

New Research Reveals That Mycamine(R) is an Effective Treatment in Children, Young Babies and Premature Infants

Staines, England (ots/PRNewswire) -

- Not for distribution in the United Kingdom

- Research Adds to Already Demonstrated Efficacy in Adult Population

Parents and paediatricians are today welcoming the results of new research that adds additional support for an effective and well tolerated treatment for children with invasive candidiasis. The research, published today in the September edition of The Pediatric Infectious Disease Journal(i), demonstrates that Mycamine(R) (micafungin) delivers high success rates(*) (i) in the treatment of premature infants, babies up to four weeks old and children. The study also shows significantly less adverse events (i) leading to treatment discontinuation with Mycamine(R) compared to liposomal amphotericin B therapy.

The research is the largest comparative assessment of therapies for treatment of invasive candidiasis and candidemia in paediatric patients to date and demonstrates that Mycamine(R) is a new treatment option for paediatric patients with life-threatening Candida infections. This is particularly important given the increasing prevalence of invasive candidiasis in premature babies and seriously ill children, with reported mortality rates in these groups of around 25%, rising to around 37% in more difficult to treat types of Candida(ii), (iii). Historically, there has been a lack of substantive paediatric data about antifungal therapies on which to base treatment selection (iii).

Dr Antonio Arrieta, Chief of the Division of Infectious Diseases at the Children's Hospital, California, said: "Systemic fungal infections are increasing in frequency as a consequence of the successful treatment of serious diseases such as cancer and prematurity. These children are often very fragile hosts with severely compromised immune systems and easy prey for infections with opportunistic microbes including fungus.

"It is then imperative that we continue to develop newer, safer therapeutic modalities to address these infections," he continued.

The new research demonstrates that Mycamine(R) had significantly fewer adverse events leading to treatment discontinuation compared to liposomal amphotericin B (3.8% versus 16.7%; $p = 0.05$) which suggests a safety advantage for Mycamine(R) in this population.

The research is a substudy of a trial in adults(iv) and was conducted by an international team of infectious disease experts at 27 sites across Europe, South and North America, South Africa, India and Thailand, in 109 paediatric patients. It contributes to the already substantial Mycamine(R) clinical development programme covering 3,500 patients, including 300 children.

Commenting on the results of the study, Dr Arrieta observed: "Large randomised double blind comparative trials like the one mentioned above are of critical importance to evaluate the safety and efficacy of new agents. Our data suggests that micafungin, a new antifungal agent, is as effective as currently available agents and it may have better safety."

*Clinical and mycological response at the end of therapy

Notes to Editors

Invasive candidiasis

Invasive candidiasis, with reported mortality rates ranging from 25% to 37% of paediatric patients, is a frequent cause of morbidity and mortality in high risk patients(ii, iii). Medical advances in the management of a wide range of conditions has been accompanied by an increase in the number of patients at risk of invasive candidiasis. These include solid organ or haematopoietic stem cell transplantation, improved management of patients with burns, cancers and of low weight infants, and increased numbers of patients with HIV infection or AIDS. Astellas seeks to satisfy unmet treatment needs beyond those afforded by existing therapies by providing treatment alternatives for invasive candidiasis.

Mycamine(R) (micafungin)

The indications for adults, adolescents greater than or equal to

16 years of age and the elderly are: treatment of invasive candidiasis; treatment of oesophageal candidiasis in patients for whom intravenous therapy is appropriate; prophylaxis of Candida infection in patients undergoing allogeneic haematopoietic stem cell transplantation or patients who are expected to have neutropenia (absolute neutrophil count < 500 cells/micro litre) for 10 or more days. For children (including neonates) and adolescents <16 years of age, Mycamine(R) is indicated for: treatment of invasive candidiasis; prophylaxis of Candida infection in patients undergoing allogeneic haematopoietic stem cell transplantation or patients who are expected to have neutropenia (absolute neutrophil count < 500 cells/micro litre) for 10 or more days.

Astellas Pharma Europe Ltd.

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i Queiroz-Telles F, Berezin E, Leverger G et al. Micafungin versus Liposomal Amphotericin B for Pediatric Patients with Invasive Candidiasis: Substudy of a Randomized Double-blind Trial. *The Pediatric Infect Dis J.* 1st August 2008 [publish ahead of print version].

ii Celebi S et al. Nosocomial candidaemia in children: results of a 9-year study. *Mycoses* 2008;51:248-257.

iii Almirante B and Rodriguez D. Antifungal agents in neonates. *Pediatr Drugs* 2007;9(5):311-321.

iv Kuse ER, Chetchotisakd P, da Cunha CA, et al. Micafungin versus liposomal amphotericin B for candidaemia and invasive candidiasis in a phase III, randomised double-blind trial. Lancet 2007;369:1519-1527.

Rückfragehinweis:

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