PRESS RELEASE

Basilea reports solid 2015 full-year results and is launching CRESEMBA®, its second hospital anti-infective, in Europe

- **CRESEMBA® approval in U.S. and Europe and launched in the U.S. by Astellas**
- **Zevtera® launched in major European countries**
- **Tumor checkpoint controller BAL101553 interim phase 2a (i.v.) study data reported and phase 1 (oral) study initiated; oncology panRAF-SRC kinase inhibitor BAL3833 phase 1 initiated**
- **CHF 200 million convertible bonds issued, year-end cash and short-term investments of CHF 364.7 million**

Basel, Switzerland, February 29, 2016 – Basilea Pharmaceutica Ltd. (SIX: BSLN) announced today its financial results for the financial year 2015 with a solid year-end cash position of 364.7 million and a net loss of CHF 61.6 million reflecting Basilea's investment in the launch of its two hospital anti-infective drugs, Zevtera® and CRESEMBA®.

Ronald Scott, Basilea's Chief Executive Officer, stated: "We achieved significant milestones in 2015. The approval of isavuconazole in the U.S. and Europe was an important step for Basilea. We are now able to provide a new treatment option for life-threatening invasive fungal infections after almost a decade during which there were no new drugs introduced in this area of high medical need. In addition, we built a dedicated commercial organization in our core European markets to launch CRESEMBA in addition to Zevtera. 2015 also marked the strengthening of our oncology pipeline. We initiated an oral phase 1 clinical study for our tumor checkpoint controller and introduced a second oncology drug candidate, a panRAF-SRC kinase inhibitor, into clinical testing."

Isavuconazole was approved by the U.S. Food and Drug Administration (FDA) for the treatment of invasive aspergillosis and invasive mucormycosis in adults and launched under the tradename CRESEMBA® by Basilea's licensee Astellas Pharma U.S. In Europe, isavuconazole was approved by the European Commission for the treatment of invasive aspergillosis in adults and the treatment of mucormycosis in adults for whom amphotericin B is inappropriate. Following submission of pricing and reimbursement dossiers for all major European markets, Basilea is launching CRESEMBA® initially in the UK and Germany, to be followed by Italy and France.

In addition to Germany, Basilea launched Zevtera® (ceftobiprole), its anti-MRSA broad-spectrum antibiotic for the treatment of severe bacterial lung infections in 2015 in France, Italy, the U.K. and Austria and achieved first formulary inclusions at the regional and hospital level. In 2015, Basilea expanded the commercial availability of Zevtera® to the Middle East and North Africa (MENA) region through a distribution agreement with Hikma.

To potentially bring the drug to the U.S. market, Basilea is currently preparing phase 3 study protocols in community-acquired bacterial pneumonia (CABP), acute bacterial skin and skin structure infections (ABSSSI), and *Staphylococcus aureus* bacteremia. Basilea plans to submit these protocols to the FDA to request Special Protocol Assessments (SPAs).

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Ceftobiprole has been assigned Qualified Infectious Disease Product (QIDP) status by the U.S. FDA for CABP and ABSSSI that results in a total of ten years of market exclusivity from marketing authorization in the U.S. Part of the proceeds from the issuance of the convertible bonds at the end of 2015 may be used for a financial participation by Basilea in the potential ceftobiprole phase 3 clinical program to gain U.S. regulatory approval.

Basilea initiated the development of an inhaled formulation of its Gram-negative antibiotic BAL30072 for the treatment of bacterial lung infections in cystic fibrosis and bronchiectasis patients with the iABC (inhaled Antibiotics in Bronchiectasis and Cystic fibrosis) consortium, which is part of the European New Drugs for Bad Bugs (ND4BB) program launched within the EU's Innovative Medicines Initiative (IMI).

In addition, Basilea advanced its oncology product candidates in 2015. The panRAF-SRC kinase inhibitor, BAL3833 for targeted cancer therapy, entered clinical phase 1. The compound potentially offers a new treatment option for resistant melanoma and other cancers. Furthermore, the tumor check point controller BAL101553 completed recruitment into a phase 1/2a study with its intravenous formulation. Interim data of that study showed first signals of clinical benefit in heavily pretreated solid tumor patients. BAL101553's oral formulation, currently in phase 1 development, potentially offers increased dosing flexibility for both single agent and drug combination treatment strategies. In particular its development for the treatment of brain cancer, an area of high medical need, is supported by its brain penetration and potent activity against glioblastoma tumor and stem-like cells and further preclinical data.

