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**Ad hoc announcement pursuant to Art. 53 LR**

# Basilea's partner Asahi Kasei Pharma filed New Drug Application for the marketing authorization of isavuconazole in Japan

**Basel, Switzerland, September 30, 2021**

Basilea Pharmaceutica Ltd. (SIX: BSLN) reported today that its partner Asahi Kasei Pharma Corporation (Asahi Kasei Pharma) has filed a New Drug Application (NDA) for the marketing authorization of isavuconazole (Cresemba®) in Japan for the treatment of the fungal infections aspergillosis, mucormycosis and cryptococcosis. The filing triggers a CHF 5 million milestone payment from Asahi Kasei Pharma to Basilea.

David Veitch, Chief Executive Officer, said: "We congratulate our partner Asahi Kasei Pharma on the filing of the NDA for isavuconazole in Japan. This is a significant step towards the goal to make isavuconazole available for patients in Japan, which is one of the commercially most important market opportunities for the brand."

The partnership between Basilea and Asahi Kasei Pharma was established in September 2016. Under the terms of the agreement, Asahi Kasei Pharma was granted an exclusive license to develop and commercialize isavuconazole in Japan. Basilea received an upfront payment of CHF 7 million and, in addition to the now triggered CHF 5 million milestone payment, will be eligible to receive further payments up to approximately CHF 55 million upon achievement of regulatory and commercial milestones. Basilea will also receive double-digit tiered royalties on product sales in Japan.

Cresemba has been approved in almost 60 countries to date and is currently marketed in 54 countries, including the United States, most EU member states and several additional countries inside and outside of Europe. For the 12 months to the end of June 2021, total "in-market" sales of Cresemba amounted to USD 285 million, a 24 percent growth year-on-year.[1]

## About isavuconazole (Cresemba)

Isavuconazole is an intravenous (i.v.) and oral azole antifungal, commercialized under the trade name Cresemba. 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] Cresemba 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. 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.

## 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 medical 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 a number of 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.

## Disclaimer

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

## References

1. IQVIA, June 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: September 29, 2021]
3. The registration status and approved indications may vary from country to country.