PRESS RELEASE

Basilea reports strong revenue growth and significant pipeline progress for full-year 2018

- **Total revenue increased 31% to CHF 133 million**
- **Revenue from Cresemba® and Zevtera® increased 56% to CHF 82 million**
- **Positive derazantinib phase 2 interim results and collaboration with Roche on combination with Tecentriq®**
- **Year-end cash position of CHF 223 million**

Basel, Switzerland, February 19, 2019 – Basilea Pharmaceutica Ltd. (SIX: BSLN) announced today its financial results for the year 2018.

David Veitch, Chief Executive Officer, said: "We continue to make great progress establishing Zevtera and in particular Cresemba, as global brands. We are very pleased with the strong sales performance in 2018. We have also significantly strengthened our pre-clinical and clinical oncology pipeline through in-licensing transactions. The encouraging interim derazantinib results in the registrational phase 2 study and the recently announced collaboration with Roche support the significant potential value in intrahepatic cholangiocarcinoma and urothelial cancer."

Key financial figures

(In CHF million, except per share data)	**2018**	**2017**
Product revenue[1]	26.2	16.3
Contract revenue[1]	79.7	74.0
Revenue from R&D services	0.2	0.3
Other revenue	26.5	10.8
Total revenue	**132.6**	**101.5**
Costs of products sold	(20.3)	(9.0)
Research & development expenses, net	(104.9)	(55.1)
Selling, general & administrative expenses	(31.4)	(54.5)
Total cost and operating expenses	**(156.7)**	**(118.6)**
Operating loss	**(24.1)**	**(17.1)**
Net loss	**(31.4)**	**(19.4)**
Net cash used in/provided by operating activities	(79.2)	19.0
Basic and diluted loss per share, in CHF	(2.89)	(1.79)

(In CHF million)	**Dec 31, 2018**	**Dec 31, 2017**
Cash and financial investments	223.0	310.7

Note: Consolidated figures in conformity with U.S. GAAP; rounding was applied consistently.

[1] Product revenue and contract revenue include Cresemba and Zevtera related revenue of CHF 82 million (2017: CHF 52.6 million) and CHF 23.9 million (2017: CHF 37.7million) related to Toctino® deferred revenue recognition.

The consolidated financial statements of Basilea Pharmaceutica Ltd. for the financial year 2018 can be found on the Company's website at http://www.basilea.com/financial-reports.

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Financial summary

During 2018 Basilea continued to substantially increase its revenues particularly driven by the strong sales performance of Cresemba, which further accelerated in the second half of 2018 mainly driving the outperformance in total revenue and operating result compared to the guidance. At the same time Basilea successfully invested in its pre-clinical and clinical pipeline, strengthening the base for potential future value creation and growth.

Total revenue in 2018 increased by 31% to CHF 132.6 million (2017: CHF 101.5 million). Together, product revenue and contract revenue continued to grow to CHF 105.9 million (2017: CHF 90.3 million), with contributions from the two marketed products Cresemba and Zevtera increasing by 56% to CHF 82.0 million (2017: CHF 52.6 million). Other revenue increased to CHF 26.5 million (2017: CHF 10.8 million), including CHF 25.9 million BARDA reimbursements (2017: CHF 10.5 million) offsetting a substantial portion of expenses incurred related to Basilea's ceftobiprole phase 3 program.

In 2018 investments in Basilea's pipeline resulted in research and development expenses of CHF 104.9 million (2017: CHF 55.1 million). Such expenses were mainly driven by costs for the two phase 3 studies for the antibiotic ceftobiprole, which started recruiting patients in 2018, the in-licensing of and costs related to the ongoing pre-clinical and clinical program for derazantinib, the phase 1/2a development of oncology drug candidate BAL101553 and the ongoing pediatric programs for ceftobiprole and isavuconazole.

Selling, general and administrative expenses declined significantly to CHF 31.4 million (2017: CHF 54.5 million). This decrease was mainly driven by the transfer of the commercialization activities of Cresemba and Zevtera from Basilea to its partners Pfizer and Correvio in the second half of 2017.

Costs of product sold, which include manufacturing costs, capacity reservation costs, shipping and handling costs as well as certain one-off expenses amounted to CHF 20.3 million (2017: CHF 9.0 million).

The operating loss in 2018 amounted to CHF 24.1 million (2017: CHF 17.1 million) outperforming the respective 2018 guidance. Net loss in 2018 was CHF 31.4 million (2017: CHF 19.4 million), resulting in a basic and diluted loss per share of CHF 2.89 (2017: CHF 1.79).

Operating activities in 2018 consumed cash of CHF 79.2 million, mainly reflecting the progress in and the expansion of Basilea's R&D pipeline. Cash consumption in the second half-year 2018 was reduced to CHF 18.8 million. Combined cash and investments amounted to CHF 223.0 million as of December 31, 2018, compared to CHF 310.7 million as of December 31, 2017.

2019 Outlook

For 2019 Basilea will focus on:

- Through its commercialization partners, continue growing revenues from Cresemba and Zevtera, including launching in further markets.
- Progress the ceftobiprole phase 3 US program: complete enrollment into the acute bacterial skin and skin structure infections (ABSSSI) study and continue enrollment into the *Staphylococcus aureus* bacteremia (SAB) study.
- For derazantinib, complete enrollment into the ongoing registrational phase 2 study in intrahepatic cholangiocarcinoma (iCCA) and initiate clinical development in urothelial cancer.
- Continue to explore opportunities to selectively expand the clinical oncology portfolio and pre-clinical pipeline through in-licensing and internal development.