CEO Ronald Scott added further: "For 2016 we are focused on launching CRESEMBA in our major European markets. We plan to further expand Zevtera's formulary access and increase sales in our major European markets. In addition, we are actively discussing Zevtera and CRESEMBA distribution agreements for further territories. We aim to enter a collaboration for ceftobiprole phase 3 development in additional indications to potentially bring the drug to the important U.S. market. Furthermore, we plan to advance our oncology portfolio by expanding our BAL101553 phase 1 oral clinical study to include glioblastoma patients."

Key figures

(In CHF million, except per share data)	**2015**	**2014**
Contract revenue	51.2	42.1
Revenue from R&D services	0.5	0.4
Other revenue	1.2	0.1
Total operating income	**52.8**	**42.6**
Research & development expenses, net	(60.1)	(54.4)
Selling, general & administration expenses	(54.2)	(30.1)
Total operating expenses	**(114.3)**	**(84.5)**
Operating loss	**(61.5)**	**(41.8)**
Net loss	**(61.6)**	**(41.5)**
Net cash (used for) operating activities	(67.8)	(71.5)
Cash and short-term investments	364.7	226.1
Basic and diluted loss per share, in CHF	(6.09)	(4.17)

Notes: Consolidated figures in conformity with US GAAP; rounding was consistently applied.

The consolidated financial statements of Basilea Pharmaceutica Ltd. for 2015 can be found on the company's website at http://annualreport.basilea.com.

Financial summary

Contract revenue 2015 amounted to CHF 51.2 million (2014: CHF 42.1 million), including CHF 37.6 million (2014: CHF 36.9 million) related to the global agreement with Stiefel, a GlaxoSmithKline (GSK) company, for Toctino® and CHF 13.6 million (2014: CHF 5.2 million) related to the license agreement with Astellas for isavuconazole. Total operating income in 2015 including sales amounted to CHF 52.8 million (2014: CHF 42.6 million).

Research and development net expenses amounted to CHF 60.1 million (2014: CHF 54.4 million) and were mainly related to activities for the phase 1/2a development of oncology drug candidate BAL101533, costs for the initiation of a pediatric program for ceftobiprole, activities related to the isavuconazole program including pre-launch inventory expenses, and the further development of antibiotic BAL30072.

Selling, general and administration expenses amounted to CHF 54.2 million (2014: CHF 30.1 million), and were mainly related to commercial activities to prepare and support the launch of isavuconazole under the trade name CRESEMBA® in major European countries and the commercialization of ceftobiprole under the trade name Zevtera®/Mabelio® in Germany, France, Italy and the UK.

In 2015, operating loss amounted to CHF 61.5 million, compared to CHF 41.8 million in 2014. This change is mainly due to higher operating expenses related to commercial activities for Zevtera®/Mabelio® and pre-launch activities for CRESEMBA®. The net loss amounted to CHF 61.6 million (2014: CHF 41.5 million) and the basic and diluted loss per share to CHF 6.09 (2014: CHF 4.17).

The net cash used for operating activities in 2015 amounted to CHF 67.8 million as compared to CHF 71.5 million in 2014. The decrease is mainly due to the milestone payment of CHF 30.0 million received from Astellas in 2015 upon approval of isavuconazole in the U.S.

Combined cash and short-term investments amounted to CHF 364.7 million as of December 31, 2015, compared to CHF 226.1 million as of December 31, 2014.

Financial outlook

Basilea is focused on launching and establishing CRESEMBA® in hospitals in Germany, France, Italy and the UK in 2016 and on commercializing Zevtera®/Mabelio® in hospitals in major European countries. Total operating expenses for 2016 are estimated at approximately CHF 9 - 10 million on average per month. Basilea's average operating loss in 2016 is estimated at approximately CHF 4 - 5 million per month. Total annual product sales are expected at approximately CHF 5 million.

Pipeline status

CRESEMBA® (isavuconazole) – *an intravenous (i.v). and oral azole antifungal marketed in the U.S. and in certain EU countries for invasive mold infections*

Isavuconazole is the active agent of the prodrug isavuconazonium sulfate. Isavuconazole was co-developed with Astellas Pharma Inc. under an agreement granting Astellas a license to commercialize isavuconazole in the U.S. Basilea holds full isavuconazole rights in markets outside the United States. CRESEMBA® was approved in March 2015 by the U.S. FDA for the use for patients 18 years of age and older in the treatment of invasive aspergillosis and invasive mucormycosis. Basilea benefits from Astellas' U.S. sales through royalties and sales milestone payments. 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.

