PRESS RELEASE

Basilea reports that ceftobiprole received QIDP designation from U.S. FDA for the treatment of lung and skin infections

Basel, Switzerland, August 12, 2015 – Basilea Pharmaceutica Ltd. (SIX: BSLN) announced today that the U.S. Food and Drug Administration (FDA) designated its investigational drug ceftobiprole as a Qualified Infectious Disease Product. The designation relates to the potential use of the drug in the treatment of community-acquired bacterial pneumonia and acute bacterial skin and skin structure infections.

Qualified Infectious Disease Product (QIDP) status, granted under the Generating Antibiotic Incentives Now (GAIN) Act, provides certain incentives for the development of antibiotics, such as priority review if the product is submitted for approval in the United States, and a five-year extension of certain periods of market exclusivity that may be applicable should it be approved.

Ronald Scott, Basilea's Chief Executive Officer, commented: "Serious bacterial lung and skin infections often involve pathogens resistant to currently available antibiotics. Basilea is committed to address the issue of resistance in underserved areas of high medical need. We are in discussions with potential collaborators for the clinical development of ceftobiprole in the U.S."

About ceftobiprole

Ceftobiprole (ceftobiprole medocaril) is a broad-spectrum intravenous cephalosporin antibiotic being developed for use against certain Gram-positive and Gram-negative bacteria, including clinical isolates that are resistant to existing therapies.[1] Ceftobiprole is currently approved in thirteen European countries for the treatment of community-acquired pneumonia and hospital-acquired pneumonia (excluding ventilator-associated pneumonia) in adults.[2]

Ceftobiprole is not approved for any use in the United States.

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

References

1 Y. Y. Syed. Ceftobiprole medocaril: A review of its use in patients with hospital- or community-acquired pneumonia. Drugs 2014 (74), 1523-1542

2 Ceftobiprole (European trade name Zevtera® or Mabelio®, depending on the country) has received national licenses for the treatment of community-acquired pneumonia and hospital-acquired pneumonia (excluding ventilator-associated pneumonia) in adults in Austria, Belgium, Denmark, Finland, France, Germany, Italy, Luxembourg, Norway, Spain, Sweden, Switzerland and the United Kingdom. Ceftobiprole is not registered in the United States.

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