	m		103	0	105	0	105
	Negative	Negative	91 (88.3%)	.	98 (93.3%)	.	98 (93.3%)
		Trace	1 (1.0%)	.	2 (1.9%)	.	2 (1.9%)
		Positive	2 (1.9%)	.	0	.	0
	Trace	Negative	6 (5.8%)	.	1 (1.0%)	.	1 (1.0%)
		Trace	0	.	1 (1.0%)	.	1 (1.0%)
	Positive	Negative	2 (1.9%)	.	2 (1.9%)	.	2 (1.9%)
		Trace	1 (1.0%)	.	0	.	0
		Positive	0	.	1 (1.0%)	.	1 (1.0%)

Parameter Week	Baseline	Post-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
Week 16	m		168	71	171	68	310
	Negative	Negative	145 (86.3%)	60 (84.5%)	159 (93.0%)	61 (89.7%)	280 (90.3%)
		Trace	3 (1.8%)	3 (4.2%)	3 (1.8%)	1 (1.5%)	7 (2.3%)
		Positive	9 (5.4%)	2 (2.8%)	1 (0.6%)	0	3 (1.0%)
	Trace	Negative	7 (4.2%)	4 (5.6%)	3 (1.8%)	5 (7.4%)	12 (3.9%)
		Trace	0	0	1 (0.6%)	0	1 (0.3%)
		Positive	0	1 (1.4%)	0	1 (1.5%)	2 (0.6%)
	Positive	Negative	2 (1.2%)	1 (1.4%)	4 (2.3%)	0	5 (1.6%)
		Trace	1 (0.6%)	0	0	0	0
		Positive	1 (0.6%)	0	0	0	0
Week 20	m		102	0	103	0	103
	Negative	Negative	89 (87.3%)	.	95 (92.2%)	.	95 (92.2%)
		Trace	2 (2.0%)	.	3 (2.9%)	.	3 (2.9%)
		Positive	2 (2.0%)	.	0	.	0
	Trace	Negative	6 (5.9%)	.	2 (1.9%)	.	2 (1.9%)
	Positive	Negative	3 (2.9%)	.	2 (1.9%)	.	2 (1.9%)
		Positive	0	.	1 (1.0%)	.	1 (1.0%)
Week 24	m		167	70	169	67	306
	Negative	Negative	144 (86.2%)	61 (87.1%)	155 (91.7%)	60 (89.6%)	276 (90.2%)
		Trace	7 (4.2%)	3 (4.3%)	6 (3.6%)	1 (1.5%)	10 (3.3%)
		Positive	5 (3.0%)	0	0	0	0
	Trace	Negative	6 (3.6%)	5 (7.1%)	2 (1.2%)	3 (4.5%)	10 (3.3%)
		Trace	1 (0.6%)	0	2 (1.2%)	2 (3.0%)	4 (1.3%)
		Positive	0	0	0	1 (1.5%)	1 (0.3%)
	Positive	Negative	4 (2.4%)	1 (1.4%)	2 (1.2%)	0	3 (1.0%)
		Trace	0	0	1 (0.6%)	0	1 (0.3%)
		Positive	0	0	1 (0.6%)	0	1 (0.3%)
LOCF Endpoint	m		181	75	179	74	328

Parameter Week	Baseline	Post-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
	Negative	Negative	155 (85.6%)	62 (82.7%)	164 (91.6%)	64 (86.5%)	290 (88.4%)
		Trace	9 (5.0%)	5 (6.7%)	7 (3.9%)	1 (1.4%)	13 (4.0%)
		Positive	6 (3.3%)	0	0	1 (1.4%)	1 (0.3%)
	Trace	Negative	6 (3.3%)	7 (9.3%)	2 (1.1%)	4 (5.4%)	13 (4.0%)
		Trace	1 (0.6%)	0	2 (1.1%)	2 (2.7%)	4 (1.2%)
		Positive	0	0	0	1 (1.4%)	1 (0.3%)
	Positive	Negative	4 (2.2%)	1 (1.3%)	2 (1.1%)	1 (1.4%)	4 (1.2%)
		Trace	0	0	1 (0.6%)	0	1 (0.3%)
		Positive	0	0	1 (0.6%)	0	1 (0.3%)
Leukocyte Esterase							
Week 4	m		106	0	106	0	106
	Negative	Negative	91 (85.8%)	.	98 (92.5%)	.	98 (92.5%)
		Trace	3 (2.8%)	.	0	.	0
		Positive	3 (2.8%)	.	0	.	0
	Trace	Negative	1 (0.9%)	.	2 (1.9%)	.	2 (1.9%)
	Positive	Negative	3 (2.8%)	.	1 (0.9%)	.	1 (0.9%)
		Trace	1 (0.9%)	.	0	.	0
		Positive	4 (3.8%)	.	5 (4.7%)	.	5 (4.7%)
Week 8	m		176	72	175	68	315
	Negative	Negative	157 (89.2%)	62 (86.1%)	150 (85.7%)	60 (88.2%)	272 (86.3%)
		Trace	2 (1.1%)	1 (1.4%)	1 (0.6%)	0	2 (0.6%)
		Positive	2 (1.1%)	1 (1.4%)	3 (1.7%)	3 (4.4%)	7 (2.2%)
	Trace	Negative	1 (0.6%)	0	5 (2.9%)	1 (1.5%)	6 (1.9%)
		Trace	0	1 (1.4%)	0	0	1 (0.3%)
		Positive	1 (0.6%)	0	0	0	0
	Positive	Negative	3 (1.7%)	2 (2.8%)	4 (2.3%)	2 (2.9%)	8 (2.5%)
		Trace	2 (1.1%)	1 (1.4%)	3 (1.7%)	0	4 (1.3%)
		Positive	8 (4.5%)	4 (5.6%)	9 (5.1%)	2 (2.9%)	15 (4.8%)

Parameter Week	Baseline	Post-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
Week 12	m		103	0	105	0	105
	Negative	Negative	95 (92.2%)	.	96 (91.4%)	.	96 (91.4%)
		Positive	0	.	1 (1.0%)	.	1 (1.0%)
	Trace	Negative	1 (1.0%)	.	1 (1.0%)	.	1 (1.0%)
		Trace	0	.	1 (1.0%)	.	1 (1.0%)
	Positive	Negative	2 (1.9%)	.	1 (1.0%)	.	1 (1.0%)
		Positive	5 (4.9%)	.	5 (4.8%)	.	5 (4.8%)
Week 16	m		168	71	171	68	310
	Negative	Negative	147 (87.5%)	61 (85.9%)	148 (86.5%)	57 (83.8%)	266 (85.8%)
		Trace	4 (2.4%)	1 (1.4%)	0	4 (5.9%)	5 (1.6%)
		Positive	4 (2.4%)	1 (1.4%)	2 (1.2%)	2 (2.9%)	5 (1.6%)
	Trace	Negative	0	1 (1.4%)	4 (2.3%)	1 (1.5%)	6 (1.9%)
		Positive	2 (1.2%)	0	1 (0.6%)	0	1 (0.3%)
	Positive	Negative	5 (3.0%)	3 (4.2%)	6 (3.5%)	2 (2.9%)	11 (3.5%)
		Trace	2 (1.2%)	1 (1.4%)	0	0	1 (0.3%)
		Positive	4 (2.4%)	3 (4.2%)	10 (5.8%)	2 (2.9%)	15 (4.8%)
Week 20	m		102	0	103	0	103
	Negative	Negative	87 (85.3%)	.	92 (89.3%)	.	92 (89.3%)
		Trace	6 (5.9%)	.	0	.	0
		Positive	1 (1.0%)	.	3 (2.9%)	.	3 (2.9%)
	Trace	Negative	1 (1.0%)	.	1 (1.0%)	.	1 (1.0%)
		Trace	0	.	1 (1.0%)	.	1 (1.0%)
	Positive	Negative	4 (3.9%)	.	1 (1.0%)	.	1 (1.0%)
		Positive	3 (2.9%)	.	5 (4.9%)	.	5 (4.9%)
Week 24	m		167	70	169	67	306
	Negative	Negative	144 (86.2%)	58 (82.9%)	143 (84.6%)	56 (83.6%)	257 (84.0%)
		Trace	4 (2.4%)	1 (1.4%)	2 (1.2%)	2 (3.0%)	5 (1.6%)
		Positive	6 (3.6%)	3 (4.3%)	4 (2.4%)	4 (6.0%)	11 (3.6%)

Parameter Week	Baseline	Post-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
	Trace	Negative	0	1 (1.4%)	4 (2.4%)	1 (1.5%)	6 (2.0%)
		Trace	1 (0.6%)	0	0	0	0
		Positive	1 (0.6%)	0	0	0	0
	Positive	Negative	2 (1.2%)	3 (4.3%)	4 (2.4%)	1 (1.5%)	8 (2.6%)
		Trace	0	1 (1.4%)	1 (0.6%)	1 (1.5%)	3 (1.0%)
		Positive	9 (5.4%)	3 (4.3%)	11 (6.5%)	2 (3.0%)	16 (5.2%)
LOCF Endpoint	m		181	75	179	74	328
	Negative	Negative	155 (85.6%)	62 (82.7%)	150 (83.8%)	61 (82.4%)	273 (83.2%)
		Trace	4 (2.2%)	1 (1.3%)	2 (1.1%)	2 (2.7%)	5 (1.5%)
		Positive	6 (3.3%)	4 (5.3%)	4 (2.2%)	5 (6.8%)	13 (4.0%)
	Trace	Negative	0	1 (1.3%)	5 (2.8%)	1 (1.4%)	7 (2.1%)
		Trace	1 (0.6%)	0	1 (0.6%)	0	1 (0.3%)
		Positive	1 (0.6%)	0	0	0	0
	Positive	Negative	4 (2.2%)	3 (4.0%)	4 (2.2%)	1 (1.4%)	8 (2.4%)
		Trace	0	1 (1.3%)	1 (0.6%)	1 (1.4%)	3 (0.9%)
		Positive	10 (5.5%)	3 (4.0%)	12 (6.7%)	3 (4.1%)	18 (5.5%)
Nitrite							
Week 4	m		106	0	106	0	106
	Negative	Negative	103 (97.2%)	.	104 (98.1%)	.	104 (98.1%)
		Positive	0	.	1 (0.9%)	.	1 (0.9%)
	Positive	Negative	1 (0.9%)	.	0	.	0
		Positive	2 (1.9%)	.	1 (0.9%)	.	1 (0.9%)
Week 8	m		176	72	175	68	315
	Negative	Negative	168 (95.5%)	69 (95.8%)	170 (97.1%)	64 (94.1%)	303 (96.2%)
		Positive	3 (1.7%)	1 (1.4%)	1 (0.6%)	2 (2.9%)	4 (1.3%)
	Positive	Negative	2 (1.1%)	1 (1.4%)	3 (1.7%)	1 (1.5%)	5 (1.6%)
		Positive	3 (1.7%)	1 (1.4%)	1 (0.6%)	1 (1.5%)	3 (1.0%)

Parameter Week	Baseline	Post-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
Week 12	m		103	0	105	0	105
	Negative	Negative	100 (97.1%)	.	102 (97.1%)	.	102 (97.1%)
		Positive	0	.	2 (1.9%)	.	2 (1.9%)
	Positive	Negative	1 (1.0%)	.	0	.	0
		Positive	2 (1.9%)	.	1 (1.0%)	.	1 (1.0%)
Week 16	m		168	71	171	68	310
	Negative	Negative	159 (94.6%)	67 (94.4%)	164 (95.9%)	66 (97.1%)	297 (95.8%)
		Positive	4 (2.4%)	2 (2.8%)	3 (1.8%)	0	5 (1.6%)
	Positive	Negative	3 (1.8%)	1 (1.4%)	2 (1.2%)	1 (1.5%)	4 (1.3%)
		Positive	2 (1.2%)	1 (1.4%)	2 (1.2%)	1 (1.5%)	4 (1.3%)
Week 20	m		102	0	103	0	103
	Negative	Negative	99 (97.1%)	.	100 (97.1%)	.	100 (97.1%)
		Positive	0	.	2 (1.9%)	.	2 (1.9%)
	Positive	Positive	3 (2.9%)	.	1 (1.0%)	.	1 (1.0%)
Week 24	m		167	70	169	67	306
	Negative	Negative	159 (95.2%)	64 (91.4%)	162 (95.9%)	64 (95.5%)	290 (94.8%)
		Positive	3 (1.8%)	4 (5.7%)	3 (1.8%)	1 (1.5%)	8 (2.6%)
	Positive	Negative	3 (1.8%)	1 (1.4%)	1 (0.6%)	2 (3.0%)	4 (1.3%)
		Positive	2 (1.2%)	1 (1.4%)	3 (1.8%)	0	4 (1.3%)
LOCF Endpoint	m		181	75	179	74	328
	Negative	Negative	170 (93.9%)	69 (92.0%)	172 (96.1%)	70 (94.6%)	311 (94.8%)
		Positive	6 (3.3%)	4 (5.3%)	3 (1.7%)	1 (1.4%)	8 (2.4%)
	Positive	Negative	3 (1.7%)	1 (1.3%)	1 (0.6%)	3 (4.1%)	5 (1.5%)
		Positive	2 (1.1%)	1 (1.3%)	3 (1.7%)	0	4 (1.2%)
Occult Blood							
Week 4	m		106	0	106	0	106

Parameter Week	Baseline	Post-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
	Negative	Negative	97 (91.5%)	.	99 (93.4%)	.	99 (93.4%)
		Trace	3 (2.8%)	.	0	.	0
		Positive	2 (1.9%)	.	1 (0.9%)	.	1 (0.9%)
	Trace	Negative	1 (0.9%)	.	3 (2.8%)	.	3 (2.8%)
		Trace	1 (0.9%)	.	0	.	0
	Positive	Negative	1 (0.9%)	.	1 (0.9%)	.	1 (0.9%)
		Trace	0	.	1 (0.9%)	.	1 (0.9%)
		Positive	1 (0.9%)	.	1 (0.9%)	.	1 (0.9%)
Week 8	m		176	72	175	68	315
	Negative	Negative	164 (93.2%)	67 (93.1%)	160 (91.4%)	62 (91.2%)	289 (91.7%)
		Trace	4 (2.3%)	0	1 (0.6%)	1 (1.5%)	2 (0.6%)
		Positive	1 (0.6%)	2 (2.8%)	1 (0.6%)	2 (2.9%)	5 (1.6%)
	Trace	Negative	3 (1.7%)	1 (1.4%)	7 (4.0%)	0	8 (2.5%)
	Positive	Negative	2 (1.1%)	1 (1.4%)	4 (2.3%)	2 (2.9%)	7 (2.2%)
		Trace	0	0	2 (1.1%)	0	2 (0.6%)
		Positive	2 (1.1%)	1 (1.4%)	0	1 (1.5%)	2 (0.6%)
Week 12	m		103	0	105	0	105
	Negative	Negative	97 (94.2%)	.	95 (90.5%)	.	95 (90.5%)
		Trace	1 (1.0%)	.	3 (2.9%)	.	3 (2.9%)
		Positive	1 (1.0%)	.	1 (1.0%)	.	1 (1.0%)
	Trace	Negative	2 (1.9%)	.	2 (1.9%)	.	2 (1.9%)
		Trace	0	.	1 (1.0%)	.	1 (1.0%)
	Positive	Negative	1 (1.0%)	.	3 (2.9%)	.	3 (2.9%)
		Positive	1 (1.0%)	.	0	.	0
Week 16	m		168	71	171	68	310
	Negative	Negative	159 (94.6%)	66 (93.0%)	155 (90.6%)	64 (94.1%)	285 (91.9%)
		Trace	0	1 (1.4%)	2 (1.2%)	1 (1.5%)	4 (1.3%)
		Positive	4 (2.4%)	1 (1.4%)	1 (0.6%)	0	2 (0.6%)

Parameter Week	Baseline	Post-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
	Trace	Negative	1 (0.6%)	1 (1.4%)	6 (3.5%)	0	7 (2.3%)
		Trace	1 (0.6%)	0	0	0	0
		Positive	0	0	1 (0.6%)	0	1 (0.3%)
	Positive	Negative	2 (1.2%)	0	5 (2.9%)	2 (2.9%)	7 (2.3%)
		Trace	0	0	1 (0.6%)	1 (1.5%)	2 (0.6%)
		Positive	1 (0.6%)	2 (2.8%)	0	0	2 (0.6%)
Week 20	m		102	0	103	0	103
	Negative	Negative	95 (93.1%)	.	92 (89.3%)	.	92 (89.3%)
		Trace	2 (2.0%)	.	2 (1.9%)	.	2 (1.9%)
		Positive	1 (1.0%)	.	3 (2.9%)	.	3 (2.9%)
	Trace	Negative	1 (1.0%)	.	3 (2.9%)	.	3 (2.9%)
		Trace	1 (1.0%)	.	0	.	0
	Positive	Negative	1 (1.0%)	.	2 (1.9%)	.	2 (1.9%)
		Trace	0	.	1 (1.0%)	.	1 (1.0%)
		Positive	1 (1.0%)	.	0	.	0
Week 24	m		167	70	169	67	306
	Negative	Negative	155 (92.8%)	63 (90.0%)	153 (90.5%)	61 (91.0%)	277 (90.5%)
		Trace	5 (3.0%)	1 (1.4%)	1 (0.6%)	2 (3.0%)	4 (1.3%)
		Positive	2 (1.2%)	3 (4.3%)	2 (1.2%)	1 (1.5%)	6 (2.0%)
	Trace	Negative	2 (1.2%)	0	6 (3.6%)	0	6 (2.0%)
		Trace	0	1 (1.4%)	1 (0.6%)	0	2 (0.7%)
	Positive	Negative	2 (1.2%)	0	4 (2.4%)	3 (4.5%)	7 (2.3%)
		Trace	0	0	1 (0.6%)	0	1 (0.3%)
		Positive	1 (0.6%)	2 (2.9%)	1 (0.6%)	0	3 (1.0%)
LOCF Endpoint	m		181	75	179	74	328
	Negative	Negative	166 (91.7%)	68 (90.7%)	162 (90.5%)	67 (90.5%)	297 (90.5%)
		Trace	6 (3.3%)	1 (1.3%)	1 (0.6%)	2 (2.7%)	4 (1.2%)
		Positive	2 (1.1%)	3 (4.0%)	2 (1.1%)	1 (1.4%)	6 (1.8%)

Parameter Week	Baseline	Post-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
	Trace	Negative	3 (1.7%)	0	6 (3.4%)	0	6 (1.8%)
		Trace	0	1 (1.3%)	1 (0.6%)	0	2 (0.6%)
	Positive	Negative	2 (1.1%)	0	4 (2.2%)	3 (4.1%)	7 (2.1%)
		Trace	0	0	1 (0.6%)	1 (1.4%)	2 (0.6%)
		Positive	2 (1.1%)	2 (2.7%)	2 (1.1%)	0	4 (1.2%)
pH							
Week 4	m		106	0	106	0	106
	5.5	5.5	12 (11.3%)	.	10 (9.4%)	.	10 (9.4%)
		6	10 (9.4%)	.	6 (5.7%)	.	6 (5.7%)
		6.5	1 (0.9%)	.	0	.	0
	6	5.5	10 (9.4%)	.	12 (11.3%)	.	12 (11.3%)
		6	24 (22.6%)	.	21 (19.8%)	.	21 (19.8%)
		6.5	10 (9.4%)	.	6 (5.7%)	.	6 (5.7%)
		7	2 (1.9%)	.	5 (4.7%)	.	5 (4.7%)
		7.5	0	.	1 (0.9%)	.	1 (0.9%)
	6.5	5.5	5 (4.7%)	.	2 (1.9%)	.	2 (1.9%)
		6	7 (6.6%)	.	9 (8.5%)	.	9 (8.5%)
		6.5	9 (8.5%)	.	13 (12.3%)	.	13 (12.3%)
		7	5 (4.7%)	.	5 (4.7%)	.	5 (4.7%)
	7	5.5	0	.	1 (0.9%)	.	1 (0.9%)
		6	1 (0.9%)	.	4 (3.8%)	.	4 (3.8%)
		6.5	3 (2.8%)	.	3 (2.8%)	.	3 (2.8%)
		7	2 (1.9%)	.	4 (3.8%)	.	4 (3.8%)
		7.5	1 (0.9%)	.	1 (0.9%)	.	1 (0.9%)
	7.5	6	1 (0.9%)	.	0	.	0
		7	2 (1.9%)	.	2 (1.9%)	.	2 (1.9%)
	8	6.5	0	.	1 (0.9%)	.	1 (0.9%)
		7	1 (0.9%)	.	0	.	0
Week 8	m		176	72	175	68	315

Parameter Week	Baseline	Post-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
	5	5.5	0	1 (1.4%)	1 (0.6%)	2 (2.9%)	4 (1.3%)
		6	1 (0.6%)	1 (1.4%)	0	1 (1.5%)	2 (0.6%)
	5.5	5	2 (1.1%)	3 (4.2%)	1 (0.6%)	1 (1.5%)	5 (1.6%)
		5.5	32 (18.2%)	19 (26.4%)	20 (11.4%)	18 (26.5%)	57 (18.1%)
		6	14 (8.0%)	7 (9.7%)	11 (6.3%)	7 (10.3%)	25 (7.9%)
		6.5	3 (1.7%)	1 (1.4%)	1 (0.6%)	1 (1.5%)	3 (1.0%)
		7	1 (0.6%)	1 (1.4%)	0	1 (1.5%)	2 (0.6%)
		7.5	0	0	1 (0.6%)	0	1 (0.3%)
	6	5	0	1 (1.4%)	1 (0.6%)	1 (1.5%)	3 (1.0%)
		5.5	16 (9.1%)	6 (8.3%)	24 (13.7%)	5 (7.4%)	35 (11.1%)
		6	43 (24.4%)	11 (15.3%)	37 (21.1%)	15 (22.1%)	63 (20.0%)
		6.5	11 (6.3%)	3 (4.2%)	13 (7.4%)	2 (2.9%)	18 (5.7%)
		7	2 (1.1%)	0	3 (1.7%)	0	3 (1.0%)
	6.5	5	1 (0.6%)	0	0	0	0
		5.5	6 (3.4%)	2 (2.8%)	3 (1.7%)	3 (4.4%)	8 (2.5%)
		6	10 (5.7%)	3 (4.2%)	20 (11.4%)	3 (4.4%)	26 (8.3%)
		6.5	9 (5.1%)	1 (1.4%)	14 (8.0%)	2 (2.9%)	17 (5.4%)
		7	6 (3.4%)	3 (4.2%)	4 (2.3%)	1 (1.5%)	8 (2.5%)
		7.5	0	1 (1.4%)	0	0	1 (0.3%)
	7	5.5	0	1 (1.4%)	2 (1.1%)	0	3 (1.0%)
		6	3 (1.7%)	3 (4.2%)	5 (2.9%)	4 (5.9%)	12 (3.8%)
		6.5	3 (1.7%)	2 (2.8%)	5 (2.9%)	0	7 (2.2%)
		7	3 (1.7%)	1 (1.4%)	4 (2.3%)	1 (1.5%)	6 (1.9%)
		7.5	4 (2.3%)	0	2 (1.1%)	0	2 (0.6%)
	7.5	6.5	3 (1.7%)	1 (1.4%)	0	0	1 (0.3%)
		7	0	0	1 (0.6%)	0	1 (0.3%)
		7.5	1 (0.6%)	0	1 (0.6%)	0	1 (0.3%)
	8	7	1 (0.6%)	0	0	0	0
		7.5	0	0	1 (0.6%)	0	1 (0.3%)
	8.5	7	1 (0.6%)	0	0	0	0

Parameter Week	Baseline	Post-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
Week 12	m		103	0	105	0	105
	5.5	5.5	12 (11.7%)	.	11 (10.5%)	.	11 (10.5%)
		6	9 (8.7%)	.	3 (2.9%)	.	3 (2.9%)
		6.5	1 (1.0%)	.	0	.	0
		7	0	.	1 (1.0%)	.	1 (1.0%)
		7.5	0	.	1 (1.0%)	.	1 (1.0%)
	6	5.5	10 (9.7%)	.	8 (7.6%)	.	8 (7.6%)
		6	24 (23.3%)	.	19 (18.1%)	.	19 (18.1%)
		6.5	9 (8.7%)	.	12 (11.4%)	.	12 (11.4%)
		7	2 (1.9%)	.	4 (3.8%)	.	4 (3.8%)
		7.5	0	.	1 (1.0%)	.	1 (1.0%)
		8	0	.	1 (1.0%)	.	1 (1.0%)
	6.5	5.5	2 (1.9%)	.	2 (1.9%)	.	2 (1.9%)
		6	12 (11.7%)	.	11 (10.5%)	.	11 (10.5%)
		6.5	9 (8.7%)	.	14 (13.3%)	.	14 (13.3%)
		7	2 (1.9%)	.	2 (1.9%)	.	2 (1.9%)
		7.5	1 (1.0%)	.	0	.	0
	7	6	1 (1.0%)	.	4 (3.8%)	.	4 (3.8%)
		6.5	1 (1.0%)	.	5 (4.8%)	.	5 (4.8%)
		7	3 (2.9%)	.	3 (2.9%)	.	3 (2.9%)
		7.5	1 (1.0%)	.	1 (1.0%)	.	1 (1.0%)
	7.5	5.5	1 (1.0%)	.	0	.	0
		6.5	0	.	1 (1.0%)	.	1 (1.0%)
		7	1 (1.0%)	.	0	.	0
		7.5	1 (1.0%)	.	0	.	0
	8	7	1 (1.0%)	.	0	.	0
		7.5	0	.	1 (1.0%)	.	1 (1.0%)
Week 16	m		168	71	171	68	310
	5	5	0	1 (1.4%)	0	0	1 (0.3%)
		5.5	1 (0.6%)	0	1 (0.6%)	1 (1.5%)	2 (0.6%)

Parameter Week	Baseline	Post-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
		6	0	1 (1.4%)	0	2 (2.9%)	3 (1.0%)
	5.5	5	1 (0.6%)	0	1 (0.6%)	2 (2.9%)	3 (1.0%)
		5.5	23 (13.7%)	11 (15.5%)	16 (9.4%)	11 (16.2%)	38 (12.3%)
		6	21 (12.5%)	19 (26.8%)	9 (5.3%)	14 (20.6%)	42 (13.5%)
		6.5	3 (1.8%)	0	2 (1.2%)	1 (1.5%)	3 (1.0%)
		7	2 (1.2%)	0	1 (0.6%)	0	1 (0.3%)
		7.5	0	0	2 (1.2%)	0	2 (0.6%)
	6	5.5	13 (7.7%)	3 (4.2%)	17 (9.9%)	2 (2.9%)	22 (7.1%)
		6	38 (22.6%)	12 (16.9%)	42 (24.6%)	19 (27.9%)	73 (23.5%)
		6.5	14 (8.3%)	6 (8.5%)	14 (8.2%)	2 (2.9%)	22 (7.1%)
		7	2 (1.2%)	0	2 (1.2%)	0	2 (0.6%)
		7.5	0	0	3 (1.8%)	0	3 (1.0%)
		8.5	1 (0.6%)	0	0	0	0
	6.5	5.5	2 (1.2%)	0	2 (1.2%)	2 (2.9%)	4 (1.3%)
		6	14 (8.3%)	4 (5.6%)	16 (9.4%)	3 (4.4%)	23 (7.4%)
		6.5	6 (3.6%)	3 (4.2%)	11 (6.4%)	2 (2.9%)	16 (5.2%)
		7	8 (4.8%)	3 (4.2%)	12 (7.0%)	2 (2.9%)	17 (5.5%)
		7.5	1 (0.6%)	0	0	0	0
	7	5.5	0	0	1 (0.6%)	0	1 (0.3%)
		6	6 (3.6%)	3 (4.2%)	9 (5.3%)	3 (4.4%)	15 (4.8%)
		6.5	1 (0.6%)	3 (4.2%)	2 (1.2%)	0	5 (1.6%)
		7	4 (2.4%)	1 (1.4%)	5 (2.9%)	1 (1.5%)	7 (2.3%)
		7.5	1 (0.6%)	0	1 (0.6%)	1 (1.5%)	2 (0.6%)
	7.5	5.5	0	1 (1.4%)	0	0	1 (0.3%)
		6	1 (0.6%)	0	0	0	0
		6.5	2 (1.2%)	0	0	0	0
		7	0	0	1 (0.6%)	0	1 (0.3%)
		8	1 (0.6%)	0	0	0	0
	8	7	0	0	1 (0.6%)	0	1 (0.3%)
		7.5	1 (0.6%)	0	0	0	0
	8.5	6.5	1 (0.6%)	0	0	0	0

Parameter Week	Baseline	Post-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
Week 20	m		102	0	103	0	103
	5.5	5.5	10 (9.8%)	.	9 (8.7%)	.	9 (8.7%)
		6	8 (7.8%)	.	3 (2.9%)	.	3 (2.9%)
		6.5	4 (3.9%)	.	2 (1.9%)	.	2 (1.9%)
		8	0	.	1 (1.0%)	.	1 (1.0%)
	6	5.5	6 (5.9%)	.	6 (5.8%)	.	6 (5.8%)
		6	21 (20.6%)	.	25 (24.3%)	.	25 (24.3%)
		6.5	10 (9.8%)	.	7 (6.8%)	.	7 (6.8%)
		7	5 (4.9%)	.	5 (4.9%)	.	5 (4.9%)
		7.5	2 (2.0%)	.	1 (1.0%)	.	1 (1.0%)
	6.5	5.5	3 (2.9%)	.	2 (1.9%)	.	2 (1.9%)
		6	8 (7.8%)	.	9 (8.7%)	.	9 (8.7%)
		6.5	8 (7.8%)	.	13 (12.6%)	.	13 (12.6%)
		7	6 (5.9%)	.	3 (2.9%)	.	3 (2.9%)
		7.5	1 (1.0%)	.	2 (1.9%)	.	2 (1.9%)
	7	6	1 (1.0%)	.	4 (3.9%)	.	4 (3.9%)
		6.5	3 (2.9%)	.	3 (2.9%)	.	3 (2.9%)
		7	2 (2.0%)	.	4 (3.9%)	.	4 (3.9%)
		7.5	0	.	1 (1.0%)	.	1 (1.0%)
		8	0	.	1 (1.0%)	.	1 (1.0%)
	7.5	6	1 (1.0%)	.	0	.	0
		6.5	0	.	1 (1.0%)	.	1 (1.0%)
		7	1 (1.0%)	.	0	.	0
		7.5	1 (1.0%)	.	0	.	0
	8	6.5	0	.	1 (1.0%)	.	1 (1.0%)
		7.5	1 (1.0%)	.	0	.	0
Week 24	m		167	70	169	67	306
	5	5.5	1 (0.6%)	1 (1.4%)	1 (0.6%)	3 (4.5%)	5 (1.6%)
		6	0	1 (1.4%)	0	0	1 (0.3%)

Parameter Week	Baseline	Post-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
	5.5	5	2 (1.2%)	0	0	1 (1.5%)	1 (0.3%)
		5.5	16 (9.6%)	13 (18.6%)	13 (7.7%)	10 (14.9%)	36 (11.8%)
		6	25 (15.0%)	15 (21.4%)	13 (7.7%)	16 (23.9%)	44 (14.4%)
		6.5	5 (3.0%)	0	3 (1.8%)	1 (1.5%)	4 (1.3%)
		7	1 (0.6%)	0	1 (0.6%)	0	1 (0.3%)
		7.5	0	1 (1.4%)	0	0	1 (0.3%)
	6	5.5	7 (4.2%)	3 (4.3%)	15 (8.9%)	3 (4.5%)	21 (6.9%)
		6	40 (24.0%)	10 (14.3%)	40 (23.7%)	14 (20.9%)	64 (20.9%)
		6.5	17 (10.2%)	4 (5.7%)	16 (9.5%)	4 (6.0%)	24 (7.8%)
		7	4 (2.4%)	4 (5.7%)	2 (1.2%)	1 (1.5%)	7 (2.3%)
		7.5	0	0	5 (3.0%)	1 (1.5%)	6 (2.0%)
	6.5	5.5	4 (2.4%)	1 (1.4%)	2 (1.2%)	0	3 (1.0%)
		6	9 (5.4%)	7 (10.0%)	19 (11.2%)	5 (7.5%)	31 (10.1%)
		6.5	12 (7.2%)	1 (1.4%)	7 (4.1%)	0	8 (2.6%)
		7	2 (1.2%)	1 (1.4%)	10 (5.9%)	2 (3.0%)	13 (4.2%)
		7.5	4 (2.4%)	0	2 (1.2%)	0	2 (0.7%)
		8.5	0	0	0	1 (1.5%)	1 (0.3%)
	7	5.5	0	0	1 (0.6%)	0	1 (0.3%)
		6	1 (0.6%)	4 (5.7%)	6 (3.6%)	1 (1.5%)	11 (3.6%)
		6.5	6 (3.6%)	2 (2.9%)	3 (1.8%)	3 (4.5%)	8 (2.6%)
		7	3 (1.8%)	1 (1.4%)	8 (4.7%)	1 (1.5%)	10 (3.3%)
		7.5	2 (1.2%)	0	0	0	0
	7.5	6	2 (1.2%)	0	0	0	0
		6.5	1 (0.6%)	0	0	0	0
		7	0	1 (1.4%)	1 (0.6%)	0	2 (0.7%)
		7.5	1 (0.6%)	0	0	0	0
	8	7	1 (0.6%)	0	0	0	0
		7.5	0	0	1 (0.6%)	0	1 (0.3%)
	8.5	7	1 (0.6%)	0	0	0	0
LOCF Endpoint	m		181	75	179	74	328