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Reflecting these key priorities, for 2019 Basilea anticipates continued strong revenue growth from Cresemba and Zevtera to CHF 100–110 million (+22–34% y-on-y), resulting in a significant reduction in net cash consumption to CHF 55–65 million. Total revenues are expected to amount to CHF 128–138 million. The cash generating revenue growth from its two marketed products is expected to compensate for the completion of non-cash revenue recognition from Toctino. Total operating expenses are expected to remain at approximately the same level as 2018, leading to an anticipated operating loss of CHF 20–30 million for 2019.

Portfolio – Strengthened and progressed in 2018/early 2019

Significantly expanded commercial reach of Cresemba and Zevtera

In 2018, Pfizer launched Cresemba in Switzerland, Greece, Ireland, the Netherlands and Portugal. In addition, Grupo Biotoscana was granted regulatory approval for Cresemba in Peru, the first country in Latin America. This triggered a regulatory milestone payment of CHF 2 million to Basilea. In addition, Cresemba was approved in Jordan, the first country in the MENA region. By now, Cresemba is marketed in around 20 countries globally and this number is expected to increase to more than 60 countries by 2021. In 2018, global in-market sales of Cresemba exceeded USD 150 million.

Zevtera was launched by Basilea's partners in Argentina, Canada, Peru, Spain and Saudi Arabia. In total, the brand has been launched in 15 countries now. Zevtera sales continued to increase throughout the year and sales growth is expected to further accelerate with increasing contributions from the newly launched countries inside and outside of Europe.

Strengthened oncology pipeline by in-licensing of derazantinib

In April 2018, Basilea entered into a license agreement with ArQule, Inc., for its late-stage oncology drug candidate derazantinib (BAL087), which targets the fibroblast growth factor receptor (FGFR) family of kinases. The exclusive license grants Basilea worldwide rights to derazantinib, excluding China, Hong Kong, Macao and Taiwan. Basilea made an upfront payment of USD 10 million and ArQule is eligible to receive up to USD 326 million upon reaching certain clinical, regulatory and sales milestones, as well as staggered single to double-digit royalties on sales upon commercialization.

In addition, Basilea has entered into a licensing and research collaboration. The pre-clinical project focuses on the biomarker-driven development of potential first-in-class selective inhibitors of a kinase involved in controlling the process of chromosome segregation during cell division.

Positive interim results from registrational phase 2 study with derazantinib

In January 2019, Basilea reported results from an interim analysis from the ongoing registrational phase 2 study in FGFR2-fusion positive intrahepatic cholangiocarcinoma (iCCA).[1] The efficacy results were encouraging and the analysis also confirmed the safety profile and tolerability of derazantinib observed in previous clinical studies. The objective response rate, defined as the proportion of patients in the study that experienced 30% or greater shrinkage of the target lesions (partial response), was 21%; in comparison to the literature which cites objective response rates of less than 10% for iCCA patients receiving second-line chemotherapy. To investigate whether the application of derazantinib can be expanded, Basilea plans to extend the current iCCA study by including an additional group of patients with other FGFR gene aberrations.

New collaboration to explore combination of derazantinib with immunotherapy

In January 2019, Basilea entered into a collaboration with Roche to explore a combination of derazantinib and Roche's PD-L1-blocking immune-checkpoint inhibitor atezolizumab (Tecentriq®) in patients with urothelial cancer. Basilea expects to start a biomarker-driven multi-cohort phase 1/2 study mid-2019. The study will assess the safety, tolerability and efficacy of derazantinib alone and in combination with atezolizumab in patients with advanced urothelial cancer and confirmed FGFR genomic aberrations.

Significant progress made in clinical-stage programs

In 2018, Basilea started two cross-supportive phase 3 studies with ceftobiprole aiming at gaining regulatory approval for the antibiotic in the U.S. The first study, in acute bacterial skin and skin structure infections (ABSSSI)[2], started patient recruitment in February and the second study, in *Staphylococcus aureus* bacteremia (SAB), followed in August.[3] The studies are conducted under Special Protocol Assessments (SPAs) agreed with the FDA. The phase 3 program 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.

In April 2018, Basilea's partner for isavuconazole in Japan, Asahi Kasei Pharma, initiated a phase 3 study to support a potential future regulatory filing in Japan.[4]

In June 2018, Basilea started a phase 2a expansion study with its tumor checkpoint controller BAL101553.[5] The study is conducted in Switzerland and explores weekly 48-hour infusion of BAL101553 in patients with recurrent glioblastoma, an aggressive form of brain cancer. A separate arm in this study includes patients with platinum-resistant ovarian cancer.

Finally, the phase 1 study with panRAF/SRC kinase inhibitor, BAL3833, was completed.[6]

Conference call and webcast

Basilea Pharmaceutica Ltd. will host a conference call and webcast today, Tuesday, February 19, 2019, at 4 p.m. (CET), to discuss the Company's financial and operating results.

Via audio webcast with presentation:
The live audio webcast of the results presentation can be followed here. Please note that there is no function to ask questions via webcast. For questions, please additionally dial-in via phone (see below).

Via phone:
To listen by phone and ask questions, please use the dial-in details below. To ensure prompt access, please call approximately five minutes prior to the scheduled start of the call.

+41 (0) 58 310 5000 (Europe and RoW)
+1 (1) 866 291 4166 (USA)
+44 (0) 207 107 0613 (U.K.)

Replay:
The webcast, along with presentation will be available online shortly after the event and accessible for three months.

About Basilea

Basilea Pharmaceutica Ltd. is a commercial stage biopharmaceutical company, focused on the development of products that address the medical challenges in the therapeutic areas of oncology 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.

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

References

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