



Astellas Submits U.S. New Drug Application for Isavuconazole for the Treatment of Invasive Aspergillosis and Invasive Mucormycosis

NORTHBROOK, Ill., July 9, 2014 /PRNewswire/ --Astellas today announced it has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) seeking approval for isavuconazole for the treatment of invasive aspergillosis and invasive mucormycosis (also known as zygomycosis), life-threatening fungal infections predominantly occurring in immunocompromised patients.

"This NDA submission is a significant achievement for Astellas' Infectious Disease franchise and, if approved, isavuconazole will be another tool physicians will be able to use to combat these serious infections," said Bernie Zeiher, executive vice president, Global Development and therapeutic area head of Infectious Diseases at Astellas. "There is a growing need for new antifungal therapies like isavuconazole. Serious fungal infections are on the rise due to the increasing numbers of immunosuppressed patients such as those undergoing high-dose chemotherapy and/or hematopoietic stem-cell transplantation for leukemia."

In February, the FDA designated isavuconazole as a Qualified Infectious Disease Product (QIDP) for invasive mucormycosis. QIDP designation for the treatment of invasive aspergillosis was granted last year. QIDP status provides priority review and a five-year extension of market exclusivity in the United States. These incentives were granted under the 2012 U.S. Generating Antibiotic Incentives Now (GAIN) Act as a part of the FDA Safety and Innovation Act. Also, in 2013, isavuconazole was granted orphan drug status for invasive aspergillosis and invasive mucormycosis.

About Isavuconazole

Isavuconazole (drug substance: isavuconazonium sulfate) is an investigational once-daily intravenous and oral broad-spectrum antifungal being developed for the treatment of severe invasive and life-threatening fungal infections. Isavuconazole is the active moiety of the prodrug isavuconazonium sulfate. Information regarding isavuconazole ongoing clinical trials is available at clinicaltrials.gov.

Isavuconazole demonstrated *in-vitro* and *in-vivo* coverage of a broad range of yeasts (such as *Candida* species) and molds (such as *Aspergillus* species) as well as activity against emerging and often fatal molds including those that cause mucormycosis.

In the Phase 3 invasive aspergillosis study, isavuconazole demonstrated non-inferiority to voriconazole on the primary endpoint of all-cause mortality at day 42. The treatment-emergent adverse events for isavuconazole were statistically fewer relative to voriconazole in the System Organ Classes of hepatobiliary, skin and eye disorders. In both treatment groups, the most common treatment emergent adverse events were nausea, vomiting, pyrexia (fever) and diarrhea.

Isavuconazole is being co-developed with Basilea Pharmaceutica International Ltd.

About Astellas Infectious Disease

Astellas' commitment to the field of infectious diseases is an active one. We're expanding the knowledge base of this therapeutic area and empowering physicians to make evidence-based clinical decisions.

Our proud history of collaborating with investigators around the world provides ideal environments to study compounds that have the potential for significant breakthroughs and allows us to generate and publish key information on our advances. In fact, Astellas has performed some of the world's largest clinical trials in fungal infections.

About Astellas

Astellas is a pharmaceutical company dedicated to improving the health of people around the world through provision of innovative and reliable pharmaceuticals. For more information on Astellas, please visit our website at www.astellas.us.

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