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Press release

Basilea announces approval of antifungal Cresemba® (isavuconazole) for invasive aspergillosis in China

- **Chinese National Medical Products Administration (NMPA) granted Drug Approval License to Basilea's license partner Pfizer**
- **Second approved indication after invasive mucormycosis in December 2021**

Basel, Switzerland, January 13, 2022

Basilea Pharmaceutica Ltd. (SIX: BSLN), a commercial-stage biopharmaceutical company committed to meeting the needs of patients with infectious diseases and cancer, 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 oral formulation of its antifungal Cresemba® (isavuconazole) for the treatment of adult patients with invasive aspergillosis.

This is the second approved indication for oral Cresemba in China, after the approval for the treatment of adult patients with invasive mucormycosis, which was received in December 2021. Pfizer submitted separate marketing authorization applications for the intravenous formulations of Cresemba for the treatment of invasive aspergillosis and mucormycosis and these are under regulatory review by the Center for Drug Evaluation at the NMPA.

David Veitch, Basilea's CEO said: "Invasive aspergillosis is the more frequent infection than mucormycosis and we congratulate our partner Pfizer on this second approval of Cresemba in China, thus broadening the range of approved indications. Invasive fungal infections can pose a serious threat to patients. With this approval, patients in China who are suffering from invasive aspergillosis will now have access to a treatment that can help to address their unmet needs. China is a very important commercial market for Cresemba, accounting for approximately 20 percent of global sales for newer antifungals."

The license agreement between Basilea and Pfizer covers Europe (excluding the Nordic countries), Russia, Turkey, Israel, as well as China (including Hong Kong and Macao) and sixteen countries in the Asia Pacific region. In addition to receiving mid-teen royalties on sales, Basilea remains eligible for further milestone payments of up to approximately USD 600 million under the agreement with Pfizer.

Cresemba has been approved in more than 60 countries to date and is currently marketed in 56 countries, including the United States, most EU member states and additional countries inside and outside of Europe. In the twelve months between October 2020 and September 2021, total

in-market sales of Cresemba amounted to more than USD 300 million, a 26.5 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 formulation is 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 cancer and infectious diseases. 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 cancer and infectious diseases 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, September 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: January 12, 2022]
3. The registration status and approved indications may vary from country to country.