PRESS RELEASE

European Medicines Agency accepts Basilea's isavuconazole Marketing Authorization Application for review

Basel, Switzerland, August 21, 2014 – Basilea Pharmaceutica Ltd. (SIX: BSLN) announces today that the European Medicines Agency (EMA) has accepted its isavuconazole Marketing Authorization Application (MAA) for review. Basilea's MAA seeks approval of isavuconazole for the treatment of invasive aspergillosis and mucormycosis (zygomycosis) in adults.

Ronald Scott, Basilea's CEO, stated: "We are very pleased with the EMA's acceptance of our MAA for review. This is an important milestone in the development of isavuconazole. Based on its profile, isavuconazole could potentially play an important role in the treatment of life-threatening invasive mold infections." He added: "Basilea is committed to bring new therapeutic options to patients with invasive infections."

The EMA will review the application under the centralized marketing authorization procedure. If approved by the EMA, isavuconazole would receive marketing authorization in all 28 member states of the European Union (EU), as well as in Iceland, Liechtenstein and Norway.

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.

In July 2014, Basilea's co-development partner Astellas Pharma Inc. submitted a U.S. New Drug Application (NDA) seeking isavuconazole approval for the treatment of invasive aspergillosis and mucormycosis. Basilea is eligible to receive a milestone payment from Astellas upon the FDA's acceptance of Astellas' U.S. NDA submission.

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]

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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]

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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