Parameter Week	Baseline	Post-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
	5	5.5	1 (0.6%)	1 (1.3%)	1 (0.6%)	3 (4.1%)	5 (1.5%)
		6	0	1 (1.3%)	0	0	1 (0.3%)
	5.5	5	3 (1.7%)	1 (1.3%)	1 (0.6%)	1 (1.4%)	3 (0.9%)
		5.5	20 (11.0%)	14 (18.7%)	17 (9.5%)	10 (13.5%)	41 (12.5%)
		6	25 (13.8%)	15 (20.0%)	14 (7.8%)	19 (25.7%)	48 (14.6%)
		6.5	5 (2.8%)	0	3 (1.7%)	1 (1.4%)	4 (1.2%)
		7	1 (0.6%)	0	1 (0.6%)	0	1 (0.3%)
		7.5	0	1 (1.3%)	0	0	1 (0.3%)
	6	5.5	10 (5.5%)	4 (5.3%)	17 (9.5%)	4 (5.4%)	25 (7.6%)
		6	42 (23.2%)	11 (14.7%)	40 (22.3%)	14 (18.9%)	65 (19.8%)
		6.5	18 (9.9%)	4 (5.3%)	16 (8.9%)	4 (5.4%)	24 (7.3%)
		7	4 (2.2%)	4 (5.3%)	2 (1.1%)	1 (1.4%)	7 (2.1%)
		7.5	0	0	5 (2.8%)	1 (1.4%)	6 (1.8%)
	6.5	5.5	5 (2.8%)	1 (1.3%)	2 (1.1%)	1 (1.4%)	4 (1.2%)
		6	10 (5.5%)	7 (9.3%)	19 (10.6%)	6 (8.1%)	32 (9.8%)
		6.5	12 (6.6%)	1 (1.3%)	7 (3.9%)	0	8 (2.4%)
		7	2 (1.1%)	1 (1.3%)	11 (6.1%)	2 (2.7%)	14 (4.3%)
		7.5	4 (2.2%)	0	2 (1.1%)	0	2 (0.6%)
		8.5	0	0	0	1 (1.4%)	1 (0.3%)
	7	5.5	0	0	1 (0.6%)	0	1 (0.3%)
		6	2 (1.1%)	5 (6.7%)	6 (3.4%)	2 (2.7%)	13 (4.0%)
		6.5	6 (3.3%)	2 (2.7%)	3 (1.7%)	3 (4.1%)	8 (2.4%)
		7	3 (1.7%)	1 (1.3%)	8 (4.5%)	1 (1.4%)	10 (3.0%)
		7.5	2 (1.1%)	0	0	0	0
	7.5	6	2 (1.1%)	0	0	0	0
		6.5	1 (0.6%)	0	0	0	0
		7	0	1 (1.3%)	2 (1.1%)	0	3 (0.9%)
		7.5	1 (0.6%)	0	0	0	0
	8	7	1 (0.6%)	0	0	0	0
		7.5	0	0	1 (0.6%)	0	1 (0.3%)
	8.5	7	1 (0.6%)	0	0	0	0

Parameter Week	Baseline	Post-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
Specific Gravity							
Week 4	m		106	0	106	0	106
	Low	Low	1 (0.9%)	.	2 (1.9%)	.	2 (1.9%)
		Normal	0	.	1 (0.9%)	.	1 (0.9%)
	Normal	Low	2 (1.9%)	.	1 (0.9%)	.	1 (0.9%)
		Normal	103 (97.2%)	.	102 (96.2%)	.	102 (96.2%)
Week 8	m		176	72	175	68	315
	Low	Low	1 (0.6%)	0	2 (1.1%)	0	2 (0.6%)
		Normal	0	1 (1.4%)	1 (0.6%)	0	2 (0.6%)
	Normal	Low	1 (0.6%)	0	0	0	0
		Normal	173 (98.3%)	71 (98.6%)	170 (97.1%)	67 (98.5%)	308 (97.8%)
		High	1 (0.6%)	0	0	1 (1.5%)	1 (0.3%)
	High	Normal	0	0	2 (1.1%)	0	2 (0.6%)
Week 12	m		103	0	105	0	105
	Low	Low	1 (1.0%)	.	1 (1.0%)	.	1 (1.0%)
		Normal	0	.	2 (1.9%)	.	2 (1.9%)
	Normal	Low	2 (1.9%)	.	1 (1.0%)	.	1 (1.0%)
		Normal	100 (97.1%)	.	101 (96.2%)	.	101 (96.2%)
Week 16	m		168	71	171	68	310
	Low	Low	0	0	1 (0.6%)	0	1 (0.3%)
		Normal	1 (0.6%)	1 (1.4%)	2 (1.2%)	0	3 (1.0%)
	Normal	Low	0	0	2 (1.2%)	0	2 (0.6%)
		Normal	167 (99.4%)	69 (97.2%)	164 (95.9%)	67 (98.5%)	300 (96.8%)
		High	0	1 (1.4%)	0	1 (1.5%)	2 (0.6%)
	High	Normal	0	0	2 (1.2%)	0	2 (0.6%)
Week 20	m		102	0	103	0	103

Parameter Week	Baseline	Post-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
	Low	Low	0	.	2 (1.9%)	.	2 (1.9%)
		Normal	1 (1.0%)	.	1 (1.0%)	.	1 (1.0%)
	Normal	Low	2 (2.0%)	.	2 (1.9%)	.	2 (1.9%)
		Normal	99 (97.1%)	.	98 (95.1%)	.	98 (95.1%)
Week 24	m		167	70	169	67	306
	Low	Low	1 (0.6%)	0	0	0	0
		Normal	0	1 (1.4%)	2 (1.2%)	0	3 (1.0%)
	Normal	Low	1 (0.6%)	0	0	0	0
		Normal	162 (97.0%)	69 (98.6%)	165 (97.6%)	66 (98.5%)	300 (98.0%)
		High	3 (1.8%)	0	0	1 (1.5%)	1 (0.3%)
	High	Normal	0	0	2 (1.2%)	0	2 (0.7%)
LOCF Endpoint	m		181	75	179	74	328
	Low	Low	1 (0.6%)	0	1 (0.6%)	0	1 (0.3%)
		Normal	0	1 (1.3%)	2 (1.1%)	0	3 (0.9%)
	Normal	Low	1 (0.6%)	0	0	0	0
		Normal	174 (96.1%)	73 (97.3%)	173 (96.6%)	73 (98.6%)	319 (97.3%)
		High	5 (2.8%)	1 (1.3%)	1 (0.6%)	1 (1.4%)	3 (0.9%)
	High	Normal	0	0	2 (1.1%)	0	2 (0.6%)
Urine Glucose							
Week 4	m		106	0	106	0	106
	Negative	Negative	55 (51.9%)	.	58 (54.7%)	.	58 (54.7%)
		Trace	7 (6.6%)	.	4 (3.8%)	.	4 (3.8%)
		Positive	9 (8.5%)	.	2 (1.9%)	.	2 (1.9%)
	Trace	Negative	1 (0.9%)	.	16 (15.1%)	.	16 (15.1%)
		Trace	5 (4.7%)	.	3 (2.8%)	.	3 (2.8%)
		Positive	7 (6.6%)	.	1 (0.9%)	.	1 (0.9%)
	Positive	Negative	5 (4.7%)	.	12 (11.3%)	.	12 (11.3%)
		Trace	3 (2.8%)	.	4 (3.8%)	.	4 (3.8%)

Parameter Week	Baseline	Post-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
		Positive	14 (13.2%)	.	6 (5.7%)	.	6 (5.7%)
Week 8	m		176	72	175	68	315
	Negative	Negative	101 (57.4%)	51 (70.8%)	107 (61.1%)	40 (58.8%)	198 (62.9%)
		Trace	8 (4.5%)	0	5 (2.9%)	0	5 (1.6%)
		Positive	14 (8.0%)	2 (2.8%)	3 (1.7%)	2 (2.9%)	7 (2.2%)
	Trace	Negative	2 (1.1%)	0	16 (9.1%)	0	16 (5.1%)
		Trace	7 (4.0%)	0	2 (1.1%)	0	2 (0.6%)
		Positive	4 (2.3%)	0	2 (1.1%)	0	2 (0.6%)
	Positive	Negative	15 (8.5%)	7 (9.7%)	17 (9.7%)	19 (27.9%)	43 (13.7%)
		Trace	3 (1.7%)	0	6 (3.4%)	0	6 (1.9%)
		Positive	22 (12.5%)	12 (16.7%)	17 (9.7%)	7 (10.3%)	36 (11.4%)
Week 12	m		103	0	105	0	105
	Negative	Negative	58 (56.3%)	.	57 (54.3%)	.	57 (54.3%)
		Trace	7 (6.8%)	.	2 (1.9%)	.	2 (1.9%)
		Positive	5 (4.9%)	.	4 (3.8%)	.	4 (3.8%)
	Trace	Negative	5 (4.9%)	.	13 (12.4%)	.	13 (12.4%)
		Trace	3 (2.9%)	.	4 (3.8%)	.	4 (3.8%)
		Positive	5 (4.9%)	.	3 (2.9%)	.	3 (2.9%)
	Positive	Negative	7 (6.8%)	.	12 (11.4%)	.	12 (11.4%)
		Trace	4 (3.9%)	.	3 (2.9%)	.	3 (2.9%)
		Positive	9 (8.7%)	.	7 (6.7%)	.	7 (6.7%)
Week 16	m		168	71	171	68	310
	Negative	Negative	101 (60.1%)	47 (66.2%)	106 (62.0%)	38 (55.9%)	191 (61.6%)
		Trace	9 (5.4%)	0	0	0	0
		Positive	9 (5.4%)	6 (8.5%)	5 (2.9%)	4 (5.9%)	15 (4.8%)
	Trace	Negative	7 (4.2%)	0	11 (6.4%)	0	11 (3.5%)
		Trace	1 (0.6%)	0	6 (3.5%)	0	6 (1.9%)
		Positive	5 (3.0%)	0	3 (1.8%)	0	3 (1.0%)

Parameter Week	Baseline	Post-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
	Positive	Negative	14 (8.3%)	8 (11.3%)	19 (11.1%)	15 (22.1%)	42 (13.5%)
		Trace	6 (3.6%)	0	4 (2.3%)	0	4 (1.3%)
		Positive	16 (9.5%)	10 (14.1%)	17 (9.9%)	11 (16.2%)	38 (12.3%)
Week 20	m		102	0	103	0	103
	Negative	Negative	54 (52.9%)	.	59 (57.3%)	.	59 (57.3%)
		Trace	7 (6.9%)	.	1 (1.0%)	.	1 (1.0%)
		Positive	9 (8.8%)	.	2 (1.9%)	.	2 (1.9%)
	Trace	Negative	5 (4.9%)	.	13 (12.6%)	.	13 (12.6%)
		Trace	2 (2.0%)	.	2 (1.9%)	.	2 (1.9%)
		Positive	6 (5.9%)	.	5 (4.9%)	.	5 (4.9%)
	Positive	Negative	6 (5.9%)	.	8 (7.8%)	.	8 (7.8%)
		Trace	4 (3.9%)	.	6 (5.8%)	.	6 (5.8%)
		Positive	9 (8.8%)	.	7 (6.8%)	.	7 (6.8%)
Week 24	m		167	70	169	67	306
	Negative	Negative	93 (55.7%)	47 (67.1%)	105 (62.1%)	36 (53.7%)	188 (61.4%)
		Trace	10 (6.0%)	0	1 (0.6%)	0	1 (0.3%)
		Positive	15 (9.0%)	5 (7.1%)	4 (2.4%)	6 (9.0%)	15 (4.9%)
	Trace	Negative	8 (4.8%)	0	12 (7.1%)	0	12 (3.9%)
		Trace	2 (1.2%)	0	3 (1.8%)	0	3 (1.0%)
		Positive	3 (1.8%)	0	5 (3.0%)	0	5 (1.6%)
	Positive	Negative	12 (7.2%)	5 (7.1%)	19 (11.2%)	14 (20.9%)	38 (12.4%)
		Trace	5 (3.0%)	0	3 (1.8%)	0	3 (1.0%)
		Positive	19 (11.4%)	13 (18.6%)	17 (10.1%)	11 (16.4%)	41 (13.4%)
LOCF Endpoint	m		181	75	179	74	328
	Negative	Negative	95 (52.5%)	47 (62.7%)	111 (62.0%)	41 (55.4%)	199 (60.7%)
		Trace	10 (5.5%)	0	1 (0.6%)	0	1 (0.3%)
		Positive	19 (10.5%)	6 (8.0%)	5 (2.8%)	6 (8.1%)	17 (5.2%)
	Trace	Negative	8 (4.4%)	0	12 (6.7%)	0	12 (3.7%)

Parameter Week	Baseline	Post-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
		Trace	2 (1.1%)	0	3 (1.7%)	0	3 (0.9%)
		Positive	3 (1.7%)	0	5 (2.8%)	0	5 (1.5%)
	Positive	Negative	12 (6.6%)	5 (6.7%)	19 (10.6%)	14 (18.9%)	38 (11.6%)
		Trace	5 (2.8%)	0	3 (1.7%)	0	3 (0.9%)
		Positive	27 (14.9%)	17 (22.7%)	20 (11.2%)	13 (17.6%)	50 (15.2%)
Urine Protein							
Week 4	m		106	0	106	0	106
	Negative	Negative	35 (33.0%)	.	29 (27.4%)	.	29 (27.4%)
		Trace	9 (8.5%)	.	9 (8.5%)	.	9 (8.5%)
		Positive	0	.	2 (1.9%)	.	2 (1.9%)
	Trace	Negative	6 (5.7%)	.	13 (12.3%)	.	13 (12.3%)
		Trace	31 (29.2%)	.	28 (26.4%)	.	28 (26.4%)
		Positive	8 (7.5%)	.	1 (0.9%)	.	1 (0.9%)
	Positive	Negative	2 (1.9%)	.	3 (2.8%)	.	3 (2.8%)
		Trace	3 (2.8%)	.	8 (7.5%)	.	8 (7.5%)
		Positive	12 (11.3%)	.	13 (12.3%)	.	13 (12.3%)
Week 8	m		176	72	175	68	315
	Negative	Negative	64 (36.4%)	39 (54.2%)	64 (36.6%)	33 (48.5%)	136 (43.2%)
		Trace	19 (10.8%)	3 (4.2%)	18 (10.3%)	4 (5.9%)	25 (7.9%)
		Positive	4 (2.3%)	0	7 (4.0%)	4 (5.9%)	11 (3.5%)
	Trace	Negative	12 (6.8%)	5 (6.9%)	20 (11.4%)	7 (10.3%)	32 (10.2%)
		Trace	38 (21.6%)	5 (6.9%)	29 (16.6%)	7 (10.3%)	41 (13.0%)
		Positive	8 (4.5%)	4 (5.6%)	5 (2.9%)	0	9 (2.9%)
	Positive	Negative	6 (3.4%)	6 (8.3%)	5 (2.9%)	5 (7.4%)	16 (5.1%)
		Trace	7 (4.0%)	4 (5.6%)	12 (6.9%)	2 (2.9%)	18 (5.7%)
		Positive	18 (10.2%)	6 (8.3%)	15 (8.6%)	6 (8.8%)	27 (8.6%)
Week 12	m		103	0	105	0	105
	Negative	Negative	29 (28.2%)	.	25 (23.8%)	.	25 (23.8%)

Parameter Week	Baseline	Post-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
		Trace	12 (11.7%)	.	13 (12.4%)	.	13 (12.4%)
		Positive	3 (2.9%)	.	2 (1.9%)	.	2 (1.9%)
	Trace	Negative	10 (9.7%)	.	15 (14.3%)	.	15 (14.3%)
		Trace	22 (21.4%)	.	21 (20.0%)	.	21 (20.0%)
		Positive	10 (9.7%)	.	5 (4.8%)	.	5 (4.8%)
	Positive	Negative	1 (1.0%)	.	2 (1.9%)	.	2 (1.9%)
		Trace	9 (8.7%)	.	10 (9.5%)	.	10 (9.5%)
		Positive	7 (6.8%)	.	12 (11.4%)	.	12 (11.4%)
Week 16	m		168	71	171	68	310
	Negative	Negative	64 (38.1%)	37 (52.1%)	68 (39.8%)	29 (42.6%)	134 (43.2%)
		Trace	18 (10.7%)	4 (5.6%)	16 (9.4%)	9 (13.2%)	29 (9.4%)
		Positive	4 (2.4%)	0	3 (1.8%)	3 (4.4%)	6 (1.9%)
	Trace	Negative	22 (13.1%)	7 (9.9%)	20 (11.7%)	7 (10.3%)	34 (11.0%)
		Trace	20 (11.9%)	4 (5.6%)	24 (14.0%)	4 (5.9%)	32 (10.3%)
		Positive	12 (7.1%)	3 (4.2%)	8 (4.7%)	3 (4.4%)	14 (4.5%)
	Positive	Negative	8 (4.8%)	7 (9.9%)	7 (4.1%)	2 (2.9%)	16 (5.2%)
		Trace	5 (3.0%)	3 (4.2%)	11 (6.4%)	1 (1.5%)	15 (4.8%)
		Positive	15 (8.9%)	6 (8.5%)	14 (8.2%)	10 (14.7%)	30 (9.7%)
Week 20	m		102	0	103	0	103
	Negative	Negative	29 (28.4%)	.	26 (25.2%)	.	26 (25.2%)
		Trace	12 (11.8%)	.	9 (8.7%)	.	9 (8.7%)
		Positive	3 (2.9%)	.	3 (2.9%)	.	3 (2.9%)
	Trace	Negative	17 (16.7%)	.	19 (18.4%)	.	19 (18.4%)
		Trace	21 (20.6%)	.	19 (18.4%)	.	19 (18.4%)
		Positive	4 (3.9%)	.	3 (2.9%)	.	3 (2.9%)
	Positive	Negative	0	.	5 (4.9%)	.	5 (4.9%)
		Trace	9 (8.8%)	.	9 (8.7%)	.	9 (8.7%)
		Positive	7 (6.9%)	.	10 (9.7%)	.	10 (9.7%)

Parameter Week	Baseline	Post-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
Week 24	m		167	70	169	67	306
	Negative	Negative	62 (37.1%)	35 (50.0%)	68 (40.2%)	32 (47.8%)	135 (44.1%)
		Trace	21 (12.6%)	4 (5.7%)	13 (7.7%)	7 (10.4%)	24 (7.8%)
		Positive	3 (1.8%)	2 (2.9%)	5 (3.0%)	1 (1.5%)	8 (2.6%)
	Trace	Negative	24 (14.4%)	6 (8.6%)	30 (17.8%)	10 (14.9%)	46 (15.0%)
		Trace	21 (12.6%)	3 (4.3%)	16 (9.5%)	4 (6.0%)	23 (7.5%)
		Positive	8 (4.8%)	5 (7.1%)	5 (3.0%)	0	10 (3.3%)
	Positive	Negative	7 (4.2%)	3 (4.3%)	8 (4.7%)	5 (7.5%)	16 (5.2%)
		Trace	9 (5.4%)	6 (8.6%)	9 (5.3%)	3 (4.5%)	18 (5.9%)
		Positive	12 (7.2%)	6 (8.6%)	15 (8.9%)	5 (7.5%)	26 (8.5%)
LOCF Endpoint	m		181	75	179	74	328
	Negative	Negative	64 (35.4%)	35 (46.7%)	71 (39.7%)	36 (48.6%)	142 (43.3%)
		Trace	22 (12.2%)	6 (8.0%)	15 (8.4%)	8 (10.8%)	29 (8.8%)
		Positive	3 (1.7%)	2 (2.7%)	5 (2.8%)	1 (1.4%)	8 (2.4%)
	Trace	Negative	26 (14.4%)	6 (8.0%)	32 (17.9%)	10 (13.5%)	48 (14.6%)
		Trace	26 (14.4%)	3 (4.0%)	17 (9.5%)	4 (5.4%)	24 (7.3%)
		Positive	8 (4.4%)	5 (6.7%)	6 (3.4%)	0	11 (3.4%)
	Positive	Negative	7 (3.9%)	3 (4.0%)	8 (4.5%)	6 (8.1%)	17 (5.2%)
		Trace	10 (5.5%)	7 (9.3%)	9 (5.0%)	4 (5.4%)	20 (6.1%)
		Positive	15 (8.3%)	8 (10.7%)	16 (8.9%)	5 (6.8%)	29 (8.8%)
Urobilinogen							
Week 4	m		106	0	106	0	106
	Normal	Normal	102 (96.2%)	.	104 (98.1%)	.	104 (98.1%)
		Abnormal	3 (2.8%)	.	0	.	0
	Abnormal	Normal	1 (0.9%)	.	2 (1.9%)	.	2 (1.9%)
Week 8	m		176	72	175	68	315
	Normal	Normal	170 (96.6%)	65 (90.3%)	168 (96.0%)	66 (97.1%)	299 (94.9%)
		Abnormal	2 (1.1%)	2 (2.8%)	0	0	2 (0.6%)

Parameter Week	Baseline	Post-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
	Abnormal	Normal	3 (1.7%)	5 (6.9%)	4 (2.3%)	1 (1.5%)	10 (3.2%)
		Abnormal	1 (0.6%)	0	3 (1.7%)	1 (1.5%)	4 (1.3%)
Week 12	m		103	0	105	0	105
	Normal	Normal	101 (98.1%)	.	103 (98.1%)	.	103 (98.1%)
		Abnormal	1 (1.0%)	.	0	.	0
	Abnormal	Normal	1 (1.0%)	.	2 (1.9%)	.	2 (1.9%)
Week 16	m		168	71	171	68	310
	Normal	Normal	160 (95.2%)	63 (88.7%)	160 (93.6%)	64 (94.1%)	287 (92.6%)
		Abnormal	4 (2.4%)	3 (4.2%)	4 (2.3%)	2 (2.9%)	9 (2.9%)
	Abnormal	Normal	3 (1.8%)	3 (4.2%)	5 (2.9%)	2 (2.9%)	10 (3.2%)
		Abnormal	1 (0.6%)	2 (2.8%)	2 (1.2%)	0	4 (1.3%)
Week 20	m		102	0	103	0	103
	Normal	Normal	99 (97.1%)	.	99 (96.1%)	.	99 (96.1%)
		Abnormal	2 (2.0%)	.	2 (1.9%)	.	2 (1.9%)
	Abnormal	Normal	1 (1.0%)	.	1 (1.0%)	.	1 (1.0%)
		Abnormal	0	.	1 (1.0%)	.	1 (1.0%)
Week 24	m		167	70	169	67	306
	Normal	Normal	160 (95.8%)	63 (90.0%)	161 (95.3%)	59 (88.1%)	283 (92.5%)
		Abnormal	3 (1.8%)	2 (2.9%)	1 (0.6%)	6 (9.0%)	9 (2.9%)
	Abnormal	Normal	4 (2.4%)	3 (4.3%)	5 (3.0%)	1 (1.5%)	9 (2.9%)
		Abnormal	0	2 (2.9%)	2 (1.2%)	1 (1.5%)	5 (1.6%)
LOCF Endpoint	m		181	75	179	74	328
	Normal	Normal	174 (96.1%)	68 (90.7%)	171 (95.5%)	66 (89.2%)	305 (93.0%)
		Abnormal	3 (1.7%)	2 (2.7%)	1 (0.6%)	6 (8.1%)	9 (2.7%)
	Abnormal	Normal	4 (2.2%)	3 (4.0%)	5 (2.8%)	1 (1.4%)	9 (2.7%)

Parameter Week	Baseline	Post-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
		Abnormal	0	2 (2.7%)	2 (1.1%)	1 (1.4%)	5 (1.5%)

- 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-180-labot-24wdb.sas, 2020-03-06T00:14:46>>

Table S-181 Shift of Laboratory Findings of Coagulation in 24-Week Double-blind Period with Monotherapy (PXL008-014, PXL008-018; Safety Population)

Parameter Week	Baseline	Post-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
Activated Partial Thromboplastin Time (sec)							
Week 12	m		163	71	169	66	306
	Low	Low	13 (8.0%)	0	10 (5.9%)	0	10 (3.3%)
		Normal	7 (4.3%)	0	13 (7.7%)	0	13 (4.2%)
	Normal	Low	14 (8.6%)	0	3 (1.8%)	0	3 (1.0%)
		Normal	124 (76.1%)	64 (90.1%)	135 (79.9%)	65 (98.5%)	264 (86.3%)
		High	0	2 (2.8%)	4 (2.4%)	0	6 (2.0%)
	High	Normal	3 (1.8%)	5 (7.0%)	3 (1.8%)	1 (1.5%)	9 (2.9%)
		High	2 (1.2%)	0	1 (0.6%)	0	1 (0.3%)
Week 24	m		164	69	163	65	297
	Low	Low	13 (7.9%)	0	11 (6.7%)	0	11 (3.7%)
		Normal	8 (4.9%)	0	11 (6.7%)	0	11 (3.7%)
	Normal	Low	16 (9.8%)	0	5 (3.1%)	1 (1.5%)	6 (2.0%)
		Normal	120 (73.2%)	61 (88.4%)	130 (79.8%)	61 (93.8%)	252 (84.8%)
		High	2 (1.2%)	3 (4.3%)	2 (1.2%)	2 (3.1%)	7 (2.4%)
	High	Normal	5 (3.0%)	4 (5.8%)	4 (2.5%)	1 (1.5%)	9 (3.0%)
		High	0	1 (1.4%)	0	0	1 (0.3%)
LOCF Endpoint	m		167	71	172	66	309
	Low	Low	13 (7.8%)	0	12 (7.0%)	0	12 (3.9%)
		Normal	8 (4.8%)	0	12 (7.0%)	0	12 (3.9%)
	Normal	Low	16 (9.6%)	0	5 (2.9%)	1 (1.5%)	6 (1.9%)
		Normal	123 (73.7%)	63 (88.7%)	137 (79.7%)	62 (93.9%)	262 (84.8%)
		High	2 (1.2%)	3 (4.2%)	2 (1.2%)	2 (3.0%)	7 (2.3%)
	High	Normal	5 (3.0%)	4 (5.6%)	4 (2.3%)	1 (1.5%)	9 (2.9%)
		High	0	1 (1.4%)	0	0	1 (0.3%)

Parameter Week	Baseline	Post-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
Prothrombin Intl. Normalized Ratio							
Week 12	m		64	71	66	66	203
	Low	Normal	0	0	1 (1.5%)	2 (3.0%)	3 (1.5%)
		High	1 (1.6%)	0	0	0	0
	Normal	Normal	26 (40.6%)	32 (45.1%)	28 (42.4%)	25 (37.9%)	85 (41.9%)
		High	10 (15.6%)	14 (19.7%)	14 (21.2%)	9 (13.6%)	37 (18.2%)
	High	Normal	16 (25.0%)	16 (22.5%)	14 (21.2%)	18 (27.3%)	48 (23.6%)
		High	11 (17.2%)	9 (12.7%)	9 (13.6%)	12 (18.2%)	30 (14.8%)
Week 24	m		63	69	65	65	199
	Low	Normal	1 (1.6%)	0	1 (1.5%)	1 (1.5%)	2 (1.0%)
		High	0	0	0	1 (1.5%)	1 (0.5%)
	Normal	Normal	28 (44.4%)	37 (53.6%)	36 (55.4%)	26 (40.0%)	99 (49.7%)
		High	7 (11.1%)	8 (11.6%)	5 (7.7%)	7 (10.8%)	20 (10.1%)
	High	Normal	19 (30.2%)	19 (27.5%)	19 (29.2%)	22 (33.8%)	60 (30.2%)
		High	8 (12.7%)	5 (7.2%)	4 (6.2%)	8 (12.3%)	17 (8.5%)
LOCF Endpoint	m		65	71	67	66	204
	Low	Normal	1 (1.5%)	0	1 (1.5%)	1 (1.5%)	2 (1.0%)
		High	0	0	0	1 (1.5%)	1 (0.5%)
	Normal	Normal	30 (46.2%)	37 (52.1%)	38 (56.7%)	26 (39.4%)	101 (49.5%)
		High	7 (10.8%)	9 (12.7%)	5 (7.5%)	8 (12.1%)	22 (10.8%)
	High	Normal	19 (29.2%)	19 (26.8%)	19 (28.4%)	22 (33.3%)	60 (29.4%)
		High	8 (12.3%)	6 (8.5%)	4 (6.0%)	8 (12.1%)	18 (8.8%)
Prothrombin Time (sec)							
Week 12	m		99	0	103	0	103
	Low	Low	0	.	2 (1.9%)	.	2 (1.9%)
		Normal	7 (7.1%)	.	2 (1.9%)	.	2 (1.9%)
	Normal	Low	6 (6.1%)	.	4 (3.9%)	.	4 (3.9%)

Parameter Week	Baseline	Post-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
		Normal	86 (86.9%)	.	93 (90.3%)	.	93 (90.3%)
		High	0	.	1 (1.0%)	.	1 (1.0%)
	High	High	0	.	1 (1.0%)	.	1 (1.0%)
Week 24	m		101	0	98	0	98
	Low	Low	1 (1.0%)	.	0	.	0
		Normal	6 (5.9%)	.	4 (4.1%)	.	4 (4.1%)
	Normal	Low	2 (2.0%)	.	2 (2.0%)	.	2 (2.0%)
		Normal	92 (91.1%)	.	91 (92.9%)	.	91 (92.9%)
	High	High	0	.	1 (1.0%)	.	1 (1.0%)
LOCF Endpoint	m		102	0	105	0	105
	Low	Low	1 (1.0%)	.	0	.	0
		Normal	6 (5.9%)	.	4 (3.8%)	.	4 (3.8%)
	Normal	Low	2 (2.0%)	.	2 (1.9%)	.	2 (1.9%)
		Normal	93 (91.2%)	.	98 (93.3%)	.	98 (93.3%)
	High	High	0	.	1 (1.0%)	.	1 (1.0%)

- 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-181-labot-24wdb.sas, 2020-03-06T00:14:52>>

Table S-183 Shift of Laboratory Findings of UACR (Albuminuria) in 24-Week Double-blind Period with Monotherapy (PXL008-014, PXL008-018; Safety Population)

Parameter Week	Baseline	Post-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
Albumin/Creatinine (mg/g)							
Week 12	m		102	0	105	0	105
	Normal	Normal	71 (69.6%)	.	65 (61.9%)	.	65 (61.9%)
		Micro	7 (6.9%)	.	4 (3.8%)	.	4 (3.8%)
	Micro	Normal	11 (10.8%)	.	12 (11.4%)	.	12 (11.4%)
		Micro	13 (12.7%)	.	17 (16.2%)	.	17 (16.2%)
		Macro	0	.	3 (2.9%)	.	3 (2.9%)
	Macro	Micro	0	.	1 (1.0%)	.	1 (1.0%)
		Macro	0	.	3 (2.9%)	.	3 (2.9%)
Week 16	m		0	0	0	1	1
	Macro	Macro	.	.	.	1 (100.0%)	1 (100.0%)
Week 24	m		161	59	159	65	283
	Normal	Normal	92 (57.1%)	36 (61.0%)	103 (64.8%)	42 (64.6%)	181 (64.0%)
		Micro	23 (14.3%)	7 (11.9%)	8 (5.0%)	2 (3.1%)	17 (6.0%)
	Micro	Normal	16 (9.9%)	2 (3.4%)	10 (6.3%)	2 (3.1%)	14 (4.9%)
		Micro	28 (17.4%)	10 (16.9%)	28 (17.6%)	15 (23.1%)	53 (18.7%)
		Macro	1 (0.6%)	3 (5.1%)	5 (3.1%)	1 (1.5%)	9 (3.2%)
	Macro	Micro	0	1 (1.7%)	1 (0.6%)	0	2 (0.7%)
		Macro	1 (0.6%)	0	4 (2.5%)	3 (4.6%)	7 (2.5%)
LOCF Endpoint	m		161	59	161	65	285
	Normal	Normal	92 (57.1%)	36 (61.0%)	104 (64.6%)	42 (64.6%)	182 (63.9%)
		Micro	23 (14.3%)	7 (11.9%)	8 (5.0%)	2 (3.1%)	17 (6.0%)
	Micro	Normal	16 (9.9%)	2 (3.4%)	10 (6.2%)	2 (3.1%)	14 (4.9%)
		Micro	28 (17.4%)	10 (16.9%)	29 (18.0%)	15 (23.1%)	54 (18.9%)
		Macro	1 (0.6%)	3 (5.1%)	5 (3.1%)	1 (1.5%)	9 (3.2%)
	Macro	Micro	0	1 (1.7%)	1 (0.6%)	0	2 (0.7%)

