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O0109 A prospective, open-label study to assess the safety and efficacy of anidulafungin in children with invasive candidiasis, including candidaemia

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Background: *Candida spp.* are a notable cause of nosocomial infection and associated with increased mortality in paediatric patients. An open-label, non-comparative, international study (NCT00761267) evaluated safety and efficacy of anidulafungin for the treatment of IC in patients aged 1 month-<18 years. Results for patients aged 2-<18 years have been reported previously (Roilides E, et al. *Pediatr Infect Dis J* 2018, [Epub ahead of print]). We present results from the complete study, including patients aged 1 month-<2 years.

Materials/methods: Eligible patients aged 1 month-<18 years (including patients 1 month-<2 years at high risk of IC) received intravenous (IV) anidulafungin for 5-35 days (3 mg/kg Day 1, 1.5 mg/kg daily thereafter) followed by optional switch to oral fluconazole (6-12 mg/kg/day, maximum 800 mg/day). Safety (primary objective) was assessed through Week 6 follow-up. Efficacy, measured by global clinical and microbiological response, was assessed at end of IV therapy (EOIVT); end of treatment; and Weeks 2 and 6 follow-up.

Results: Sixty-eight patients received ≥1 dose of anidulafungin (median duration: 11 days; range: 1-35 days) and were assessed for safety. Nineteen patients were aged 1 month-<2 years; the overall mean age was 5.8 years. Sixty-six patients (97.1%) reported all-causality treatment-emergent adverse events (TEAEs). Vomiting (23.5%), diarrhoea (22.1%) and pyrexia (19.1%) were the most common TEAEs overall (Table); anaemia (26.3%) was the most common TEAE in patients aged 1 month-<2 years. Seven patients discontinued due to TEAEs, 5 (71.4%) discontinuations were considered anidulafungin-related (1 in the 1 month-<2 years group). Sixty-four patients had microbiologically confirmed IC and were evaluated for efficacy. The most common baseline pathogens were *Candida albicans* (25 [39.1%]), *C. parapsilosis* (17 [26.6%]) and *C. tropicalis* (9 [14.1%]). At EOIVT, global response success rate was 70.3% (45/64) overall (1 month-<2 years, 68.8% [11/16]; 2-<5 years, 77.8% [14/18]; 5-<18 years, 66.7% [20/30]). All-cause mortality was 12.5% (8/64) overall, and 6.3% (1/16) in patients aged 1 month-<2 years; no deaths were considered treatment-related.

Conclusions: Anidulafungin was well tolerated and efficacious at studied dose in IC paediatric patients, with findings comparable to the known drug profile.

Table. Summary of TEAEs (safety population)

n, %	**1 month-<2 years (N=19)**	**2-<5 years (N=19)**	**5-<18 years (N=30)**	**Overall (N=68)**
All-causality TEAEs	17 (89.5)	19 (100)	30 (100)	66 (97.1)
Treatment-related TEAEs	3 (15.8)	4 (21.1)	14 (46.7)	21 (30.9)
SAEs	7 (36.8)	10 (52.6)	13 (43.3)	30 (44.1)
Severe TEAEs	7 (36.8)	8 (42.1)	13 (43.3)	28 (41.2)
Discontinued due to TEAEs	2 (10.5)	2 (10.5)	3 (10.0)	7 (10.3)
Most common TEAEs (≥20% in any age sub-group)				
Vomiting	4 (21.1)	7 (36.8)	5 (16.7)	16 (23.5)
Diarrhoea	4 (21.1)	2 (10.5)	9 (30.0)	15 (22.1)
Pyrexia	4 (21.1)	3 (15.8)	6 (20.0)	13 (19.1)
Anaemia	5 (26.3)	3 (15.8)	1 (3.3)	9 (13.2)
Headache	0	1 (5.3)	6 (20.0)	7 (10.3)

N, number of patients in each treatment group; n, number of patients with TEAEs;
TEAE, treatment-emergent adverse event; SAE, serious adverse event.