PRESS RELEASE

Basilea's antifungal Cresemba® (isavuconazole) launched in France

Basel, Switzerland, November 15, 2016 – Basilea Pharmaceutica Ltd. (SIX: BSLN) announces that it has launched its antifungal Cresemba® (isavuconazole) in France and that it has sponsored a symposium on current challenges and recent opportunities in the treatment of invasive mold infections. The event was held on November 10, 2016 in Paris, France, and was co-chaired by Professor Élie Azoulay, Medical Intensive Care, Saint-Louis Teaching Hospital, Paris; Professor Jean-Pierre Gangneux, Laboratory of Parasitology and Mycology, University Hospital Rennes, and Professor Olivier Lortholary, Department of Infectious Diseases, Necker - Enfants Malades Hospital, Paris.

David Veitch, Basilea's Chief Commercial Officer, commented: "We are excited to have launched Cresemba in France. The symposium provided an opportunity both for clinicians to discuss important clinical data and to share their experiences in the management of patients with potentially life-threatening invasive mold infections. Cresemba addresses an important medical need for these patients."

Isavuconazole was approved by the European Commission in October 2015 for the treatment of adults with invasive aspergillosis and the treatment of adults with mucormycosis for whom amphotericin B is inappropriate. Invasive aspergillosis and mucormycosis are life-threatening fungal infections that often affect immunocompromised patients, such as patients with cancer and after transplantation. Invasive aspergillosis is often fatal. Mucormycosis (also known as zygomycosis) is a rapidly progressive invasive fungal infection, often affecting the nose and sinuses with high mortality.

Professor Raoul Herbrecht, Department of Oncology and Hematology, Hautepierre University Hospital Strasbourg, stated: "There is a significant medical need in invasive aspergillosis and mucormycosis. They can cause severe morbidity and rapid deterioration in a patient's condition and may be associated with mortality rates approaching 100% if untreated or if effective treatment is delayed. Isavuconazole's safety and tolerability profile can be beneficial for highly vulnerable patients with invasive mold infections, as for instance patients with comorbidities or the need for long-term use, or high-risk patients receiving concomitant medications such as immunosuppressants."

Professor Jean-Pierre Gangneux added: "There are gaps in the spectrum of various currently available antifungal drugs. Isavuconazole is characterized by a broad spectrum with activity against filamentous fungi such as *Aspergillus* spp. and Mucorales."

About Cresemba (isavuconazole)

Isavuconazole is an intravenous (i.v.) and oral azole antifungal and the active agent of the prodrug isavuconazonium sulfate. It is approved in the United States for patients 18 years of age and older in the treatment of invasive aspergillosis and invasive mucormycosis.[1] In Europe, isavuconazole received marketing authorization for the treatment of adult patients with invasive aspergillosis and for the treatment of adult patients with mucormycosis for whom amphotericin B is inappropriate.[2] Isavuconazole has orphan drug designation for the approved indications in Europe and the US. Basilea is marketing isavuconazole as Cresemba in Germany, Italy, the UK, France and Austria and is seeking national pricing and reimbursement in additional EU countries. In the US, the drug is marketed by Basilea's license partner Astellas Pharma US. Outside the US

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and the EU, isavuconazole is currently not approved for commercial use. The European marketing authorization is valid in all 28 European Union (EU) member states, as well as in Iceland, Liechtenstein and Norway.

About the isavuconazole invasive aspergillosis and mucormycosis studies

The approval of Cresemba is based on results from the isavuconazole development program. The safety and efficacy profile of isavuconazole in adult patients with invasive aspergillosis was demonstrated based on data from two phase 3 clinical studies: SECURE, a randomized, double-blind, active-control study in 516 patients (intent-to-treat population, ITT) with invasive aspergillosis, and VITAL, an open-label non-comparative 146-patient study (ITT) of isavuconazole in the treatment of invasive aspergillosis patients with renal impairment, or invasive fungal disease (IFD) caused by emerging molds, yeasts or dimorphic fungi, including invasive mucormycosis.

In the SECURE study, isavuconazole was non-inferior to voriconazole based on the primary endpoint of all-cause mortality at Day 42 in the intent-to-treat population. All-cause mortality through Day 42 was 19% in the isavuconazole treatment group and 20% in the voriconazole treatment group.[3]

In the SECURE study, similar rates of non-fatal adverse events were observed for isavuconazole and the comparator, voriconazole. Further, the percentage of study drug-related adverse events in invasive aspergillosis patients was 42% for isavuconazole and 60% for voriconazole. In addition, the percentage of treatment-emergent adverse events in the system organ classes of hepatobiliary disorders was 9% for isavuconazole versus 16% for voriconazole; skin or subcutaneous tissue disorders was 33% for isavuconazole versus 42% for voriconazole; and eye disorders was 15% for isavuconazole versus 27% for voriconazole.[3]

The safety and efficacy profile of isavuconazole in patients with mucormycosis was demonstrated based on data from the VITAL study, which included a subpopulation of 37 patients with proven or probable mucormycosis, of whom 21 received isavuconazole as primary treatment for their infection. All-cause mortality at Day 42 was 38% which is similar to mortality rates reported in literature for the treatment of mucormycosis. In this trial the rate of overall response against mucormycosis at the end of therapy was 31%, with an additional 29% exhibiting a stable response. For patients receiving isavuconazole as primary therapy, this number was 32%, with an additional 32% having stable disease.[4] The efficacy of isavuconazole for the treatment of mucormycosis has not been evaluated in concurrent, controlled clinical trials.

The most frequent adverse events for patients treated with isavuconazole in clinical phase 3 studies were nausea (26%), vomiting (25%), diarrhea (22%), headache (17%), elevated liver chemistry tests (17%), hypokalemia (14%), constipation (13%), dyspnea (12%), cough (12%), peripheral edema (11%), and back pain (10%).

About Basilea

Basilea Pharmaceutica Ltd. is a biopharmaceutical company developing products that address increasing resistance and non-response to current treatment options in the therapeutic areas of bacterial infections, fungal infections and cancer. The company uses the integrated research, development and commercial operations of its subsidiary Basilea Pharmaceutica International Ltd. to discover, develop and commercialize innovative pharmaceutical products to meet the medical needs of patients with serious and potentially life-threatening conditions. Basilea Pharmaceutica Ltd. is headquartered in Basel, Switzerland and listed on the SIX Swiss Exchange (SIX: BSLN). Additional information can be found at Basilea's website www.basilea.com.

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

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