PRESS RELEASE

Basilea announces that CHMP recommends approval of isavuconazole (CRESEMBA®) as a treatment for invasive aspergillosis and mucormycosis in the European Union

Basel, Switzerland, July 24, 2015 – Basilea Pharmaceutica Ltd. (SIX: BSLN) announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency adopted a positive opinion recommending the approval of isavuconazole for the treatment of adult patients with invasive aspergillosis and adult patients with mucormycosis for whom amphotericin B is inappropriate. Invasive aspergillosis and mucormycosis are life-threatening fungal infections predominantly occurring in cancer and other immuno-compromised patients. Isavuconazole will be marketed under the trade name of CRESEMBA® if approved in the European Union.

"Today's positive CHMP opinion is a major step forward in making isavuconazole available in Europe for patients suffering from serious invasive fungal infections. Invasive aspergillosis and mucormycosis are life-threatening infections predominantly affecting cancer and other immunocompromised patients and are associated with high morbidity and mortality. We are committed to bring innovative treatments to patients with high medical need and look forward to the European Commission's decision in the coming months," said Ronald Scott, Basilea's Chief Executive Officer.

The European Commission (EC) will now review the CHMP's positive opinion for isavuconazole. The EC generally follows CHMP recommendations. If approved by the EC, the marketing authorization for isavuconazole will be valid in all 28 European Union member states, as well as in Iceland, Liechtenstein and Norway.

The positive CHMP opinion 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 with invasive aspergillosis, and VITAL, an open-label non-comparative 146-patient study of isavuconazole in renally impaired patients with invasive aspergillosis, or in patients with invasive fungal disease caused by other emerging fungi.

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 18.6% in the isavuconazole treatment group and 20.2% in the voriconazole treatment group.[1]

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 was 9% for isavuconazole versus 16% for voriconazole; skin was 33% for isavuconazole versus 42% for voriconazole; and eye was 15% for isavuconazole versus 27% for voriconazole.[1]

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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 mucormycosis. All-cause mortality at Day 42 was 38% which is similar to mortality rates reported in literature for the treatment of mucormycosis. 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 isavuconazole

Isavuconazole is an azole antifungal and the active agent of the prodrug isavuconazonium sulfate. Basilea is co-developing the drug with Astellas Pharma Inc. The United States Food and Drug Administration (FDA) approved Astellas' New Drug Application (NDA) for the use of isavuconazonium sulfate for patients 18 years of age and older in the treatment of invasive aspergillosis and invasive mucormycosis on March 6, 2015. Astellas is marketing the drug as CRESEMBA® in the United States.

In the event the marketing authorization is granted by the European Commission, detailed recommendations for the use of isavuconazole in Europe will be described in the Summary of Product Characteristics.

About invasive aspergillosis and mucormycosis

Invasive aspergillosis and mucormycosis are life-threatening fungal infections that predominantly affect immunocompromised patients, such as patients with cancer. Invasive aspergillosis is known for high morbidity and mortality. Mucormycosis (also known as zygomycosis) is a rapidly progressing and life-threatening invasive fungal infection, known for high morbidity and mortality.

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 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.

References

1 A. J. Ullmann et al. A comparison of the safety profiles of isavuconazole vs voriconazole in the phase 3 SECURE study in patients with invasive mould infections. European Congress of Clinical Microbiology and Infectious Diseases (ECCMID) 2014, ePoster EP018; https://www.escmid.org/escmid_library/online_lecture_library/material/?mid=20850 (Accessed July 24, 2015)