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News Release

Astellas announces recruitment completion of phase 3 pivotal study of isavuconazole, an agent for the potential primary treatment of invasive and life-threatening fungal infections

Tokyo, December 14, 2012 – Astellas Pharma Inc. (Tokyo:4503) announced today that patient recruitment for the isavuconazole phase 3 registration study SECURE has been completed. Isavuconazole is an investigational intravenous (i.v.) and oral broad-spectrum antifungal being jointly developed by Basilea and Astellas.

The SECURE study is a global double-blind randomized phase 3 study, designed to evaluate the safety and efficacy of once-daily isavuconazole versus twice-daily voriconazole for up to 84 days of therapy in the primary treatment of invasive fungal disease caused by *Aspergillus* species or other filamentous fungi. Five hundred and twenty-seven (527) patients were enrolled in the study. Acute invasive fungal infections are serious, life-threatening diseases associated with high mortality. The primary endpoint of this non-inferiority study is all-cause mortality through day 42. Basilea and Astellas expect that results of this study will be available in the second half of 2013.

In addition, enrollment into the VITAL study, an open-label phase 3 study of isavuconazole in the treatment of aspergillosis patients with pre-existing renal impairment or patients with invasive fungal disease caused by rare but often fatal molds, yeasts or dimorphic fungi has achieved the targeted recruitment of 100 patients and will continue to recruit to further expand the data base on the use of isavuconazole in the treatment of the diverse rare mold infections. The ACTIVE study, a double-blind randomized phase 3 study evaluating the use of isavuconazole i.v. and oral versus caspofungin i.v. followed by oral voriconazole for the treatment of candidemia and other invasive *Candida* infections, will likely continue to recruit into 2014.

“Invasive aspergillosis and other rare mold infections are life-threatening diseases occurring primarily in immunocompromised patients. The antifungal spectrum as well as oral and IV pre-clinical and clinical data for isavuconazole support that isavuconazole may have the potential to overcome certain limitations of current treatment options. Together with our partner Basilea, we are pleased to have completed recruitment in the SECURE study, the largest invasive aspergillosis trial ever conducted,” said Bernie Zeiher, Immunology/Infectious Disease/Transplant Therapeutic Area Head of Astellas Pharma Global Development Inc.

About isavuconazole

Isavuconazole is an investigational intravenous and oral broad-spectrum antifungal. In collaboration with Astellas Pharma Inc., isavuconazole is being investigated in phase 3 clinical studies for the treatment of severe invasive fungal infections. The drug demonstrated excellent 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 in-vitro activity against less prevalent but often fatal molds such as Mucorales spp. In clinical studies, isavuconazole achieves predictable drug levels allowing reliable dosing and a switch from intravenous administration to a convenient once-daily oral dose.

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