

Table S2. Treatment-emergent Adverse Events During the Study (PK portion and extended-use phase)

System Organ Class Preferred Term	CYP3A5 Expressor (N=35)				CYP3A5 Non-Expressor (N=11)			
	LCPT		IR-Tac		LCPT		IR-Tac	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Subjects with >=1 TEAE	17 (48.6)	49	17 (48.6)	86	10 (90.9)	34	5 (45.5)	19
Blood and lymphatic system disorders	0	0	1 (2.9)	1	0	0	1 (9.1)	1
Anemia	0	0	1 (2.9)	1	0	0	1 (9.1)	1
Cardiac disorders	0	0	1 (2.9)	1	0	0	0	0
Cardiac failure acute	0	0	1 (2.9)	1	0	0	0	0
Eye disorders	0	0	2 (5.7)	2	0	0	0	0
Glaucoma	0	0	1 (2.9)	1	0	0	0	0
Uveitis	0	0	1 (2.9)	1	0	0	0	0
Abdominal pain upper	1 (2.9)	1	0	0	0	0	0	0
Abdominal tenderness	0	0	1 (2.9)	1	0	0	0	0
Gastrointestinal disorders	4 (11.4)	6	7 (20.0)	10	3 (27.3)	4	1 (9.1)	1
Constipation	0	0	3 (8.6)	3	0	0	0	0
Diarrhea	2 (5.7)	2	3 (8.6)	3	1 (9.1)	1	0	0
Dyspepsia	0	0	0	0	1 (9.1)	1	0	0
Nausea	2 (5.7)	2	2 (5.7)	2	1 (9.1)	1	1 (9.1)	1
Vomiting	1 (2.9)	1	1 (2.9)	1	1 (9.1)	1	0	0
General disorders and administration site conditions	3 (8.6)	3	4 (11.4)	4	1 (9.1)	1	2 (18.2)	3
Chest pain	0	0	1 (2.9)	1	1 (9.1)	1	1 (9.1)	2
Fatigue	1 (2.9)	1	1 (2.9)	1	0	0	1 (9.1)	1
Local swelling	0	0	1 (2.9)	1	0	0	0	0
Malaise	1 (2.9)	1	0	0	0	0	0	0
Edema peripheral	1 (2.9)	1	1 (2.9)	1	0	0	0	0
Immune system disorders	1 (2.9)	1	0	0	0	0	0	0
Seasonal allergy	1 (2.9)	1	0	0	0	0	0	0
Infections and infestations	6 (17.1)	8	9 (25.7)	10	2 (18.2)	4	4 (36.4)	4
BK virus infection	0	0	1 (2.9)	1	0	0	0	0
Bronchitis	1 (2.9)	1	0	0	0	0	0	0
Cellulitis	0	0	1 (2.9)	1	1 (9.1)	1	0	0
Corona virus infection	0	0	1 (2.9)	1	0	0	0	0
Gastroenteritis	0	0	0	0	1 (9.1)	1	0	0
Gastroenteritis viral	0	0	1 (2.9)	1	0	0	0	0
Influenza	1 (2.9)	1	1 (2.9)	1	0	0	0	0
Nasopharyngitis	2 (5.7)	2	2 (5.7)	2	1 (9.1)	1	3 (27.3)	3
Oral herpes	0	0	0	0	0	0	1 (9.1)	1
Otitis media	1 (2.9)	1	0	0	0	0	0	0
Pneumonia	1 (2.9)	1	1 (2.9)	1	0	0	0	0
Upper respiratory tract infection	1 (2.9)	1	1 (2.9)	1	0	0	0	0
Urinary tract infection	1 (2.9)	1	1 (2.9)	1	1 (9.1)	1	0	0
Injury, poisoning and procedural complications	1 (2.9)	1	2 (5.7)	5	0	0	1 (9.1)	1
Fall	0	0	2 (5.7)	3	0	0	0	0
Ligament sprain	0	0	1 (2.9)	1	0	0	0	0
Medication error	1 (2.9)	1	0	0	0	0	0	0