Parameter Week	Baseline	Post-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
		Macro	1 (0.6%)	0	4 (2.5%)	3 (4.6%)	7 (2.5%)

- 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-183-labot-24wdb.sas, 2020-03-06T00:15:04>>

Table S-184 Shift of Laboratory Findings of Lactate Concentration in 24-Week Double-blind Period with Monotherapy (PXL008-014, PXL008-018; Safety Population)

Parameter Week	Baseline	Post-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
Lactic Acid (mmol/L)							
Week 2	m		74	75	73	71	219
	Low	Low	1 (1.4%)	0	0	0	0
		Normal	1 (1.4%)	1 (1.3%)	0	0	1 (0.5%)
	Normal	Low	2 (2.7%)	0	1 (1.4%)	0	1 (0.5%)
		Normal	63 (85.1%)	67 (89.3%)	70 (95.9%)	68 (95.8%)	205 (93.6%)
		High	1 (1.4%)	5 (6.7%)	0	1 (1.4%)	6 (2.7%)
	High	Normal	5 (6.8%)	1 (1.3%)	1 (1.4%)	2 (2.8%)	4 (1.8%)
		High	1 (1.4%)	1 (1.3%)	1 (1.4%)	0	2 (0.9%)
Week 4	m		72	75	71	68	214
	Low	Low	1 (1.4%)	0	0	0	0
		Normal	1 (1.4%)	1 (1.3%)	0	0	1 (0.5%)
	Normal	Low	0	1 (1.3%)	0	0	1 (0.5%)
		Normal	64 (88.9%)	69 (92.0%)	69 (97.2%)	65 (95.6%)	203 (94.9%)
		High	1 (1.4%)	2 (2.7%)	0	1 (1.5%)	3 (1.4%)
	High	Normal	4 (5.6%)	0	1 (1.4%)	2 (2.9%)	3 (1.4%)
		High	1 (1.4%)	2 (2.7%)	1 (1.4%)	0	3 (1.4%)
Week 8	m		70	72	69	68	209
	Low	Low	1 (1.4%)	0	0	0	0
		Normal	1 (1.4%)	1 (1.4%)	0	0	1 (0.5%)
	Normal	Normal	60 (85.7%)	68 (94.4%)	66 (95.7%)	66 (97.1%)	200 (95.7%)
		High	2 (2.9%)	2 (2.8%)	1 (1.4%)	0	3 (1.4%)
	High	Normal	5 (7.1%)	0	1 (1.4%)	1 (1.5%)	2 (1.0%)
		High	1 (1.4%)	1 (1.4%)	1 (1.4%)	1 (1.5%)	3 (1.4%)
Week 12	m		167	72	171	67	310
	Low	Normal	2 (1.2%)	1 (1.4%)	0	0	1 (0.3%)

Parameter Week	Baseline	Post-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
	Normal	Normal	149 (89.2%)	67 (93.1%)	160 (93.6%)	62 (92.5%)	289 (93.2%)
		High	5 (3.0%)	3 (4.2%)	0	3 (4.5%)	6 (1.9%)
	High	Normal	9 (5.4%)	0	6 (3.5%)	0	6 (1.9%)
		High	2 (1.2%)	1 (1.4%)	5 (2.9%)	2 (3.0%)	8 (2.6%)
Week 16	m		66	71	67	68	206
	Low	Normal	2 (3.0%)	1 (1.4%)	0	0	1 (0.5%)
	Normal	Low	0	0	2 (3.0%)	0	2 (1.0%)
		Normal	57 (86.4%)	66 (93.0%)	63 (94.0%)	63 (92.6%)	192 (93.2%)
		High	2 (3.0%)	3 (4.2%)	0	3 (4.4%)	6 (2.9%)
	High	Normal	5 (7.6%)	0	1 (1.5%)	1 (1.5%)	2 (1.0%)
		High	0	1 (1.4%)	1 (1.5%)	1 (1.5%)	3 (1.5%)
Week 20	m		66	70	66	67	203
	Low	Normal	2 (3.0%)	1 (1.4%)	0	0	1 (0.5%)
	Normal	Low	0	0	2 (3.0%)	0	2 (1.0%)
		Normal	57 (86.4%)	67 (95.7%)	60 (90.9%)	63 (94.0%)	190 (93.6%)
		High	2 (3.0%)	2 (2.9%)	2 (3.0%)	2 (3.0%)	6 (3.0%)
	High	Normal	4 (6.1%)	0	2 (3.0%)	1 (1.5%)	3 (1.5%)
		High	1 (1.5%)	0	0	1 (1.5%)	1 (0.5%)
Week 24	m		166	69	168	67	304
	Low	Normal	2 (1.2%)	1 (1.4%)	0	0	1 (0.3%)
	Normal	Low	0	0	1 (0.6%)	0	1 (0.3%)
		Normal	149 (89.8%)	61 (88.4%)	154 (91.7%)	61 (91.0%)	276 (90.8%)
		High	4 (2.4%)	7 (10.1%)	3 (1.8%)	4 (6.0%)	14 (4.6%)
	High	Normal	6 (3.6%)	0	6 (3.6%)	1 (1.5%)	7 (2.3%)
		High	5 (3.0%)	0	4 (2.4%)	1 (1.5%)	5 (1.6%)
LOCF Endpoint	m		176	75	178	75	328
	Low	Normal	2 (1.1%)	1 (1.3%)	0	0	1 (0.3%)

Parameter Week	Baseline	Post-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
	Normal	Low	0	0	2 (1.1%)	0	2 (0.6%)
		Normal	158 (89.8%)	65 (86.7%)	161 (90.4%)	69 (92.0%)	295 (89.9%)
		High	4 (2.3%)	7 (9.3%)	4 (2.2%)	4 (5.3%)	15 (4.6%)
	High	Normal	7 (4.0%)	2 (2.7%)	7 (3.9%)	1 (1.3%)	10 (3.0%)
		High	5 (2.8%)	0	4 (2.2%)	1 (1.3%)	5 (1.5%)

- 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-184-labot-24wdb.sas, 2020-03-06T00:14:54>>

Table S-185 Shift of ECG Findings in 24-Week Double-blind Period with Monotherapy (PXL008-014, PXL008-018; Safety Population)

Week	Baseline	Post-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
Interpretation							
Week 2	m		74	75	73	71	219
	Normal	Normal	53 (71.6%)	54 (72.0%)	49 (67.1%)	52 (73.2%)	155 (70.8%)
		Abnormal, not clinically significant	4 (5.4%)	3 (4.0%)	2 (2.7%)	2 (2.8%)	7 (3.2%)
	Abnormal, not clinically significant	Normal	1 (1.4%)	6 (8.0%)	4 (5.5%)	6 (8.5%)	16 (7.3%)
		Abnormal, not clinically significant	16 (21.6%)	12 (16.0%)	17 (23.3%)	10 (14.1%)	39 (17.8%)
	Abnormal, clinically significant	Abnormal, clinically significant	0	0	1 (1.4%)	1 (1.4%)	2 (0.9%)
Week 4	m		73	75	72	70	217
	Normal	Normal	52 (71.2%)	56 (74.7%)	48 (66.7%)	48 (68.6%)	152 (70.0%)
		Abnormal, not clinically significant	5 (6.8%)	1 (1.3%)	3 (4.2%)	5 (7.1%)	9 (4.1%)
	Abnormal, not clinically significant	Normal	1 (1.4%)	7 (9.3%)	2 (2.8%)	4 (5.7%)	13 (6.0%)
		Abnormal, not clinically significant	15 (20.5%)	11 (14.7%)	18 (25.0%)	12 (17.1%)	41 (18.9%)
	Abnormal, clinically significant	Abnormal, clinically significant	0	0	1 (1.4%)	1 (1.4%)	2 (0.9%)
Week 8	m		70	72	69	68	209
	Normal	Normal	52 (74.3%)	51 (70.8%)	43 (62.3%)	48 (70.6%)	142 (67.9%)
		Abnormal, not clinically significant	3 (4.3%)	3 (4.2%)	6 (8.7%)	3 (4.4%)	12 (5.7%)
	Abnormal, not clinically significant	Normal	1 (1.4%)	8 (11.1%)	6 (8.7%)	5 (7.4%)	19 (9.1%)

Week	Baseline	Post-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
		Abnormal, not clinically significant	14 (20.0%)	10 (13.9%)	13 (18.8%)	11 (16.2%)	34 (16.3%)
	Abnormal, clinically significant	Abnormal, clinically significant	0	0	1 (1.4%)	1 (1.5%)	2 (1.0%)
Week 12	m		171	72	173	68	313
	Normal	Normal	126 (73.7%)	49 (68.1%)	122 (70.5%)	48 (70.6%)	219 (70.0%)
		Abnormal, not clinically significant	4 (2.3%)	5 (6.9%)	5 (2.9%)	3 (4.4%)	13 (4.2%)
	Abnormal, not clinically significant	Normal	10 (5.8%)	6 (8.3%)	9 (5.2%)	7 (10.3%)	22 (7.0%)
		Abnormal, not clinically significant	31 (18.1%)	12 (16.7%)	36 (20.8%)	9 (13.2%)	57 (18.2%)
	Abnormal, clinically significant	Abnormal, clinically significant	0	0	1 (0.6%)	1 (1.5%)	2 (0.6%)
Week 16	m		66	71	67	68	206
	Normal	Normal	49 (74.2%)	50 (70.4%)	46 (68.7%)	48 (70.6%)	144 (69.9%)
		Abnormal, not clinically significant	3 (4.5%)	3 (4.2%)	1 (1.5%)	3 (4.4%)	7 (3.4%)
	Abnormal, not clinically significant	Normal	1 (1.5%)	7 (9.9%)	5 (7.5%)	5 (7.4%)	17 (8.3%)
		Abnormal, not clinically significant	13 (19.7%)	11 (15.5%)	14 (20.9%)	11 (16.2%)	36 (17.5%)
	Abnormal, clinically significant	Abnormal, clinically significant	0	0	1 (1.5%)	1 (1.5%)	2 (1.0%)
Week 20	m		66	70	66	67	203
	Normal	Normal	49 (74.2%)	49 (70.0%)	44 (66.7%)	47 (70.1%)	140 (69.0%)
		Abnormal, not clinically significant	3 (4.5%)	3 (4.3%)	2 (3.0%)	3 (4.5%)	8 (3.9%)

Week	Baseline	Post-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
	Abnormal, not clinically significant	Normal	3 (4.5%)	6 (8.6%)	2 (3.0%)	4 (6.0%)	12 (5.9%)
		Abnormal, not clinically significant	11 (16.7%)	12 (17.1%)	17 (25.8%)	12 (17.9%)	41 (20.2%)
	Abnormal, clinically significant	Abnormal, clinically significant	0	0	1 (1.5%)	1 (1.5%)	2 (1.0%)
Week 24	m		167	70	169	67	306
	Normal	Normal	116 (69.5%)	49 (70.0%)	120 (71.0%)	48 (71.6%)	217 (70.9%)
		Abnormal, not clinically significant	11 (6.6%)	3 (4.3%)	4 (2.4%)	2 (3.0%)	9 (2.9%)
	Abnormal, not clinically significant	Normal	10 (6.0%)	5 (7.1%)	9 (5.3%)	5 (7.5%)	19 (6.2%)
		Abnormal, not clinically significant	30 (18.0%)	13 (18.6%)	35 (20.7%)	10 (14.9%)	58 (19.0%)
		Abnormal, clinically significant	0	0	0	1 (1.5%)	1 (0.3%)
	Abnormal, clinically significant	Abnormal, clinically significant	0	0	1 (0.6%)	1 (1.5%)	2 (0.7%)
LOCF Endpoint	m		180	75	180	75	330
	Normal	Normal	124 (68.9%)	54 (72.0%)	125 (69.4%)	56 (74.7%)	235 (71.2%)
		Abnormal, not clinically significant	11 (6.1%)	3 (4.0%)	6 (3.3%)	2 (2.7%)	11 (3.3%)
	Abnormal, not clinically significant	Normal	11 (6.1%)	5 (6.7%)	9 (5.0%)	5 (6.7%)	19 (5.8%)
		Abnormal, not clinically significant	34 (18.9%)	13 (17.3%)	39 (21.7%)	10 (13.3%)	62 (18.8%)
		Abnormal, clinically significant	0	0	0	1 (1.3%)	1 (0.3%)

Week	Baseline	Post-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
	Abnormal, clinically significant	Abnormal, clinically significant	0	0	1 (0.6%)	1 (1.3%)	2 (0.6%)

- 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-185-ecgqt-24wdb.sas, 2020-03-06T00:14:15>>

Table S-186 Shift of Laboratory Findings of Hematology 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
Basophils (10^9/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	124	63	64	64	65	62	69	63	574	706
	Normal	Normal	132 (100.0%)	124 (100.0%)	63 (100.0%)	64 (100.0%)	64 (100.0%)	65 (100.0%)	62 (100.0%)	69 (100.0%)	63 (100.0%)	574 (100.0%)	706 (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%)	63 (100.0%)	64 (100.0%)	65 (100.0%)	61 (100.0%)	69 (100.0%)	63 (100.0%)	569 (100.0%)	699 (100.0%)
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%)

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
	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	127 (100.0%)	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%)	680 (100.0%)
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%)
Basophils/Leukocytes (%)													
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%)	62 (96.9%)	65 (100.0%)	63 (100.0%)	69 (98.6%)	62 (98.4%)	572 (98.6%)	702 (98.3%)
		High	3 (2.2%)	1 (0.8%)	1 (1.6%)	0	0	0	0	1 (1.4%)	1 (1.6%)	4 (0.7%)	7 (1.0%)
	High	Normal	0	1 (0.8%)	0	0	1 (1.6%)	0	0	0	0	2 (0.3%)	2 (0.3%)
		High	1 (0.7%)	1 (0.8%)	0	0	1 (1.6%)	0	0	0	0	2 (0.3%)	3 (0.4%)
Week 8	m		132	124	63	64	64	65	62	69	63	574	706
	Normal	Normal	130 (98.5%)	123 (99.2%)	63 (100.0%)	63 (98.4%)	62 (96.9%)	65 (100.0%)	62 (100.0%)	69 (100.0%)	61 (96.8%)	568 (99.0%)	698 (98.9%)
		High	1 (0.8%)	0	0	1 (1.6%)	0	0	0	0	2 (3.2%)	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
	High	Normal	1 (0.8%)	1 (0.8%)	0	0	2 (3.1%)	0	0	0	0	3 (0.5%)	4 (0.6%)
Week 12	m		131	123	63	64	64	65	62	68	63	572	703
	Normal	Normal	130 (99.2%)	121 (98.4%)	63 (100.0%)	64 (100.0%)	62 (96.9%)	65 (100.0%)	62 (100.0%)	68 (100.0%)	62 (98.4%)	567 (99.1%)	697 (99.1%)
		High	0	1 (0.8%)	0	0	0	0	0	0	1 (1.6%)	2 (0.3%)	2 (0.3%)
	High	Normal	0	1 (0.8%)	0	0	1 (1.6%)	0	0	0	0	2 (0.3%)	2 (0.3%)
		High	1 (0.8%)	0	0	0	1 (1.6%)	0	0	0	0	1 (0.2%)	2 (0.3%)
Week 16	m		130	123	63	64	64	64	62	69	63	572	702
	Normal	Normal	129 (99.2%)	122 (99.2%)	63 (100.0%)	63 (98.4%)	62 (96.9%)	64 (100.0%)	62 (100.0%)	69 (100.0%)	63 (100.0%)	568 (99.3%)	697 (99.3%)
		High	0	0	0	1 (1.6%)	0	0	0	0	0	1 (0.2%)	1 (0.1%)
	High	Normal	0	1 (0.8%)	0	0	1 (1.6%)	0	0	0	0	2 (0.3%)	2 (0.3%)
		High	1 (0.8%)	0	0	0	1 (1.6%)	0	0	0	0	1 (0.2%)	2 (0.3%)
Week 20	m		130	123	62	63	64	65	61	69	63	570	700
	Normal	Normal	129 (99.2%)	121 (98.4%)	62 (100.0%)	63 (100.0%)	62 (96.9%)	65 (100.0%)	61 (100.0%)	69 (100.0%)	63 (100.0%)	566 (99.3%)	695 (99.3%)
		High	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
	High	Normal	0	0	0	0	1 (1.6%)	0	0	0	0	1 (0.2%)	1 (0.1%)
		High	1 (0.8%)	1 (0.8%)	0	0	1 (1.6%)	0	0	0	0	2 (0.4%)	3 (0.4%)
Week 24	m		130	122	62	63	64	65	61	69	63	569	699
	Normal	Normal	128 (98.5%)	121 (99.2%)	62 (100.0%)	63 (100.0%)	62 (96.9%)	65 (100.0%)	61 (100.0%)	69 (100.0%)	63 (100.0%)	566 (99.5%)	694 (99.3%)
		High	1 (0.8%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
	High	Normal	1 (0.8%)	1 (0.8%)	0	0	1 (1.6%)	0	0	0	0	2 (0.4%)	3 (0.4%)
		High	0	0	0	0	1 (1.6%)	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	126 (98.4%)	118 (98.3%)	62 (100.0%)	60 (100.0%)	60 (96.8%)	65 (100.0%)	60 (100.0%)	69 (100.0%)	63 (100.0%)	557 (99.3%)	683 (99.1%)
		High	1 (0.8%)	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	2 (0.3%)
	High	Normal	1 (0.8%)	1 (0.8%)	0	0	1 (1.6%)	0	0	0	0	2 (0.4%)	3 (0.4%)
		High	0	0	0	0	1 (1.6%)	0	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	127 (99.2%)	119 (99.2%)	60 (100.0%)	59 (100.0%)	60 (96.8%)	65 (100.0%)	60 (100.0%)	69 (100.0%)	62 (98.4%)	554 (99.3%)	681 (99.3%)
		High	0	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	1 (0.1%)
	High	Normal	0	1 (0.8%)	0	0	1 (1.6%)	0	0	0	0	2 (0.4%)	2 (0.3%)
		High	1 (0.8%)	0	0	0	1 (1.6%)	0	0	0	0	1 (0.2%)	2 (0.3%)
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%)	59 (100.0%)	60 (96.8%)	65 (100.0%)	60 (100.0%)	66 (100.0%)	62 (98.4%)	549 (99.3%)	675 (99.3%)
		High	0	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	1 (0.1%)
	High	Normal	1 (0.8%)	1 (0.8%)	0	0	2 (3.2%)	0	0	0	0	3 (0.5%)	4 (0.6%)
Week 52	m		126	116	59	58	62	65	60	67	62	549	675
	Normal	Normal	125 (99.2%)	115 (99.1%)	59 (100.0%)	58 (100.0%)	60 (96.8%)	65 (100.0%)	60 (100.0%)	67 (100.0%)	61 (98.4%)	545 (99.3%)	670 (99.3%)
		High	0	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	1 (0.1%)
	High	Normal	0	1 (0.9%)	0	0	1 (1.6%)	0	0	0	0	2 (0.4%)	2 (0.3%)
		High	1 (0.8%)	0	0	0	1 (1.6%)	0	0	0	0	1 (0.2%)	2 (0.3%)
LOCF Endpoint	m		134	127	64	64	64	65	63	70	63	580	714
	Normal	Normal	133 (99.3%)	125 (98.4%)	64 (100.0%)	64 (100.0%)	62 (96.9%)	65 (100.0%)	63 (100.0%)	70 (100.0%)	62 (98.4%)	575 (99.1%)	708 (99.2%)

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	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	1 (0.1%)
	High	Normal	0	2 (1.6%)	0	0	1 (1.6%)	0	0	0	0	3 (0.5%)	3 (0.4%)
		High	1 (0.7%)	0	0	0	1 (1.6%)	0	0	0	0	1 (0.2%)	2 (0.3%)
Eosinophils (10^9/L)													
Week 4	m		134	127	64	64	64	65	63	70	63	580	714
	Normal	Normal	132 (98.5%)	126 (99.2%)	63 (98.4%)	63 (98.4%)	63 (98.4%)	65 (100.0%)	63 (100.0%)	68 (97.1%)	63 (100.0%)	574 (99.0%)	706 (98.9%)
		High	2 (1.5%)	0	1 (1.6%)	0	0	0	0	0	0	1 (0.2%)	3 (0.4%)
	High	Normal	0	1 (0.8%)	0	0	0	0	0	1 (1.4%)	0	2 (0.3%)	2 (0.3%)
		High	0	0	0	1 (1.6%)	1 (1.6%)	0	0	1 (1.4%)	0	3 (0.5%)	3 (0.4%)
Week 8	m		132	124	63	64	64	65	62	69	63	574	706
	Normal	Normal	132 (100.0%)	123 (99.2%)	63 (100.0%)	63 (98.4%)	63 (98.4%)	65 (100.0%)	62 (100.0%)	67 (97.1%)	63 (100.0%)	569 (99.1%)	701 (99.3%)
	High	Normal	0	1 (0.8%)	0	0	1 (1.6%)	0	0	2 (2.9%)	0	4 (0.7%)	4 (0.6%)
		High	0	0	0	1 (1.6%)	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
	Normal	Normal	131 (100.0%)	120 (97.6%)	63 (100.0%)	63 (98.4%)	63 (98.4%)	65 (100.0%)	62 (100.0%)	66 (97.1%)	63 (100.0%)	565 (98.8%)	696 (99.0%)
		High	0	2 (1.6%)	0	0	0	0	0	0	0	2 (0.3%)	2 (0.3%)
	High	Normal	0	1 (0.8%)	0	0	1 (1.6%)	0	0	1 (1.5%)	0	3 (0.5%)	3 (0.4%)
		High	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
	Normal	Normal	129 (99.2%)	122 (99.2%)	63 (100.0%)	63 (98.4%)	63 (98.4%)	64 (100.0%)	62 (100.0%)	67 (97.1%)	63 (100.0%)	567 (99.1%)	696 (99.1%)
		High	1 (0.8%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
	High	Normal	0	1 (0.8%)	0	0	0	0	0	1 (1.4%)	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
		High	0	0	0	1 (1.6%)	1 (1.6%)	0	0	1 (1.4%)	0	3 (0.5%)	3 (0.4%)
Week 20	m		130	123	62	63	64	65	61	69	63	570	700
	Normal	Normal	130 (100.0%)	122 (99.2%)	62 (100.0%)	62 (98.4%)	63 (98.4%)	64 (98.5%)	61 (100.0%)	67 (97.1%)	63 (100.0%)	564 (98.9%)	694 (99.1%)
		High	0	0	0	0	0	1 (1.5%)	0	0	0	1 (0.2%)	1 (0.1%)
	High	Normal	0	1 (0.8%)	0	0	1 (1.6%)	0	0	1 (1.4%)	0	3 (0.5%)	3 (0.4%)
		High	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	129 (99.2%)	120 (98.4%)	62 (100.0%)	62 (98.4%)	63 (98.4%)	65 (100.0%)	61 (100.0%)	67 (97.1%)	63 (100.0%)	563 (98.9%)	692 (99.0%)
		High	1 (0.8%)	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	2 (0.3%)
	High	Normal	0	1 (0.8%)	0	0	1 (1.6%)	0	0	1 (1.4%)	0	3 (0.5%)	3 (0.4%)
		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%)	119 (99.2%)	62 (100.0%)	58 (96.7%)	60 (96.8%)	65 (100.0%)	60 (100.0%)	67 (97.1%)	63 (100.0%)	554 (98.8%)	681 (98.8%)
		High	1 (0.8%)	0	0	1 (1.7%)	1 (1.6%)	0	0	0	0	2 (0.4%)	3 (0.4%)
	High	Normal	0	1 (0.8%)	0	0	0	0	0	1 (1.4%)	0	2 (0.4%)	2 (0.3%)
		High	0	0	0	1 (1.7%)	1 (1.6%)	0	0	1 (1.4%)	0	3 (0.5%)	3 (0.4%)
Week 40	m		128	120	60	59	62	65	60	69	63	558	686
	Normal	Normal	127 (99.2%)	118 (98.3%)	59 (98.3%)	58 (98.3%)	60 (96.8%)	65 (100.0%)	60 (100.0%)	67 (97.1%)	63 (100.0%)	550 (98.6%)	677 (98.7%)
		High	1 (0.8%)	1 (0.8%)	1 (1.7%)	0	1 (1.6%)	0	0	0	0	3 (0.5%)	4 (0.6%)
	High	Normal	0	1 (0.8%)	0	1 (1.7%)	0	0	0	1 (1.4%)	0	3 (0.5%)	3 (0.4%)
		High	0	0	0	0	1 (1.6%)	0	0	1 (1.4%)	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
Week 48	m		127	118	60	59	62	65	60	66	63	553	680
	Normal	Normal	125 (98.4%)	115 (97.5%)	59 (98.3%)	58 (98.3%)	61 (98.4%)	65 (100.0%)	60 (100.0%)	63 (95.5%)	63 (100.0%)	544 (98.4%)	669 (98.4%)
		High	2 (1.6%)	2 (1.7%)	1 (1.7%)	0	0	0	0	1 (1.5%)	0	4 (0.7%)	6 (0.9%)
	High	Normal	0	1 (0.8%)	0	0	1 (1.6%)	0	0	1 (1.5%)	0	3 (0.5%)	3 (0.4%)
		High	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	124 (98.4%)	114 (98.3%)	58 (98.3%)	58 (100.0%)	61 (98.4%)	65 (100.0%)	60 (100.0%)	65 (97.0%)	62 (100.0%)	543 (98.9%)	667 (98.8%)
		High	2 (1.6%)	1 (0.9%)	1 (1.7%)	0	0	0	0	0	0	2 (0.4%)	4 (0.6%)
	High	Normal	0	1 (0.9%)	0	0	0	0	0	1 (1.5%)	0	2 (0.4%)	2 (0.3%)
		High	0	0	0	0	1 (1.6%)	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	132 (98.5%)	125 (98.4%)	63 (98.4%)	63 (98.4%)	63 (98.4%)	65 (100.0%)	63 (100.0%)	68 (97.1%)	63 (100.0%)	573 (98.8%)	705 (98.7%)
		High	2 (1.5%)	1 (0.8%)	1 (1.6%)	0	0	0	0	0	0	2 (0.3%)	4 (0.6%)
	High	Normal	0	1 (0.8%)	0	0	0	0	0	1 (1.4%)	0	2 (0.3%)	2 (0.3%)
		High	0	0	0	1 (1.6%)	1 (1.6%)	0	0	1 (1.4%)	0	3 (0.5%)	3 (0.4%)
Eosinophils/Leukocytes (%)													
Week 4	m		134	127	64	64	64	65	63	70	63	580	714
	Normal	Normal	130 (97.0%)	120 (94.5%)	59 (92.2%)	62 (96.9%)	61 (95.3%)	65 (100.0%)	62 (98.4%)	67 (95.7%)	62 (98.4%)	558 (96.2%)	688 (96.4%)
		High	2 (1.5%)	3 (2.4%)	2 (3.1%)	1 (1.6%)	0	0	0	1 (1.4%)	0	7 (1.2%)	9 (1.3%)
	High	Normal	1 (0.7%)	3 (2.4%)	2 (3.1%)	0	2 (3.1%)	0	1 (1.6%)	0	1 (1.6%)	9 (1.6%)	10 (1.4%)
		High	1 (0.7%)	1 (0.8%)	1 (1.6%)	1 (1.6%)	1 (1.6%)	0	0	2 (2.9%)	0	6 (1.0%)	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 8	m		132	124	63	64	64	65	62	69	63	574	706
	Normal	Normal	129 (97.7%)	117 (94.4%)	59 (93.7%)	63 (98.4%)	61 (95.3%)	65 (100.0%)	61 (98.4%)	66 (95.7%)	61 (96.8%)	553 (96.3%)	682 (96.6%)
		High	1 (0.8%)	3 (2.4%)	1 (1.6%)	0	0	0	0	1 (1.4%)	1 (1.6%)	6 (1.0%)	7 (1.0%)
	High	Normal	1 (0.8%)	1 (0.8%)	1 (1.6%)	0	2 (3.1%)	0	1 (1.6%)	1 (1.4%)	1 (1.6%)	7 (1.2%)	8 (1.1%)
		High	1 (0.8%)	3 (2.4%)	2 (3.2%)	1 (1.6%)	1 (1.6%)	0	0	1 (1.4%)	0	8 (1.4%)	9 (1.3%)
Week 12	m		131	123	63	64	64	65	62	68	63	572	703
	Normal	Normal	127 (96.9%)	118 (95.9%)	59 (93.7%)	62 (96.9%)	61 (95.3%)	65 (100.0%)	61 (98.4%)	65 (95.6%)	62 (98.4%)	553 (96.7%)	680 (96.7%)
		High	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%)
	High	Normal	1 (0.8%)	3 (2.4%)	2 (3.2%)	0	2 (3.1%)	0	1 (1.6%)	1 (1.5%)	1 (1.6%)	10 (1.7%)	11 (1.6%)
		High	1 (0.8%)	1 (0.8%)	1 (1.6%)	1 (1.6%)	1 (1.6%)	0	0	1 (1.5%)	0	5 (0.9%)	6 (0.9%)
Week 16	m		130	123	63	64	64	64	62	69	63	572	702
	Normal	Normal	126 (96.9%)	119 (96.7%)	59 (93.7%)	63 (98.4%)	61 (95.3%)	63 (98.4%)	61 (98.4%)	67 (97.1%)	62 (98.4%)	555 (97.0%)	681 (97.0%)
		High	2 (1.5%)	0	1 (1.6%)	0	0	1 (1.6%)	0	0	0	2 (0.3%)	4 (0.6%)
	High	Normal	1 (0.8%)	4 (3.3%)	2 (3.2%)	0	1 (1.6%)	0	1 (1.6%)	1 (1.4%)	1 (1.6%)	10 (1.7%)	11 (1.6%)
		High	1 (0.8%)	0	1 (1.6%)	1 (1.6%)	2 (3.1%)	0	0	1 (1.4%)	0	5 (0.9%)	6 (0.9%)
Week 20	m		130	123	62	63	64	65	61	69	63	570	700
	Normal	Normal	128 (98.5%)	117 (95.1%)	58 (93.5%)	62 (98.4%)	61 (95.3%)	64 (98.5%)	60 (98.4%)	66 (95.7%)	62 (98.4%)	550 (96.5%)	678 (96.9%)
		High	0	2 (1.6%)	1 (1.6%)	0	0	1 (1.5%)	0	1 (1.4%)	0	5 (0.9%)	5 (0.7%)
	High	Normal	1 (0.8%)	3 (2.4%)	2 (3.2%)	0	2 (3.1%)	0	1 (1.6%)	1 (1.4%)	1 (1.6%)	10 (1.8%)	11 (1.6%)
		High	1 (0.8%)	1 (0.8%)	1 (1.6%)	1 (1.6%)	1 (1.6%)	0	0	1 (1.4%)	0	5 (0.9%)	6 (0.9%)
Week 24	m		130	122	62	63	64	65	61	69	63	569	699
	Normal	Normal	126 (96.9%)	117 (95.9%)	58 (93.5%)	62 (98.4%)	61 (95.3%)	62 (95.4%)	60 (98.4%)	66 (95.7%)	62 (98.4%)	548 (96.3%)	674 (96.4%)

