

PRESS RELEASE

Basilea reports start of clinical phase 3 study in Japan by Asahi Kasei Pharma with antifungal isavuconazole

Basel, Switzerland, April 18, 2018 – Basilea Pharmaceutica Ltd. (SIX: BSLN) announced today that its license partner Asahi Kasei Pharma Corporation (“Asahi Kasei Pharma”) has started enrollment in a clinical phase 3 study with the antifungal isavuconazole for the treatment of deep-seated mycosis, comprised of invasive aspergillosis, chronic pulmonary aspergillosis, mucormycosis and cryptococcosis. The study is part of an abbreviated development program. If the study is successfully completed, Asahi Kasei Pharma plans to proceed with the submission of a marketing authorization application for isavuconazole in Japan.

Ronald Scott, Chief Executive Officer, said: “Invasive fungal infections can be life-threatening and are an area of significant medical need worldwide. Basilea is working together with its partners to bring isavuconazole to patients around the world. We are pleased that Asahi Kasei Pharma has enrolled the first patient in the phase 3 isavuconazole program in deep-seated mycosis. This is an important milestone on the path toward making this new antifungal available to patients in Japan.”

The randomized, open-label multicenter study aims to establish the safety and efficacy of intravenously (i.v.) or orally administered isavuconazole (as the prodrug isavuconazonium sulfate) versus i.v. or oral voriconazole as active comparator in the treatment of Japanese patients with deep-seated mycosis. The study is anticipated to enroll approximately 100 adult patients.

About isavuconazole

Isavuconazole is an intravenous (i.v.) and oral azole antifungal, commercialized under the trade name Cresemba. Basilea has entered into license and distribution agreements for isavuconazole covering the United States, Europe, China, Japan, Latin America, Canada, Russia, Turkey, Israel and the Asia-Pacific and Middle East and North Africa regions. Isavuconazole is approved in the United States to treat patients 18 years of age and older for invasive aspergillosis and invasive mucormycosis.¹ In the 28 European Union member states, as well as in Iceland, Liechtenstein and Norway, 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 In Switzerland, isavuconazole is approved for the treatment of adult patients with invasive aspergillosis and for the treatment of mucormycosis in adult patients who are resistant to or intolerant of amphotericin B and in adult patients with moderate to severe renal impairment.³ Isavuconazole has U.S. and European orphan drug designation for its approved indications. Outside the U.S. and Europe, the drug is currently not approved for commercial use.

About Basilea

Basilea Pharmaceutica Ltd. is a commercial stage biopharmaceutical company developing products that address the medical challenge of increasing resistance and non-response to current treatment options in the therapeutic areas of bacterial infections, fungal infections and cancer. 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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For further information, please contact:

Peer Nils Schröder, PhD Head of Corporate Communications & Investor Relations +41 61 606 1102 media_relations@basilea.com investor_relations@basilea.com

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

References

- 1 Cresemba [US prescribing information](#) [Accessed: April 17, 2018]
- 2 European Public Assessment Report (EPAR) Cresemba: <http://www.ema.europa.eu> [Accessed: April 17, 2018]
- 3 Full indication in: Swissmedic-approved information for healthcare professionals as of August 2017