

PRESS RELEASE

Basilea announces that European Commission maintained isavuconazole's orphan drug status

Basel, Switzerland, October 23, 2015 – Basilea Pharmaceutica Ltd. (SIX: BSLN) announced today that the orphan drug designation of the antifungal isavuconazole for the treatment of invasive aspergillosis and mucormycosis has been maintained. Accordingly, isavuconazole will benefit from ten years of market exclusivity associated with orphan medicinal product status in the European Union.

About isavuconazole

Isavuconazole is an intravenous and oral azole antifungal and the active agent of the prodrug isavuconazonium sulfate. The drug is being co-developed with Astellas Pharma Inc. under an agreement granting Astellas a license to commercialize isavuconazole in the U.S.; Basilea holds full rights to commercialize isavuconazole in markets outside the United States. On March 6, 2015, the United States Food and Drug Administration (FDA) approved Astellas' New Drug Application (NDA) for the use of isavuconazonium sulfate for patients 18 years of age and older in the treatment of invasive aspergillosis and invasive mucormycosis. Astellas markets the drug as CRESEMBA® in the United States. On October 15, 2015, the European Commission granted marketing authorization to isavuconazole for the treatment of adult patients with invasive aspergillosis and for the treatment of adult patients with mucormycosis for whom amphotericin B is inappropriate. The European marketing authorization is valid in all 28 European Union (EU) member states, as well as in Iceland, Liechtenstein and Norway. Outside the United States and the EU, isavuconazole is currently an investigational product and not approved for commercial use.

About Basilea

Basilea Pharmaceutica Ltd. is a biopharmaceutical company developing products that address increasing resistance and non-response to current treatment options in the therapeutic areas of bacterial infections, fungal infections and cancer. The company uses the integrated research, development and commercial operations of its subsidiary Basilea Pharmaceutica International Ltd. to discover, develop and commercialize innovative pharmaceutical products to meet the medical needs of patients with serious and potentially 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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