

Ad hoc announcement pursuant to Art. 53 LR

Basilea's partner Asahi Kasei Pharma prepares NDA filing for the marketing authorization of isavuconazole in Japan based on positive phase 3 study results

Basel, Switzerland, July 26, 2021

Basilea Pharmaceutica Ltd. (SIX: BSLN) reported today that its partner Asahi Kasei Pharma Corporation (Asahi Kasei Pharma) is planning to file a New Drug Application (NDA) for the marketing authorization of the antifungal isavuconazole (Cresemba®) in Japan, based on the positive results of the recently completed phase 3 study in deep-seated mycoses. Asahi Kasei Pharma plans to publish topline results of the study at a later point in time.

The phase 3, multi-center, open-label study enrolled 103 patients and was assessing the safety and efficacy of intravenously or orally administered isavuconazole for the treatment of adult Japanese patients suffering from deep-seated mycoses, including invasive aspergillosis, chronic pulmonary aspergillosis (CPA), mucormycosis and cryptococcosis.¹ The primary endpoint of the study was safety, i.e. the proportion of patients who developed adverse events upon treatment and the study included voriconazole as an active comparator for patients with aspergillosis. Patient recruitment was completed in January 2021.²

David Veitch, Chief Executive Officer, said: "We congratulate our partner Asahi Kasei Pharma on the successful completion of the phase 3 study in Japan. This is another confirmation of the utility of isavuconazole in the treatment of severe fungal infections. We are now looking forward to the filing of the marketing authorization application later this year with the goal to make isavuconazole available for patients in Japan, which is one of the commercially most important new market opportunities."

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 will be eligible to receive up to approximately CHF 60 million of additional payments, 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 53 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 March 2021, total "in-market" sales of Cresemba amounted to USD 266 million, an 18 percent growth year-on-year.³



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.⁴ Cresemba is also approved in the United States and several additional countries in Europe and beyond.⁵ 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.

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

References

1. Clinicaltrials.gov identifier NCT03471988
2. Basilea [press release](#) published on January 7, 2021
3. IQVIA, March 2021. In-market sales reported as moving annual total (MAT) in U.S. Dollar corrected for currency fluctuations.
4. European Public Assessment Report (EPAR) Cresemba: <http://www.ema.europa.eu> [Accessed: July 25, 2021]
5. The registration status and approved indications may vary from country to country.