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	2 (1.5%)	1 (0.8%)	1 (1.6%)	0	0	3 (4.6%)	0	1 (1.4%)	0	6 (1.1%)	8 (1.1%)
	High	Normal	1 (0.8%)	2 (1.6%)	1 (1.6%)	0	2 (3.1%)	0	1 (1.6%)	1 (1.4%)	1 (1.6%)	8 (1.4%)	9 (1.3%)
		High	1 (0.8%)	2 (1.6%)	2 (3.2%)	1 (1.6%)	1 (1.6%)	0	0	1 (1.4%)	0	7 (1.2%)	8 (1.1%)
Week 32	m		128	120	62	60	62	65	60	69	63	561	689
	Normal	Normal	123 (96.1%)	114 (95.0%)	58 (93.5%)	56 (93.3%)	58 (93.5%)	64 (98.5%)	59 (98.3%)	67 (97.1%)	62 (98.4%)	538 (95.9%)	661 (95.9%)
		High	3 (2.3%)	2 (1.7%)	1 (1.6%)	3 (5.0%)	1 (1.6%)	1 (1.5%)	0	0	0	8 (1.4%)	11 (1.6%)
	High	Normal	1 (0.8%)	2 (1.7%)	2 (3.2%)	0	1 (1.6%)	0	1 (1.7%)	1 (1.4%)	1 (1.6%)	8 (1.4%)	9 (1.3%)
		High	1 (0.8%)	2 (1.7%)	1 (1.6%)	1 (1.7%)	2 (3.2%)	0	0	1 (1.4%)	0	7 (1.2%)	8 (1.2%)
Week 40	m		128	120	60	59	62	65	60	69	63	558	686
	Normal	Normal	126 (98.4%)	115 (95.8%)	57 (95.0%)	57 (96.6%)	59 (95.2%)	65 (100.0%)	57 (95.0%)	67 (97.1%)	62 (98.4%)	539 (96.6%)	665 (96.9%)
		High	0	1 (0.8%)	1 (1.7%)	1 (1.7%)	0	0	2 (3.3%)	0	0	5 (0.9%)	5 (0.7%)
	High	Normal	1 (0.8%)	2 (1.7%)	1 (1.7%)	0	0	0	1 (1.7%)	1 (1.4%)	0	5 (0.9%)	6 (0.9%)
		High	1 (0.8%)	2 (1.7%)	1 (1.7%)	1 (1.7%)	3 (4.8%)	0	0	1 (1.4%)	1 (1.6%)	9 (1.6%)	10 (1.5%)
Week 48	m		127	118	60	59	62	65	60	66	63	553	680
	Normal	Normal	124 (97.6%)	112 (94.9%)	57 (95.0%)	57 (96.6%)	57 (91.9%)	65 (100.0%)	57 (95.0%)	63 (95.5%)	60 (95.2%)	528 (95.5%)	652 (95.9%)
		High	1 (0.8%)	2 (1.7%)	1 (1.7%)	1 (1.7%)	2 (3.2%)	0	2 (3.3%)	1 (1.5%)	2 (3.2%)	11 (2.0%)	12 (1.8%)
	High	Normal	1 (0.8%)	2 (1.7%)	1 (1.7%)	0	1 (1.6%)	0	1 (1.7%)	1 (1.5%)	0	6 (1.1%)	7 (1.0%)
		High	1 (0.8%)	2 (1.7%)	1 (1.7%)	1 (1.7%)	2 (3.2%)	0	0	1 (1.5%)	1 (1.6%)	8 (1.4%)	9 (1.3%)
Week 52	m		126	116	59	58	62	65	60	67	62	549	675
	Normal	Normal	121 (96.0%)	111 (95.7%)	56 (94.9%)	54 (93.1%)	58 (93.5%)	65 (100.0%)	59 (98.3%)	65 (97.0%)	61 (98.4%)	529 (96.4%)	650 (96.3%)
		High	3 (2.4%)	1 (0.9%)	1 (1.7%)	4 (6.9%)	1 (1.6%)	0	0	0	0	7 (1.3%)	10 (1.5%)
	High	Normal	1 (0.8%)	1 (0.9%)	1 (1.7%)	0	2 (3.2%)	0	0	1 (1.5%)	0	5 (0.9%)	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
		High	1 (0.8%)	3 (2.6%)	1 (1.7%)	0	1 (1.6%)	0	1 (1.7%)	1 (1.5%)	1 (1.6%)	8 (1.5%)	9 (1.3%)
LOCF Endpoint	m		134	127	64	64	64	65	63	70	63	580	714
	Normal	Normal	129 (96.3%)	122 (96.1%)	60 (93.8%)	59 (92.2%)	60 (93.8%)	65 (100.0%)	62 (98.4%)	68 (97.1%)	62 (98.4%)	558 (96.2%)	687 (96.2%)
		High	3 (2.2%)	1 (0.8%)	1 (1.6%)	4 (6.3%)	1 (1.6%)	0	0	0	0	7 (1.2%)	10 (1.4%)
	High	Normal	1 (0.7%)	1 (0.8%)	1 (1.6%)	0	2 (3.1%)	0	0	1 (1.4%)	0	5 (0.9%)	6 (0.8%)
		High	1 (0.7%)	3 (2.4%)	2 (3.1%)	1 (1.6%)	1 (1.6%)	0	1 (1.6%)	1 (1.4%)	1 (1.6%)	10 (1.7%)	11 (1.5%)
Ery. Mean Corpuscular Hemoglobin (pg)													
Week 4	m		134	127	64	64	64	65	63	70	63	580	714
	Low	Low	0	0	0	0	1 (1.6%)	0	0	0	0	1 (0.2%)	1 (0.1%)
	Normal	Normal	132 (98.5%)	124 (97.6%)	64 (100.0%)	64 (100.0%)	62 (96.9%)	64 (98.5%)	60 (95.2%)	68 (97.1%)	62 (98.4%)	568 (97.9%)	700 (98.0%)
		High	0	1 (0.8%)	0	0	1 (1.6%)	0	1 (1.6%)	0	0	3 (0.5%)	3 (0.4%)
	High	Normal	1 (0.7%)	1 (0.8%)	0	0	0	0	1 (1.6%)	1 (1.4%)	0	3 (0.5%)	4 (0.6%)
		High	1 (0.7%)	1 (0.8%)	0	0	0	1 (1.5%)	1 (1.6%)	1 (1.4%)	1 (1.6%)	5 (0.9%)	6 (0.8%)
Week 8	m		132	124	63	64	64	65	62	69	63	574	706
	Low	Low	0	0	0	0	1 (1.6%)	0	0	0	0	1 (0.2%)	1 (0.1%)
	Normal	Normal	130 (98.5%)	121 (97.6%)	63 (100.0%)	64 (100.0%)	63 (98.4%)	64 (98.5%)	59 (95.2%)	67 (97.1%)	61 (96.8%)	562 (97.9%)	692 (98.0%)
		High	0	1 (0.8%)	0	0	0	0	1 (1.6%)	0	1 (1.6%)	3 (0.5%)	3 (0.4%)
	High	Normal	1 (0.8%)	1 (0.8%)	0	0	0	0	0	1 (1.4%)	0	2 (0.3%)	3 (0.4%)
		High	1 (0.8%)	1 (0.8%)	0	0	0	1 (1.5%)	2 (3.2%)	1 (1.4%)	1 (1.6%)	6 (1.0%)	7 (1.0%)
Week 12	m		131	123	63	64	64	65	62	68	63	572	703
	Low	Low	0	0	0	0	1 (1.6%)	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	0	0	0	0	0	0	1 (1.6%)	0	0	1 (0.2%)	1 (0.1%)
		Normal	129 (98.5%)	119 (96.7%)	63 (100.0%)	64 (100.0%)	63 (98.4%)	64 (98.5%)	58 (93.5%)	66 (97.1%)	62 (98.4%)	559 (97.7%)	688 (97.9%)
		High	0	2 (1.6%)	0	0	0	0	1 (1.6%)	0	0	3 (0.5%)	3 (0.4%)
	High	Normal	0	0	0	0	0	0	1 (1.6%)	1 (1.5%)	1 (1.6%)	3 (0.5%)	3 (0.4%)
		High	2 (1.5%)	2 (1.6%)	0	0	0	1 (1.5%)	1 (1.6%)	1 (1.5%)	0	5 (0.9%)	7 (1.0%)
Week 16	m		130	123	63	64	64	64	62	69	63	572	702
	Low	Low	0	0	0	0	1 (1.6%)	0	0	0	0	1 (0.2%)	1 (0.1%)
	Normal	Low	0	0	0	0	0	0	1 (1.6%)	0	0	1 (0.2%)	1 (0.1%)
		Normal	128 (98.5%)	118 (95.9%)	63 (100.0%)	64 (100.0%)	61 (95.3%)	62 (96.9%)	56 (90.3%)	66 (95.7%)	60 (95.2%)	550 (96.2%)	678 (96.6%)
		High	0	3 (2.4%)	0	0	2 (3.1%)	1 (1.6%)	3 (4.8%)	1 (1.4%)	2 (3.2%)	12 (2.1%)	12 (1.7%)
	High	Normal	0	0	0	0	0	0	0	1 (1.4%)	1 (1.6%)	2 (0.3%)	2 (0.3%)
		High	2 (1.5%)	2 (1.6%)	0	0	0	1 (1.6%)	2 (3.2%)	1 (1.4%)	0	6 (1.0%)	8 (1.1%)
Week 20	m		130	123	62	63	64	65	61	69	63	570	700
	Low	Low	0	0	0	0	1 (1.6%)	0	0	0	0	1 (0.2%)	1 (0.1%)
	Normal	Low	0	0	0	0	0	0	1 (1.6%)	0	0	1 (0.2%)	1 (0.1%)
		Normal	127 (97.7%)	117 (95.1%)	62 (100.0%)	63 (100.0%)	61 (95.3%)	62 (95.4%)	55 (90.2%)	67 (97.1%)	61 (96.8%)	548 (96.1%)	675 (96.4%)
		High	1 (0.8%)	4 (3.3%)	0	0	2 (3.1%)	2 (3.1%)	3 (4.9%)	0	1 (1.6%)	12 (2.1%)	13 (1.9%)
	High	Normal	0	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	1 (0.1%)
		High	2 (1.5%)	2 (1.6%)	0	0	0	1 (1.5%)	2 (3.3%)	2 (2.9%)	0	7 (1.2%)	9 (1.3%)
Week 24	m		130	122	62	63	64	65	61	69	63	569	699
	Low	Low	0	0	0	0	1 (1.6%)	0	0	0	0	1 (0.2%)	1 (0.1%)
	Normal	Low	0	0	0	0	0	0	1 (1.6%)	0	0	1 (0.2%)	1 (0.1%)
		Normal	126 (96.9%)	115 (94.3%)	61 (98.4%)	62 (98.4%)	61 (95.3%)	62 (95.4%)	53 (86.9%)	66 (95.7%)	61 (96.8%)	541 (95.1%)	667 (95.4%)

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	2 (1.5%)	5 (4.1%)	1 (1.6%)	1 (1.6%)	2 (3.1%)	2 (3.1%)	5 (8.2%)	1 (1.4%)	1 (1.6%)	18 (3.2%)	20 (2.9%)
	High	Normal	0	0	0	0	0	0	1 (1.6%)	0	1 (1.6%)	2 (0.4%)	2 (0.3%)
		High	2 (1.5%)	2 (1.6%)	0	0	0	1 (1.5%)	1 (1.6%)	2 (2.9%)	0	6 (1.1%)	8 (1.1%)
Week 32	m		128	120	62	60	62	65	60	69	63	561	689
	Low	Low	0	0	0	0	1 (1.6%)	0	0	0	0	1 (0.2%)	1 (0.1%)
	Normal	Low	0	0	0	0	0	0	1 (1.7%)	0	0	1 (0.2%)	1 (0.1%)
		Normal	122 (95.3%)	116 (96.7%)	61 (98.4%)	60 (100.0%)	60 (96.8%)	62 (95.4%)	55 (91.7%)	66 (95.7%)	61 (96.8%)	541 (96.4%)	663 (96.2%)
		High	4 (3.1%)	2 (1.7%)	1 (1.6%)	0	1 (1.6%)	2 (3.1%)	2 (3.3%)	1 (1.4%)	1 (1.6%)	10 (1.8%)	14 (2.0%)
	High	Normal	0	0	0	0	0	0	1 (1.7%)	2 (2.9%)	1 (1.6%)	4 (0.7%)	4 (0.6%)
		High	2 (1.6%)	2 (1.7%)	0	0	0	1 (1.5%)	1 (1.7%)	0	0	4 (0.7%)	6 (0.9%)
Week 40	m		128	120	60	59	62	65	60	69	63	558	686
	Low	Low	0	0	0	0	1 (1.6%)	0	0	0	0	1 (0.2%)	1 (0.1%)
	Normal	Normal	126 (98.4%)	114 (95.0%)	60 (100.0%)	59 (100.0%)	60 (96.8%)	62 (95.4%)	55 (91.7%)	66 (95.7%)	59 (93.7%)	535 (95.9%)	661 (96.4%)
		High	0	4 (3.3%)	0	0	1 (1.6%)	2 (3.1%)	3 (5.0%)	1 (1.4%)	3 (4.8%)	14 (2.5%)	14 (2.0%)
	High	Normal	1 (0.8%)	0	0	0	0	0	0	1 (1.4%)	1 (1.6%)	2 (0.4%)	3 (0.4%)
		High	1 (0.8%)	2 (1.7%)	0	0	0	1 (1.5%)	2 (3.3%)	1 (1.4%)	0	6 (1.1%)	7 (1.0%)
Week 48	m		127	118	60	59	62	65	60	66	63	553	680
	Low	Low	0	0	0	0	1 (1.6%)	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	124 (97.6%)	111 (94.1%)	60 (100.0%)	58 (98.3%)	58 (93.5%)	63 (96.9%)	55 (91.7%)	63 (95.5%)	60 (95.2%)	528 (95.5%)	652 (95.9%)
		High	1 (0.8%)	5 (4.2%)	0	1 (1.7%)	2 (3.2%)	1 (1.5%)	3 (5.0%)	1 (1.5%)	2 (3.2%)	15 (2.7%)	16 (2.4%)
	High	Normal	0	0	0	0	0	0	1 (1.7%)	1 (1.5%)	1 (1.6%)	3 (0.5%)	3 (0.4%)
		High	2 (1.6%)	2 (1.7%)	0	0	0	1 (1.5%)	1 (1.7%)	1 (1.5%)	0	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 52	m		126	116	59	58	62	65	60	67	62	549	675
	Low	Low	0	0	0	0	1 (1.6%)	0	0	0	0	1 (0.2%)	1 (0.1%)
	Normal	Low	0	0	0	0	1 (1.6%)	1 (1.5%)	0	0	0	2 (0.4%)	2 (0.3%)
		Normal	122 (96.8%)	109 (94.0%)	59 (100.0%)	58 (100.0%)	59 (95.2%)	63 (96.9%)	55 (91.7%)	65 (97.0%)	60 (96.8%)	528 (96.2%)	650 (96.3%)
		High	2 (1.6%)	5 (4.3%)	0	0	1 (1.6%)	0	3 (5.0%)	0	1 (1.6%)	10 (1.8%)	12 (1.8%)
	High	Normal	0	1 (0.9%)	0	0	0	0	1 (1.7%)	2 (3.0%)	1 (1.6%)	5 (0.9%)	5 (0.7%)
		High	2 (1.6%)	1 (0.9%)	0	0	0	1 (1.5%)	1 (1.7%)	0	0	3 (0.5%)	5 (0.7%)
LOCF Endpoint	m		134	127	64	64	64	65	63	70	63	580	714
	Low	Low	0	0	0	0	1 (1.6%)	0	0	0	0	1 (0.2%)	1 (0.1%)
	Normal	Low	0	0	0	0	1 (1.6%)	1 (1.5%)	1 (1.6%)	0	0	3 (0.5%)	3 (0.4%)
		Normal	130 (97.0%)	120 (94.5%)	64 (100.0%)	64 (100.0%)	61 (95.3%)	63 (96.9%)	57 (90.5%)	68 (97.1%)	61 (96.8%)	558 (96.2%)	688 (96.4%)
		High	2 (1.5%)	5 (3.9%)	0	0	1 (1.6%)	0	3 (4.8%)	0	1 (1.6%)	10 (1.7%)	12 (1.7%)
	High	Normal	0	1 (0.8%)	0	0	0	0	1 (1.6%)	2 (2.9%)	1 (1.6%)	5 (0.9%)	5 (0.7%)
		High	2 (1.5%)	1 (0.8%)	0	0	0	1 (1.5%)	1 (1.6%)	0	0	3 (0.5%)	5 (0.7%)
Ery. Mean Corpuscular HGB Concentration (g/L)													
Week 4	m		134	127	64	64	64	65	63	70	63	580	714
	Normal	Low	0	0	0	0	0	0	0	1 (1.4%)	0	1 (0.2%)	1 (0.1%)
		Normal	134 (100.0%)	127 (100.0%)	64 (100.0%)	64 (100.0%)	64 (100.0%)	65 (100.0%)	63 (100.0%)	69 (98.6%)	63 (100.0%)	579 (99.8%)	713 (99.9%)
Week 8	m		132	124	63	64	64	65	62	69	63	574	706
	Normal	Low	0	0	0	0	1 (1.6%)	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	132 (100.0%)	124 (100.0%)	63 (100.0%)	64 (100.0%)	63 (98.4%)	65 (100.0%)	62 (100.0%)	69 (100.0%)	63 (100.0%)	573 (99.8%)	705 (99.9%)
Week 12	m		131	123	63	64	64	65	62	68	63	572	703
	Normal	Low	0	1 (0.8%)	0	0	1 (1.6%)	0	0	1 (1.5%)	0	3 (0.5%)	3 (0.4%)
		Normal	131 (100.0%)	122 (99.2%)	63 (100.0%)	64 (100.0%)	63 (98.4%)	65 (100.0%)	62 (100.0%)	67 (98.5%)	63 (100.0%)	569 (99.5%)	700 (99.6%)
Week 16	m		130	123	63	64	64	64	62	69	63	572	702
	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%)	63 (100.0%)	64 (100.0%)	63 (98.4%)	64 (100.0%)	62 (100.0%)	69 (100.0%)	63 (100.0%)	571 (99.8%)	701 (99.9%)
Week 20	m		130	123	62	63	64	65	61	69	63	570	700
	Normal	Low	0	0	0	0	1 (1.6%)	0	1 (1.6%)	0	1 (1.6%)	3 (0.5%)	3 (0.4%)
		Normal	130 (100.0%)	123 (100.0%)	62 (100.0%)	63 (100.0%)	63 (98.4%)	65 (100.0%)	60 (98.4%)	69 (100.0%)	62 (98.4%)	567 (99.5%)	697 (99.6%)
Week 24	m		130	122	62	63	64	65	61	69	63	569	699
	Normal	Low	0	0	0	0	2 (3.1%)	0	2 (3.3%)	0	0	4 (0.7%)	4 (0.6%)
		Normal	130 (100.0%)	122 (100.0%)	62 (100.0%)	63 (100.0%)	62 (96.9%)	65 (100.0%)	59 (96.7%)	69 (100.0%)	63 (100.0%)	565 (99.3%)	695 (99.4%)
Week 32	m		128	120	62	60	62	65	60	69	63	561	689
	Normal	Low	0	1 (0.8%)	2 (3.2%)	1 (1.7%)	0	0	2 (3.3%)	0	0	6 (1.1%)	6 (0.9%)
		Normal	128 (100.0%)	119 (99.2%)	60 (96.8%)	59 (98.3%)	62 (100.0%)	65 (100.0%)	58 (96.7%)	69 (100.0%)	63 (100.0%)	555 (98.9%)	683 (99.1%)
Week 40	m		128	120	60	59	62	65	60	69	63	558	686
	Normal	Low	0	1 (0.8%)	0	0	1 (1.6%)	1 (1.5%)	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	128 (100.0%)	119 (99.2%)	60 (100.0%)	59 (100.0%)	61 (98.4%)	64 (98.5%)	60 (100.0%)	69 (100.0%)	62 (98.4%)	554 (99.3%)	682 (99.4%)
Week 48	m		127	118	60	59	62	65	60	66	63	553	680
	Normal	Low	0	0	0	0	1 (1.6%)	1 (1.5%)	1 (1.7%)	0	1 (1.6%)	4 (0.7%)	4 (0.6%)
		Normal	127 (100.0%)	118 (100.0%)	60 (100.0%)	59 (100.0%)	61 (98.4%)	64 (98.5%)	59 (98.3%)	66 (100.0%)	62 (98.4%)	549 (99.3%)	676 (99.4%)
Week 52	m		126	116	59	58	62	65	60	67	62	549	675
	Normal	Low	0	1 (0.9%)	0	0	2 (3.2%)	1 (1.5%)	1 (1.7%)	1 (1.5%)	0	6 (1.1%)	6 (0.9%)
		Normal	126 (100.0%)	115 (99.1%)	59 (100.0%)	58 (100.0%)	60 (96.8%)	64 (98.5%)	59 (98.3%)	66 (98.5%)	62 (100.0%)	543 (98.9%)	669 (99.1%)
LOCF Endpoint	m		134	127	64	64	64	65	63	70	63	580	714
	Normal	Low	0	1 (0.8%)	0	0	2 (3.1%)	1 (1.5%)	1 (1.6%)	1 (1.4%)	0	6 (1.0%)	6 (0.8%)
		Normal	134 (100.0%)	126 (99.2%)	64 (100.0%)	64 (100.0%)	62 (96.9%)	64 (98.5%)	62 (98.4%)	69 (98.6%)	63 (100.0%)	574 (99.0%)	708 (99.2%)
Ery. Mean Corpuscular Volume (fL)													
Week 4	m		134	127	64	64	64	65	63	70	63	580	714
	Low	Low	0	0	0	0	1 (1.6%)	0	0	0	0	1 (0.2%)	1 (0.1%)
		Normal	0	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	1 (0.1%)
	Normal	Normal	129 (96.3%)	119 (93.7%)	59 (92.2%)	63 (98.4%)	57 (89.1%)	59 (90.8%)	58 (92.1%)	64 (91.4%)	50 (79.4%)	529 (91.2%)	658 (92.2%)
		High	2 (1.5%)	1 (0.8%)	4 (6.3%)	1 (1.6%)	1 (1.6%)	1 (1.5%)	1 (1.6%)	1 (1.4%)	5 (7.9%)	15 (2.6%)	17 (2.4%)
	High	Normal	0	2 (1.6%)	0	0	0	3 (4.6%)	0	1 (1.4%)	1 (1.6%)	7 (1.2%)	7 (1.0%)
		High	3 (2.2%)	5 (3.9%)	1 (1.6%)	0	5 (7.8%)	2 (3.1%)	4 (6.3%)	4 (5.7%)	6 (9.5%)	27 (4.7%)	30 (4.2%)

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 8	m		132	124	63	64	64	65	62	69	63	574	706
	Low	Low	0	0	0	0	1 (1.6%)	0	0	0	0	1 (0.2%)	1 (0.1%)
		Normal	0	0	0	0	0	0	0	0	1 (1.6%)	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	128 (97.0%)	114 (91.9%)	58 (92.1%)	64 (100.0%)	58 (90.6%)	57 (87.7%)	56 (90.3%)	63 (91.3%)	52 (82.5%)	522 (90.9%)	650 (92.1%)
		High	1 (0.8%)	2 (1.6%)	4 (6.3%)	0	0	3 (4.6%)	2 (3.2%)	1 (1.4%)	3 (4.8%)	15 (2.6%)	16 (2.3%)
	High	Normal	1 (0.8%)	1 (0.8%)	1 (1.6%)	0	1 (1.6%)	2 (3.1%)	0	1 (1.4%)	2 (3.2%)	8 (1.4%)	9 (1.3%)
		High	2 (1.5%)	6 (4.8%)	0	0	4 (6.3%)	3 (4.6%)	4 (6.5%)	4 (5.8%)	5 (7.9%)	26 (4.5%)	28 (4.0%)
Week 12	m		131	123	63	64	64	65	62	68	63	572	703
	Low	Low	0	0	0	0	1 (1.6%)	0	0	0	0	1 (0.2%)	1 (0.1%)
		Normal	0	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	1 (0.1%)
	Normal	Low	0	0	0	0	0	0	1 (1.6%)	0	0	1 (0.2%)	1 (0.1%)
		Normal	128 (97.7%)	114 (92.7%)	58 (92.1%)	63 (98.4%)	58 (90.6%)	56 (86.2%)	56 (90.3%)	61 (89.7%)	52 (82.5%)	518 (90.6%)	646 (91.9%)
		High	0	2 (1.6%)	4 (6.3%)	1 (1.6%)	0	4 (6.2%)	1 (1.6%)	2 (2.9%)	3 (4.8%)	17 (3.0%)	17 (2.4%)
	High	Normal	1 (0.8%)	0	1 (1.6%)	0	1 (1.6%)	2 (3.1%)	0	2 (2.9%)	1 (1.6%)	7 (1.2%)	8 (1.1%)
		High	2 (1.5%)	7 (5.7%)	0	0	4 (6.3%)	3 (4.6%)	4 (6.5%)	3 (4.4%)	6 (9.5%)	27 (4.7%)	29 (4.1%)
Week 16	m		130	123	63	64	64	64	62	69	63	572	702
	Low	Low	0	0	0	0	1 (1.6%)	0	0	0	0	1 (0.2%)	1 (0.1%)
		Normal	0	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	1 (0.1%)
	Normal	Low	0	1 (0.8%)	0	0	0	0	1 (1.6%)	0	0	2 (0.3%)	2 (0.3%)
		Normal	122 (93.8%)	110 (89.4%)	55 (87.3%)	64 (100.0%)	56 (87.5%)	53 (82.8%)	54 (87.1%)	62 (89.9%)	50 (79.4%)	504 (88.1%)	626 (89.2%)
		High	5 (3.8%)	5 (4.1%)	7 (11.1%)	0	2 (3.1%)	6 (9.4%)	3 (4.8%)	2 (2.9%)	5 (7.9%)	30 (5.2%)	35 (5.0%)
	High	Normal	0	0	1 (1.6%)	0	1 (1.6%)	3 (4.7%)	0	2 (2.9%)	2 (3.2%)	9 (1.6%)	9 (1.3%)
		High	3 (2.3%)	7 (5.7%)	0	0	4 (6.3%)	2 (3.1%)	4 (6.5%)	3 (4.3%)	5 (7.9%)	25 (4.4%)	28 (4.0%)

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 20	m		130	123	62	63	64	65	61	69	63	570	700
	Low	Low	0	0	0	0	1 (1.6%)	0	0	0	0	1 (0.2%)	1 (0.1%)
		Normal	0	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	1 (0.1%)
	Normal	Low	0	0	0	0	0	0	1 (1.6%)	0	0	1 (0.2%)	1 (0.1%)
		Normal	121 (93.1%)	109 (88.6%)	56 (90.3%)	61 (96.8%)	55 (85.9%)	51 (78.5%)	50 (82.0%)	61 (88.4%)	47 (74.6%)	490 (86.0%)	611 (87.3%)
		High	6 (4.6%)	7 (5.7%)	5 (8.1%)	2 (3.2%)	3 (4.7%)	9 (13.8%)	6 (9.8%)	3 (4.3%)	8 (12.7%)	43 (7.5%)	49 (7.0%)
	High	Normal	0	1 (0.8%)	0	0	1 (1.6%)	1 (1.5%)	0	2 (2.9%)	2 (3.2%)	7 (1.2%)	7 (1.0%)
		High	3 (2.3%)	6 (4.9%)	1 (1.6%)	0	4 (6.3%)	4 (6.2%)	4 (6.6%)	3 (4.3%)	5 (7.9%)	27 (4.7%)	30 (4.3%)
Week 24	m		130	122	62	63	64	65	61	69	63	569	699
	Low	Low	0	0	0	0	1 (1.6%)	0	0	0	0	1 (0.2%)	1 (0.1%)
		Normal	0	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	1 (0.1%)
	Normal	Low	0	0	0	0	0	0	1 (1.6%)	0	0	1 (0.2%)	1 (0.1%)
		Normal	119 (91.5%)	107 (87.7%)	55 (88.7%)	58 (92.1%)	56 (87.5%)	50 (76.9%)	49 (80.3%)	60 (87.0%)	46 (73.0%)	481 (84.5%)	600 (85.8%)
		High	8 (6.2%)	8 (6.6%)	6 (9.7%)	5 (7.9%)	2 (3.1%)	10 (15.4%)	7 (11.5%)	4 (5.8%)	9 (14.3%)	51 (9.0%)	59 (8.4%)
	High	Normal	0	0	0	0	1 (1.6%)	0	0	2 (2.9%)	2 (3.2%)	5 (0.9%)	5 (0.7%)
		High	3 (2.3%)	7 (5.7%)	1 (1.6%)	0	4 (6.3%)	5 (7.7%)	4 (6.6%)	3 (4.3%)	5 (7.9%)	29 (5.1%)	32 (4.6%)
Week 32	m		128	120	62	60	62	65	60	69	63	561	689
	Low	Low	0	0	0	0	1 (1.6%)	0	0	0	0	1 (0.2%)	1 (0.1%)
		Normal	0	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	1 (0.1%)
	Normal	Low	0	0	0	0	0	0	1 (1.7%)	0	0	1 (0.2%)	1 (0.1%)
		Normal	110 (85.9%)	104 (86.7%)	52 (83.9%)	55 (91.7%)	54 (87.1%)	48 (73.8%)	49 (81.7%)	60 (87.0%)	46 (73.0%)	468 (83.4%)	578 (83.9%)
		High	15 (11.7%)	9 (7.5%)	9 (14.5%)	5 (8.3%)	2 (3.2%)	12 (18.5%)	6 (10.0%)	4 (5.8%)	9 (14.3%)	56 (10.0%)	71 (10.3%)
	High	Normal	0	0	0	0	0	0	0	3 (4.3%)	2 (3.2%)	5 (0.9%)	5 (0.7%)
		High	3 (2.3%)	7 (5.8%)	1 (1.6%)	0	5 (8.1%)	5 (7.7%)	4 (6.7%)	2 (2.9%)	5 (7.9%)	29 (5.2%)	32 (4.6%)

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 40	m		128	120	60	59	62	65	60	69	63	558	686
	Low	Low	0	0	0	0	1 (1.6%)	0	0	0	0	1 (0.2%)	1 (0.1%)
		Normal	0	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	1 (0.1%)
	Normal	Normal	111 (86.7%)	104 (86.7%)	53 (88.3%)	56 (94.9%)	54 (87.1%)	53 (81.5%)	48 (80.0%)	58 (84.1%)	45 (71.4%)	471 (84.4%)	582 (84.8%)
		High	14 (10.9%)	9 (7.5%)	6 (10.0%)	3 (5.1%)	2 (3.2%)	7 (10.8%)	8 (13.3%)	6 (8.7%)	10 (15.9%)	51 (9.1%)	65 (9.5%)
	High	Normal	0	0	0	0	1 (1.6%)	1 (1.5%)	0	0	2 (3.2%)	4 (0.7%)	4 (0.6%)
		High	3 (2.3%)	7 (5.8%)	1 (1.7%)	0	4 (6.5%)	4 (6.2%)	4 (6.7%)	5 (7.2%)	5 (7.9%)	30 (5.4%)	33 (4.8%)
Week 48	m		127	118	60	59	62	65	60	66	63	553	680
	Low	Low	0	0	0	0	1 (1.6%)	0	0	0	0	1 (0.2%)	1 (0.1%)
		Normal	0	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	1 (0.1%)
	Normal	Normal	113 (89.0%)	106 (89.8%)	54 (90.0%)	56 (94.9%)	51 (82.3%)	52 (80.0%)	51 (85.0%)	57 (86.4%)	49 (77.8%)	476 (86.1%)	589 (86.6%)
		High	11 (8.7%)	5 (4.2%)	5 (8.3%)	3 (5.1%)	5 (8.1%)	8 (12.3%)	5 (8.3%)	4 (6.1%)	6 (9.5%)	41 (7.4%)	52 (7.6%)
	High	Normal	0	0	0	0	1 (1.6%)	0	0	0	3 (4.8%)	4 (0.7%)	4 (0.6%)
		High	3 (2.4%)	7 (5.9%)	1 (1.7%)	0	4 (6.5%)	5 (7.7%)	4 (6.7%)	5 (7.6%)	4 (6.3%)	30 (5.4%)	33 (4.9%)
Week 52	m		126	116	59	58	62	65	60	67	62	549	675
	Low	Low	0	0	0	0	1 (1.6%)	0	0	0	0	1 (0.2%)	1 (0.1%)
		Normal	0	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	1 (0.1%)
	Normal	Normal	121 (96.0%)	101 (87.1%)	54 (91.5%)	56 (96.6%)	55 (88.7%)	51 (78.5%)	52 (86.7%)	59 (88.1%)	48 (77.4%)	476 (86.7%)	597 (88.4%)
		High	2 (1.6%)	8 (6.9%)	4 (6.8%)	2 (3.4%)	1 (1.6%)	9 (13.8%)	4 (6.7%)	3 (4.5%)	7 (11.3%)	38 (6.9%)	40 (5.9%)
	High	Normal	0	0	0	0	1 (1.6%)	1 (1.5%)	1 (1.7%)	2 (3.0%)	3 (4.8%)	8 (1.5%)	8 (1.2%)
		High	3 (2.4%)	7 (6.0%)	1 (1.7%)	0	4 (6.5%)	4 (6.2%)	3 (5.0%)	3 (4.5%)	3 (4.8%)	25 (4.6%)	28 (4.1%)
LOCF Endpoint	m		134	127	64	64	64	65	63	70	63	580	714

