Press release

Basilea announces approval for additional formulation of antifungal Cresemba® (isavuconazole) in China

- **Chinese National Medical Products Administration (NMPA) granted Drug Approval License to Basilea's license partner, Pfizer Inc.**
- **Intravenous use of Cresemba approved for the treatment of adult patients with invasive aspergillosis and invasive mucormycosis following previous approval of oral dosage form**

Basel/Allschwil, Switzerland, June 24, 2022

Basilea Pharmaceutica Ltd. (SIX: BSLN), a commercial-stage biopharmaceutical company, announced today that its license partner, Pfizer Inc. (NYSE: PFE, "Pfizer"), has received a Drug Approval License from the National Medical Products Administration (NMPA) in China, for the intravenous formulation of Cresemba® (isavuconazole) for the treatment of adult patients with invasive aspergillosis and invasive mucormycosis.

This is the second approved formulation for Cresemba in China, in addition to the oral formulation for invasive aspergillosis and invasive mucormycosis.

David Veitch, Basilea's CEO said: "We congratulate our partner Pfizer on this additional approval of Cresemba in China. Invasive fungal infections can pose a serious threat to patients. Offering both the oral and the intravenous formulation of Cresemba gives adult patients suffering from invasive aspergillosis and invasive mucormycosis access to the full range of treatment options with Cresemba. China is a very important commercial market, accounting for approximately 20 percent of global sales for newer antifungals."

Cresemba is approved in 68 countries to date and is currently marketed in 57 countries, including the United States, most EU member states and additional countries inside and outside of Europe. In the twelve months between January and December 2021, total global in-market sales of Cresemba amounted to USD 324 million, a 28 percent growth year-on-year.[1]

About invasive aspergillosis and invasive mucormycosis

Invasive aspergillosis and invasive mucormycosis are life-threatening mold infections that predominantly affect immunocompromised patients, such as patients with hematologic malignancies (blood cancer). Both infections are associated with high morbidity and mortality.

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 the United States, Europe, China, Japan, Latin America, Asia-Pacific, the Middle East and North Africa region, Canada, Russia, Turkey and Israel. In the 27 European Union member states, as well as in Iceland, Liechtenstein, Norway and the U.K., isavuconazole is approved 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] In China, the oral and intravenous formulations are approved for the treatment of adult patients with invasive aspergillosis and invasive mucormycosis. Isavuconazole is also approved in the United States and several additional countries in Europe and beyond.[3] It has orphan drug designation in the U.S., 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 bacterial and fungal infections and cancer. We have successfully launched two hospital brands, Cresemba for the treatment of invasive fungal infections and Zevtera for the treatment of severe bacterial infections. We are conducting clinical studies with two targeted drug candidates for the treatment of a range of cancers and have several preclinical assets in both anti-infectives and cancer in our portfolio. Basilea is listed on the SIX Swiss Exchange (SIX: BSLN). Please visit basilea.com.

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

References

1. IQVIA, December 2021. In-market sales reported as moving annual total (MAT) in U.S. dollar.
2. European Public Assessment Report (EPAR) Cresemba: http://www.ema.europa.eu [Accessed: June 23, 2022]
3. The registration status and approved indications may vary from country to country.