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Press release

Basilea's partner Asahi Kasei Pharma completes patient enrolment in phase 3 study with antifungal isavuconazole (Cresemba®) in Japan

Basel, Switzerland, January 07, 2021

Basilea Pharmaceutica Ltd. (SIX: BSLN) reported today that patient enrolment has been completed in the phase 3 study with the antifungal isavuconazole (Cresemba®), which is conducted in Japan by Basilea's partner Asahi Kasei Pharma Corporation (Asahi Kasei Pharma). The study enrolled 103 patients and is assessing the safety and efficacy of isavuconazole in adult Japanese patients suffering from deep-seated mycoses, including invasive aspergillosis and mucormycosis.[1]

David Veitch, Chief Executive Officer of Basilea, said: "The completion of patient enrolment in the phase 3 study is an important step in the development of Cresemba in Japan, where we see one of the commercially most important opportunities for the drug. Our partner Asahi Kasei Pharma expects to obtain study results in the second half of 2021, which will be the next major milestone for potentially making Cresemba available for patients in Japan."

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 more than 50 countries to date and is currently marketed in 48 countries, including the United States, most EU member states and several additional countries inside and outside of Europe. For the twelve-month period to the end of September 2020, total "in-market" sales of Cresemba amounted to USD 244 million, a more than 28 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. 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] Cresemba 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. 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 invasive aspergillosis and mucormycosis

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

About Basilea

Basilea Pharmaceutica Ltd. is a commercial-stage biopharmaceutical company, focused on the development of products that address the medical challenges in the therapeutic areas of oncology and infectious diseases. With two commercialized drugs, the company is committed to discovering, developing and commercializing innovative pharmaceutical products to meet the medical needs of patients with serious and life-threatening conditions. Basilea Pharmaceutica Ltd. is headquartered in Basel, Switzerland and listed on the SIX Swiss Exchange (SIX: BSLN). Additional information can be found at Basilea's website www.basilea.com.

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

References

1. Clinicaltrials.gov identifier NCT03471988
2. IQVIA, September 2020. In-market sales reported as moving annual total (MAT) in U.S. Dollar corrected for currency fluctuations.
3. European Public Assessment Report (EPAR) Cresemba: http://www.ema.europa.eu [Accessed: January 06, 2021]
4. The registration status and approved indications may vary from country to country.