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	0	0	1 (1.6%)	0	0	0	0	1 (0.2%)	1 (0.1%)
		Normal	0	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	1 (0.1%)
	Normal	Low	0	0	0	0	0	0	1 (1.6%)	0	0	1 (0.2%)	1 (0.1%)
		Normal	128 (95.5%)	112 (88.2%)	57 (89.1%)	62 (96.9%)	57 (89.1%)	51 (78.5%)	54 (85.7%)	61 (87.1%)	48 (76.2%)	502 (86.6%)	630 (88.2%)
		High	3 (2.2%)	8 (6.3%)	6 (9.4%)	2 (3.1%)	1 (1.6%)	9 (13.8%)	4 (6.3%)	4 (5.7%)	7 (11.1%)	41 (7.1%)	44 (6.2%)
	High	Normal	0	0	0	0	1 (1.6%)	1 (1.5%)	1 (1.6%)	2 (2.9%)	3 (4.8%)	8 (1.4%)	8 (1.1%)
		High	3 (2.2%)	7 (5.5%)	1 (1.6%)	0	4 (6.3%)	4 (6.2%)	3 (4.8%)	3 (4.3%)	4 (6.3%)	26 (4.5%)	29 (4.1%)
Erythrocytes (10^12/L)													
Week 4	m		134	127	64	64	64	65	63	70	63	580	714
	Low	Low	5 (3.7%)	9 (7.1%)	4 (6.3%)	3 (4.7%)	5 (7.8%)	8 (12.3%)	6 (9.5%)	1 (1.4%)	1 (1.6%)	37 (6.4%)	42 (5.9%)
		Normal	3 (2.2%)	0	1 (1.6%)	1 (1.6%)	1 (1.6%)	4 (6.2%)	0	1 (1.4%)	1 (1.6%)	9 (1.6%)	12 (1.7%)
	Normal	Low	5 (3.7%)	4 (3.1%)	4 (6.3%)	3 (4.7%)	2 (3.1%)	6 (9.2%)	2 (3.2%)	3 (4.3%)	2 (3.2%)	26 (4.5%)	31 (4.3%)
		Normal	119 (88.8%)	114 (89.8%)	55 (85.9%)	57 (89.1%)	56 (87.5%)	47 (72.3%)	55 (87.3%)	65 (92.9%)	58 (92.1%)	507 (87.4%)	626 (87.7%)
		High	1 (0.7%)	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	2 (0.3%)
	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	63	574	706
	Low	Low	4 (3.0%)	8 (6.5%)	3 (4.8%)	3 (4.7%)	5 (7.8%)	11 (16.9%)	6 (9.7%)	0	2 (3.2%)	38 (6.6%)	42 (5.9%)
		Normal	4 (3.0%)	1 (0.8%)	2 (3.2%)	1 (1.6%)	1 (1.6%)	1 (1.5%)	0	2 (2.9%)	0	8 (1.4%)	12 (1.7%)
	Normal	Low	10 (7.6%)	4 (3.2%)	3 (4.8%)	2 (3.1%)	3 (4.7%)	7 (10.8%)	3 (4.8%)	3 (4.3%)	2 (3.2%)	27 (4.7%)	37 (5.2%)
		Normal	113 (85.6%)	110 (88.7%)	55 (87.3%)	58 (90.6%)	55 (85.9%)	46 (70.8%)	53 (85.5%)	64 (92.8%)	59 (93.7%)	500 (87.1%)	613 (86.8%)
		High	0	1 (0.8%)	0	0	0	0	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 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
	Low	Low	5 (3.8%)	9 (7.3%)	4 (6.3%)	3 (4.7%)	5 (7.8%)	10 (15.4%)	6 (9.7%)	0	2 (3.2%)	39 (6.8%)	44 (6.3%)
		Normal	3 (2.3%)	0	1 (1.6%)	1 (1.6%)	1 (1.6%)	2 (3.1%)	0	2 (2.9%)	0	7 (1.2%)	10 (1.4%)
	Normal	Low	11 (8.4%)	4 (3.3%)	9 (14.3%)	6 (9.4%)	5 (7.8%)	8 (12.3%)	3 (4.8%)	5 (7.4%)	4 (6.3%)	44 (7.7%)	55 (7.8%)
		Normal	111 (84.7%)	110 (89.4%)	49 (77.8%)	54 (84.4%)	53 (82.8%)	45 (69.2%)	53 (85.5%)	61 (89.7%)	57 (90.5%)	482 (84.3%)	593 (84.4%)
	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
	Low	Low	6 (4.6%)	9 (7.3%)	3 (4.8%)	2 (3.1%)	5 (7.8%)	9 (14.1%)	6 (9.7%)	1 (1.4%)	1 (1.6%)	36 (6.3%)	42 (6.0%)
		Normal	2 (1.5%)	0	2 (3.2%)	2 (3.1%)	1 (1.6%)	3 (4.7%)	0	1 (1.4%)	1 (1.6%)	10 (1.7%)	12 (1.7%)
	Normal	Low	14 (10.8%)	6 (4.9%)	10 (15.9%)	8 (12.5%)	8 (12.5%)	12 (18.8%)	6 (9.7%)	4 (5.8%)	4 (6.3%)	58 (10.1%)	72 (10.3%)
		Normal	107 (82.3%)	108 (87.8%)	48 (76.2%)	52 (81.3%)	50 (78.1%)	40 (62.5%)	50 (80.6%)	63 (91.3%)	57 (90.5%)	468 (81.8%)	575 (81.9%)
	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
	Low	Low	6 (4.6%)	7 (5.7%)	4 (6.5%)	1 (1.6%)	5 (7.8%)	9 (13.8%)	5 (8.2%)	2 (2.9%)	1 (1.6%)	34 (6.0%)	40 (5.7%)
		Normal	2 (1.5%)	2 (1.6%)	1 (1.6%)	3 (4.8%)	1 (1.6%)	3 (4.6%)	1 (1.6%)	0	1 (1.6%)	12 (2.1%)	14 (2.0%)
	Normal	Low	16 (12.3%)	7 (5.7%)	6 (9.7%)	11 (17.5%)	5 (7.8%)	9 (13.8%)	5 (8.2%)	4 (5.8%)	1 (1.6%)	48 (8.4%)	64 (9.1%)
		Normal	105 (80.8%)	107 (87.0%)	51 (82.3%)	48 (76.2%)	53 (82.8%)	44 (67.7%)	50 (82.0%)	63 (91.3%)	60 (95.2%)	476 (83.5%)	581 (83.0%)
	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
	Low	Low	5 (3.8%)	7 (5.7%)	2 (3.2%)	1 (1.6%)	4 (6.3%)	9 (13.8%)	5 (8.2%)	1 (1.4%)	1 (1.6%)	30 (5.3%)	35 (5.0%)
		Normal	3 (2.3%)	2 (1.6%)	3 (4.8%)	3 (4.8%)	2 (3.1%)	3 (4.6%)	1 (1.6%)	1 (1.4%)	1 (1.6%)	16 (2.8%)	19 (2.7%)
	Normal	Low	13 (10.0%)	6 (4.9%)	3 (4.8%)	6 (9.5%)	4 (6.3%)	11 (16.9%)	4 (6.6%)	7 (10.1%)	3 (4.8%)	44 (7.7%)	57 (8.2%)

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	108 (83.1%)	106 (86.9%)	54 (87.1%)	53 (84.1%)	54 (84.4%)	42 (64.6%)	51 (83.6%)	60 (87.0%)	58 (92.1%)	478 (84.0%)	586 (83.8%)
		High	0	1 (0.8%)	0	0	0	0	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
	Low	Low	5 (3.9%)	6 (5.0%)	2 (3.2%)	1 (1.7%)	5 (8.1%)	10 (15.4%)	5 (8.3%)	2 (2.9%)	1 (1.6%)	32 (5.7%)	37 (5.4%)
		Normal	3 (2.3%)	3 (2.5%)	3 (4.8%)	3 (5.0%)	1 (1.6%)	2 (3.1%)	1 (1.7%)	0	1 (1.6%)	14 (2.5%)	17 (2.5%)
	Normal	Low	8 (6.3%)	5 (4.2%)	3 (4.8%)	7 (11.7%)	3 (4.8%)	6 (9.2%)	2 (3.3%)	5 (7.2%)	0	31 (5.5%)	39 (5.7%)
		Normal	111 (86.7%)	106 (88.3%)	54 (87.1%)	49 (81.7%)	53 (85.5%)	47 (72.3%)	52 (86.7%)	62 (89.9%)	61 (96.8%)	484 (86.3%)	595 (86.4%)
	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
	Low	Low	2 (1.6%)	6 (5.0%)	1 (1.7%)	1 (1.7%)	6 (9.7%)	7 (10.8%)	5 (8.3%)	2 (2.9%)	0	28 (5.0%)	30 (4.4%)
		Normal	6 (4.7%)	3 (2.5%)	3 (5.0%)	3 (5.1%)	0	5 (7.7%)	1 (1.7%)	0	2 (3.2%)	17 (3.0%)	23 (3.4%)
	Normal	Low	5 (3.9%)	5 (4.2%)	4 (6.7%)	5 (8.5%)	1 (1.6%)	5 (7.7%)	3 (5.0%)	2 (2.9%)	2 (3.2%)	27 (4.8%)	32 (4.7%)
		Normal	114 (89.1%)	106 (88.3%)	52 (86.7%)	50 (84.7%)	55 (88.7%)	48 (73.8%)	51 (85.0%)	65 (94.2%)	59 (93.7%)	486 (87.1%)	600 (87.5%)
	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
	Low	Low	4 (3.1%)	8 (6.8%)	1 (1.7%)	1 (1.7%)	4 (6.5%)	10 (15.4%)	5 (8.3%)	1 (1.5%)	1 (1.6%)	31 (5.6%)	35 (5.1%)
		Normal	4 (3.1%)	1 (0.8%)	3 (5.0%)	3 (5.1%)	2 (3.2%)	2 (3.1%)	1 (1.7%)	0	1 (1.6%)	13 (2.4%)	17 (2.5%)
	Normal	Low	8 (6.3%)	7 (5.9%)	4 (6.7%)	4 (6.8%)	4 (6.5%)	7 (10.8%)	3 (5.0%)	4 (6.1%)	3 (4.8%)	36 (6.5%)	44 (6.5%)
		Normal	110 (86.6%)	101 (85.6%)	52 (86.7%)	51 (86.4%)	52 (83.9%)	46 (70.8%)	51 (85.0%)	61 (92.4%)	58 (92.1%)	472 (85.4%)	582 (85.6%)
		High	0	1 (0.8%)	0	0	0	0	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%)

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 52	m		126	116	59	58	62	65	60	67	62	549	675
	Low	Low	5 (4.0%)	7 (6.0%)	2 (3.4%)	1 (1.7%)	3 (4.8%)	7 (10.8%)	4 (6.7%)	2 (3.0%)	0	26 (4.7%)	31 (4.6%)
		Normal	3 (2.4%)	2 (1.7%)	2 (3.4%)	3 (5.2%)	3 (4.8%)	5 (7.7%)	2 (3.3%)	0	2 (3.2%)	19 (3.5%)	22 (3.3%)
	Normal	Low	9 (7.1%)	5 (4.3%)	4 (6.8%)	7 (12.1%)	4 (6.5%)	5 (7.7%)	4 (6.7%)	3 (4.5%)	4 (6.5%)	36 (6.6%)	45 (6.7%)
		Normal	108 (85.7%)	102 (87.9%)	51 (86.4%)	47 (81.0%)	52 (83.9%)	48 (73.8%)	50 (83.3%)	62 (92.5%)	56 (90.3%)	468 (85.2%)	576 (85.3%)
	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
	Low	Low	5 (3.7%)	7 (5.5%)	3 (4.7%)	1 (1.6%)	3 (4.7%)	7 (10.8%)	4 (6.3%)	2 (2.9%)	0	27 (4.7%)	32 (4.5%)
		Normal	3 (2.2%)	2 (1.6%)	2 (3.1%)	3 (4.7%)	3 (4.7%)	5 (7.7%)	2 (3.2%)	0	2 (3.2%)	19 (3.3%)	22 (3.1%)
	Normal	Low	10 (7.5%)	7 (5.5%)	4 (6.3%)	7 (10.9%)	4 (6.3%)	5 (7.7%)	4 (6.3%)	4 (5.7%)	4 (6.3%)	39 (6.7%)	49 (6.9%)
		Normal	115 (85.8%)	111 (87.4%)	55 (85.9%)	53 (82.8%)	54 (84.4%)	48 (73.8%)	53 (84.1%)	64 (91.4%)	57 (90.5%)	495 (85.3%)	610 (85.4%)
	High	Normal	1 (0.7%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
Hematocrit (fraction of 1)													
Week 4	m		134	127	64	64	64	65	63	70	63	580	714
	Low	Low	2 (1.5%)	2 (1.6%)	1 (1.6%)	1 (1.6%)	1 (1.6%)	3 (4.6%)	0	1 (1.4%)	0	9 (1.6%)	11 (1.5%)
		Normal	0	2 (1.6%)	1 (1.6%)	2 (3.1%)	2 (3.1%)	0	0	0	1 (1.6%)	8 (1.4%)	8 (1.1%)
	Normal	Low	2 (1.5%)	2 (1.6%)	1 (1.6%)	0	0	2 (3.1%)	0	1 (1.4%)	1 (1.6%)	7 (1.2%)	9 (1.3%)
		Normal	127 (94.8%)	120 (94.5%)	61 (95.3%)	61 (95.3%)	61 (95.3%)	60 (92.3%)	63 (100.0%)	68 (97.1%)	60 (95.2%)	554 (95.5%)	681 (95.4%)
		High	1 (0.7%)	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	2 (0.3%)
	High	Normal	2 (1.5%)	0	0	0	0	0	0	0	0	0	2 (0.3%)
		High	0	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	1 (0.1%)
Week 8	m		132	124	63	64	64	65	62	69	63	574	706

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	1 (0.8%)	2 (1.6%)	2 (3.2%)	2 (3.1%)	1 (1.6%)	3 (4.6%)	0	0	0	10 (1.7%)	11 (1.6%)
		Normal	1 (0.8%)	2 (1.6%)	0	1 (1.6%)	2 (3.1%)	0	0	1 (1.4%)	1 (1.6%)	7 (1.2%)	8 (1.1%)
	Normal	Low	1 (0.8%)	2 (1.6%)	1 (1.6%)	3 (4.7%)	0	3 (4.6%)	2 (3.2%)	1 (1.4%)	0	12 (2.1%)	13 (1.8%)
		Normal	127 (96.2%)	116 (93.5%)	60 (95.2%)	58 (90.6%)	61 (95.3%)	59 (90.8%)	60 (96.8%)	67 (97.1%)	61 (96.8%)	542 (94.4%)	669 (94.8%)
		High	0	2 (1.6%)	0	0	0	0	0	0	0	2 (0.3%)	2 (0.3%)
	High	Normal	2 (1.5%)	0	0	0	0	0	0	0	0	0	2 (0.3%)
		High	0	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	1 (0.1%)
Week 12	m		131	123	63	64	64	65	62	68	63	572	703
	Low	Low	1 (0.8%)	3 (2.4%)	1 (1.6%)	2 (3.1%)	1 (1.6%)	2 (3.1%)	0	0	0	9 (1.6%)	10 (1.4%)
		Normal	1 (0.8%)	1 (0.8%)	1 (1.6%)	1 (1.6%)	2 (3.1%)	1 (1.5%)	0	1 (1.5%)	1 (1.6%)	8 (1.4%)	9 (1.3%)
	Normal	Low	4 (3.1%)	4 (3.3%)	1 (1.6%)	5 (7.8%)	0	6 (9.2%)	2 (3.2%)	1 (1.5%)	0	19 (3.3%)	23 (3.3%)
		Normal	123 (93.9%)	113 (91.9%)	60 (95.2%)	56 (87.5%)	60 (93.8%)	56 (86.2%)	60 (96.8%)	66 (97.1%)	61 (96.8%)	532 (93.0%)	655 (93.2%)
		High	0	2 (1.6%)	0	0	1 (1.6%)	0	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%)
		High	1 (0.8%)	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	2 (0.3%)
Week 16	m		130	123	63	64	64	64	62	69	63	572	702
	Low	Low	1 (0.8%)	2 (1.6%)	1 (1.6%)	1 (1.6%)	0	2 (3.1%)	0	1 (1.4%)	1 (1.6%)	8 (1.4%)	9 (1.3%)
		Normal	1 (0.8%)	2 (1.6%)	1 (1.6%)	2 (3.1%)	3 (4.7%)	1 (1.6%)	0	0	0	9 (1.6%)	10 (1.4%)
	Normal	Low	6 (4.6%)	4 (3.3%)	1 (1.6%)	4 (6.3%)	2 (3.1%)	3 (4.7%)	2 (3.2%)	0	0	16 (2.8%)	22 (3.1%)
		Normal	120 (92.3%)	113 (91.9%)	60 (95.2%)	57 (89.1%)	59 (92.2%)	58 (90.6%)	60 (96.8%)	68 (98.6%)	61 (96.8%)	536 (93.7%)	656 (93.4%)
		High	0	2 (1.6%)	0	0	0	0	0	0	0	2 (0.3%)	2 (0.3%)
	High	Normal	2 (1.5%)	0	0	0	0	0	0	0	0	0	2 (0.3%)
		High	0	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	1 (0.1%)
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
	Low	Low	1 (0.8%)	1 (0.8%)	1 (1.6%)	1 (1.6%)	0	2 (3.1%)	0	0	0	5 (0.9%)	6 (0.9%)
		Normal	1 (0.8%)	3 (2.4%)	1 (1.6%)	2 (3.2%)	3 (4.7%)	1 (1.5%)	0	1 (1.4%)	1 (1.6%)	12 (2.1%)	13 (1.9%)
	Normal	Low	9 (6.9%)	2 (1.6%)	1 (1.6%)	3 (4.8%)	1 (1.6%)	2 (3.1%)	1 (1.6%)	1 (1.4%)	0	11 (1.9%)	20 (2.9%)
		Normal	117 (90.0%)	117 (95.1%)	59 (95.2%)	57 (90.5%)	60 (93.8%)	60 (92.3%)	60 (98.4%)	67 (97.1%)	61 (96.8%)	541 (94.9%)	658 (94.0%)
	High	Normal	2 (1.5%)	0	0	0	0	0	0	0	0	0	2 (0.3%)
		High	0	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	1 (0.1%)
Week 24	m		130	122	62	63	64	65	61	69	63	569	699
	Low	Low	0	2 (1.6%)	1 (1.6%)	1 (1.6%)	0	2 (3.1%)	0	1 (1.4%)	0	7 (1.2%)	7 (1.0%)
		Normal	2 (1.5%)	2 (1.6%)	1 (1.6%)	2 (3.2%)	3 (4.7%)	1 (1.5%)	0	0	1 (1.6%)	10 (1.8%)	12 (1.7%)
	Normal	Low	2 (1.5%)	1 (0.8%)	0	1 (1.6%)	1 (1.6%)	1 (1.5%)	1 (1.6%)	1 (1.4%)	0	6 (1.1%)	8 (1.1%)
		Normal	124 (95.4%)	115 (94.3%)	60 (96.8%)	59 (93.7%)	59 (92.2%)	61 (93.8%)	60 (98.4%)	67 (97.1%)	61 (96.8%)	542 (95.3%)	666 (95.3%)
		High	0	2 (1.6%)	0	0	1 (1.6%)	0	0	0	0	3 (0.5%)	3 (0.4%)
	High	Normal	2 (1.5%)	0	0	0	0	0	0	0	0	0	2 (0.3%)
		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	2 (1.7%)	0	1 (1.7%)	1 (1.6%)	3 (4.6%)	0	1 (1.4%)	0	8 (1.4%)	8 (1.2%)
		Normal	2 (1.6%)	2 (1.7%)	2 (3.2%)	2 (3.3%)	2 (3.2%)	0	0	0	1 (1.6%)	9 (1.6%)	11 (1.6%)
	Normal	Low	1 (0.8%)	0	0	1 (1.7%)	1 (1.6%)	2 (3.1%)	1 (1.7%)	1 (1.4%)	0	6 (1.1%)	7 (1.0%)
		Normal	122 (95.3%)	115 (95.8%)	60 (96.8%)	56 (93.3%)	58 (93.5%)	60 (92.3%)	59 (98.3%)	67 (97.1%)	60 (95.2%)	535 (95.4%)	657 (95.4%)
		High	1 (0.8%)	1 (0.8%)	0	0	0	0	0	0	1 (1.6%)	2 (0.4%)	3 (0.4%)
	High	Normal	2 (1.6%)	0	0	0	0	0	0	0	0	0	2 (0.3%)
		High	0	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	1 (0.1%)
Week 40	m		128	120	60	59	62	65	60	69	63	558	686
	Low	Low	0	0	1 (1.7%)	1 (1.7%)	1 (1.6%)	3 (4.6%)	0	1 (1.4%)	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
		Normal	2 (1.6%)	4 (3.3%)	1 (1.7%)	2 (3.4%)	2 (3.2%)	0	0	0	1 (1.6%)	10 (1.8%)	12 (1.7%)
	Normal	Low	0	3 (2.5%)	0	0	1 (1.6%)	1 (1.5%)	0	0	0	5 (0.9%)	5 (0.7%)
		Normal	123 (96.1%)	113 (94.2%)	58 (96.7%)	56 (94.9%)	58 (93.5%)	61 (93.8%)	60 (100.0%)	68 (98.6%)	60 (95.2%)	534 (95.7%)	657 (95.8%)
		High	1 (0.8%)	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	2 (0.3%)
	High	Normal	2 (1.6%)	0	0	0	0	0	0	0	0	0	2 (0.3%)
		High	0	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	1 (0.1%)
Week 48	m		127	118	60	59	62	65	60	66	63	553	680
	Low	Low	0	2 (1.7%)	1 (1.7%)	1 (1.7%)	1 (1.6%)	3 (4.6%)	0	1 (1.5%)	0	9 (1.6%)	9 (1.3%)
		Normal	2 (1.6%)	2 (1.7%)	1 (1.7%)	2 (3.4%)	2 (3.2%)	0	0	0	1 (1.6%)	8 (1.4%)	10 (1.5%)
	Normal	Low	0	1 (0.8%)	0	0	2 (3.2%)	2 (3.1%)	2 (3.3%)	0	0	7 (1.3%)	7 (1.0%)
		Normal	123 (96.9%)	111 (94.1%)	58 (96.7%)	56 (94.9%)	57 (91.9%)	60 (92.3%)	58 (96.7%)	65 (98.5%)	61 (96.8%)	526 (95.1%)	649 (95.4%)
		High	0	2 (1.7%)	0	0	0	0	0	0	0	2 (0.4%)	2 (0.3%)
	High	Normal	2 (1.6%)	0	0	0	0	0	0	0	0	0	2 (0.3%)
		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	0	1 (0.9%)	1 (1.7%)	1 (1.7%)	1 (1.6%)	1 (1.5%)	0	1 (1.5%)	0	6 (1.1%)	6 (0.9%)
		Normal	2 (1.6%)	3 (2.6%)	1 (1.7%)	2 (3.4%)	2 (3.2%)	2 (3.1%)	0	0	1 (1.6%)	11 (2.0%)	13 (1.9%)
	Normal	Low	2 (1.6%)	3 (2.6%)	1 (1.7%)	1 (1.7%)	2 (3.2%)	3 (4.6%)	1 (1.7%)	1 (1.5%)	0	12 (2.2%)	14 (2.1%)
		Normal	120 (95.2%)	107 (92.2%)	56 (94.9%)	54 (93.1%)	57 (91.9%)	59 (90.8%)	59 (98.3%)	65 (97.0%)	60 (96.8%)	517 (94.2%)	637 (94.4%)
		High	0	2 (1.7%)	0	0	0	0	0	0	0	2 (0.4%)	2 (0.3%)
	High	Normal	2 (1.6%)	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	3 (0.4%)
LOCF Endpoint	m		134	127	64	64	64	65	63	70	63	580	714
	Low	Low	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%)

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%)	3 (2.4%)	1 (1.6%)	2 (3.1%)	2 (3.1%)	2 (3.1%)	0	0	1 (1.6%)	11 (1.9%)	13 (1.8%)
	Normal	Low	2 (1.5%)	4 (3.1%)	1 (1.6%)	1 (1.6%)	2 (3.1%)	3 (4.6%)	2 (3.2%)	1 (1.4%)	0	14 (2.4%)	16 (2.2%)
		Normal	128 (95.5%)	117 (92.1%)	61 (95.3%)	60 (93.8%)	59 (92.2%)	59 (90.8%)	61 (96.8%)	68 (97.1%)	61 (96.8%)	546 (94.1%)	674 (94.4%)
		High	0	2 (1.6%)	0	0	0	0	0	0	0	2 (0.3%)	2 (0.3%)
	High	Normal	2 (1.5%)	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	3 (0.4%)
Hemoglobin (g/L)													
Week 4	m		134	127	64	64	64	65	63	70	63	580	714
	Low	Low	0	2 (1.6%)	1 (1.6%)	1 (1.6%)	2 (3.1%)	1 (1.5%)	0	0	0	7 (1.2%)	7 (1.0%)
		Normal	0	1 (0.8%)	0	0	0	0	0	2 (2.9%)	0	3 (0.5%)	3 (0.4%)
	Normal	Low	3 (2.2%)	1 (0.8%)	3 (4.7%)	1 (1.6%)	1 (1.6%)	5 (7.7%)	0	1 (1.4%)	1 (1.6%)	13 (2.2%)	16 (2.2%)
		Normal	129 (96.3%)	122 (96.1%)	60 (93.8%)	62 (96.9%)	60 (93.8%)	59 (90.8%)	63 (100.0%)	67 (95.7%)	60 (95.2%)	553 (95.3%)	682 (95.5%)
		High	1 (0.7%)	0	0	0	1 (1.6%)	0	0	0	2 (3.2%)	3 (0.5%)	4 (0.6%)
	High	Normal	1 (0.7%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
		High	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
Week 8	m		132	124	63	64	64	65	62	69	63	574	706
	Low	Low	0	2 (1.6%)	1 (1.6%)	1 (1.6%)	2 (3.1%)	1 (1.5%)	0	0	0	7 (1.2%)	7 (1.0%)
		Normal	0	1 (0.8%)	0	0	0	0	0	2 (2.9%)	0	3 (0.5%)	3 (0.4%)
	Normal	Low	2 (1.5%)	2 (1.6%)	2 (3.2%)	3 (4.7%)	2 (3.1%)	6 (9.2%)	2 (3.2%)	1 (1.4%)	0	18 (3.1%)	20 (2.8%)
		Normal	129 (97.7%)	117 (94.4%)	60 (95.2%)	60 (93.8%)	59 (92.2%)	58 (89.2%)	60 (96.8%)	66 (95.7%)	62 (98.4%)	542 (94.4%)	671 (95.0%)
		High	0	1 (0.8%)	0	0	1 (1.6%)	0	0	0	1 (1.6%)	3 (0.5%)	3 (0.4%)
	High	Normal	1 (0.8%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
		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	Low	0	3 (2.4%)	1 (1.6%)	1 (1.6%)	2 (3.1%)	0	0	0	0	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	0	0	0	0	0	1 (1.5%)	0	2 (2.9%)	0	3 (0.5%)	3 (0.4%)
	Normal	Low	4 (3.1%)	3 (2.4%)	1 (1.6%)	7 (10.9%)	1 (1.6%)	9 (13.8%)	1 (1.6%)	1 (1.5%)	0	23 (4.0%)	27 (3.8%)
		Normal	126 (96.2%)	115 (93.5%)	61 (96.8%)	56 (87.5%)	61 (95.3%)	55 (84.6%)	61 (98.4%)	65 (95.6%)	62 (98.4%)	536 (93.7%)	662 (94.2%)
		High	0	1 (0.8%)	0	0	0	0	0	0	1 (1.6%)	2 (0.3%)	2 (0.3%)
	High	Normal	1 (0.8%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
		High	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
	Low	Low	0	2 (1.6%)	1 (1.6%)	1 (1.6%)	1 (1.6%)	1 (1.6%)	0	1 (1.4%)	0	7 (1.2%)	7 (1.0%)
		Normal	0	1 (0.8%)	0	0	1 (1.6%)	0	0	1 (1.4%)	0	3 (0.5%)	3 (0.4%)
	Normal	Low	6 (4.6%)	6 (4.9%)	1 (1.6%)	6 (9.4%)	1 (1.6%)	4 (6.3%)	3 (4.8%)	1 (1.4%)	0	22 (3.8%)	28 (4.0%)
		Normal	123 (94.6%)	113 (91.9%)	61 (96.8%)	57 (89.1%)	61 (95.3%)	59 (92.2%)	59 (95.2%)	66 (95.7%)	63 (100.0%)	539 (94.2%)	662 (94.3%)
	High	Normal	1 (0.8%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
		High	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
	Low	Low	0	2 (1.6%)	1 (1.6%)	1 (1.6%)	2 (3.1%)	1 (1.5%)	0	0	0	7 (1.2%)	7 (1.0%)
		Normal	0	1 (0.8%)	0	0	0	0	0	2 (2.9%)	0	3 (0.5%)	3 (0.4%)
	Normal	Low	7 (5.4%)	2 (1.6%)	1 (1.6%)	3 (4.8%)	1 (1.6%)	4 (6.2%)	2 (3.3%)	1 (1.4%)	0	14 (2.5%)	21 (3.0%)
		Normal	122 (93.8%)	116 (94.3%)	60 (96.8%)	59 (93.7%)	60 (93.8%)	60 (92.3%)	59 (96.7%)	66 (95.7%)	62 (98.4%)	542 (95.1%)	664 (94.9%)
		High	0	1 (0.8%)	0	0	1 (1.6%)	0	0	0	1 (1.6%)	3 (0.5%)	3 (0.4%)
	High	Normal	1 (0.8%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
		High	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
	Low	Low	0	3 (2.5%)	1 (1.6%)	1 (1.6%)	1 (1.6%)	1 (1.5%)	0	0	0	7 (1.2%)	7 (1.0%)
		Normal	0	0	0	0	1 (1.6%)	0	0	2 (2.9%)	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	Low	4 (3.1%)	0	1 (1.6%)	2 (3.2%)	2 (3.1%)	3 (4.6%)	2 (3.3%)	1 (1.4%)	0	11 (1.9%)	15 (2.1%)
		Normal	125 (96.2%)	116 (95.1%)	60 (96.8%)	60 (95.2%)	59 (92.2%)	61 (93.8%)	59 (96.7%)	66 (95.7%)	63 (100.0%)	544 (95.6%)	669 (95.7%)
		High	0	2 (1.6%)	0	0	1 (1.6%)	0	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%)
		High	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
	Low	Low	0	3 (2.5%)	1 (1.6%)	1 (1.7%)	2 (3.2%)	1 (1.5%)	0	1 (1.4%)	0	9 (1.6%)	9 (1.3%)
		Normal	0	0	0	0	0	0	0	1 (1.4%)	0	1 (0.2%)	1 (0.1%)
	Normal	Low	0	1 (0.8%)	0	1 (1.7%)	3 (4.8%)	5 (7.7%)	1 (1.7%)	1 (1.4%)	0	12 (2.1%)	12 (1.7%)
		Normal	126 (98.4%)	114 (95.0%)	61 (98.4%)	58 (96.7%)	57 (91.9%)	59 (90.8%)	59 (98.3%)	66 (95.7%)	62 (98.4%)	536 (95.5%)	662 (96.1%)
		High	1 (0.8%)	1 (0.8%)	0	0	0	0	0	0	1 (1.6%)	2 (0.4%)	3 (0.4%)
	High	Normal	1 (0.8%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
		High	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
	Low	Low	0	2 (1.7%)	1 (1.7%)	1 (1.7%)	2 (3.2%)	1 (1.5%)	0	1 (1.4%)	0	8 (1.4%)	8 (1.2%)
		Normal	0	1 (0.8%)	0	0	0	0	0	1 (1.4%)	0	2 (0.4%)	2 (0.3%)
	Normal	Low	0	2 (1.7%)	0	0	3 (4.8%)	5 (7.7%)	0	0	0	10 (1.8%)	10 (1.5%)
		Normal	127 (99.2%)	114 (95.0%)	59 (98.3%)	58 (98.3%)	57 (91.9%)	59 (90.8%)	60 (100.0%)	67 (97.1%)	62 (98.4%)	536 (96.1%)	663 (96.6%)
		High	0	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	1 (0.1%)
	High	Normal	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
		High	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
	Low	Low	0	2 (1.7%)	1 (1.7%)	1 (1.7%)	2 (3.2%)	1 (1.5%)	0	1 (1.5%)	0	8 (1.4%)	8 (1.2%)
		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	0	1 (0.8%)	0	0	4 (6.5%)	6 (9.2%)	2 (3.3%)	0	0	13 (2.4%)	13 (1.9%)
		Normal	126 (99.2%)	113 (95.8%)	59 (98.3%)	58 (98.3%)	55 (88.7%)	58 (89.2%)	58 (96.7%)	65 (98.5%)	62 (98.4%)	528 (95.5%)	654 (96.2%)
		High	0	0	0	0	1 (1.6%)	0	0	0	1 (1.6%)	2 (0.4%)	2 (0.3%)
	High	Normal	1 (0.8%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
		High	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
	Low	Low	0	2 (1.7%)	1 (1.7%)	1 (1.7%)	2 (3.2%)	1 (1.5%)	0	2 (3.0%)	0	9 (1.6%)	9 (1.3%)
		Normal	0	1 (0.9%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
	Normal	Low	2 (1.6%)	3 (2.6%)	1 (1.7%)	3 (5.2%)	5 (8.1%)	4 (6.2%)	2 (3.3%)	1 (1.5%)	0	19 (3.5%)	21 (3.1%)
		Normal	123 (97.6%)	108 (93.1%)	57 (96.6%)	54 (93.1%)	55 (88.7%)	60 (92.3%)	58 (96.7%)	64 (95.5%)	62 (100.0%)	518 (94.4%)	641 (95.0%)
		High	0	1 (0.9%)	0	0	0	0	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%)
		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	Low	0	2 (1.6%)	1 (1.6%)	1 (1.6%)	2 (3.1%)	1 (1.5%)	0	2 (2.9%)	0	9 (1.6%)	9 (1.3%)
		Normal	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
	Normal	Low	2 (1.5%)	5 (3.9%)	1 (1.6%)	3 (4.7%)	5 (7.8%)	4 (6.2%)	3 (4.8%)	1 (1.4%)	0	22 (3.8%)	24 (3.4%)
		Normal	131 (97.8%)	117 (92.1%)	62 (96.9%)	60 (93.8%)	57 (89.1%)	60 (92.3%)	60 (95.2%)	67 (95.7%)	63 (100.0%)	546 (94.1%)	677 (94.8%)
		High	0	1 (0.8%)	0	0	0	0	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%)
		High	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
Leukocytes (10^9/L)													
Week 4	m		134	127	64	64	64	65	63	70	63	580	714

