

## PRESS RELEASE

# Basilea presenting at the 37th Annual J. P. Morgan Healthcare Conference - delivering on its strategy

**Basel, Switzerland, January 04, 2019** – Basilea Pharmaceutica Ltd. (SIX: BSLN) announced today that David Veitch, Chief Executive Officer of Basilea, will present at the 37<sup>th</sup> Annual J. P. Morgan Healthcare Conference on January 10, 2019 at 8:30 a.m. Pacific Standard Time / 5:30 p.m. Central European Time at the Westin St. Francis Hotel, San Francisco, CA.

David Veitch will describe both the progress made during 2018 and the priorities for 2019 to deliver on the key elements of Basilea's strategy for continued value creation. The company is focused on continuously increasing revenues from its commercialized products, the antifungal Cresemba<sup>®</sup> (isavuconazole) and the antibiotic Zevtera<sup>®</sup> (ceftobiprole), in addition to advancing and expanding its oncology and anti-infectives R&D pipeline.

David Veitch said: "We have made a big step forward last year in the execution of our strategy. We are generating growing cash flows from our commercialized products Cresemba and Zevtera. This allows us to continue investing in our R&D pipeline, which is crucial for the future growth of our company. We remain focused on advancing our clinical oncology projects and our ceftobiprole phase 3 program to the next value inflection points, while looking at selectively strengthening our portfolio through both internal and external innovation."

### Product revenues

Thanks to Basilea's successful partnerships, Cresemba and Zevtera have been launched in many additional countries throughout the last year. Global Cresemba sales by Basilea's partners exceeded USD 150 million in 2018. Basilea participates in the commercial success of its products through royalties, transfer prices and milestone payments, such as the recent CHF 10 million milestone payment from Astellas Pharma Inc. based on sales of Cresemba exceeding a sales threshold in the United States in 2018. By the end of 2018, Cresemba was marketed in more than 20 countries; together with its partners, Basilea intends to increase this number to more than 60 in the course of the next three years.

### Oncology pipeline

In 2018, the company expanded its clinical oncology portfolio through the in-licensing of the pan-FGFR kinase inhibitor derazantinib from ArQule Inc. Interim results from the ongoing registrational phase 2 study in intrahepatic cholangiocarcinoma (iCCA) are expected in early 2019 and the study is expected to complete mid-2020. Basilea is on track to start phase 2 development in additional cancer types in mid-2019.

Basilea is currently running three clinical studies with BAL101553. In Switzerland, a phase 2a expansion study in recurrent glioblastoma and platinum-resistant ovarian cancer using weekly 48-hour infusion is ongoing and expected to complete around year-end 2019. In the UK, phase 1 dose escalation is ongoing in recurrent or progressive glioblastoma patients with daily oral administration. Several dose escalation cohorts have been completed and Basilea anticipates that the study will reach its primary goal, the definition of a maximum tolerated dose, in the first half of 2019. Finally, a phase 1 study is ongoing in the U.S. in newly diagnosed glioblastoma patients with first-line oral BAL101553 in combination with radiotherapy. This study could be completed by mid-2020 and is conducted in collaboration with the Adult Brain Tumor Consortium (ABTC), which is funded by the U.S. National Cancer Institute.

BAL3833 continues to show very encouraging anticancer activity in preclinical models and the medical need for cancer patients with RAF- and RAS-driven tumors remains high. In 2018, Basilea's partners, the Institute of Cancer Research (ICR) in conjunction with The Christie and Royal Marsden NHS Foundation Trusts and the Cancer Research UK Manchester Institute at The University of Manchester, completed the first-in-human phase 1 dose-escalation study of the panRAF/SRC inhibitor BAL3833 in patients with solid tumors including metastatic melanoma. A broad dose range was investigated in the study. A maximum tolerated dose was not defined. Following the detailed analysis of available data, Basilea concluded that an alternative formulation of the drug candidate would be required to achieve appropriately high and consistent drug levels in patients. Pre-clinical activities to explore alternative formulations are planned.

In addition to the BAL3833 reformulation project, the company's oncology research portfolio includes several internal projects and one externally sourced project, all focused on the biomarker-driven development of potential first-in-class selective inhibitors of key processes in cancer development and progression.

### **Anti-infectives pipeline**

Basilea is conducting two cross-supportive phase 3 studies with ceftobiprole with the goal to gain regulatory approval for the brand in the U.S. The U.S. market is an estimated 80% of the global market for branded hospital antibiotics based on value and therefore it plays a critical role in Basilea's commercial strategy for ceftobiprole. Top line results from the first study, in acute bacterial skin and skin structure infections (ABSSSI), are expected in the second half of 2019. The second study, in *Staphylococcus aureus* bacteremia (SAB), was initiated in August 2018 and is expected to take two to three years to complete recruitment. Both studies are conducted under Special Protocol Assessments (SPAs) agreed with the FDA.

The phase 3 program for ceftobiprole is funded in part (up to USD 128 million, which is approximately 70% of the total estimated program costs) with Federal funds from the U.S. Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority (BARDA), under Contract No. HHSO100201600002C.

The demand for innovative antibiotics and antifungals continues to be high. In order to address the needs of patients suffering from serious infections, the company focuses its research activities on new or unexploited clinically relevant targets and on compounds with the potential to show superiority against established antibiotics.

### **Webcast**

The presentation will be available in PDF format on [www.basilea.com](http://www.basilea.com). To access the live and subsequently archived webcast, please use the following link: <https://jpmorgan.metameetings.net/events/healthcare19/sessions/23986-basilea-pharmaceutica-int/webcast>. The replay will be available for three months beginning 24 hours after the live presentation.

### **About Basilea**

Basilea Pharmaceutica Ltd. is a commercial stage biopharmaceutical company developing products that address the medical challenge in the therapeutic areas of cancer and anti-infectives. 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](http://www.basilea.com).

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