Table S4. TEAEs related to hostility and/or aggression (Safety Analysis Set).

	CORE STUDY		
	Cohort 1	**Cohort 2**	
	≥7 to <12 years	**≥2 to <7 years**	**Total**
	(n = 28)	**(n = 22)**	**(N = 50)**
Any TEAE related to hostility/aggression, n (%)	**9 (32.1)**	**9 (40.9)**	**18 (36.0)**
Irritability	5 (17.9)	3 (13.6)	8 (16.0)
Aggression	1 (3.6)	3 (13.6)	4 (8.0)
Abnormal behavior	2 (7.1)	1 (4.5)	3 (6.0)
Oppositional defiant disorder	1 (3.6)	2 (9.1)	3 (6.0)
Agitation	1 (3.6)	1 (4.5)	2 (4.0)
Psychomotor hyperactivity	2 (7.1)	0 (0.0)	2 (4.0)
Anger	1 (3.6)	0 (0.0)	1 (2.0)
Laceration	0 (0.0)	1 (4.5)	1 (2.0)

	EXTENSION		
	Cohort 1	**Cohort 2**	
	≥7 to <12 years	**≥2 to <7 years**	**Total**
	(n = 22)	**(n = 19)**	**(N = 41)**

Any TEAE related to hostility/aggression, n (%)	**8 (36.4)**	**9 (47.4)**	**17 (41.5)**
Irritability	5 (22.7)	3 (15.8)	8 (19.5)
Aggression	2 (9.1)	5 (26.3)	7 (17.1)
Oppositional defiant disorder	1 (4.5)	2 (10.5)	3 (7.3)
Abnormal behavior	1 (4.5)	1 (5.3)	2 (4.9)
Agitation	0 (0.0)	1 (5.3)	1 (2.4)
Anger	1 (4.5)	0 (0.0)	1 (2.4)
Laceration	0 (0.0)	1 (5.3)	1 (2.4)
Psychomotor hyperactivity	1 (4.5)	0 (0.0)	1 (2.4)

Both narrow and broad MedDRA SMQ terms were used.

A TEAE was defined as an adverse event with an onset date, or a worsening in severity from baseline, on or after the first dose of study drug up to 30 days following study drug discontinuation.

Patients with two or more adverse events in the same system organ class, or with the same preferred term, were counted only once for that system organ class, or preferred term.

MedDRA: Medical Dictionary for Regulatory Activities; SMQ: Standardized MedDRA Query; TEAE: treatment-emergent adverse event.