In July 2015, Basilea announced top-line data from the ACTIVE trial of isavuconazole in patients with invasive candidiasis or candidemia. The ACTIVE study did not meet its primary endpoint (non-inferior efficacy of isavuconazole versus the study comparator at the end of i.v. therapy). The overall response rates at two weeks after treatment were, however, comparable between the two treatment groups. Overall response at two weeks after treatment was the key secondary endpoint of the study. In addition, the secondary endpoint of all-cause mortality was comparable at study day 14 and day 56 in both treatment groups.

Zevtera®/Mabelio® (ceftobiprole medocaril) – *a broad-spectrum antibiotic for intravenous administration, marketed in key European countries, with bactericidal activity against Gram-positive and Gram-negative bacteria associated with pneumonia, including methicillin-resistant Staphylococcus aureus (MRSA) and susceptible Pseudomonas spp.*

Ceftobiprole (European trade name Zevtera® or Mabelio®, depending on the country) has been approved for sale in 13 European countries and Canada for the treatment of adult patients with community-acquired pneumonia and hospital-acquired pneumonia (excluding ventilator-associated pneumonia) and has been launched in Germany, France, Italy, the United Kingdom and Austria. Ceftobiprole is not approved in the United States.

Basilea signed an exclusive distribution and supply agreement with Hikma Pharmaceuticals LLC for Zevtera® for the Middle East and North Africa (MENA) region.

BAL30072 – *an investigational monosulfactam antibiotic with activity against many clinically relevant multidrug-resistant Gram-negative bacteria*

A phase 1 study was completed under a contract with the U.S. Biomedical Advanced Research and Development Authority (BARDA), evaluating i.v. BAL30072 in combination with the carbapenem antibiotic meropenem. Basilea has initiated the pre-clinical development of an inhaled formulation of BAL30072 for the treatment of bacterial lung infections under an agreement with the European iABC consortium (inhaled Antibiotics in Bronchiectasis and Cystic Fibrosis).

BAL101553 – *a tumor checkpoint controller candidate in phase 2a (i.v.) and phase 1 (oral) clinical testing*

BAL101553 is a microtubule-destabilizing small molecule which promotes tumor cell death through activation of a tumor checkpoint in cell proliferation. BAL101553 is currently completing phase 2a for the i.v. and in phase 1 for the oral dosage form, both in patients with solid cancers. The availability of an oral formulation of BAL101553 may offer increased flexibility with regard to both single agent and drug combination treatment strategies across different tumor types.

BAL3833 – *a phase 1 oral anti-cancer drug candidate (panRAF-SRC kinase inhibitor) targeting tumor growth and therapeutic resistance*

BAL3833 is the lead compound of a novel class of panRAF-SRC kinase inhibitors that have demonstrated activity in tumors which have developed resistance to currently available RAF kinase inhibitors. Basilea is developing BAL3833 under a license agreement with a consortium of organizations including The Institute of Cancer Research, London, Cancer Research Technology, the Wellcome Trust and The University of Manchester.

Toctino® (oral alitretinoin) – *a dermatology drug for systemic use in adults with severe chronic hand eczema unresponsive to potent topical corticosteroids*

Global rights to Toctino® were transferred to Stiefel, a GlaxoSmithKline (GSK) company, in July 2012. GSK is marketing Toctino® in several countries; in the U.S., oral alitretinoin is an investigational drug and not approved by the FDA. In January 2016, GSK informed Basilea that it

has elected to discontinue its U.S. alitretinoin program. Basilea has the option to regain alitretinoin rights in the U.S.

Conference call

Basilea Pharmaceutica Ltd. invites you to participate in a conference call on Monday, February 29, 2016, 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)
+44 (0) 203 059 5862 (UK)

A playback will be available 1 hour after the conference call until Wednesday, March 2, 2016, 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 10816 followed by the # sign.

Note to shareholders

The shareholders of Basilea Pharmaceutica Ltd. are informed that the Ordinary General Meeting of Shareholders of Basilea Pharmaceutica Ltd. will take place on **Thursday, April 21, 2016 at 2 p.m. at the Radisson Blu Hotel in Basel, Switzerland**. The invitation will be published in the Swiss Official Gazette of Commerce (*Schweizerisches Handelsamtsblatt*, SHAB). Shareholders who are recorded in the share register with voting rights on April 8, 2016 will be entitled to participate and exercise their voting rights.

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 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.

Disclaimer

This communication expressly or implicitly contains certain forward-looking statements concerning Basilea Pharmaceutica Ltd. and its business. Such statements involve certain known and unknown risks, uncertainties and other factors, which could cause the actual results, financial condition, performance or achievements of Basilea Pharmaceutica Ltd. to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Basilea Pharmaceutica Ltd. is providing this communication as of this date and does not undertake to update any forward-looking statements contained herein as a result of new information, future events or otherwise.

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