Treatment-Emergent Adverse Events: By Treatment and Body System
Short-Term Double-Blind Phase (Day 1-28)
Safety Population

Body System/ Preferred Term	Ilo (N=300) GG (N=227)	Ilo (N=300) NON-GG GA (N=62)	Ilo (N=300) NON-GG AA (N=7)	Ilo (N=300) NON-GG COMBINED (N=69)	Pbo (N=147) GG (N=118)	Pbo (N=147) NON-GG GA (N=21)	Pbo (N=147) NON-GG AA (N=6)	Pbo (N=147) NON-GG COMBINED (N=27)
Total Number of TEAEs	751	202	22	224	273	51	10	61
Patients With at Least One TEAE	191 (84.1%)	53 (85.5%)	7 (100.0%)	60 (87.0%)	88 (74.6%)	15 (71.4%)	4 (66.7%)	19 (70.4%)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	1 (0.4%)	1 (1.6%)	0	1 (1.4%)	0	0	0	0
ANAEMIA	1 (0.4%)	0	0	0	0	0	0	0
MICROCYTIC ANAEMIA	0	1 (1.6%)	0	1 (1.4%)	0	0	0	0
CARDIAC DISORDERS	33 (14.5%)	4 (6.5%)	2 (28.6%)	6 (8.7%)	5 (4.2%)	0	0	0
TACHYCARDIA	24 (10.6%)	3 (4.8%)	1 (14.3%)	4 (5.8%)	1 (0.8%)	0	0	0
PALPITATIONS	4 (1.8%)	0	0	0	1 (0.8%)	0	0	0
SINUS TACHYCARDIA	3 (1.3%)	1 (1.6%)	0	1 (1.4%)	0	0	0	0
ATRIOVENTRICULAR BLOCK FIRST DEGREE	1 (0.4%)	0	0	0	0	0	0	0
BRADYCARDIA	1 (0.4%)	0	1 (14.3%)	1 (1.4%)	2 (1.7%)	0	0	0
VENTRICULAR EXTRASYSTOLES	1 (0.4%)	0	0	0	0	0	0	0
MYOCARDIAL INFARCTION	0	0	0	0	1 (0.8%)	0	0	0
EAR AND LABYRINTH DISORDERS	6 (2.6%)	0	0	0	2 (1.7%)	0	0	0
EAR PAIN	2 (0.9%)	0	0	0	1 (0.8%)	0	0	0
TINNITUS	2 (0.9%)	0	0	0	0	0	0	0
VERTIGO	2 (0.9%)	0	0	0	0	0	0	0
EAR CONGESTION	0	0	0	0	1 (0.8%)	0	0	0
EYE DISORDERS	12 (5.3%)	4 (6.5%)	1 (14.3%)	5 (7.2%)	5 (4.2%)	1 (4.8%)	0	1 (3.7%)
VISION BLURRED	3 (1.3%)	0	0	0	2 (1.7%)	1 (4.8%)	0	1 (3.7%)
BLEPHARITIS	2 (0.9%)	1 (1.6%)	0	1 (1.4%)	0	0	0	0
CONJUNCTIVITIS	2 (0.9%)	1 (1.6%)	0	1 (1.4%)	1 (0.8%)	0	0	0

Notes:

TEAE: Treatment-Emergent Adverse Events
Adverse Events are coded using the MedDRA dictionary (Version 8.1).
Patients experiencing the same Adverse Event multiple times are only counted once for the corresponding Preferred Term. Similarly, patients experiencing multiple adverse events within the same System Organ Class are counted only once for that same System Organ Class.
Adverse Events are sorted alphabetically by System Organ Class and within each System Organ Class the Preferred Term is presented by decreasing order of total frequency.
Percentages are based on the total number of patients in the Safety Population within each treatment group.
Adverse events for patients where genotype information could not be determined or were not collected are not represented in tabulations.

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BLEPHAROSPASM	1 (0.4%)	0	0	0	0	0	0	0
CONJUNCTIVITIS ALLERGIC	1 (0.4%)	0	0	0	0	0	0	0
DRY EYE	1 (0.4%)	2 (3.2%)	0	2 (2.9%)	0	0	0	0
EYELID SENSORY DISORDER	1 (0.4%)	0	0	0	0	0	0	0
SCOTOMA	1 (0.4%)	0	0	0	0	0	0	0
DIPLOPIA	0	0	1 (14.3%)	1 (1.4%)	0	0	0	0
EYE PAIN	0	0	0	0	1 (0.8%)	0	0	0
EYE PRURITUS	0	0	0	0	1 (0.8%)	0	0	0
GASTROINTESTINAL DISORDERS	95 (41.9%)	20 (32.3%)	3 (42.9%)	23 (33.3%)	44 (37.3%)	8 (38.1%)	1 (16.7%)	9 (33.3%)
NAUSEA	23 (10.1%)	6 (9.7%)	0	6 (8.7%)	11 (9.3%)	2 (9.5%)	0	2 (7.4%)
DRY MOUTH	21 (9.3%)	4 (6.5%)	1 (14.3%)	5 (7.2%)	1 (0.8%)	0	0	0
DYSPEPSIA	21 (9.3%)	2 (3.2%)	1 (14.3%)	3 (4.3%)	14 (11.9%)	1 (4.8%)	0	1 (3.7%)
CONSTIPATION	18 (7.9%)	7 (11.3%)	1 (14.3%)	8 (11.6%)	10 (8.5%)	4 (19.0%)	0	4 (14.8%)
VOMITING	16 (7.0%)	1 (1.6%)	0	1 (1.4%)	7 (5.9%)	3 (14.3%)	0	3 (11.1%)
DIARRHOEA	15 (6.6%)	5 (8.1%)	0	5 (7.2%)	10 (8.5%)	0	0	0
TOOTHACHE	12 (5.3%)	2 (3.2%)	0	2 (2.9%)	8 (6.8%)	0	0	0
ABDOMINAL DISCOMFORT	7 (3.1%)	1 (1.6%)	1 (14.3%)	2 (2.9%)	1 (0.8%)	0	0	0
STOMACH DISCOMFORT	7 (3.1%)	4 (6.5%)	0	4 (5.8%)	8 (6.8%)	0	0	0
ABDOMINAL PAIN	2 (0.9%)	1 (1.6%)	1 (14.3%)	2 (2.9%)	3 (2.5%)	0	0	0
GASTRITIS	2 (0.9%)	1 (1.6%)	0	1 (1.4%)	0	0	0	0
HYPOAESTHESIA ORAL	2 (0.9%)	0	0	0	0	0	0	0
ABDOMINAL DISTENSION	1 (0.4%)	1 (1.6%)	0	1 (1.4%)	1 (0.8%)	0	0	0

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