Ad hoc announcement pursuant to Art. 53 LR

European Commission Decision to approve the pediatric use of antifungal Cresemba® (isavuconazole) and extension of market exclusivity triggers CHF 10 million milestone payment to Basilea

Allschwil, Switzerland, August 27, 2024

Basilea Pharmaceutica Ltd, Allschwil (SIX: BSLN), a commercial-stage biopharmaceutical company committed to meeting the needs of patients with severe bacterial and fungal infections, announced today that the European Commission (EC) has extended the indications of the antifungal Cresemba® (isavuconazole) to pediatric patients and also granted an extension of market exclusivity by two additional years, which triggered a CHF 10 million milestone payment from Basilea's license partner Pfizer Inc.

Dr. Marc Engelhardt, Chief Medical Officer of Basilea, said: "We are very pleased to have received the European Commission Decision to approve Cresemba for the use in children who suffer from invasive aspergillosis or mucormycosis. These severe mold infections primarily affect children suffering from hematologic malignancies, or immunodeficiency disorders and there is a high unmet medical need for new antifungal treatment options in the pediatric population. We are pleased that access to Cresemba is now available to this vulnerable patient population in Europe."

The approval is based on results from two pediatric clinical studies, including a phase 2 open label, non-comparative, multicenter study, evaluating the safety, efficacy and pharmacokinetics of Cresemba for the treatment of invasive aspergillosis and invasive mucormycosis in pediatric patients aged 1 to 17 years old.[1, 2]

In addition to the approval, the EC granted pediatric exclusivity for Cresemba, which extends the period of market exclusivity for Cresemba in the European Union by an additional two years to October 2027.

About isavuconazole (Cresemba®)

Isavuconazole is an intravenous (i.v.) and oral azole antifungal, commercialized under the trade name Cresemba®. Basilea has entered into several license and distribution agreements for isavuconazole covering approximately 115 countries. In the 27 European Union member states, as well as in Iceland, Liechtenstein and Norway, isavuconazole is approved for patients aged from 1 year of age and older for the treatment of invasive aspergillosis and for the treatment of mucormycosis in patients for whom amphotericin B is inappropriate.[3] Isavuconazole is also approved in the United States (US) and several additional countries in Europe and beyond,

including the U.K., China and Japan.[4] It has orphan drug designation in the US, Europe and Australia for its approved indications.

About Basilea

Basilea is a commercial-stage biopharmaceutical company founded in 2000 and headquartered in Switzerland. We are committed to discovering, developing and commercializing innovative drugs to meet the needs of patients with severe bacterial and fungal infections. We have successfully launched two hospital brands, Cresemba for the treatment of invasive fungal infections and Zevtera for the treatment of bacterial infections. In addition, we have preclinical and clinical anti-infective assets in our portfolio. Basilea is listed on the SIX Swiss Exchange (SIX: BSLN). Please visit basilea.com.

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This ad hoc announcement can be downloaded from www.basilea.com.

References

1. ClinicalTrials.gov identifier: NCT03816176
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2. ClinicalTrials.gov identifier: NCT03241550
   A. C. Arrieta, M. Neely, J. C. Day, et al. Tolerability, and Population Pharmacokinetics of Intravenous and Oral Isavuconazonium Sulfate in Pediatric Patients. Antimicrobial Agents and Chemotherapy 2021;65(8):e0029021
3. European Commission Decision on file with Basilea. European Public Assessment Report (EPAR) Cresemba not yet updated to reflect extension to pediatric patients: https://www.ema.europa.eu/en/medicines/human/EPAR/cresemba [Accessed: August 26, 2024]
4. The registration status and approved indications may vary from country to country.