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	6 (4.5%)	5 (3.9%)	1 (1.6%)	1 (1.6%)	2 (3.1%)	2 (3.1%)	0	0	0	11 (1.9%)	17 (2.4%)
		Normal	3 (2.2%)	8 (6.3%)	3 (4.7%)	3 (4.7%)	2 (3.1%)	4 (6.2%)	1 (1.6%)	4 (5.7%)	2 (3.2%)	27 (4.7%)	30 (4.2%)
	Normal	Low	1 (0.7%)	1 (0.8%)	0	1 (1.6%)	3 (4.7%)	3 (4.6%)	3 (4.8%)	0	2 (3.2%)	13 (2.2%)	14 (2.0%)
		Normal	124 (92.5%)	111 (87.4%)	60 (93.8%)	57 (89.1%)	56 (87.5%)	55 (84.6%)	58 (92.1%)	66 (94.3%)	57 (90.5%)	520 (89.7%)	644 (90.2%)
		High	0	1 (0.8%)	0	2 (3.1%)	0	1 (1.5%)	0	0	1 (1.6%)	5 (0.9%)	5 (0.7%)
	High	Normal	0	1 (0.8%)	0	0	1 (1.6%)	0	1 (1.6%)	0	1 (1.6%)	4 (0.7%)	4 (0.6%)
Week 8	m		132	124	63	64	64	65	62	69	63	574	706
	Low	Low	6 (4.5%)	4 (3.2%)	1 (1.6%)	2 (3.1%)	1 (1.6%)	3 (4.6%)	0	1 (1.4%)	1 (1.6%)	13 (2.3%)	19 (2.7%)
		Normal	3 (2.3%)	9 (7.3%)	3 (4.8%)	2 (3.1%)	3 (4.7%)	3 (4.6%)	1 (1.6%)	3 (4.3%)	1 (1.6%)	25 (4.4%)	28 (4.0%)
	Normal	Low	3 (2.3%)	2 (1.6%)	0	3 (4.7%)	2 (3.1%)	0	4 (6.5%)	2 (2.9%)	2 (3.2%)	15 (2.6%)	18 (2.5%)
		Normal	120 (90.9%)	106 (85.5%)	59 (93.7%)	56 (87.5%)	57 (89.1%)	58 (89.2%)	56 (90.3%)	62 (89.9%)	58 (92.1%)	512 (89.2%)	632 (89.5%)
		High	0	2 (1.6%)	0	1 (1.6%)	0	1 (1.5%)	0	1 (1.4%)	0	5 (0.9%)	5 (0.7%)
	High	Normal	0	1 (0.8%)	0	0	1 (1.6%)	0	1 (1.6%)	0	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	5 (3.8%)	6 (4.9%)	3 (4.8%)	1 (1.6%)	1 (1.6%)	5 (7.7%)	0	1 (1.5%)	1 (1.6%)	18 (3.1%)	23 (3.3%)
		Normal	4 (3.1%)	7 (5.7%)	1 (1.6%)	3 (4.7%)	3 (4.7%)	1 (1.5%)	1 (1.6%)	3 (4.4%)	1 (1.6%)	20 (3.5%)	24 (3.4%)
	Normal	Low	4 (3.1%)	1 (0.8%)	2 (3.2%)	2 (3.1%)	3 (4.7%)	3 (4.6%)	3 (4.8%)	0	2 (3.2%)	16 (2.8%)	20 (2.8%)
		Normal	117 (89.3%)	105 (85.4%)	57 (90.5%)	57 (89.1%)	55 (85.9%)	55 (84.6%)	57 (91.9%)	64 (94.1%)	58 (92.1%)	508 (88.8%)	625 (88.9%)
		High	1 (0.8%)	3 (2.4%)	0	1 (1.6%)	1 (1.6%)	1 (1.5%)	0	0	0	6 (1.0%)	7 (1.0%)
	High	Normal	0	1 (0.8%)	0	0	1 (1.6%)	0	1 (1.6%)	0	1 (1.6%)	4 (0.7%)	4 (0.6%)
Week 16	m		130	123	63	64	64	64	62	69	63	572	702
	Low	Low	7 (5.4%)	7 (5.7%)	3 (4.8%)	2 (3.1%)	1 (1.6%)	4 (6.3%)	0	1 (1.4%)	1 (1.6%)	19 (3.3%)	26 (3.7%)
		Normal	2 (1.5%)	6 (4.9%)	1 (1.6%)	2 (3.1%)	3 (4.7%)	2 (3.1%)	1 (1.6%)	3 (4.3%)	1 (1.6%)	19 (3.3%)	21 (3.0%)
	Normal	Low	1 (0.8%)	0	1 (1.6%)	2 (3.1%)	2 (3.1%)	3 (4.7%)	3 (4.8%)	1 (1.4%)	2 (3.2%)	14 (2.4%)	15 (2.1%)

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	118 (90.8%)	108 (87.8%)	58 (92.1%)	57 (89.1%)	56 (87.5%)	54 (84.4%)	56 (90.3%)	63 (91.3%)	58 (92.1%)	510 (89.2%)	628 (89.5%)
		High	2 (1.5%)	1 (0.8%)	0	1 (1.6%)	1 (1.6%)	1 (1.6%)	1 (1.6%)	1 (1.4%)	0	6 (1.0%)	8 (1.1%)
	High	Normal	0	1 (0.8%)	0	0	1 (1.6%)	0	1 (1.6%)	0	1 (1.6%)	4 (0.7%)	4 (0.6%)
Week 20	m		130	123	62	63	64	65	61	69	63	570	700
	Low	Low	6 (4.6%)	6 (4.9%)	1 (1.6%)	1 (1.6%)	1 (1.6%)	4 (6.2%)	0	1 (1.4%)	1 (1.6%)	15 (2.6%)	21 (3.0%)
		Normal	3 (2.3%)	7 (5.7%)	3 (4.8%)	2 (3.2%)	3 (4.7%)	2 (3.1%)	1 (1.6%)	3 (4.3%)	1 (1.6%)	22 (3.9%)	25 (3.6%)
		High	0	0	0	1 (1.6%)	0	0	0	0	0	1 (0.2%)	1 (0.1%)
	Normal	Low	1 (0.8%)	2 (1.6%)	0	3 (4.8%)	2 (3.1%)	2 (3.1%)	3 (4.9%)	1 (1.4%)	2 (3.2%)	15 (2.6%)	16 (2.3%)
		Normal	120 (92.3%)	107 (87.0%)	57 (91.9%)	55 (87.3%)	56 (87.5%)	56 (86.2%)	55 (90.2%)	64 (92.8%)	57 (90.5%)	507 (88.9%)	627 (89.6%)
		High	0	0	1 (1.6%)	1 (1.6%)	1 (1.6%)	1 (1.5%)	1 (1.6%)	0	1 (1.6%)	6 (1.1%)	6 (0.9%)
	High	Normal	0	1 (0.8%)	0	0	1 (1.6%)	0	1 (1.6%)	0	1 (1.6%)	4 (0.7%)	4 (0.6%)
Week 24	m		130	122	62	63	64	65	61	69	63	569	699
	Low	Low	7 (5.4%)	5 (4.1%)	2 (3.2%)	1 (1.6%)	2 (3.1%)	4 (6.2%)	0	2 (2.9%)	1 (1.6%)	17 (3.0%)	24 (3.4%)
		Normal	2 (1.5%)	8 (6.6%)	2 (3.2%)	3 (4.8%)	2 (3.1%)	2 (3.1%)	1 (1.6%)	2 (2.9%)	1 (1.6%)	21 (3.7%)	23 (3.3%)
	Normal	Low	3 (2.3%)	0	2 (3.2%)	2 (3.2%)	3 (4.7%)	5 (7.7%)	2 (3.3%)	0	2 (3.2%)	16 (2.8%)	19 (2.7%)
		Normal	117 (90.0%)	108 (88.5%)	56 (90.3%)	56 (88.9%)	55 (85.9%)	53 (81.5%)	57 (93.4%)	65 (94.2%)	58 (92.1%)	508 (89.3%)	625 (89.4%)
		High	1 (0.8%)	0	0	1 (1.6%)	1 (1.6%)	1 (1.5%)	0	0	0	3 (0.5%)	4 (0.6%)
	High	Normal	0	1 (0.8%)	0	0	1 (1.6%)	0	0	0	1 (1.6%)	3 (0.5%)	3 (0.4%)
		High	0	0	0	0	0	0	1 (1.6%)	0	0	1 (0.2%)	1 (0.1%)
Week 32	m		128	120	62	60	62	65	60	69	63	561	689
	Low	Low	6 (4.7%)	4 (3.3%)	1 (1.6%)	2 (3.3%)	2 (3.2%)	5 (7.7%)	0	1 (1.4%)	1 (1.6%)	16 (2.9%)	22 (3.2%)
		Normal	3 (2.3%)	9 (7.5%)	3 (4.8%)	2 (3.3%)	2 (3.2%)	1 (1.5%)	1 (1.7%)	3 (4.3%)	1 (1.6%)	22 (3.9%)	25 (3.6%)
	Normal	Low	3 (2.3%)	1 (0.8%)	1 (1.6%)	3 (5.0%)	1 (1.6%)	4 (6.2%)	1 (1.7%)	0	1 (1.6%)	12 (2.1%)	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	111 (86.7%)	105 (87.5%)	57 (91.9%)	53 (88.3%)	55 (88.7%)	54 (83.1%)	57 (95.0%)	65 (94.2%)	59 (93.7%)	505 (90.0%)	616 (89.4%)
		High	5 (3.9%)	0	0	0	1 (1.6%)	1 (1.5%)	0	0	0	2 (0.4%)	7 (1.0%)
	High	Normal	0	1 (0.8%)	0	0	1 (1.6%)	0	1 (1.7%)	0	1 (1.6%)	4 (0.7%)	4 (0.6%)
Week 40	m		128	120	60	59	62	65	60	69	63	558	686
	Low	Low	4 (3.1%)	8 (6.7%)	2 (3.3%)	3 (5.1%)	3 (4.8%)	3 (4.6%)	1 (1.7%)	1 (1.4%)	2 (3.2%)	23 (4.1%)	27 (3.9%)
		Normal	5 (3.9%)	5 (4.2%)	2 (3.3%)	1 (1.7%)	1 (1.6%)	3 (4.6%)	0	3 (4.3%)	0	15 (2.7%)	20 (2.9%)
	Normal	Low	4 (3.1%)	4 (3.3%)	1 (1.7%)	2 (3.4%)	3 (4.8%)	5 (7.7%)	2 (3.3%)	0	1 (1.6%)	18 (3.2%)	22 (3.2%)
		Normal	115 (89.8%)	101 (84.2%)	54 (90.0%)	52 (88.1%)	53 (85.5%)	53 (81.5%)	56 (93.3%)	65 (94.2%)	59 (93.7%)	493 (88.4%)	608 (88.6%)
		High	0	1 (0.8%)	1 (1.7%)	1 (1.7%)	1 (1.6%)	1 (1.5%)	0	0	0	5 (0.9%)	5 (0.7%)
	High	Normal	0	1 (0.8%)	0	0	1 (1.6%)	0	1 (1.7%)	0	1 (1.6%)	4 (0.7%)	4 (0.6%)
Week 48	m		127	118	60	59	62	65	60	66	63	553	680
	Low	Low	5 (3.9%)	5 (4.2%)	2 (3.3%)	1 (1.7%)	1 (1.6%)	4 (6.2%)	0	1 (1.5%)	2 (3.2%)	16 (2.9%)	21 (3.1%)
		Normal	4 (3.1%)	8 (6.8%)	2 (3.3%)	3 (5.1%)	3 (4.8%)	2 (3.1%)	1 (1.7%)	3 (4.5%)	0	22 (4.0%)	26 (3.8%)
	Normal	Low	2 (1.6%)	2 (1.7%)	1 (1.7%)	1 (1.7%)	5 (8.1%)	3 (4.6%)	1 (1.7%)	2 (3.0%)	1 (1.6%)	16 (2.9%)	18 (2.6%)
		Normal	116 (91.3%)	102 (86.4%)	54 (90.0%)	53 (89.8%)	52 (83.9%)	55 (84.6%)	56 (93.3%)	60 (90.9%)	59 (93.7%)	491 (88.8%)	607 (89.3%)
		High	0	0	1 (1.7%)	1 (1.7%)	0	1 (1.5%)	1 (1.7%)	0	0	4 (0.7%)	4 (0.6%)
	High	Normal	0	1 (0.8%)	0	0	1 (1.6%)	0	1 (1.7%)	0	1 (1.6%)	4 (0.7%)	4 (0.6%)
Week 52	m		126	116	59	58	62	65	60	67	62	549	675
	Low	Low	8 (6.3%)	7 (6.0%)	2 (3.4%)	2 (3.4%)	2 (3.2%)	3 (4.6%)	0	2 (3.0%)	1 (1.6%)	19 (3.5%)	27 (4.0%)
		Normal	1 (0.8%)	6 (5.2%)	2 (3.4%)	2 (3.4%)	2 (3.2%)	3 (4.6%)	1 (1.7%)	2 (3.0%)	1 (1.6%)	19 (3.5%)	20 (3.0%)
	Normal	Low	3 (2.4%)	5 (4.3%)	3 (5.1%)	3 (5.2%)	2 (3.2%)	3 (4.6%)	3 (5.0%)	0	2 (3.2%)	21 (3.8%)	24 (3.6%)
		Normal	114 (90.5%)	95 (81.9%)	52 (88.1%)	51 (87.9%)	55 (88.7%)	54 (83.1%)	55 (91.7%)	63 (94.0%)	57 (91.9%)	482 (87.8%)	596 (88.3%)
		High	0	2 (1.7%)	0	0	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
	High	Normal	0	1 (0.9%)	0	0	1 (1.6%)	0	1 (1.7%)	0	1 (1.6%)	4 (0.7%)	4 (0.6%)
LOCF Endpoint	m		134	127	64	64	64	65	63	70	63	580	714
	Low	Low	8 (6.0%)	7 (5.5%)	2 (3.1%)	2 (3.1%)	2 (3.1%)	3 (4.6%)	0	2 (2.9%)	1 (1.6%)	19 (3.3%)	27 (3.8%)
		Normal	1 (0.7%)	6 (4.7%)	2 (3.1%)	2 (3.1%)	2 (3.1%)	3 (4.6%)	1 (1.6%)	2 (2.9%)	1 (1.6%)	19 (3.3%)	20 (2.8%)
	Normal	Low	4 (3.0%)	5 (3.9%)	3 (4.7%)	3 (4.7%)	2 (3.1%)	3 (4.6%)	3 (4.8%)	1 (1.4%)	2 (3.2%)	22 (3.8%)	26 (3.6%)
		Normal	121 (90.3%)	106 (83.5%)	57 (89.1%)	57 (89.1%)	57 (89.1%)	54 (83.1%)	58 (92.1%)	65 (92.9%)	58 (92.1%)	512 (88.3%)	633 (88.7%)
		High	0	2 (1.6%)	0	0	0	2 (3.1%)	0	0	0	4 (0.7%)	4 (0.6%)
	High	Normal	0	1 (0.8%)	0	0	1 (1.6%)	0	1 (1.6%)	0	1 (1.6%)	4 (0.7%)	4 (0.6%)
Lymphocytes (10^9/L)													
Week 4	m		134	127	64	64	64	65	63	70	63	580	714
	Low	Low	0	0	0	0	0	1 (1.5%)	0	0	0	1 (0.2%)	1 (0.1%)
		Normal	0	1 (0.8%)	0	0	2 (3.1%)	1 (1.5%)	0	1 (1.4%)	1 (1.6%)	6 (1.0%)	6 (0.8%)
	Normal	Low	0	1 (0.8%)	0	1 (1.6%)	0	0	0	0	0	2 (0.3%)	2 (0.3%)
		Normal	131 (97.8%)	121 (95.3%)	62 (96.9%)	62 (96.9%)	61 (95.3%)	63 (96.9%)	62 (98.4%)	67 (95.7%)	59 (93.7%)	557 (96.0%)	688 (96.4%)
		High	0	0	2 (3.1%)	1 (1.6%)	1 (1.6%)	0	1 (1.6%)	0	2 (3.2%)	7 (1.2%)	7 (1.0%)
	High	Normal	3 (2.2%)	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	4 (0.6%)
		High	0	3 (2.4%)	0	0	0	0	0	2 (2.9%)	1 (1.6%)	6 (1.0%)	6 (0.8%)
Week 8	m		132	124	63	64	64	65	62	69	63	574	706
	Low	Low	0	0	0	0	0	2 (3.1%)	0	0	0	2 (0.3%)	2 (0.3%)
		Normal	0	1 (0.8%)	0	0	2 (3.1%)	0	0	1 (1.4%)	1 (1.6%)	5 (0.9%)	5 (0.7%)
	Normal	Low	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
		Normal	129 (97.7%)	115 (92.7%)	62 (98.4%)	64 (100.0%)	61 (95.3%)	63 (96.9%)	61 (98.4%)	66 (95.7%)	60 (95.2%)	552 (96.2%)	681 (96.5%)
		High	0	3 (2.4%)	1 (1.6%)	0	1 (1.6%)	0	1 (1.6%)	0	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
	High	Normal	2 (1.5%)	1 (0.8%)	0	0	0	0	0	1 (1.4%)	0	2 (0.3%)	4 (0.6%)
		High	1 (0.8%)	3 (2.4%)	0	0	0	0	0	1 (1.4%)	1 (1.6%)	5 (0.9%)	6 (0.8%)
Week 12	m		131	123	63	64	64	65	62	68	63	572	703
	Low	Low	0	1 (0.8%)	0	0	0	1 (1.5%)	0	1 (1.5%)	0	3 (0.5%)	3 (0.4%)
		Normal	0	0	0	0	2 (3.1%)	1 (1.5%)	0	0	1 (1.6%)	4 (0.7%)	4 (0.6%)
	Normal	Low	0	2 (1.6%)	0	1 (1.6%)	1 (1.6%)	0	0	0	0	4 (0.7%)	4 (0.6%)
		Normal	128 (97.7%)	115 (93.5%)	62 (98.4%)	63 (98.4%)	60 (93.8%)	63 (96.9%)	61 (98.4%)	65 (95.6%)	61 (96.8%)	550 (96.2%)	678 (96.4%)
		High	0	1 (0.8%)	1 (1.6%)	0	1 (1.6%)	0	1 (1.6%)	0	0	4 (0.7%)	4 (0.6%)
	High	Normal	2 (1.5%)	3 (2.4%)	0	0	0	0	0	0	0	3 (0.5%)	5 (0.7%)
		High	1 (0.8%)	1 (0.8%)	0	0	0	0	0	2 (2.9%)	1 (1.6%)	4 (0.7%)	5 (0.7%)
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	0	1 (0.8%)	0	0	1 (1.6%)	1 (1.6%)	0	1 (1.4%)	1 (1.6%)	5 (0.9%)	5 (0.7%)
	Normal	Low	0	0	0	2 (3.1%)	2 (3.1%)	0	0	0	0	4 (0.7%)	4 (0.6%)
		Normal	125 (96.2%)	116 (94.3%)	61 (96.8%)	62 (96.9%)	59 (92.2%)	61 (95.3%)	62 (100.0%)	66 (95.7%)	60 (95.2%)	547 (95.6%)	672 (95.7%)
		High	2 (1.5%)	2 (1.6%)	2 (3.2%)	0	1 (1.6%)	1 (1.6%)	0	0	1 (1.6%)	7 (1.2%)	9 (1.3%)
	High	Normal	0	1 (0.8%)	0	0	0	0	0	1 (1.4%)	0	2 (0.3%)	2 (0.3%)
		High	3 (2.3%)	3 (2.4%)	0	0	0	0	0	1 (1.4%)	1 (1.6%)	5 (0.9%)	8 (1.1%)
Week 20	m		130	123	62	63	64	65	61	69	63	570	700
	Low	Low	0	0	0	0	1 (1.6%)	2 (3.1%)	0	0	0	3 (0.5%)	3 (0.4%)
		Normal	0	1 (0.8%)	0	0	1 (1.6%)	0	0	1 (1.4%)	1 (1.6%)	4 (0.7%)	4 (0.6%)
	Normal	Low	1 (0.8%)	0	0	0	0	0	1 (1.6%)	0	0	1 (0.2%)	2 (0.3%)
		Normal	123 (94.6%)	117 (95.1%)	62 (100.0%)	63 (100.0%)	61 (95.3%)	62 (95.4%)	59 (96.7%)	66 (95.7%)	61 (96.8%)	551 (96.7%)	674 (96.3%)
		High	3 (2.3%)	1 (0.8%)	0	0	1 (1.6%)	1 (1.5%)	1 (1.6%)	0	0	4 (0.7%)	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
	High	Normal	1 (0.8%)	1 (0.8%)	0	0	0	0	0	1 (1.4%)	0	2 (0.4%)	3 (0.4%)
		High	2 (1.5%)	3 (2.4%)	0	0	0	0	0	1 (1.4%)	1 (1.6%)	5 (0.9%)	7 (1.0%)
Week 24	m		130	122	62	63	64	65	61	69	63	569	699
	Low	Normal	0	1 (0.8%)	0	0	2 (3.1%)	2 (3.1%)	0	1 (1.4%)	1 (1.6%)	7 (1.2%)	7 (1.0%)
	Normal	Low	0	1 (0.8%)	0	0	0	1 (1.5%)	0	0	0	2 (0.4%)	2 (0.3%)
		Normal	127 (97.7%)	116 (95.1%)	62 (100.0%)	63 (100.0%)	61 (95.3%)	62 (95.4%)	61 (100.0%)	66 (95.7%)	61 (96.8%)	552 (97.0%)	679 (97.1%)
		High	0	0	0	0	1 (1.6%)	0	0	0	0	1 (0.2%)	1 (0.1%)
	High	Normal	1 (0.8%)	3 (2.5%)	0	0	0	0	0	0	0	3 (0.5%)	4 (0.6%)
		High	2 (1.5%)	1 (0.8%)	0	0	0	0	0	2 (2.9%)	1 (1.6%)	4 (0.7%)	6 (0.9%)
Week 32	m		128	120	62	60	62	65	60	69	63	561	689
	Low	Low	0	0	0	0	1 (1.6%)	1 (1.5%)	0	0	0	2 (0.4%)	2 (0.3%)
		Normal	0	1 (0.8%)	0	0	1 (1.6%)	1 (1.5%)	0	1 (1.4%)	1 (1.6%)	5 (0.9%)	5 (0.7%)
	Normal	Low	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
		Normal	125 (97.7%)	114 (95.0%)	61 (98.4%)	60 (100.0%)	59 (95.2%)	63 (96.9%)	60 (100.0%)	66 (95.7%)	60 (95.2%)	543 (96.8%)	668 (97.0%)
		High	0	0	1 (1.6%)	0	1 (1.6%)	0	0	0	1 (1.6%)	3 (0.5%)	3 (0.4%)
	High	Normal	2 (1.6%)	0	0	0	0	0	0	0	0	0	2 (0.3%)
		High	1 (0.8%)	4 (3.3%)	0	0	0	0	0	2 (2.9%)	1 (1.6%)	7 (1.2%)	8 (1.2%)
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	0	1 (1.6%)	4 (0.7%)	4 (0.6%)
		Normal	0	0	0	0	1 (1.6%)	1 (1.5%)	0	1 (1.4%)	0	3 (0.5%)	3 (0.4%)
	Normal	Low	2 (1.6%)	1 (0.8%)	0	0	0	0	1 (1.7%)	0	0	2 (0.4%)	4 (0.6%)
		Normal	122 (95.3%)	114 (95.0%)	58 (96.7%)	59 (100.0%)	60 (96.8%)	63 (96.9%)	59 (98.3%)	66 (95.7%)	59 (93.7%)	538 (96.4%)	660 (96.2%)
		High	1 (0.8%)	0	2 (3.3%)	0	0	0	0	0	2 (3.2%)	4 (0.7%)	5 (0.7%)
	High	Normal	2 (1.6%)	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	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
		High	1 (0.8%)	3 (2.5%)	0	0	0	0	0	2 (2.9%)	1 (1.6%)	6 (1.1%)	7 (1.0%)
Week 48	m		127	118	60	59	62	65	60	66	63	553	680
	Low	Low	0	0	0	0	1 (1.6%)	0	0	0	0	1 (0.2%)	1 (0.1%)
		Normal	0	1 (0.8%)	0	0	1 (1.6%)	2 (3.1%)	0	1 (1.5%)	1 (1.6%)	6 (1.1%)	6 (0.9%)
	Normal	Low	1 (0.8%)	1 (0.8%)	0	0	0	0	0	1 (1.5%)	2 (3.2%)	4 (0.7%)	5 (0.7%)
		Normal	122 (96.1%)	112 (94.9%)	58 (96.7%)	59 (100.0%)	60 (96.8%)	63 (96.9%)	60 (100.0%)	62 (93.9%)	59 (93.7%)	533 (96.4%)	655 (96.3%)
		High	1 (0.8%)	0	2 (3.3%)	0	0	0	0	0	0	2 (0.4%)	3 (0.4%)
	High	Normal	3 (2.4%)	0	0	0	0	0	0	0	0	0	3 (0.4%)
		High	0	4 (3.4%)	0	0	0	0	0	2 (3.0%)	1 (1.6%)	7 (1.3%)	7 (1.0%)
Week 52	m		126	116	59	58	62	65	60	67	62	549	675
	Low	Low	0	1 (0.9%)	0	0	1 (1.6%)	0	0	0	0	2 (0.4%)	2 (0.3%)
		Normal	0	0	0	0	1 (1.6%)	2 (3.1%)	0	1 (1.5%)	1 (1.6%)	5 (0.9%)	5 (0.7%)
	Normal	Low	1 (0.8%)	3 (2.6%)	0	0	0	0	1 (1.7%)	1 (1.5%)	0	5 (0.9%)	6 (0.9%)
		Normal	122 (96.8%)	106 (91.4%)	59 (100.0%)	58 (100.0%)	60 (96.8%)	63 (96.9%)	59 (98.3%)	63 (94.0%)	60 (96.8%)	528 (96.2%)	650 (96.3%)
		High	0	2 (1.7%)	0	0	0	0	0	0	0	2 (0.4%)	2 (0.3%)
	High	Normal	2 (1.6%)	1 (0.9%)	0	0	0	0	0	0	0	1 (0.2%)	3 (0.4%)
		High	1 (0.8%)	3 (2.6%)	0	0	0	0	0	2 (3.0%)	1 (1.6%)	6 (1.1%)	7 (1.0%)
LOCF Endpoint	m		134	127	64	64	64	65	63	70	63	580	714
	Low	Low	0	1 (0.8%)	0	0	1 (1.6%)	0	0	0	0	2 (0.3%)	2 (0.3%)
		Normal	0	0	0	0	1 (1.6%)	2 (3.1%)	0	1 (1.4%)	1 (1.6%)	5 (0.9%)	5 (0.7%)
	Normal	Low	2 (1.5%)	3 (2.4%)	0	0	0	0	1 (1.6%)	1 (1.4%)	0	5 (0.9%)	7 (1.0%)
		Normal	129 (96.3%)	117 (92.1%)	64 (100.0%)	64 (100.0%)	62 (96.9%)	63 (96.9%)	62 (98.4%)	66 (94.3%)	61 (96.8%)	559 (96.4%)	688 (96.4%)
		High	0	2 (1.6%)	0	0	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
	High	Normal	2 (1.5%)	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	3 (0.4%)
		High	1 (0.7%)	3 (2.4%)	0	0	0	0	0	2 (2.9%)	1 (1.6%)	6 (1.0%)	7 (1.0%)
Lymphocytes/Leukocytes (%)													
Week 4	m		134	127	64	64	64	65	63	70	63	580	714
	Low	Normal	0	1 (0.8%)	1 (1.6%)	0	1 (1.6%)	1 (1.5%)	1 (1.6%)	1 (1.4%)	0	6 (1.0%)	6 (0.8%)
	Normal	Low	0	1 (0.8%)	0	1 (1.6%)	1 (1.6%)	1 (1.5%)	1 (1.6%)	2 (2.9%)	0	7 (1.2%)	7 (1.0%)
		Normal	132 (98.5%)	121 (95.3%)	61 (95.3%)	59 (92.2%)	58 (90.6%)	60 (92.3%)	60 (95.2%)	63 (90.0%)	61 (96.8%)	543 (93.6%)	675 (94.5%)
		High	1 (0.7%)	1 (0.8%)	0	0	2 (3.1%)	2 (3.1%)	0	1 (1.4%)	0	6 (1.0%)	7 (1.0%)
	High	Normal	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%)
		High	0	3 (2.4%)	2 (3.1%)	1 (1.6%)	2 (3.1%)	1 (1.5%)	0	2 (2.9%)	1 (1.6%)	12 (2.1%)	12 (1.7%)
Week 8	m		132	124	63	64	64	65	62	69	63	574	706
	Low	Low	0	0	0	0	0	1 (1.5%)	1 (1.6%)	0	0	2 (0.3%)	2 (0.3%)
		Normal	0	1 (0.8%)	1 (1.6%)	0	1 (1.6%)	0	0	1 (1.4%)	0	4 (0.7%)	4 (0.6%)
	Normal	Low	0	1 (0.8%)	0	1 (1.6%)	0	0	0	1 (1.4%)	0	3 (0.5%)	3 (0.4%)
		Normal	130 (98.5%)	118 (95.2%)	59 (93.7%)	58 (90.6%)	61 (95.3%)	63 (96.9%)	60 (96.8%)	63 (91.3%)	60 (95.2%)	542 (94.4%)	672 (95.2%)
		High	1 (0.8%)	1 (0.8%)	1 (1.6%)	1 (1.6%)	0	0	0	1 (1.4%)	1 (1.6%)	5 (0.9%)	6 (0.8%)
	High	Normal	0	1 (0.8%)	1 (1.6%)	4 (6.3%)	1 (1.6%)	0	1 (1.6%)	1 (1.4%)	1 (1.6%)	10 (1.7%)	10 (1.4%)
		High	1 (0.8%)	2 (1.6%)	1 (1.6%)	0	1 (1.6%)	1 (1.5%)	0	2 (2.9%)	1 (1.6%)	8 (1.4%)	9 (1.3%)
Week 12	m		131	123	63	64	64	65	62	68	63	572	703
	Low	Low	0	0	0	0	0	0	0	1 (1.5%)	0	1 (0.2%)	1 (0.1%)
		Normal	0	1 (0.8%)	1 (1.6%)	0	1 (1.6%)	1 (1.5%)	1 (1.6%)	0	0	5 (0.9%)	5 (0.7%)
	Normal	Low	2 (1.5%)	2 (1.6%)	0	1 (1.6%)	2 (3.1%)	0	0	0	0	5 (0.9%)	7 (1.0%)
		Normal	125 (95.4%)	115 (93.5%)	59 (93.7%)	58 (90.6%)	59 (92.2%)	62 (95.4%)	60 (96.8%)	64 (94.1%)	60 (95.2%)	537 (93.9%)	662 (94.2%)

