

## PRESS RELEASE

# Basilea's antifungal CRESEMBA® (isavuconazole) launched in Italy

*Basel, Switzerland, June 27, 2016* – Basilea Pharmaceutica Ltd. (SIX: BSLN) announces that it has launched its new azole antifungal CRESEMBA® (isavuconazole) in Italy and will sponsor today a continuing medical education event on current challenges and recent developments in the management of invasive fungal infections in Bologna, Italy. The event will be co-chaired by Prof. Claudio Viscoli MD, Professor of Infectious Diseases, University of Genova and Prof. Corrado Girmenia MD, Professor of Haematology, Sapienza University of Rome.

David Veitch, Basilea's Chief Commercial Officer, commented: "We are very pleased to have launched CRESEMBA in Italy and to support this important scientific congress. The congress provides an excellent opportunity for clinicians to both discuss clinical data and share their experiences in the management of patients with potentially life-threatening invasive fungal infections. CRESEMBA is now available in Germany, Italy, Austria and the UK and, as we continue to secure market access in further countries, we will be launching in additional key European markets."

CRESEMBA® (isavuconazole) was approved by the European Commission in October 2015 for the treatment of adults with invasive aspergillosis and the treatment of adults with mucormycosis for whom amphotericin B is inappropriate. Invasive aspergillosis and mucormycosis are life-threatening fungal infections that often affect immunocompromised patients such as patients with cancer and after transplantation. Invasive aspergillosis is all too often fatal. Mucormycosis (also known as zygomycosis) is a rapidly progressive invasive fungal infection, often affecting the nose, sinuses and brain with an associated high mortality.

Prof. Claudio Viscoli stated: "In times of shortage of new treatments, a new antifungal is very welcome. Although daily experience in use is limited so far, data from clinical trials show that, with respect to other triazoles, isavuconazole is well tolerated, reliable in terms of pathway of elimination and well-absorbed orally. Drug-drug interactions occur less often than with other azoles, and seem more manageable and predictable. Its microbiological activity and approval for the treatment of infections with significant mortality, aspergillosis and mucormycosis, make isavuconazole a very attractive drug for many specialists, especially those in infectious diseases and haematology."

Prof. Corrado Girmenia added: "Triazoles have for years been the cornerstone in the prevention and treatment of most invasive fungal diseases, but several pharmacokinetic, toxicity and drug-drug interaction problems can result in a limit to their use. Isavuconazole has many of the advantages and fewer of the challenges with the current triazoles. These features make isavuconazole a new key antifungal drug."

### About CRESEMBA® (isavuconazole)

Isavuconazole is an intravenous and oral azole antifungal and the active agent of the prodrug isavuconazonium sulfate. Isavuconazole was approved in March 2015 by the United States Food and Drug Administration (FDA) for patients 18 years of age and older in the treatment of invasive aspergillosis and invasive mucormycosis. The European Commission granted marketing authorization in October 2015 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. Isavuconazole has orphan drug designation for the treatment of invasive aspergillosis and mucormycosis in Europe and the U.S. Basilea has licensed the U.S. rights to Astellas Pharma Inc. Isavuconazole is commercialized under the trade name CRESEMBA® by Basilea in certain European countries and by Astellas in the U.S. Outside the U.S. and the EU, isavuconazole is currently an investigational product and not approved for commercial use. The drug was co-developed by Basilea and its U.S. licensee Astellas.

### About the isavuconazole invasive aspergillosis and mucormycosis studies

The approval of CRESEMBA® is based on results from the isavuconazole development program. The safety and efficacy profile of isavuconazole in adult patients with invasive aspergillosis was demonstrated based on data from two phase 3 clinical studies: SECURE, a randomized, double-blind, active-control study in 516 patients (intent-to-treat population, ITT) with invasive aspergillosis, and VITAL, an open-label non-comparative 146-patient study (ITT) of isavuconazole in the treatment of invasive aspergillosis patients with renal impairment, or invasive fungal disease (IFD) caused by emerging molds, yeasts or dimorphic fungi, including invasive mucormycosis.

In the SECURE study, isavuconazole was non-inferior to voriconazole based on the primary endpoint of all-cause mortality at Day 42 in the intent-to-treat population. All-cause mortality through Day 42 was 19% in the isavuconazole treatment group and 20% in the voriconazole treatment group.<sup>1</sup>

In the SECURE study, similar rates of non-fatal adverse events were observed for isavuconazole and the comparator, voriconazole. Further, the percentage of study drug-related adverse events in invasive aspergillosis patients was 42% for isavuconazole and 60% for voriconazole. In addition, the percentage of treatment-emergent adverse events in the system organ classes of hepatobiliary disorders was 9% for isavuconazole versus 16% for voriconazole; skin or subcutaneous tissue disorders was 33% for isavuconazole versus 42% for voriconazole; and eye disorders was 15% for isavuconazole versus 27% for voriconazole.<sup>1</sup>

The safety and efficacy profile of isavuconazole in patients with mucormycosis was demonstrated based on data from the VITAL study, which included a subpopulation of 37 patients with proven or probable mucormycosis, of whom 21 received isavuconazole as primary treatment for their infection. All-cause mortality at Day 42 was 38% which is similar to mortality rates reported in literature for the treatment of mucormycosis. In this trial the rate of overall response against mucormycosis at the end of therapy was 31%, with an additional 29% exhibiting a stable response. For patients receiving isavuconazole as primary therapy, this number was 32%, with an additional 32% having stable disease.<sup>2</sup> The efficacy of isavuconazole for the treatment of mucormycosis has not been evaluated in concurrent, controlled clinical trials.

The most frequent adverse events for patients treated with isavuconazole in clinical phase 3 studies were nausea (26%), vomiting (25%), diarrhea (22%), headache (17%), elevated liver chemistry tests (17%), hypokalemia (14%), constipation (13%), dyspnea (12%), cough (12%), peripheral edema (11%), and back pain (10%).

### 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](http://www.basilea.com).

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This press release can be downloaded from [www.basilea.com](http://www.basilea.com).

## References

- 1 J. A. Maertens et al. Isavuconazole versus voriconazole for primary treatment of invasive mould disease caused by *Aspergillus* and other filamentous fungi (SECURE): a phase 3, randomised-controlled, non-inferiority trial. *The Lancet* 2016 (387), 760-769
- 2 F. M. Marty et al. Isavuconazole treatment for mucormycosis: a single-arm open-label trial and case-control analysis. *The Lancet Infectious Diseases* 2016, published online on May 8, 2016