NEWS RELEASE

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Astellas Announces FDA Anti-Infective Drugs Advisory Committee Recommends Approval of CRESEMBA® (isavuconazonium) for Treatment of Invasive Aspergillosis and Mucormycosis

NORTHBROOK, Ill., January 22, 2015, – Astellas today announced that the U.S. Food and Drug Administration's (FDA) Anti-infective Drugs Advisory Committee voted unanimously to recommend approval of the investigational once-daily intravenous and oral broad-spectrum CRESEMBA® (isavuconazonium) for the treatment of invasive aspergillosis, and 8 to 2 with one abstention to recommend approval for the treatment of invasive mucormycosis (also known as zygomycosis), life-threatening fungal infections predominantly occurring in immunocompromised patients.

"We're pleased with today's positive recommendation for the approval of CRESEMBA for both indications," said Bernie Zeiher, M.D., executive vice president, Global Development and therapeutic area head of Infectious Disease at Astellas. "We look forward to working with the FDA to bring this important new therapy to patients to address an unmet need in the treatment of these life threatening infections."

The Advisory Committee's recommendation is based on data from the CRESEMBA development program, which included analyses from two Phase 3 clinical trials in adult patients with invasive fungal infections: SECURE, a randomized, double-blind, active-control study of adult patients with invasive aspergillosis; and VITAL, an open-label non-comparative study of CRESEMBA in adult patients with invasive aspergillosis and renal impairment or in patients with invasive fungal disease caused by other rare fungi.

The Advisory Committee provides the FDA with independent expert advice and recommendations. The FDA is not bound by the committee's guidance, but its input will be considered by the Agency in its review of the CRESEMBA New Drug Application (NDA), which was submitted by Astellas on July 8, 2014. According to the timelines established by the Prescription Drug User Fee Act (PDUFA), the review of the NDA is expected to be complete by March 8, 2015.

CRESEMBA is being co-developed with Basilea Pharmaceutica International Ltd. Basilea submitted a European Marketing Authorization Application on July 16, 2014 for the treatment of invasive aspergillosis and mucormycosis in adults.

For additional information on the January 22, 2015 Advisory Committee meeting please visit http://www.fda.gov/AdvisoryCommittees/Calendar/ucm424436.htm.

About Invasive Aspergillosis
Invasive aspergillosis is a life-threatening fungal infection that is seen predominantly in immunocompromised patients, such as patients with leukemia. Invasive aspergillosis is known for high morbidity and mortality.

About Invasive Mucormycosis
Mucormycosis is a rapidly progressing and devastating invasive fungal infection. Invasive mucormycosis is also known for high morbidity and mortality.

About Astellas Infectious Disease
Astellas is committed to the field of infectious diseases. Astellas is expanding the knowledge base of this therapeutic area and empowering physicians to make evidence-based clinical decisions.

Astellas' proud history of collaborating with investigators around the world provides ideal environments to study compounds that have the potential for significant breakthroughs for patients. 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. Follow us on Twitter at www.twitter.com/AstellasUS.

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