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	3 (2.3%)	2 (1.6%)	1 (1.6%)	1 (1.6%)	0	1 (1.5%)	0	0	1 (1.6%)	6 (1.0%)	9 (1.3%)
	High	Normal	0	0	2 (3.2%)	4 (6.3%)	1 (1.6%)	0	1 (1.6%)	0	0	8 (1.4%)	8 (1.1%)
		High	1 (0.8%)	3 (2.4%)	0	0	1 (1.6%)	1 (1.5%)	0	3 (4.4%)	2 (3.2%)	10 (1.7%)	11 (1.6%)
Week 16	m		130	123	63	64	64	64	62	69	63	572	702
	Low	Normal	0	1 (0.8%)	1 (1.6%)	0	1 (1.6%)	1 (1.6%)	1 (1.6%)	1 (1.4%)	0	6 (1.0%)	6 (0.9%)
	Normal	Low	1 (0.8%)	0	0	0	1 (1.6%)	0	0	1 (1.4%)	0	2 (0.3%)	3 (0.4%)
		Normal	127 (97.7%)	118 (95.9%)	60 (95.2%)	59 (92.2%)	59 (92.2%)	61 (95.3%)	60 (96.8%)	62 (89.9%)	60 (95.2%)	539 (94.2%)	666 (94.9%)
		High	1 (0.8%)	1 (0.8%)	0	1 (1.6%)	1 (1.6%)	1 (1.6%)	0	2 (2.9%)	1 (1.6%)	7 (1.2%)	8 (1.1%)
	High	Normal	1 (0.8%)	1 (0.8%)	1 (1.6%)	4 (6.3%)	2 (3.1%)	0	1 (1.6%)	1 (1.4%)	1 (1.6%)	11 (1.9%)	12 (1.7%)
		High	0	2 (1.6%)	1 (1.6%)	0	0	1 (1.6%)	0	2 (2.9%)	1 (1.6%)	7 (1.2%)	7 (1.0%)
Week 20	m		130	123	62	63	64	65	61	69	63	570	700
	Low	Normal	0	1 (0.8%)	1 (1.6%)	0	1 (1.6%)	1 (1.5%)	1 (1.6%)	1 (1.4%)	0	6 (1.1%)	6 (0.9%)
	Normal	Low	2 (1.5%)	0	1 (1.6%)	2 (3.2%)	0	1 (1.5%)	1 (1.6%)	0	0	5 (0.9%)	7 (1.0%)
		Normal	125 (96.2%)	119 (96.7%)	58 (93.5%)	57 (90.5%)	60 (93.8%)	62 (95.4%)	56 (91.8%)	63 (91.3%)	60 (95.2%)	535 (93.9%)	660 (94.3%)
		High	2 (1.5%)	0	0	0	1 (1.6%)	0	2 (3.3%)	2 (2.9%)	1 (1.6%)	6 (1.1%)	8 (1.1%)
	High	Normal	1 (0.8%)	0	1 (1.6%)	4 (6.3%)	2 (3.1%)	0	1 (1.6%)	2 (2.9%)	1 (1.6%)	11 (1.9%)	12 (1.7%)
		High	0	3 (2.4%)	1 (1.6%)	0	0	1 (1.5%)	0	1 (1.4%)	1 (1.6%)	7 (1.2%)	7 (1.0%)
Week 24	m		130	122	62	63	64	65	61	69	63	569	699
	Low	Normal	0	1 (0.8%)	1 (1.6%)	0	1 (1.6%)	1 (1.5%)	1 (1.6%)	1 (1.4%)	0	6 (1.1%)	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	129 (99.2%)	116 (95.1%)	59 (95.2%)	59 (93.7%)	60 (93.8%)	63 (96.9%)	58 (95.1%)	65 (94.2%)	60 (95.2%)	540 (94.9%)	669 (95.7%)
		High	0	2 (1.6%)	0	0	0	0	0	0	1 (1.6%)	3 (0.5%)	3 (0.4%)
	High	Normal	1 (0.8%)	1 (0.8%)	1 (1.6%)	3 (4.8%)	1 (1.6%)	0	1 (1.6%)	0	1 (1.6%)	8 (1.4%)	9 (1.3%)
		High	0	2 (1.6%)	1 (1.6%)	1 (1.6%)	1 (1.6%)	1 (1.5%)	0	3 (4.3%)	1 (1.6%)	10 (1.8%)	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 32	m		128	120	62	60	62	65	60	69	63	561	689
	Low	Low	0	0	0	0	0	0	1 (1.7%)	0	0	1 (0.2%)	1 (0.1%)
		Normal	0	1 (0.8%)	1 (1.6%)	0	1 (1.6%)	1 (1.5%)	0	1 (1.4%)	0	5 (0.9%)	5 (0.7%)
	Normal	Low	0	0	1 (1.6%)	0	1 (1.6%)	0	1 (1.7%)	0	0	3 (0.5%)	3 (0.4%)
		Normal	127 (99.2%)	116 (96.7%)	57 (91.9%)	56 (93.3%)	58 (93.5%)	61 (93.8%)	57 (95.0%)	64 (92.8%)	61 (96.8%)	530 (94.5%)	657 (95.4%)
		High	0	0	1 (1.6%)	0	0	2 (3.1%)	0	1 (1.4%)	0	4 (0.7%)	4 (0.6%)
	High	Normal	1 (0.8%)	1 (0.8%)	1 (1.6%)	3 (5.0%)	2 (3.2%)	0	1 (1.7%)	1 (1.4%)	1 (1.6%)	10 (1.8%)	11 (1.6%)
		High	0	2 (1.7%)	1 (1.6%)	1 (1.7%)	0	1 (1.5%)	0	2 (2.9%)	1 (1.6%)	8 (1.4%)	8 (1.2%)
Week 40	m		128	120	60	59	62	65	60	69	63	558	686
	Low	Normal	0	1 (0.8%)	1 (1.7%)	0	1 (1.6%)	1 (1.5%)	0	1 (1.4%)	0	5 (0.9%)	5 (0.7%)
	Normal	Low	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%)
		Normal	126 (98.4%)	112 (93.3%)	58 (96.7%)	55 (93.2%)	58 (93.5%)	63 (96.9%)	58 (96.7%)	65 (94.2%)	60 (95.2%)	529 (94.8%)	655 (95.5%)
		High	0	2 (1.7%)	0	0	0	0	0	0	0	2 (0.4%)	2 (0.3%)
	High	Normal	0	2 (1.7%)	1 (1.7%)	3 (5.1%)	1 (1.6%)	1 (1.5%)	1 (1.7%)	2 (2.9%)	1 (1.6%)	12 (2.2%)	12 (1.7%)
		High	1 (0.8%)	1 (0.8%)	0	1 (1.7%)	1 (1.6%)	0	0	1 (1.4%)	1 (1.6%)	5 (0.9%)	6 (0.9%)
Week 48	m		127	118	60	59	62	65	60	66	63	553	680
	Low	Normal	0	1 (0.8%)	1 (1.7%)	0	1 (1.6%)	1 (1.5%)	0	1 (1.5%)	0	5 (0.9%)	5 (0.7%)
	Normal	Low	2 (1.6%)	1 (0.8%)	0	2 (3.4%)	0	2 (3.1%)	1 (1.7%)	0	1 (1.6%)	7 (1.3%)	9 (1.3%)
		Normal	124 (97.6%)	112 (94.9%)	58 (96.7%)	53 (89.8%)	57 (91.9%)	61 (93.8%)	58 (96.7%)	62 (93.9%)	60 (95.2%)	521 (94.2%)	645 (94.9%)
		High	0	1 (0.8%)	0	0	2 (3.2%)	0	0	0	0	3 (0.5%)	3 (0.4%)
	High	Normal	1 (0.8%)	2 (1.7%)	1 (1.7%)	4 (6.8%)	2 (3.2%)	0	1 (1.7%)	2 (3.0%)	1 (1.6%)	13 (2.4%)	14 (2.1%)
		High	0	1 (0.8%)	0	0	0	1 (1.5%)	0	1 (1.5%)	1 (1.6%)	4 (0.7%)	4 (0.6%)
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
	Low	Normal	0	1 (0.9%)	1 (1.7%)	0	1 (1.6%)	1 (1.5%)	0	1 (1.5%)	0	5 (0.9%)	5 (0.7%)
	Normal	Low	0	0	0	0	0	1 (1.5%)	2 (3.3%)	0	0	3 (0.5%)	3 (0.4%)
		Normal	125 (99.2%)	110 (94.8%)	57 (96.6%)	54 (93.1%)	59 (95.2%)	62 (95.4%)	55 (91.7%)	63 (94.0%)	60 (96.8%)	520 (94.7%)	645 (95.6%)
		High	0	2 (1.7%)	0	0	0	0	2 (3.3%)	0	0	4 (0.7%)	4 (0.6%)
	High	Normal	1 (0.8%)	1 (0.9%)	0	4 (6.9%)	2 (3.2%)	0	1 (1.7%)	3 (4.5%)	1 (1.6%)	12 (2.2%)	13 (1.9%)
		High	0	2 (1.7%)	1 (1.7%)	0	0	1 (1.5%)	0	0	1 (1.6%)	5 (0.9%)	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	1 (1.6%)	0	0	1 (0.2%)	1 (0.1%)
		Normal	0	1 (0.8%)	1 (1.6%)	0	1 (1.6%)	1 (1.5%)	0	1 (1.4%)	0	5 (0.9%)	5 (0.7%)
	Normal	Low	1 (0.7%)	0	0	0	0	1 (1.5%)	2 (3.2%)	0	0	3 (0.5%)	4 (0.6%)
		Normal	131 (97.8%)	121 (95.3%)	61 (95.3%)	60 (93.8%)	61 (95.3%)	62 (95.4%)	57 (90.5%)	66 (94.3%)	61 (96.8%)	549 (94.7%)	680 (95.2%)
		High	1 (0.7%)	2 (1.6%)	0	0	0	0	2 (3.2%)	0	0	4 (0.7%)	5 (0.7%)
	High	Normal	1 (0.7%)	1 (0.8%)	1 (1.6%)	4 (6.3%)	2 (3.1%)	0	1 (1.6%)	3 (4.3%)	1 (1.6%)	13 (2.2%)	14 (2.0%)
		High	0	2 (1.6%)	1 (1.6%)	0	0	1 (1.5%)	0	0	1 (1.6%)	5 (0.9%)	5 (0.7%)
Monocytes (10^9/L)													
Week 4	m		134	127	64	64	64	65	63	70	63	580	714
	Low	Normal	0	0	0	0	0	1 (1.5%)	0	0	0	1 (0.2%)	1 (0.1%)
	Normal	Low	0	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	1 (0.1%)
		Normal	134 (100.0%)	127 (100.0%)	64 (100.0%)	64 (100.0%)	63 (98.4%)	64 (98.5%)	63 (100.0%)	70 (100.0%)	61 (96.8%)	576 (99.3%)	710 (99.4%)
		High	0	0	0	0	1 (1.6%)	0	0	0	1 (1.6%)	2 (0.3%)	2 (0.3%)
Week 8	m		132	124	63	64	64	65	62	69	63	574	706
	Low	Low	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
	Normal	Normal	132 (100.0%)	124 (100.0%)	63 (100.0%)	64 (100.0%)	64 (100.0%)	64 (98.5%)	62 (100.0%)	69 (100.0%)	63 (100.0%)	573 (99.8%)	705 (99.9%)
Week 12	m		131	123	63	64	64	65	62	68	63	572	703
	Low	Low	0	0	0	0	0	1 (1.5%)	0	0	0	1 (0.2%)	1 (0.1%)
	Normal	Low	0	2 (1.6%)	0	0	0	0	0	0	0	2 (0.3%)	2 (0.3%)
		Normal	131 (100.0%)	121 (98.4%)	63 (100.0%)	64 (100.0%)	64 (100.0%)	64 (98.5%)	62 (100.0%)	67 (98.5%)	63 (100.0%)	568 (99.3%)	699 (99.4%)
		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	0	0	0	0	0	1 (1.6%)	0	0	0	1 (0.2%)	1 (0.1%)
	Normal	Normal	130 (100.0%)	123 (100.0%)	63 (100.0%)	64 (100.0%)	64 (100.0%)	63 (98.4%)	62 (100.0%)	69 (100.0%)	63 (100.0%)	571 (99.8%)	701 (99.9%)
Week 20	m		130	123	62	63	64	65	61	69	63	570	700
	Low	Normal	0	0	0	0	0	1 (1.5%)	0	0	0	1 (0.2%)	1 (0.1%)
	Normal	Low	1 (0.8%)	0	0	0	0	1 (1.5%)	0	0	0	1 (0.2%)	2 (0.3%)
		Normal	129 (99.2%)	123 (100.0%)	62 (100.0%)	63 (100.0%)	64 (100.0%)	62 (95.4%)	60 (98.4%)	69 (100.0%)	63 (100.0%)	566 (99.3%)	695 (99.3%)
		High	0	0	0	0	0	1 (1.5%)	1 (1.6%)	0	0	2 (0.4%)	2 (0.3%)
Week 24	m		130	122	62	63	64	65	61	69	63	569	699
	Low	Normal	0	0	0	0	0	1 (1.5%)	0	0	0	1 (0.2%)	1 (0.1%)
	Normal	Low	0	0	1 (1.6%)	0	0	2 (3.1%)	0	0	1 (1.6%)	4 (0.7%)	4 (0.6%)
		Normal	130 (100.0%)	122 (100.0%)	61 (98.4%)	63 (100.0%)	64 (100.0%)	62 (95.4%)	61 (100.0%)	69 (100.0%)	62 (98.4%)	564 (99.1%)	694 (99.3%)
Week 32	m		128	120	62	60	62	65	60	69	63	561	689
	Low	Normal	0	0	0	0	0	1 (1.5%)	0	0	0	1 (0.2%)	1 (0.1%)
	Normal	Low	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
		Normal	128 (100.0%)	120 (100.0%)	61 (98.4%)	60 (100.0%)	61 (98.4%)	63 (96.9%)	60 (100.0%)	69 (100.0%)	63 (100.0%)	557 (99.3%)	685 (99.4%)
		High	0	0	1 (1.6%)	0	1 (1.6%)	0	0	0	0	2 (0.4%)	2 (0.3%)
Week 40	m		128	120	60	59	62	65	60	69	63	558	686
	Low	Normal	0	0	0	0	0	1 (1.5%)	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	127 (99.2%)	120 (100.0%)	60 (100.0%)	59 (100.0%)	62 (100.0%)	64 (98.5%)	60 (100.0%)	69 (100.0%)	63 (100.0%)	557 (99.8%)	684 (99.7%)
Week 48	m		127	118	60	59	62	65	60	66	63	553	680
	Low	Low	0	0	0	0	0	1 (1.5%)	0	0	0	1 (0.2%)	1 (0.1%)
	Normal	Low	0	0	0	0	0	1 (1.5%)	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%)	63 (96.9%)	60 (100.0%)	66 (100.0%)	63 (100.0%)	550 (99.5%)	677 (99.6%)
		High	0	0	0	0	1 (1.6%)	0	0	0	0	1 (0.2%)	1 (0.1%)
Week 52	m		126	116	59	58	62	65	60	67	62	549	675
	Low	Low	0	0	0	0	0	1 (1.5%)	0	0	0	1 (0.2%)	1 (0.1%)
	Normal	Normal	126 (100.0%)	116 (100.0%)	59 (100.0%)	58 (100.0%)	61 (98.4%)	64 (98.5%)	60 (100.0%)	67 (100.0%)	62 (100.0%)	547 (99.6%)	673 (99.7%)
		High	0	0	0	0	1 (1.6%)	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	Low	0	0	0	0	0	1 (1.5%)	0	0	0	1 (0.2%)	1 (0.1%)
	Normal	Normal	134 (100.0%)	127 (100.0%)	64 (100.0%)	64 (100.0%)	63 (98.4%)	64 (98.5%)	63 (100.0%)	70 (100.0%)	63 (100.0%)	578 (99.7%)	712 (99.7%)
		High	0	0	0	0	1 (1.6%)	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
Monocytes/Leukocytes (%)													
Week 4	m		134	127	64	64	64	65	63	70	63	580	714
	Low	Normal	0	0	0	0	0	1 (1.5%)	0	0	0	1 (0.2%)	1 (0.1%)
	Normal	Normal	134 (100.0%)	127 (100.0%)	63 (98.4%)	63 (98.4%)	63 (98.4%)	62 (95.4%)	63 (100.0%)	70 (100.0%)	62 (98.4%)	573 (98.8%)	707 (99.0%)
		High	0	0	1 (1.6%)	0	0	1 (1.5%)	0	0	1 (1.6%)	3 (0.5%)	3 (0.4%)
	High	High	0	0	0	1 (1.6%)	1 (1.6%)	1 (1.5%)	0	0	0	3 (0.5%)	3 (0.4%)
Week 8	m		132	124	63	64	64	65	62	69	63	574	706
	Low	Low	0	0	0	0	0	1 (1.5%)	0	0	0	1 (0.2%)	1 (0.1%)
	Normal	Low	1 (0.8%)	0	1 (1.6%)	0	0	0	0	0	0	1 (0.2%)	2 (0.3%)
		Normal	131 (99.2%)	123 (99.2%)	61 (96.8%)	63 (98.4%)	63 (98.4%)	63 (96.9%)	62 (100.0%)	69 (100.0%)	63 (100.0%)	567 (98.8%)	698 (98.9%)
		High	0	1 (0.8%)	1 (1.6%)	0	0	0	0	0	0	2 (0.3%)	2 (0.3%)
	High	High	0	0	0	1 (1.6%)	1 (1.6%)	1 (1.5%)	0	0	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	1 (1.5%)	0	0	0	1 (0.2%)	1 (0.1%)
	Normal	Low	0	0	0	0	0	1 (1.5%)	2 (3.2%)	1 (1.5%)	0	4 (0.7%)	4 (0.6%)
		Normal	131 (100.0%)	122 (99.2%)	62 (98.4%)	63 (98.4%)	63 (98.4%)	62 (95.4%)	60 (96.8%)	66 (97.1%)	63 (100.0%)	561 (98.1%)	692 (98.4%)
		High	0	1 (0.8%)	1 (1.6%)	0	0	0	0	1 (1.5%)	0	3 (0.5%)	3 (0.4%)
	High	Normal	0	0	0	0	0	1 (1.5%)	0	0	0	1 (0.2%)	1 (0.1%)
		High	0	0	0	1 (1.6%)	1 (1.6%)	0	0	0	0	2 (0.3%)	2 (0.3%)
Week 16	m		130	123	63	64	64	64	62	69	63	572	702
	Low	Low	0	0	0	0	0	1 (1.6%)	0	0	0	1 (0.2%)	1 (0.1%)
	Normal	Low	0	0	0	0	0	1 (1.6%)	1 (1.6%)	1 (1.4%)	1 (1.6%)	4 (0.7%)	4 (0.6%)
		Normal	130 (100.0%)	122 (99.2%)	63 (100.0%)	63 (98.4%)	62 (96.9%)	61 (95.3%)	61 (98.4%)	68 (98.6%)	62 (98.4%)	562 (98.3%)	692 (98.6%)

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	1 (0.8%)	0	0	1 (1.6%)	0	0	0	0	2 (0.3%)	2 (0.3%)
	High	Normal	0	0	0	0	1 (1.6%)	0	0	0	0	1 (0.2%)	1 (0.1%)
		High	0	0	0	1 (1.6%)	0	1 (1.6%)	0	0	0	2 (0.3%)	2 (0.3%)
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	Low	2 (1.5%)	0	2 (3.2%)	0	0	1 (1.5%)	0	0	1 (1.6%)	4 (0.7%)	6 (0.9%)
		Normal	128 (98.5%)	122 (99.2%)	60 (96.8%)	62 (98.4%)	63 (98.4%)	62 (95.4%)	61 (100.0%)	69 (100.0%)	62 (98.4%)	561 (98.4%)	689 (98.4%)
		High	0	1 (0.8%)	0	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
	High	High	0	0	0	1 (1.6%)	1 (1.6%)	1 (1.5%)	0	0	0	3 (0.5%)	3 (0.4%)
Week 24	m		130	122	62	63	64	65	61	69	63	569	699
	Low	Low	0	0	0	0	0	1 (1.5%)	0	0	0	1 (0.2%)	1 (0.1%)
	Normal	Low	2 (1.5%)	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	3 (0.4%)
		Normal	128 (98.5%)	120 (98.4%)	62 (100.0%)	62 (98.4%)	63 (98.4%)	63 (96.9%)	61 (100.0%)	69 (100.0%)	62 (98.4%)	562 (98.8%)	690 (98.7%)
		High	0	2 (1.6%)	0	0	0	0	0	0	0	2 (0.4%)	2 (0.3%)
	High	Normal	0	0	0	0	1 (1.6%)	0	0	0	0	1 (0.2%)	1 (0.1%)
		High	0	0	0	1 (1.6%)	0	1 (1.5%)	0	0	0	2 (0.4%)	2 (0.3%)
Week 32	m		128	120	62	60	62	65	60	69	63	561	689
	Low	Normal	0	0	0	0	0	1 (1.5%)	0	0	0	1 (0.2%)	1 (0.1%)
	Normal	Low	0	0	0	0	0	0	0	1 (1.4%)	0	1 (0.2%)	1 (0.1%)
		Normal	127 (99.2%)	120 (100.0%)	62 (100.0%)	58 (96.7%)	61 (98.4%)	63 (96.9%)	60 (100.0%)	68 (98.6%)	63 (100.0%)	555 (98.9%)	682 (99.0%)
		High	1 (0.8%)	0	0	1 (1.7%)	0	0	0	0	0	1 (0.2%)	2 (0.3%)
	High	High	0	0	0	1 (1.7%)	1 (1.6%)	1 (1.5%)	0	0	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	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%)	0	0	0	0	1 (1.4%)	0	2 (0.4%)	3 (0.4%)
		Normal	126 (98.4%)	120 (100.0%)	59 (98.3%)	58 (98.3%)	61 (98.4%)	63 (96.9%)	60 (100.0%)	68 (98.6%)	63 (100.0%)	552 (98.9%)	678 (98.8%)
		High	1 (0.8%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
	High	High	0	0	0	1 (1.7%)	1 (1.6%)	1 (1.5%)	0	0	0	3 (0.5%)	3 (0.4%)
Week 48	m		127	118	60	59	62	65	60	66	63	553	680
	Low	Low	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	0	0	0	0	0	0	1 (0.2%)	2 (0.3%)
		Normal	126 (99.2%)	117 (99.2%)	59 (98.3%)	58 (98.3%)	61 (98.4%)	63 (96.9%)	60 (100.0%)	66 (100.0%)	63 (100.0%)	547 (98.9%)	673 (99.0%)
		High	0	0	1 (1.7%)	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
	High	High	0	0	0	1 (1.7%)	1 (1.6%)	1 (1.5%)	0	0	0	3 (0.5%)	3 (0.4%)
Week 52	m		126	116	59	58	62	65	60	67	62	549	675
	Low	Low	0	0	0	0	0	1 (1.5%)	0	0	0	1 (0.2%)	1 (0.1%)
	Normal	Low	0	0	0	1 (1.7%)	0	0	0	0	0	1 (0.2%)	1 (0.1%)
		Normal	126 (100.0%)	114 (98.3%)	59 (100.0%)	56 (96.6%)	61 (98.4%)	63 (96.9%)	60 (100.0%)	67 (100.0%)	61 (98.4%)	541 (98.5%)	667 (98.8%)
		High	0	2 (1.7%)	0	0	0	0	0	0	1 (1.6%)	3 (0.5%)	3 (0.4%)
	High	Normal	0	0	0	0	0	1 (1.5%)	0	0	0	1 (0.2%)	1 (0.1%)
		High	0	0	0	1 (1.7%)	1 (1.6%)	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	1 (1.5%)	0	0	0	1 (0.2%)	1 (0.1%)
	Normal	Low	0	0	0	1 (1.6%)	0	0	0	0	0	1 (0.2%)	1 (0.1%)
		Normal	134 (100.0%)	125 (98.4%)	64 (100.0%)	62 (96.9%)	63 (98.4%)	63 (96.9%)	63 (100.0%)	70 (100.0%)	62 (98.4%)	572 (98.6%)	706 (98.9%)
		High	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
	High	Normal	0	0	0	0	0	1 (1.5%)	0	0	0	1 (0.2%)	1 (0.1%)
		High	0	0	0	1 (1.6%)	1 (1.6%)	0	0	0	0	2 (0.3%)	2 (0.3%)
Neutrophils (10^9/L)													
Week 4	m		134	127	64	64	64	65	63	70	63	580	714
	Low	Low	6 (4.5%)	3 (2.4%)	2 (3.1%)	1 (1.6%)	4 (6.3%)	3 (4.6%)	0	1 (1.4%)	1 (1.6%)	15 (2.6%)	21 (2.9%)
		Normal	4 (3.0%)	8 (6.3%)	1 (1.6%)	3 (4.7%)	3 (4.7%)	3 (4.6%)	3 (4.8%)	4 (5.7%)	1 (1.6%)	26 (4.5%)	30 (4.2%)
	Normal	Low	2 (1.5%)	5 (3.9%)	1 (1.6%)	2 (3.1%)	1 (1.6%)	2 (3.1%)	1 (1.6%)	1 (1.4%)	2 (3.2%)	15 (2.6%)	17 (2.4%)
		Normal	121 (90.3%)	107 (84.3%)	59 (92.2%)	57 (89.1%)	55 (85.9%)	57 (87.7%)	56 (88.9%)	63 (90.0%)	58 (92.1%)	512 (88.3%)	633 (88.7%)
		High	1 (0.7%)	3 (2.4%)	1 (1.6%)	0	0	0	1 (1.6%)	1 (1.4%)	0	6 (1.0%)	7 (1.0%)
	High	Normal	0	1 (0.8%)	0	0	1 (1.6%)	0	1 (1.6%)	0	1 (1.6%)	4 (0.7%)	4 (0.6%)
		High	0	0	0	1 (1.6%)	0	0	1 (1.6%)	0	0	2 (0.3%)	2 (0.3%)
Week 8	m		132	124	63	64	64	65	62	69	63	574	706
	Low	Low	5 (3.8%)	3 (2.4%)	0	1 (1.6%)	3 (4.7%)	2 (3.1%)	0	2 (2.9%)	1 (1.6%)	12 (2.1%)	17 (2.4%)
		Normal	5 (3.8%)	8 (6.5%)	3 (4.8%)	3 (4.7%)	4 (6.3%)	4 (6.2%)	3 (4.8%)	3 (4.3%)	1 (1.6%)	29 (5.1%)	34 (4.8%)
	Normal	Low	2 (1.5%)	3 (2.4%)	0	2 (3.1%)	1 (1.6%)	1 (1.5%)	1 (1.6%)	2 (2.9%)	2 (3.2%)	12 (2.1%)	14 (2.0%)
		Normal	120 (90.9%)	107 (86.3%)	60 (95.2%)	56 (87.5%)	55 (85.9%)	57 (87.7%)	56 (90.3%)	61 (88.4%)	58 (92.1%)	510 (88.9%)	630 (89.2%)
		High	0	2 (1.6%)	0	1 (1.6%)	0	1 (1.5%)	0	1 (1.4%)	0	5 (0.9%)	5 (0.7%)
	High	Normal	0	1 (0.8%)	0	0	1 (1.6%)	0	1 (1.6%)	0	1 (1.6%)	4 (0.7%)	4 (0.6%)
		High	0	0	0	1 (1.6%)	0	0	1 (1.6%)	0	0	2 (0.3%)	2 (0.3%)
Week 12	m		131	123	63	64	64	65	62	68	63	572	703
	Low	Low	4 (3.1%)	4 (3.3%)	2 (3.2%)	2 (3.1%)	4 (6.3%)	5 (7.7%)	0	2 (2.9%)	1 (1.6%)	20 (3.5%)	24 (3.4%)
		Normal	6 (4.6%)	7 (5.7%)	1 (1.6%)	2 (3.1%)	3 (4.7%)	1 (1.5%)	3 (4.8%)	3 (4.4%)	1 (1.6%)	21 (3.7%)	27 (3.8%)
	Normal	Low	2 (1.5%)	5 (4.1%)	4 (6.3%)	2 (3.1%)	3 (4.7%)	3 (4.6%)	1 (1.6%)	1 (1.5%)	1 (1.6%)	20 (3.5%)	22 (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
		Normal	117 (89.3%)	103 (83.7%)	56 (88.9%)	56 (87.5%)	52 (81.3%)	56 (86.2%)	56 (90.3%)	62 (91.2%)	59 (93.7%)	500 (87.4%)	617 (87.8%)
		High	2 (1.5%)	3 (2.4%)	0	1 (1.6%)	1 (1.6%)	0	0	0	0	5 (0.9%)	7 (1.0%)
	High	Normal	0	1 (0.8%)	0	0	1 (1.6%)	0	2 (3.2%)	0	1 (1.6%)	5 (0.9%)	5 (0.7%)
		High	0	0	0	1 (1.6%)	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
	Low	Low	4 (3.1%)	2 (1.6%)	2 (3.2%)	1 (1.6%)	3 (4.7%)	5 (7.8%)	1 (1.6%)	1 (1.4%)	1 (1.6%)	16 (2.8%)	20 (2.8%)
		Normal	6 (4.6%)	9 (7.3%)	1 (1.6%)	3 (4.7%)	4 (6.3%)	1 (1.6%)	2 (3.2%)	4 (5.8%)	1 (1.6%)	25 (4.4%)	31 (4.4%)
	Normal	Low	2 (1.5%)	4 (3.3%)	3 (4.8%)	1 (1.6%)	2 (3.1%)	2 (3.1%)	0	2 (2.9%)	2 (3.2%)	16 (2.8%)	18 (2.6%)
		Normal	115 (88.5%)	105 (85.4%)	57 (90.5%)	58 (90.6%)	53 (82.8%)	55 (85.9%)	56 (90.3%)	61 (88.4%)	58 (92.1%)	503 (87.9%)	618 (88.0%)
		High	3 (2.3%)	2 (1.6%)	0	0	1 (1.6%)	1 (1.6%)	1 (1.6%)	1 (1.4%)	0	6 (1.0%)	9 (1.3%)
	High	Normal	0	1 (0.8%)	0	1 (1.6%)	0	0	2 (3.2%)	0	1 (1.6%)	5 (0.9%)	5 (0.7%)
		High	0	0	0	0	1 (1.6%)	0	0	0	0	1 (0.2%)	1 (0.1%)
Week 20	m		130	123	62	63	64	65	61	69	63	570	700
	Low	Low	6 (4.6%)	6 (4.9%)	1 (1.6%)	1 (1.6%)	2 (3.1%)	5 (7.7%)	0	1 (1.4%)	0	16 (2.8%)	22 (3.1%)
		Normal	4 (3.1%)	5 (4.1%)	2 (3.2%)	2 (3.2%)	5 (7.8%)	1 (1.5%)	3 (4.9%)	4 (5.8%)	2 (3.2%)	24 (4.2%)	28 (4.0%)
		High	0	0	0	1 (1.6%)	0	0	0	0	0	1 (0.2%)	1 (0.1%)
	Normal	Low	3 (2.3%)	1 (0.8%)	0	2 (3.2%)	1 (1.6%)	1 (1.5%)	1 (1.6%)	1 (1.4%)	1 (1.6%)	8 (1.4%)	11 (1.6%)
		Normal	115 (88.5%)	108 (87.8%)	58 (93.5%)	56 (88.9%)	54 (84.4%)	56 (86.2%)	54 (88.5%)	63 (91.3%)	59 (93.7%)	508 (89.1%)	623 (89.0%)
		High	2 (1.5%)	2 (1.6%)	1 (1.6%)	0	1 (1.6%)	2 (3.1%)	1 (1.6%)	0	0	7 (1.2%)	9 (1.3%)
	High	Normal	0	1 (0.8%)	0	1 (1.6%)	1 (1.6%)	0	2 (3.3%)	0	1 (1.6%)	6 (1.1%)	6 (0.9%)
Week 24	m		130	122	62	63	64	65	61	69	63	569	699
	Low	Low	5 (3.8%)	4 (3.3%)	1 (1.6%)	2 (3.2%)	4 (6.3%)	4 (6.2%)	0	3 (4.3%)	0	18 (3.2%)	23 (3.3%)
		Normal	5 (3.8%)	7 (5.7%)	2 (3.2%)	2 (3.2%)	3 (4.7%)	2 (3.1%)	3 (4.9%)	2 (2.9%)	2 (3.2%)	23 (4.0%)	28 (4.0%)
	Normal	Low	1 (0.8%)	2 (1.6%)	2 (3.2%)	2 (3.2%)	1 (1.6%)	3 (4.6%)	3 (4.9%)	1 (1.4%)	2 (3.2%)	16 (2.8%)	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
		Normal	118 (90.8%)	106 (86.9%)	57 (91.9%)	56 (88.9%)	54 (84.4%)	55 (84.6%)	52 (85.2%)	63 (91.3%)	58 (92.1%)	501 (88.0%)	619 (88.6%)
		High	1 (0.8%)	2 (1.6%)	0	0	1 (1.6%)	1 (1.5%)	1 (1.6%)	0	0	5 (0.9%)	6 (0.9%)
	High	Normal	0	1 (0.8%)	0	0	1 (1.6%)	0	1 (1.6%)	0	1 (1.6%)	4 (0.7%)	4 (0.6%)
		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
	Low	Low	5 (3.9%)	4 (3.3%)	1 (1.6%)	2 (3.3%)	4 (6.5%)	6 (9.2%)	0	1 (1.4%)	1 (1.6%)	19 (3.4%)	24 (3.5%)
		Normal	5 (3.9%)	7 (5.8%)	2 (3.2%)	2 (3.3%)	3 (4.8%)	0	3 (5.0%)	4 (5.8%)	1 (1.6%)	22 (3.9%)	27 (3.9%)
	Normal	Low	1 (0.8%)	2 (1.7%)	2 (3.2%)	2 (3.3%)	1 (1.6%)	4 (6.2%)	1 (1.7%)	1 (1.4%)	1 (1.6%)	14 (2.5%)	15 (2.2%)
		Normal	112 (87.5%)	105 (87.5%)	56 (90.3%)	53 (88.3%)	52 (83.9%)	55 (84.6%)	53 (88.3%)	63 (91.3%)	59 (93.7%)	496 (88.4%)	608 (88.2%)
		High	5 (3.9%)	1 (0.8%)	1 (1.6%)	0	1 (1.6%)	0	1 (1.7%)	0	0	4 (0.7%)	9 (1.3%)
	High	Normal	0	1 (0.8%)	0	1 (1.7%)	1 (1.6%)	0	2 (3.3%)	0	1 (1.6%)	6 (1.1%)	6 (0.9%)
Week 40	m		128	120	60	59	62	65	60	69	63	558	686
	Low	Low	4 (3.1%)	6 (5.0%)	3 (5.0%)	2 (3.4%)	5 (8.1%)	3 (4.6%)	2 (3.3%)	2 (2.9%)	1 (1.6%)	24 (4.3%)	28 (4.1%)
		Normal	6 (4.7%)	5 (4.2%)	0	2 (3.4%)	2 (3.2%)	3 (4.6%)	1 (1.7%)	3 (4.3%)	1 (1.6%)	17 (3.0%)	23 (3.4%)
	Normal	Low	3 (2.3%)	7 (5.8%)	0	3 (5.1%)	4 (6.5%)	2 (3.1%)	0	0	1 (1.6%)	17 (3.0%)	20 (2.9%)
		Normal	115 (89.8%)	101 (84.2%)	55 (91.7%)	51 (86.4%)	49 (79.0%)	57 (87.7%)	56 (93.3%)	64 (92.8%)	59 (93.7%)	492 (88.2%)	607 (88.5%)
		High	0	0	2 (3.3%)	0	1 (1.6%)	0	0	0	0	3 (0.5%)	3 (0.4%)
	High	Normal	0	1 (0.8%)	0	0	1 (1.6%)	0	0	0	1 (1.6%)	3 (0.5%)	3 (0.4%)
		High	0	0	0	1 (1.7%)	0	0	1 (1.7%)	0	0	2 (0.4%)	2 (0.3%)
Week 48	m		127	118	60	59	62	65	60	66	63	553	680
	Low	Low	5 (3.9%)	4 (3.4%)	1 (1.7%)	1 (1.7%)	2 (3.2%)	5 (7.7%)	0	1 (1.5%)	1 (1.6%)	15 (2.7%)	20 (2.9%)
		Normal	5 (3.9%)	7 (5.9%)	2 (3.3%)	3 (5.1%)	5 (8.1%)	1 (1.5%)	3 (5.0%)	4 (6.1%)	1 (1.6%)	26 (4.7%)	31 (4.6%)
	Normal	Low	1 (0.8%)	5 (4.2%)	2 (3.3%)	2 (3.4%)	3 (4.8%)	4 (6.2%)	0	0	3 (4.8%)	19 (3.4%)	20 (2.9%)

