

PRESS RELEASE

Basilea reports on first Cresemba® approval in MENA region

Basel, Switzerland, August 13, 2018 – Basilea Pharmaceutica Ltd. (SIX: BSLN) announced today that its partner Hikma Pharmaceuticals LLC, gained regulatory approval for the antifungal Cresemba® (isavuconazole) in Jordan, which is the first approval of the brand in the Middle East and North Africa (MENA) region.

Adesh Kaul, Chief Corporate Development Officer, said: “We are very pleased with the approval of Cresemba in Jordan, which will facilitate the regulatory process in other countries in the MENA region. Hikma has a strong local presence and a well-established sales force with a track record of successfully launching hospital anti-infectives in this region. We are looking forward to Hikma making Cresemba available to patients in Jordan and other countries following further regulatory approvals.”

Hikma is Basilea’s distribution partner for Cresemba and the antibiotic Zevtera (ceftobiprole) in the MENA region.

About Cresemba (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. In the EU and EEA member states, as well as in Jordan and Peru, 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.¹ It is also approved in the U.S. and Switzerland.^{2, 3} Isavuconazole has U.S. and European orphan drug designation for its approved indications.

About Zevtera (ceftobiprole)

Ceftobiprole is a cephalosporin antibiotic for intravenous administration with rapid bactericidal activity against a wide range of Gram-positive and Gram-negative bacteria, including methicillin-susceptible and resistant *Staphylococcus aureus* (MSSA, MRSA) and susceptible *Pseudomonas* spp.⁴ Ceftobiprole is approved for the treatment of adult patients with community-acquired pneumonia (CAP) and hospital-acquired pneumonia (HAP), excluding ventilator-associated pneumonia (VAP).⁴ It is marketed in major European countries, Argentina, Canada and Saudi Arabia. Basilea has entered into license and distribution agreements for the brand in Europe, Latin America, China, Canada, Israel, and the Middle East and North Africa (MENA) region. Ceftobiprole is currently in a phase 3 clinical program for registration in the U.S.

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

References

- 1 European Public Assessment Report (EPAR) Cresemba: <http://www.ema.europa.eu> [Accessed: August 12, 2018]
- 2 In the United States, Cresemba is approved to treat patients 18 years of age and older for invasive aspergillosis and invasive mucormycosis (Cresemba [US prescribing information](#), accessed August 12, 2018).
- 3 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 (full indication in: Swissmedic-approved information for healthcare professionals as of August 2017).
- 4 U.K. Summary of Product Characteristics (SPC) Zevtera: <http://www.mhra.gov.uk/> [Accessed: August 12, 2018]