

Press release

Basilea announces regulatory approval of antifungal Cresemba® (isavuconazole) in Japan

- Japanese regulatory authority granted marketing authorization to Basilea's license partner, Asahi Kasei Pharma
- Intravenous and oral use of Cresemba approved for the treatment of adult patients with aspergillosis, mucormycosis, and cryptococcosis

Basel/Allschwil, Switzerland, December 23, 2022

Basilea Pharmaceutica Ltd (SIX: BSLN), a commercial-stage biopharmaceutical company committed to meeting the needs of patients with severe bacterial and fungal infections, announced today that its license partner Asahi Kasei Pharma ("AKP"), has received the marketing authorization from the Ministry of Health, Labour and Welfare (MHLW) in Japan for Cresemba® (isavuconazole) for the treatment of adult patients with aspergillosis, mucormycosis, and cryptococcosis. Aspergillosis and cryptococcosis were recently listed by the World Health Organization as most critical fungal infections that pose a major health risk.¹

David Veitch, Basilea's CEO, stated: "We congratulate our partner AKP on the approval of Cresemba in Japan, which is an important commercial market for newer antifungals. We look forward to continue working together with AKP to make Cresemba available to patients for whom invasive fungal infections can pose a serious threat."

Cresemba is approved in 69 countries to date and is currently marketed in 59 countries, including the United States, China, most EU member states and additional countries inside and outside of Europe. In the twelve months between July 2021 and June 2022, total global in-market sales of Cresemba amounted to USD 352 million, a 24 percent growth year-on-year.²

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, 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.³ 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.⁴ 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 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 several preclinical 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 press release can be downloaded from www.basilea.com.

References

1. WHO fungal priority pathogen list to guide research, development and public health action: <https://www.who.int/publications/i/item/9789240060241> [Accessed: December 22, 2022]
2. IQVIA Analytics Link, June 2022. In-market sales reported as moving annual total (MAT) in U.S. dollar.
3. European Public Assessment Report (EPAR) Cresemba: <http://www.ema.europa.eu> [Accessed: December 22, 2022]



4. The registration status and approved indications may vary from country to country.