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	LCPT		IR-Tac		LCPT		IR-Tac	
	n (%)	Event s	n (%)	Event s	n (%)	Event s	n (%)	Event s
Muscle strain	0	0	0	0	0	0	1 (9.1)	1
Wound	0	0	1 (2.9)	1	0	0	0	0
Investigations	7 (20.0)	10	4 (11.4)	5	5 (45.5)	12	1 (9.1)	1
Blood creatinine increased	4 (11.4)	4	3 (8.6)	3	3 (27.3)	4	1 (9.1)	1
Blood glucose increased	1 (2.9)	1	0	0	0	0	0	0
Glomerular filtration rate decreased	2 (5.7)	2	1 (2.9)	1	3 (27.3)	3	0	0
Glucose urine present	1 (2.9)	1	0	0	0	0	0	0
Liver function test abnormal	1 (2.9)	1	0	0	1 (9.1)	1	0	0
Transaminases increased	0	0	1 (2.9)	1	0	0	0	0
Urine calcium	0	0	0	0	1 (9.1)	1	0	0
Urine leukocyte esterase positive	0	0	0	0	1 (9.1)	1	0	0
White blood cell count decreased	0	0	0	0	1 (9.1)	1	0	0
White blood cell count increased	1 (2.9)	1	0	0	0	0	0	0
White blood cells urine positive	0	0	0	0	1 (9.1)	1	0	0
							2	
Metabolism and nutrition disorders	4 (11.4)	4	6 (17.1)	10	4 (36.4)	7	(18.2)	2
Decreased appetite	1 (2.9)	1	0	0	0	0	1 (9.1)	1
Dehydration	0	0	2 (5.7)	2	0	0	0	0
Diabetes mellitus	1 (2.9)	1	0	0	0	0	0	0
Hyperglycemia	0	0	1 (2.9)	3	1 (9.1)	2	0	0
Hyperkalemia	2 (5.7)	2	0	0	0	0	0	0
Hypoglycemia	0	0	1 (2.9)	1	2 (18.2)	3	0	0
Hypokalemia	0	0	0	0	2 (18.2)	2	0	0
Hypomagnesemia	0	0	2 (5.7)	2	0	0	1 (9.1)	1
Hyponatremia	0	0	1 (2.9)	1	0	0	0	0
Vitamin D deficiency	0	0	1 (2.9)	1	0	0	0	0
Musculoskeletal and connective tissue disorders	2 (5.7)	2	6 (17.1)	8	1 (9.1)	1	0	0
Arthralgia	0	0	2 (5.7)	2	0	0	0	0
Arthritis	1 (2.9)	1	0	0	0	0	0	0
Back pain	0	0	2 (5.7)	2	1 (9.1)	1	0	0
Flank pain	1 (2.9)	1	0	0	0	0	0	0
Neck pain	0	0	1 (2.9)	1	0	0	0	0
Pain in extremity	0	0	3 (8.6)	3	0	0	0	0
Nervous system disorders	1 (2.9)	1	4 (11.4)	6	1 (9.1)	2	1 (9.1)	1
Dizziness	0	0	1 (2.9)	1	1 (9.1)	2	0	0
Headache	0	0	2 (5.7)	2	0	0	1 (9.1)	1
Sciatica	0	0	1 (2.9)	1	0	0	0	0
Sinus headache	0	0	1 (2.9)	1	0	0	0	0
Tremor	1 (2.9)	1	1 (2.9)	1	0	0	0	0
Psychiatric disorders	1 (2.9)	1	4 (11.4)	4	0	0	0	0
Depression	0	0	1 (2.9)	1	0	0	0	0
Insomnia	1 (2.9)	1	1 (2.9)	1	0	0	0	0
Panic attack	0	0	1 (2.9)	1	0	0	0	0
Suicide attempt	0	0	1 (2.9)	1	0	0	0	0
Renal and urinary disorders	0	0	3 (8.6)	7	1 (9.1)	1	1 (9.1)	1
Dysuria	0	0	1 (2.9)	1	0	0	0	0

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	LCPT		IR-Tac		LCPT		IR-Tac	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Glycosuria	0	0	1 (2.9)	1	0	0	0	0
Hematuria	0	0	1 (2.9)	1	0	0	0	0
Pollakiuria	0	0	1 (2.9)	1	0	0	0	0
Proteinuria	0	0	1 (2.9)	1	0	0	1 (9.1)	1
Renal failure acute	0	0	1 (2.9)	1	1 (9.1)	1	0	0
Urinary incontinence	0	0	1 (2.9)	1	0	0	0	0
Reproductive system and breast disorders	0	0	1 (2.9)	2	0	0	0	0
Cervical polyp	0	0	1 (2.9)	1	0	0	0	0
Vaginal discharge	0	0	1 (2.9)	1	0	0	0	0
Respiratory, thoracic and mediastinal disorders	3 (8.6)	6	2 (5.7)	4	0	0	(27.3)	3
Cough	2 (5.7)	2	1 (2.9)	2	0	0	0	0
Dyspnea	1 (2.9)	1	0	0	0	0	0	0
Dyspnea exertional	0	0	1 (2.9)	1	0	0	0	0
Epistaxis	0	0	0	0	0	0	1 (9.1)	1
Hypoxia	1 (2.9)	1	0	0	0	0	0	0
Oropharyngeal pain	0	0	1 (2.9)	1	0	0	1 (9.1)	1
Sinus congestion	1 (2.9)	1	0	0	0	0	0	0
Sneezing	1 (2.9)	1	0	0	0	0	0	0
Throat irritation	0	0	0	0	0	0	1 (9.1)	1
Acne	0	0	1 (2.9)	1	0	0	0	0
Skin and subcutaneous tissue disorders	4 (11.4)	4	3 (8.6)	3	2 (18.2)	2	0	0
Alopecia	1 (2.9)	1	0	0	1 (9.1)	1	0	0
Blister	0	0	1 (2.9)	1	0	0	0	0
Nail discoloration	1 (2.9)	1	0	0	0	0	0	0
Papule	1 (2.9)	1	0	0	0	0	0	0
Rash	1 (2.9)	1	0	0	1 (9.1)	1	0	0
Skin irritation	0	0	1 (2.9)	1	0	0	0	0
Acrochordon excision	0	0	1 (2.9)	1	0	0	0	0
Surgical and medical procedures	1 (2.9)	1	2 (5.7)	2	0	0	0	0
Cataract operation	0	0	1 (2.9)	1	0	0	0	0
Tooth extraction	1 (2.9)	1	0	0	0	0	0	0
Vascular disorders	1 (2.9)	1	2 (5.7)	2	0	0	1 (9.1)	1
Deep vein thrombosis	0	0	0	0	0	0	1 (9.1)	1
Hypertension	1 (2.9)	1	0	0	0	0	0	0
Hypotension	0	0	2 (5.7)	2	0	0	0	0