PRESS RELEASE

Basilea announces that FDA's Anti-Infective Drugs Advisory Committee recommends approval of isavuconazole for the treatment of invasive aspergillosis and mucormycosis

Basel, Switzerland, January 22, 2015 – Basilea Pharmaceutica Ltd. (SIX: BSLN) today announced that the U.S. Food and Drug Administration's (FDA) Anti-Infective Drugs Advisory Committee voted unanimously to recommend approval of the investigational once-daily intravenous and oral antifungal isavuconazole, the active moiety of the prodrug isavuconazonium sulfate, for the treatment of invasive aspergillosis, and eight to two with one abstention to recommend approval for the treatment of invasive mucormycosis (also known as zygomycosis), life-threatening fungal infections predominantly occurring in immunocompromised patients. Basilea's partner Astellas presented the data to the FDA and, if approved, intends to market the drug as Cresemba® in the United States.

"The Advisory Committee's positive vote is an important regulatory step in the ongoing FDA review of isavuconazole," said Ronald Scott, Basilea's Chief Executive Officer.

The Advisory Committee's recommendation is based on data from the isavuconazole development program, which included analyses from two phase 3 clinical trials in adult patients with invasive fungal infections: SECURE, a randomized, double-blind, active-control study of adult patients with invasive aspergillosis, and VITAL, an open-label non-comparative study of isavuconazole in adult patients with invasive aspergillosis and renal impairment or in patients with invasive fungal disease caused by other fungi, including those causing mucormycosis.

The Advisory Committee provides the FDA with independent expert advice and recommendations. The FDA is not bound by the Advisory Committee's recommendations, but its input will be considered by the FDA in its review of the isavuconazole New Drug Application (NDA), which was submitted by a subsidiary of Basilea's licensing partner Astellas Pharma Inc. on July 8, 2014. The Prescription Drug User Fee Act (PDUFA) date for the isavuconazole NDA is March 8, 2015, which is the target date for the FDA to complete its review.

For additional information on the January 22, 2015 Advisory Committee meeting please visit http://www.fda.gov/AdvisoryCommittees/Calendar/ucm424436.htm.

Isavuconazole is also currently under regulatory review by the European Medicines Agency (EMA) for the treatment of invasive aspergillosis and mucormycosis in adults. The regulatory review of the Marketing Authorization Application (MAA), which was submitted by Basilea on July 16, 2014, is anticipated to be completed in the fourth quarter of 2015.

Enrollment of patients into a third phase 3 study, ACTIVE, which assesses isavuconazole in the treatment of candidemia and other invasive *Candida* infections, was completed in January 2015 and topline data are anticipated for the second half of this year, following completion of treatment and follow-up periods.

About isavuconazole

Isavuconazole is an investigational product and not approved for commercial use in any markets – it is currently under review by the FDA and the EMA.

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Conference call

Basilea Pharmaceutica Ltd. invites you to participate in a conference call on Friday, January 23, 2015, 4 p.m. (CET), during which the company will discuss today's press release.

Dial-in numbers are:
+41 (0) 58 310 5000 (Europe and ROW)
+1 (1) 631 570 5613 (USA)
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A playback will be available 1 hour after the conference call until Monday, January 26, 2015, 6 p.m. (CET). Participants requesting a digital playback may dial:
+41 (0) 91 612 4330 (Europe and ROW)
+1 (1) 866 416 2558 (USA)
+44 (0) 207 108 6233 (UK)
and will be asked to enter the ID 11607 followed by the # sign.

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 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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