

PRESS RELEASE

Basilea provides update on ceftobiprole's U.S. regulatory status

Basel, Switzerland, June 25, 2014 – Basilea Pharmaceutica Ltd. (SIX: BSLN) reports that it had a further discussion regarding ceftobiprole with the U.S. Food and Drug Administration (FDA) in light of new regulatory requirements for pneumonia in the U.S. In this recent discussion, the FDA confirmed that a potential regulatory approval of ceftobiprole for the treatment of pneumonia in the U.S. would require additional phase 3 data. The FDA confirmed that the current ceftobiprole studies should be complemented with prospective data in community and hospital-acquired pneumonia in accordance with its new guidelines. Basilea does not currently intend to initiate new phase 3 trials for ceftobiprole without a partner for the U.S.

Ronald Scott, Basilea's Chief Executive Officer, stated: "We are currently focused on preparing the launch of ceftobiprole for the treatment of community and hospital-acquired pneumonia in Europe with a pharmaceutical distributor or contract sales organization. We anticipate that ceftobiprole will be available in the first key European markets in the second half of this year." He continued: "Another major milestone for Basilea will be the regulatory submission of isavuconazole for the treatment of invasive aspergillosis and mucormycosis. We anticipate filing in Europe mid this year and we also anticipate a mid-year filing by our partner Astellas in the U.S. We are excited to potentially adding a second anti-infective to our commercial portfolio of hospital drugs. The significant overlap in the prescribing base between ceftobiprole and isavuconazole could provide a unique opportunity to optimize the value of both drugs by leveraging significant promotional synergy."

About ceftobiprole

Ceftobiprole (ceftobiprole medocartil) is a broad-spectrum intravenous antibiotic from the cephalosporin class for the first-line treatment of severe bacterial infections. Ceftobiprole has gained regulatory authorization from twelve European states for the treatment of hospital-acquired pneumonia (HAP, excluding ventilator-associated pneumonia, VAP) and community-acquired pneumonia (CAP) in patients 18 years of age and older, and is currently under regulatory review in Switzerland. In the U.S., ceftobiprole is an investigational drug. Ceftobiprole demonstrated broad-spectrum *in-vitro* bactericidal activity against Gram-positive bacteria including methicillin-resistant and vancomycin-resistant *Staphylococcus aureus* (MRSA, VRSA) and penicillin- and ceftriaxone-resistant *Streptococcus pneumoniae* (PRSP, CRSP) as well as Gram-negative pathogens including strains of Enterobacteriaceae and *Pseudomonas*.

About isavuconazole

Isavuconazole (isavuconazonium sulfate) is an investigational once-daily intravenous and oral broad-spectrum antifungal for the potential treatment of severe invasive and life-threatening fungal infections. It is currently in phase 3 of clinical development. Detailed results from the SECURE phase 3 study were reported in May 2014, while topline data of the VITAL phase 3 study were reported in February 2014. The two studies will form the basis of a potential regulatory filing for isavuconazole in Europe and the U.S. mid-2014.

Isavuconazole demonstrated *in-vitro* and *in-vivo* coverage of a broad range of yeasts (such as *Candida* species) and molds (such as *Aspergillus* species), including emerging and often fatal molds such as those that cause mucormycosis. In the U.S., isavuconazole was granted FDA fast-

track status and received QIDP and orphan drug designations for invasive aspergillosis and mucormycosis (zygomycosis).

Isavuconazole is being co-developed with Astellas Pharma Inc. Basilea holds full rights to isavuconazole in all markets outside of the U.S. and Canada, where Astellas is the license holder.

Conference call

Basilea Pharmaceutica Ltd. invites you to participate in a conference call on Wednesday, June 25, 2014, 4 p.m. (CEST), during which the company will discuss today's press release.

Dial-in numbers are:

- +41 (0) 58 310 50 00 (Europe and ROW)
- +1 (1) 631 570 5613 (USA)
- +44 (0) 203 059 5862 (UK)

A playback will be available 1 hour after the conference call until Friday, June 27, 2014, 6 p.m. (CEST). 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 14167 followed by the # sign.

About Basilea

Basilea Pharmaceutica Ltd. is headquartered in Basel, Switzerland and listed on the SIX Swiss Exchange (SIX: BSLN). Through the fully integrated research and development operations of its Swiss subsidiary Basilea Pharmaceutica International Ltd., the company focuses on innovative pharmaceutical products in the therapeutic areas of bacterial infections, fungal infections and oncology, targeting the medical challenge of rising resistance and non-response to current treatment options.

Disclaimer

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