PRESS RELEASE

Basilea's partner Astellas receives notification from U.S. FDA of acceptance of filing of isavuconazole NDA for the treatment of invasive aspergillosis and invasive mucormycosis

Basel, Switzerland, September 06, 2014 – Basilea Pharmaceutica Ltd. (SIX: BSLN) reports today that the U.S. Food and Drug Administration (FDA) has accepted for filing the New Drug Application for isavuconazole submitted by Basilea's license partner Astellas Pharma Inc. The NDA seeks approval of isavuconazole for the treatment of invasive aspergillosis and invasive mucormycosis (also known as zygomycosis) in adults. In accordance with the FDA Prescription Drug User Fee Act (PDUFA), the FDA designated the date of March 8, 2015 for the completion of the review.

Based on the FDA's acceptance of filing of the U.S. NDA, Basilea will receive a CHF 12 million milestone payment from Astellas. Ronald Scott, Basilea's CEO, stated: "We are pleased with the FDA acceptance of the NDA filing shortly after our European MAA was accepted." He added: "Isavuconazole has the potential to be a valuable new therapeutic option for patients suffering from invasive fungal infections."

The European regulatory review of Basilea's MAA could be completed by the fourth quarter of 2015.

Isavuconazole (drug substance: isavuconazonium sulfate) is an investigational once-daily intravenous and oral broad-spectrum antifungal for the potential treatment of life-threatening invasive fungal infections which predominantly occur in immunocompromised patients such as cancer patients undergoing chemotherapy. It has EU and U.S. orphan drug status for the treatment of invasive aspergillosis and mucormycosis. In the U.S., isavuconazole was granted FDA fast-track status and designated a Qualified Infectious Disease Product (QIDP) for invasive aspergillosis, mucormycosis and candidiasis under the U.S. GAIN Act.

Basilea holds full rights to isavuconazole in markets outside of the U.S. and Canada where Astellas is the exclusive license holder.

About invasive aspergillosis and mucormycosis

Invasive aspergillosis is estimated to occur in 5-13% of bone marrow transplant recipients, 5-25% of patients who have received heart or lung transplants, and 10-20% of patients who have received intensive chemotherapy for leukemia.[1] Mortality rates for transplant patients with invasive aspergillosis have been reported to be between 34% and 58%.[2] Around 47% of solid organ transplant recipients who developed invasive aspergillosis had renal insufficiency and acute renal failure was reported for 43% of intensive care unit (ICU) patients with invasive aspergillosis, compared to 20% in the general ICU population.[2, 3]

Mucormycosis (also known as zygomycosis) is an often lethal fungal infection caused by certain emerging molds. Mucormycosis is associated with high morbidity and mortality rates in immunocompromised patients such as patients undergoing chemotherapy or bone marrow transplantation.[4, 5] Left untreated, mucormycosis is almost always lethal, and even with appropriate medical management, mortality rates remain high.[6]

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About Basilea

Basilea Pharmaceutica Ltd. is headquartered in Basel, Switzerland and listed on the SIX Swiss Exchange (SIX: BSLN). Through the integrated research, development and commercial operations of its Swiss subsidiary Basilea Pharmaceutica International Ltd., the company develops and commercializes innovative pharmaceutical products in the therapeutic areas of bacterial infections, fungal infections and oncology, targeting the medical challenge of rising resistance and non-response to current treatment options.

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This press release can be downloaded from www.basilea.com.

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