Safety and efficacy of anidulafungin in the treatment of invasive candidiasis in children

Emmanuel Roolides,1 Fabienne Carlès,2 Heidi Leister-Tebbe,3 Humberto Conte,4 Jean Li Yan,5 Ping Liu,5 Margaret Tawadrous,5 Jalal A. Aram,5 Flavio Queiroz-Telles5

Infectious Diseases Unit, 3rd Department of Pediatrics, Faculty of Medicine, Aristotle University School of Health Sciences, Hippokration General Hospital, Thessaloniki, Greece; 1Institute of Pediatric Oncology (GRAIAC), Universidade Federal de São Paulo (UNIFESP), São Paulo, Brazil; 2Pizer Inc., New York, NY, USA; 3Pizer Inc., Beijing, China; 4Department of Public Health, Universidade Federal do Paraná, Hospital de Clínicas, Curitiba, Paraná, Brazil

Safety

Safety and efficacy of anidulafungin in the treatment of invasive candidiasis in children

INTRODUCTION

- Patients at high risk to invade candidiasis, including candidemia (ECC) have aspects that are similar. However, studies have identified differences in Candida species distribution across age groups and different patient populations
- ECC (European Society of Antimicrobial and Echinocandins (ESAT) and the ESCMID (European Society for Clinical Microbiology and Infectious Diseases) consensus of their management) of the treatment of Candida species (C. albicans, C. krusei, C. tropicalis, C. glabrata, C. parapsilosis, C. albicans, C. albicans)] in children aged 0–17 years) were recorded. Includes data up to 30 days after last dose of study drug
- The incidence of AEs of all causalities (affecting at least 5% of safety population) is shown in Table 2.

RESULTS

Demographic and baseline characteristics

- In total, 20 patients were assessed for safety, Table 3, with no record response rate for the week 6 follow-up. There were no relapses or new infections reported at the Week 2 follow-up examination.
- Global response success rates according to the site of infection and baseline pathogen are shown in Table 5.

Efficacy

- Overall, 22 patients (45.8%) reported serious AEs (SAEs), n = 13 (66.7%) in the 5–17 years age group and 18 (60.0%) in the 0–17 years age group
- A proposed IV dosing regimen (3.0/1.5 mg/kg every 24 hours) is considered to be ANID of 11.5 days (range: 1–28 days) in the 2–5 years age group
- The primary endpoint was safety and tolerability, assessed by monitoring
- There were no relapses or new infections reported at the Week 2 follow-up examination
- There were no relapses or new infections reported at the Week 2 follow-up examination
- The incidence of AEs of all causalities (affecting at least 5% of safety population) is shown in Table 2.

Persistence and efficacy of anidulafungin in the treatment of invasive candidiasis in children

Pharmacokinetics

- Aspartate aminotransferase increased 1 (5.6) 2 (6.7) 3 (6.3)
- Neutrophils ≥ 500/mm3 1/2 (50.0) 3/6 (50.0) 4/8 (50.0)
- Mean age, years (SD) 3.0 (0.7) 10.7 (3.7) 7.8 (4.7)
- Septic shock 1 (5.6) 2 (6.7) 3 (6.3)
- Overall, 22 patients (45.8%) reported serious AEs (SAEs), n = 13 (66.7%) in the 5–17 years age group and 18 (60.0%) in the 0–17 years age group
- A proposed IV dosing regimen (3.0/1.5 mg/kg every 24 hours) is considered to be ANID of 11.5 days (range: 1–28 days) in the 2–5 years age group

CONCLUSIONS

- All-cause mortality, n (%) 2 (11.1) 5 (16.7) 7 (14.6)
- The primary endpoint was safety and tolerability, assessed by monitoring
- There were no relapses or new infections reported at the Week 2 follow-up examination
- There were no relapses or new infections reported at the Week 2 follow-up examination
- There were no relapses or new infections reported at the Week 2 follow-up examination

ACKNOWLEDGMENTS

- The authors would like to thank all the investigators and patients and their families of all the participating centers for the collection of the above-mentioned data

REFERENCES

6. CONCLUSIONS

- All-cause mortality, n (%) 2 (11.1) 5 (16.7) 7 (14.6)
- The primary endpoint was safety and tolerability, assessed by monitoring
- There were no relapses or new infections reported at the Week 2 follow-up examination
- There were no relapses or new infections reported at the Week 2 follow-up examination
- There were no relapses or new infections reported at the Week 2 follow-up examination

ACKNOWLEDGMENTS

- The authors would like to thank all the investigators and patients and their families of all the participating centers for the collection of the above-mentioned data

REFERENCES

6. CONCLUSIONS

- All-cause mortality, n (%) 2 (11.1) 5 (16.7) 7 (14.6)
- The primary endpoint was safety and tolerability, assessed by monitoring
- There were no relapses or new infections reported at the Week 2 follow-up examination
- There were no relapses or new infections reported at the Week 2 follow-up examination
- There were no relapses or new infections reported at the Week 2 follow-up examination

ACKNOWLEDGMENTS

- The authors would like to thank all the investigators and patients and their families of all the participating centers for the collection of the above-mentioned data

REFERENCES

6. CONCLUSIONS

- All-cause mortality, n (%) 2 (11.1) 5 (16.7) 7 (14.6)
- The primary endpoint was safety and tolerability, assessed by monitoring
- There were no relapses or new infections reported at the Week 2 follow-up examination
- There were no relapses or new infections reported at the Week 2 follow-up examination
- There were no relapses or new infections reported at the Week 2 follow-up examination

ACKNOWLEDGMENTS

- The authors would like to thank all the investigators and patients and their families of all the participating centers for the collection of the above-mentioned data

REFERENCES