Basilea Pharmaceutica Ltd.
Grenzacherstrasse 487 | PO Box | 4005 Basel | Switzerland
basilea.com

Press release

Basilea reports acceptance for regulatory review of Pfizer's marketing authorization application for antifungal isavuconazole (Cresemba®) in China

Basel, Switzerland, August 07, 2020

Basilea Pharmaceutica Ltd. (SIX: BSLN) announced today that the marketing authorization application (MAA) for the antifungal isavuconazole (Cresemba®) for the treatment of patients with mucormycosis, which was submitted by Basilea's license partner Pfizer Inc. (NYSE: PFE, "Pfizer"), has been accepted for regulatory review by the Center for Drug Evaluation at the National Medical Products Administration (NMPA) of China.

David Veitch, Chief Executive Officer, said: "China is commercially a very important market for Cresemba, accounting for more than 15 percent of the global market for newer antifungals. We are therefore very pleased with the progress Pfizer is making in China, in order to address the unmet medical needs of patients suffering from invasive mold infections."

In November 2017, Basilea and Pfizer extended their existing license agreement for Europe (excluding the Nordics), Russia, Turkey and Israel, to include China, including Hong Kong and Macao, and sixteen countries in the Asia Pacific region. Under the agreement with Pfizer, Basilea is still eligible for regulatory and sales milestone payments of up to approximately USD 630 million, in addition to receiving mid-teen royalties on sales.

Cresemba has been approved in more than 50 countries to date and is currently marketed in 45 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 March 2020, total "in-market" sales of Cresemba amounted to USD 220 million, a more than 30 percent growth year-on-year.[1]

About Cresemba (isavuconazole)

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 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.

Disclaimer

This communication expressly or implicitly contains certain forward-looking statements, such as "believe", "assume", "expect", "forecast", "project", "may", "could", "might", "will" or similar expressions concerning Basilea Pharmaceutica Ltd. and its business, including with respect to the progress, timing and completion of research, development and clinical studies for product candidates. Such statements involve certain known and unknown risks, uncertainties and other factors, which could cause the actual results, financial condition, performance or achievements of Basilea Pharmaceutica Ltd. to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Basilea Pharmaceutica Ltd. is providing this communication as of this date and does not undertake to update any forward-looking statements contained herein as a result of new information, future events or otherwise.

For further information, please contact:

Peer Nils Schröder, PhD

Head of Corporate Communications & Investor Relations

Phone +41 61 606 1102

E-mail media_relations@basilea.com
investor_relations@basilea.com

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

References

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