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	115 (90.6%)	101 (85.6%)	54 (90.0%)	51 (86.4%)	51 (82.3%)	53 (81.5%)	56 (93.3%)	61 (92.4%)	57 (90.5%)	484 (87.5%)	599 (88.1%)
		High	1 (0.8%)	0	1 (1.7%)	1 (1.7%)	0	2 (3.1%)	0	0	0	4 (0.7%)	5 (0.7%)
	High	Normal	0	1 (0.8%)	0	1 (1.7%)	1 (1.6%)	0	1 (1.7%)	0	1 (1.6%)	5 (0.9%)	5 (0.7%)
Week 52	m		126	116	59	58	62	65	60	67	62	549	675
	Low	Low	5 (4.0%)	4 (3.4%)	3 (5.1%)	2 (3.4%)	4 (6.5%)	5 (7.7%)	0	2 (3.0%)	0	20 (3.6%)	25 (3.7%)
		Normal	5 (4.0%)	7 (6.0%)	0	2 (3.4%)	3 (4.8%)	1 (1.5%)	3 (5.0%)	3 (4.5%)	2 (3.2%)	21 (3.8%)	26 (3.9%)
	Normal	Low	3 (2.4%)	4 (3.4%)	3 (5.1%)	4 (6.9%)	2 (3.2%)	2 (3.1%)	1 (1.7%)	2 (3.0%)	2 (3.2%)	20 (3.6%)	23 (3.4%)
		Normal	112 (88.9%)	99 (85.3%)	51 (86.4%)	48 (82.8%)	52 (83.9%)	54 (83.1%)	55 (91.7%)	60 (89.6%)	57 (91.9%)	476 (86.7%)	588 (87.1%)
		High	1 (0.8%)	1 (0.9%)	2 (3.4%)	1 (1.7%)	0	3 (4.6%)	0	0	0	7 (1.3%)	8 (1.2%)
	High	Normal	0	1 (0.9%)	0	1 (1.7%)	1 (1.6%)	0	1 (1.7%)	0	1 (1.6%)	5 (0.9%)	5 (0.7%)
LOCF Endpoint	m		134	127	64	64	64	65	63	70	63	580	714
	Low	Low	5 (3.7%)	4 (3.1%)	3 (4.7%)	2 (3.1%)	4 (6.3%)	5 (7.7%)	0	2 (2.9%)	0	20 (3.4%)	25 (3.5%)
		Normal	5 (3.7%)	7 (5.5%)	0	2 (3.1%)	3 (4.7%)	1 (1.5%)	3 (4.8%)	3 (4.3%)	2 (3.2%)	21 (3.6%)	26 (3.6%)
	Normal	Low	4 (3.0%)	4 (3.1%)	4 (6.3%)	5 (7.8%)	2 (3.1%)	2 (3.1%)	1 (1.6%)	3 (4.3%)	2 (3.2%)	23 (4.0%)	27 (3.8%)
		Normal	118 (88.1%)	110 (86.6%)	55 (85.9%)	53 (82.8%)	54 (84.4%)	54 (83.1%)	57 (90.5%)	62 (88.6%)	58 (92.1%)	503 (86.7%)	621 (87.0%)
		High	2 (1.5%)	1 (0.8%)	2 (3.1%)	1 (1.6%)	0	3 (4.6%)	0	0	0	7 (1.2%)	9 (1.3%)
	High	Normal	0	1 (0.8%)	0	1 (1.6%)	1 (1.6%)	0	2 (3.2%)	0	1 (1.6%)	6 (1.0%)	6 (0.8%)
Neutrophils/Leukocytes (%)													
Week 4	m		134	127	64	64	64	65	63	70	63	580	714
	Low	Low	0	1 (0.8%)	0	0	1 (1.6%)	1 (1.5%)	0	1 (1.4%)	1 (1.6%)	5 (0.9%)	5 (0.7%)
		Normal	0	0	0	1 (1.6%)	1 (1.6%)	0	0	2 (2.9%)	1 (1.6%)	5 (0.9%)	5 (0.7%)
	Normal	Low	0	1 (0.8%)	1 (1.6%)	0	1 (1.6%)	0	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
		Normal	131 (97.8%)	121 (95.3%)	61 (95.3%)	62 (96.9%)	57 (89.1%)	61 (93.8%)	60 (95.2%)	63 (90.0%)	61 (96.8%)	546 (94.1%)	677 (94.8%)
		High	2 (1.5%)	1 (0.8%)	0	0	1 (1.6%)	1 (1.5%)	1 (1.6%)	2 (2.9%)	0	6 (1.0%)	8 (1.1%)
	High	Normal	1 (0.7%)	2 (1.6%)	2 (3.1%)	0	1 (1.6%)	2 (3.1%)	1 (1.6%)	2 (2.9%)	0	10 (1.7%)	11 (1.5%)
		High	0	1 (0.8%)	0	1 (1.6%)	2 (3.1%)	0	1 (1.6%)	0	0	5 (0.9%)	5 (0.7%)
Week 8	m		132	124	63	64	64	65	62	69	63	574	706
	Low	Low	0	0	0	0	0	1 (1.5%)	0	0	1 (1.6%)	2 (0.3%)	2 (0.3%)
		Normal	0	1 (0.8%)	0	1 (1.6%)	2 (3.1%)	0	0	3 (4.3%)	1 (1.6%)	8 (1.4%)	8 (1.1%)
	Normal	Low	1 (0.8%)	2 (1.6%)	3 (4.8%)	1 (1.6%)	1 (1.6%)	0	0	1 (1.4%)	2 (3.2%)	10 (1.7%)	11 (1.6%)
		Normal	129 (97.7%)	117 (94.4%)	58 (92.1%)	61 (95.3%)	57 (89.1%)	61 (93.8%)	60 (96.8%)	62 (89.9%)	59 (93.7%)	535 (93.2%)	664 (94.1%)
		High	1 (0.8%)	1 (0.8%)	0	0	1 (1.6%)	1 (1.5%)	0	1 (1.4%)	0	4 (0.7%)	5 (0.7%)
	High	Normal	1 (0.8%)	2 (1.6%)	2 (3.2%)	0	3 (4.7%)	1 (1.5%)	1 (1.6%)	2 (2.9%)	0	11 (1.9%)	12 (1.7%)
		High	0	1 (0.8%)	0	1 (1.6%)	0	1 (1.5%)	1 (1.6%)	0	0	4 (0.7%)	4 (0.6%)
Week 12	m		131	123	63	64	64	65	62	68	63	572	703
	Low	Low	0	1 (0.8%)	0	0	0	0	0	3 (4.4%)	1 (1.6%)	5 (0.9%)	5 (0.7%)
		Normal	0	0	0	1 (1.6%)	2 (3.1%)	1 (1.5%)	0	0	1 (1.6%)	5 (0.9%)	5 (0.7%)
	Normal	Low	1 (0.8%)	2 (1.6%)	1 (1.6%)	1 (1.6%)	0	0	0	0	1 (1.6%)	5 (0.9%)	6 (0.9%)
		Normal	127 (96.9%)	114 (92.7%)	60 (95.2%)	61 (95.3%)	57 (89.1%)	61 (93.8%)	58 (93.5%)	63 (92.6%)	60 (95.2%)	534 (93.4%)	661 (94.0%)
		High	2 (1.5%)	3 (2.4%)	0	0	2 (3.1%)	1 (1.5%)	2 (3.2%)	0	0	8 (1.4%)	10 (1.4%)
	High	Normal	1 (0.8%)	3 (2.4%)	2 (3.2%)	0	1 (1.6%)	2 (3.1%)	2 (3.2%)	1 (1.5%)	0	11 (1.9%)	12 (1.7%)
		High	0	0	0	1 (1.6%)	2 (3.1%)	0	0	1 (1.5%)	0	4 (0.7%)	4 (0.6%)
Week 16	m		130	123	63	64	64	64	62	69	63	572	702
	Low	Low	0	0	0	0	0	1 (1.6%)	0	1 (1.4%)	1 (1.6%)	3 (0.5%)	3 (0.4%)
		Normal	0	1 (0.8%)	0	1 (1.6%)	2 (3.1%)	0	0	2 (2.9%)	1 (1.6%)	7 (1.2%)	7 (1.0%)
	Normal	Low	2 (1.5%)	3 (2.4%)	1 (1.6%)	0	1 (1.6%)	1 (1.6%)	0	1 (1.4%)	0	7 (1.2%)	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
		Normal	125 (96.2%)	116 (94.3%)	60 (95.2%)	60 (93.8%)	55 (85.9%)	60 (93.8%)	59 (95.2%)	62 (89.9%)	61 (96.8%)	533 (93.2%)	658 (93.7%)
		High	2 (1.5%)	0	0	2 (3.1%)	3 (4.7%)	0	1 (1.6%)	1 (1.4%)	0	7 (1.2%)	9 (1.3%)
	High	Normal	1 (0.8%)	2 (1.6%)	2 (3.2%)	1 (1.6%)	1 (1.6%)	2 (3.1%)	2 (3.2%)	1 (1.4%)	0	11 (1.9%)	12 (1.7%)
		High	0	1 (0.8%)	0	0	2 (3.1%)	0	0	1 (1.4%)	0	4 (0.7%)	4 (0.6%)
Week 20	m		130	123	62	63	64	65	61	69	63	570	700
	Low	Low	0	1 (0.8%)	0	0	0	1 (1.5%)	0	0	0	2 (0.4%)	2 (0.3%)
		Normal	0	0	0	1 (1.6%)	2 (3.1%)	0	0	3 (4.3%)	2 (3.2%)	8 (1.4%)	8 (1.1%)
	Normal	Low	0	1 (0.8%)	1 (1.6%)	0	0	0	0	0	0	2 (0.4%)	2 (0.3%)
		Normal	127 (97.7%)	118 (95.9%)	58 (93.5%)	60 (95.2%)	58 (90.6%)	61 (93.8%)	58 (95.1%)	64 (92.8%)	61 (96.8%)	538 (94.4%)	665 (95.0%)
		High	2 (1.5%)	0	1 (1.6%)	2 (3.2%)	1 (1.6%)	1 (1.5%)	1 (1.6%)	0	0	6 (1.1%)	8 (1.1%)
	High	Normal	1 (0.8%)	3 (2.4%)	2 (3.2%)	0	1 (1.6%)	2 (3.1%)	2 (3.3%)	2 (2.9%)	0	12 (2.1%)	13 (1.9%)
		High	0	0	0	0	2 (3.1%)	0	0	0	0	2 (0.4%)	2 (0.3%)
Week 24	m		130	122	62	63	64	65	61	69	63	569	699
	Low	Low	0	0	0	0	0	1 (1.5%)	0	2 (2.9%)	0	3 (0.5%)	3 (0.4%)
		Normal	0	1 (0.8%)	0	1 (1.6%)	2 (3.1%)	0	0	1 (1.4%)	2 (3.2%)	7 (1.2%)	7 (1.0%)
	Normal	Low	0	3 (2.5%)	1 (1.6%)	1 (1.6%)	1 (1.6%)	0	0	0	0	6 (1.1%)	6 (0.9%)
		Normal	128 (98.5%)	113 (92.6%)	59 (95.2%)	60 (95.2%)	56 (87.5%)	62 (95.4%)	57 (93.4%)	63 (91.3%)	61 (96.8%)	531 (93.3%)	659 (94.3%)
		High	1 (0.8%)	2 (1.6%)	0	1 (1.6%)	2 (3.1%)	0	2 (3.3%)	1 (1.4%)	0	8 (1.4%)	9 (1.3%)
	High	Normal	1 (0.8%)	2 (1.6%)	1 (1.6%)	0	2 (3.1%)	2 (3.1%)	2 (3.3%)	2 (2.9%)	0	11 (1.9%)	12 (1.7%)
		High	0	1 (0.8%)	1 (1.6%)	0	1 (1.6%)	0	0	0	0	3 (0.5%)	3 (0.4%)
Week 32	m		128	120	62	60	62	65	60	69	63	561	689
	Low	Low	0	0	0	0	0	1 (1.5%)	0	1 (1.4%)	1 (1.6%)	3 (0.5%)	3 (0.4%)
		Normal	0	1 (0.8%)	0	1 (1.7%)	2 (3.2%)	0	0	2 (2.9%)	1 (1.6%)	7 (1.2%)	7 (1.0%)
	Normal	Low	0	2 (1.7%)	1 (1.6%)	1 (1.7%)	0	2 (3.1%)	0	2 (2.9%)	0	8 (1.4%)	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
		Normal	124 (96.9%)	114 (95.0%)	57 (91.9%)	57 (95.0%)	57 (91.9%)	60 (92.3%)	57 (95.0%)	62 (89.9%)	59 (93.7%)	523 (93.2%)	647 (93.9%)
		High	3 (2.3%)	0	2 (3.2%)	1 (1.7%)	0	0	1 (1.7%)	0	2 (3.2%)	6 (1.1%)	9 (1.3%)
	High	Normal	1 (0.8%)	2 (1.7%)	2 (3.2%)	0	0	1 (1.5%)	1 (1.7%)	2 (2.9%)	0	8 (1.4%)	9 (1.3%)
		High	0	1 (0.8%)	0	0	3 (4.8%)	1 (1.5%)	1 (1.7%)	0	0	6 (1.1%)	6 (0.9%)
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	1 (1.6%)	2 (0.4%)	2 (0.3%)
		Normal	0	0	0	1 (1.7%)	2 (3.2%)	1 (1.5%)	0	3 (4.3%)	1 (1.6%)	8 (1.4%)	8 (1.2%)
	Normal	Low	1 (0.8%)	1 (0.8%)	0	0	2 (3.2%)	1 (1.5%)	0	0	0	4 (0.7%)	5 (0.7%)
		Normal	125 (97.7%)	114 (95.0%)	56 (93.3%)	57 (96.6%)	54 (87.1%)	61 (93.8%)	58 (96.7%)	64 (92.8%)	60 (95.2%)	524 (93.9%)	649 (94.6%)
		High	1 (0.8%)	1 (0.8%)	2 (3.3%)	1 (1.7%)	1 (1.6%)	0	1 (1.7%)	0	1 (1.6%)	7 (1.3%)	8 (1.2%)
	High	Normal	1 (0.8%)	2 (1.7%)	2 (3.3%)	0	3 (4.8%)	2 (3.1%)	1 (1.7%)	2 (2.9%)	0	12 (2.2%)	13 (1.9%)
		High	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
	Low	Low	0	0	0	0	0	1 (1.5%)	0	1 (1.5%)	1 (1.6%)	3 (0.5%)	3 (0.4%)
		Normal	0	1 (0.8%)	0	1 (1.7%)	2 (3.2%)	0	0	2 (3.0%)	1 (1.6%)	7 (1.3%)	7 (1.0%)
	Normal	Low	0	1 (0.8%)	0	1 (1.7%)	3 (4.8%)	0	0	0	0	5 (0.9%)	5 (0.7%)
		Normal	125 (98.4%)	111 (94.1%)	58 (96.7%)	55 (93.2%)	54 (87.1%)	61 (93.8%)	58 (96.7%)	61 (92.4%)	60 (95.2%)	518 (93.7%)	643 (94.6%)
		High	1 (0.8%)	2 (1.7%)	0	2 (3.4%)	0	1 (1.5%)	1 (1.7%)	0	1 (1.6%)	7 (1.3%)	8 (1.2%)
	High	Normal	0	3 (2.5%)	2 (3.3%)	0	3 (4.8%)	2 (3.1%)	1 (1.7%)	2 (3.0%)	0	13 (2.4%)	13 (1.9%)
		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
	Low	Low	0	0	0	1 (1.7%)	0	1 (1.5%)	0	0	1 (1.6%)	3 (0.5%)	3 (0.4%)
		Normal	0	1 (0.9%)	0	0	2 (3.2%)	0	0	3 (4.5%)	1 (1.6%)	7 (1.3%)	7 (1.0%)
	Normal	Low	1 (0.8%)	3 (2.6%)	1 (1.7%)	0	0	0	1 (1.7%)	0	0	5 (0.9%)	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	123 (97.6%)	108 (93.1%)	55 (93.2%)	55 (94.8%)	57 (91.9%)	61 (93.8%)	56 (93.3%)	61 (91.0%)	59 (95.2%)	512 (93.3%)	635 (94.1%)
		High	1 (0.8%)	1 (0.9%)	1 (1.7%)	2 (3.4%)	0	1 (1.5%)	2 (3.3%)	1 (1.5%)	1 (1.6%)	9 (1.6%)	10 (1.5%)
	High	Normal	1 (0.8%)	2 (1.7%)	2 (3.4%)	0	3 (4.8%)	2 (3.1%)	1 (1.7%)	2 (3.0%)	0	12 (2.2%)	13 (1.9%)
		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	Low	0	0	0	1 (1.6%)	0	1 (1.5%)	0	0	1 (1.6%)	3 (0.5%)	3 (0.4%)
		Normal	0	1 (0.8%)	0	0	2 (3.1%)	0	0	3 (4.3%)	1 (1.6%)	7 (1.2%)	7 (1.0%)
	Normal	Low	1 (0.7%)	3 (2.4%)	2 (3.1%)	1 (1.6%)	0	0	1 (1.6%)	0	0	7 (1.2%)	8 (1.1%)
		Normal	130 (97.0%)	119 (93.7%)	59 (92.2%)	59 (92.2%)	59 (92.2%)	61 (93.8%)	58 (92.1%)	64 (91.4%)	60 (95.2%)	539 (92.9%)	669 (93.7%)
		High	2 (1.5%)	1 (0.8%)	1 (1.6%)	2 (3.1%)	0	1 (1.5%)	2 (3.2%)	1 (1.4%)	1 (1.6%)	9 (1.6%)	11 (1.5%)
	High	Normal	1 (0.7%)	2 (1.6%)	2 (3.1%)	1 (1.6%)	3 (4.7%)	2 (3.1%)	1 (1.6%)	2 (2.9%)	0	13 (2.2%)	14 (2.0%)
		High	0	1 (0.8%)	0	0	0	0	1 (1.6%)	0	0	2 (0.3%)	2 (0.3%)
Platelets (10^9/L)													
Week 4	m		134	126	62	64	63	65	63	70	63	576	710
	Low	Low	1 (0.7%)	2 (1.6%)	0	2 (3.1%)	0	1 (1.5%)	2 (3.2%)	2 (2.9%)	1 (1.6%)	10 (1.7%)	11 (1.5%)
		Normal	3 (2.2%)	2 (1.6%)	0	0	2 (3.2%)	2 (3.1%)	3 (4.8%)	2 (2.9%)	1 (1.6%)	12 (2.1%)	15 (2.1%)
	Normal	Low	2 (1.5%)	1 (0.8%)	0	1 (1.6%)	1 (1.6%)	1 (1.5%)	0	0	1 (1.6%)	5 (0.9%)	7 (1.0%)
		Normal	126 (94.0%)	120 (95.2%)	60 (96.8%)	61 (95.3%)	60 (95.2%)	60 (92.3%)	58 (92.1%)	66 (94.3%)	59 (93.7%)	544 (94.4%)	670 (94.4%)
		High	0	1 (0.8%)	2 (3.2%)	0	0	1 (1.5%)	0	0	0	4 (0.7%)	4 (0.6%)
	High	Normal	1 (0.7%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
		High	1 (0.7%)	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	2 (0.3%)
Week 8	m		132	122	63	64	63	65	62	69	63	571	703
	Low	Low	2 (1.5%)	2 (1.6%)	0	2 (3.1%)	0	0	3 (4.8%)	2 (2.9%)	1 (1.6%)	10 (1.8%)	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
		Normal	2 (1.5%)	2 (1.6%)	0	0	2 (3.2%)	3 (4.6%)	2 (3.2%)	2 (2.9%)	1 (1.6%)	12 (2.1%)	14 (2.0%)
	Normal	Low	2 (1.5%)	0	0	0	2 (3.2%)	0	1 (1.6%)	2 (2.9%)	1 (1.6%)	6 (1.1%)	8 (1.1%)
		Normal	124 (93.9%)	117 (95.9%)	62 (98.4%)	61 (95.3%)	59 (93.7%)	62 (95.4%)	56 (90.3%)	63 (91.3%)	59 (93.7%)	539 (94.4%)	663 (94.3%)
		High	0	1 (0.8%)	1 (1.6%)	1 (1.6%)	0	0	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%)
		High	1 (0.8%)	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	2 (0.3%)
Week 12	m		131	123	63	64	63	65	62	68	63	571	702
	Low	Low	1 (0.8%)	3 (2.4%)	0	2 (3.1%)	1 (1.6%)	3 (4.6%)	3 (4.8%)	3 (4.4%)	1 (1.6%)	16 (2.8%)	17 (2.4%)
		Normal	3 (2.3%)	1 (0.8%)	0	0	1 (1.6%)	0	2 (3.2%)	1 (1.5%)	1 (1.6%)	6 (1.1%)	9 (1.3%)
	Normal	Low	1 (0.8%)	0	0	1 (1.6%)	0	0	0	0	1 (1.6%)	2 (0.4%)	3 (0.4%)
		Normal	122 (93.1%)	119 (96.7%)	63 (100.0%)	61 (95.3%)	61 (96.8%)	61 (93.8%)	57 (91.9%)	64 (94.1%)	59 (93.7%)	545 (95.4%)	667 (95.0%)
		High	2 (1.5%)	0	0	0	0	1 (1.5%)	0	0	0	1 (0.2%)	3 (0.4%)
	High	Normal	1 (0.8%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
		High	1 (0.8%)	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	2 (0.3%)
Week 16	m		128	123	62	64	63	64	62	69	63	570	698
	Low	Low	1 (0.8%)	4 (3.3%)	0	2 (3.1%)	2 (3.2%)	1 (1.6%)	2 (3.2%)	2 (2.9%)	1 (1.6%)	14 (2.5%)	15 (2.1%)
		Normal	3 (2.3%)	0	0	0	0	2 (3.1%)	3 (4.8%)	2 (2.9%)	1 (1.6%)	8 (1.4%)	11 (1.6%)
	Normal	Low	3 (2.3%)	0	0	1 (1.6%)	0	0	0	0	2 (3.2%)	3 (0.5%)	6 (0.9%)
		Normal	119 (93.0%)	119 (96.7%)	61 (98.4%)	61 (95.3%)	61 (96.8%)	61 (95.3%)	57 (91.9%)	65 (94.2%)	58 (92.1%)	543 (95.3%)	662 (94.8%)
		High	0	0	1 (1.6%)	0	0	0	0	0	0	1 (0.2%)	1 (0.1%)
	High	High	2 (1.6%)	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	3 (0.4%)
Week 20	m		130	123	62	63	63	65	60	69	63	568	698
	Low	Low	1 (0.8%)	4 (3.3%)	0	2 (3.2%)	1 (1.6%)	2 (3.1%)	3 (5.0%)	1 (1.4%)	2 (3.2%)	15 (2.6%)	16 (2.3%)
		Normal	3 (2.3%)	0	0	0	1 (1.6%)	1 (1.5%)	2 (3.3%)	3 (4.3%)	0	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
	Normal	Low	2 (1.5%)	0	0	1 (1.6%)	0	0	1 (1.7%)	1 (1.4%)	0	3 (0.5%)	5 (0.7%)
		Normal	121 (93.1%)	119 (96.7%)	62 (100.0%)	60 (95.2%)	61 (96.8%)	61 (93.8%)	54 (90.0%)	64 (92.8%)	60 (95.2%)	541 (95.2%)	662 (94.8%)
		High	1 (0.8%)	0	0	0	0	1 (1.5%)	0	0	0	1 (0.2%)	2 (0.3%)
	High	Normal	2 (1.5%)	0	0	0	0	0	0	0	0	0	2 (0.3%)
		High	0	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	1 (0.1%)
Week 24	m		130	122	62	63	63	64	61	69	63	567	697
	Low	Low	1 (0.8%)	3 (2.5%)	0	2 (3.2%)	1 (1.6%)	2 (3.1%)	3 (4.9%)	2 (2.9%)	2 (3.2%)	15 (2.6%)	16 (2.3%)
		Normal	3 (2.3%)	1 (0.8%)	0	0	1 (1.6%)	1 (1.6%)	2 (3.3%)	2 (2.9%)	0	7 (1.2%)	10 (1.4%)
	Normal	Low	1 (0.8%)	0	0	2 (3.2%)	0	1 (1.6%)	0	0	2 (3.2%)	5 (0.9%)	6 (0.9%)
		Normal	123 (94.6%)	118 (96.7%)	61 (98.4%)	59 (93.7%)	59 (93.7%)	60 (93.8%)	56 (91.8%)	65 (94.2%)	58 (92.1%)	536 (94.5%)	659 (94.5%)
		High	0	0	1 (1.6%)	0	2 (3.2%)	0	0	0	0	3 (0.5%)	3 (0.4%)
	High	Normal	2 (1.5%)	0	0	0	0	0	0	0	0	0	2 (0.3%)
		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	61	65	60	69	63	560	688
	Low	Low	1 (0.8%)	2 (1.7%)	0	1 (1.7%)	0	1 (1.5%)	3 (5.0%)	3 (4.3%)	2 (3.2%)	12 (2.1%)	13 (1.9%)
		Normal	3 (2.3%)	2 (1.7%)	0	0	2 (3.3%)	2 (3.1%)	2 (3.3%)	1 (1.4%)	0	9 (1.6%)	12 (1.7%)
	Normal	Low	1 (0.8%)	1 (0.8%)	0	1 (1.7%)	0	0	0	0	0	2 (0.4%)	3 (0.4%)
		Normal	121 (94.5%)	114 (95.0%)	62 (100.0%)	58 (96.7%)	58 (95.1%)	62 (95.4%)	54 (90.0%)	65 (94.2%)	59 (93.7%)	532 (95.0%)	653 (94.9%)
		High	0	1 (0.8%)	0	0	1 (1.6%)	0	1 (1.7%)	0	1 (1.6%)	4 (0.7%)	4 (0.6%)
	High	Normal	1 (0.8%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
		High	1 (0.8%)	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	2 (0.3%)
Week 40	m		128	120	60	59	61	65	60	68	63	556	684
	Low	Low	0	2 (1.7%)	0	1 (1.7%)	0	1 (1.5%)	2 (3.3%)	3 (4.4%)	1 (1.6%)	10 (1.8%)	10 (1.5%)
		Normal	4 (3.1%)	2 (1.7%)	0	0	2 (3.3%)	2 (3.1%)	3 (5.0%)	1 (1.5%)	1 (1.6%)	11 (2.0%)	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	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	121 (94.5%)	114 (95.0%)	59 (98.3%)	57 (96.6%)	58 (95.1%)	61 (93.8%)	55 (91.7%)	64 (94.1%)	60 (95.2%)	528 (95.0%)	649 (94.9%)
		High	0	1 (0.8%)	1 (1.7%)	0	1 (1.6%)	0	0	0	0	3 (0.5%)	3 (0.4%)
	High	High	2 (1.6%)	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	3 (0.4%)
Week 48	m		127	118	60	59	61	65	60	66	63	552	679
	Low	Low	1 (0.8%)	3 (2.5%)	0	1 (1.7%)	0	2 (3.1%)	2 (3.3%)	2 (3.0%)	1 (1.6%)	11 (2.0%)	12 (1.8%)
		Normal	3 (2.4%)	1 (0.8%)	0	0	2 (3.3%)	1 (1.5%)	3 (5.0%)	2 (3.0%)	1 (1.6%)	10 (1.8%)	13 (1.9%)
	Normal	Low	1 (0.8%)	0	0	1 (1.7%)	0	0	0	0	1 (1.6%)	2 (0.4%)	3 (0.4%)
		Normal	116 (91.3%)	114 (96.6%)	58 (96.7%)	56 (94.9%)	58 (95.1%)	62 (95.4%)	55 (91.7%)	62 (93.9%)	59 (93.7%)	524 (94.9%)	640 (94.3%)
		High	4 (3.1%)	0	2 (3.3%)	1 (1.7%)	1 (1.6%)	0	0	0	0	4 (0.7%)	8 (1.2%)
	High	High	2 (1.6%)	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	3 (0.4%)
Week 52	m		126	116	59	58	61	65	60	67	62	548	674
	Low	Low	1 (0.8%)	1 (0.9%)	0	1 (1.7%)	0	1 (1.5%)	2 (3.3%)	1 (1.5%)	2 (3.2%)	8 (1.5%)	9 (1.3%)
		Normal	3 (2.4%)	3 (2.6%)	0	0	2 (3.3%)	2 (3.1%)	3 (5.0%)	3 (4.5%)	0	13 (2.4%)	16 (2.4%)
	Normal	Low	1 (0.8%)	0	0	1 (1.7%)	0	0	0	1 (1.5%)	0	2 (0.4%)	3 (0.4%)
		Normal	117 (92.9%)	112 (96.6%)	59 (100.0%)	55 (94.8%)	59 (96.7%)	62 (95.4%)	55 (91.7%)	62 (92.5%)	59 (95.2%)	523 (95.4%)	640 (95.0%)
		High	2 (1.6%)	0	0	1 (1.7%)	0	0	0	0	0	1 (0.2%)	3 (0.4%)
	High	Normal	1 (0.8%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
		High	1 (0.8%)	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	2 (0.3%)
LOCF Endpoint	m		134	127	64	64	63	65	63	70	63	579	713
	Low	Low	1 (0.7%)	1 (0.8%)	0	2 (3.1%)	0	1 (1.5%)	2 (3.2%)	1 (1.4%)	2 (3.2%)	9 (1.6%)	10 (1.4%)
		Normal	3 (2.2%)	3 (2.4%)	0	0	2 (3.2%)	2 (3.1%)	3 (4.8%)	3 (4.3%)	0	13 (2.2%)	16 (2.2%)
	Normal	Low	1 (0.7%)	0	0	1 (1.6%)	0	0	0	1 (1.4%)	0	2 (0.3%)	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 (93.3%)	122 (96.1%)	64 (100.0%)	60 (93.8%)	61 (96.8%)	62 (95.4%)	58 (92.1%)	65 (92.9%)	60 (95.2%)	552 (95.3%)	677 (95.0%)
		High	2 (1.5%)	1 (0.8%)	0	1 (1.6%)	0	0	0	0	0	2 (0.3%)	4 (0.6%)
	High	Normal	1 (0.7%)	0	0	0	0	0	0	0	0	0	1 (0.1%)
		High	1 (0.7%)	0	0	0	0	0	0	0	1 (1.6%)	1 (0.2%)	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.

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