

Ad hoc announcement pursuant to Art. 53 LR

## Basilea announces exclusive license and option agreement for potential first-in-class clinical-stage antibacterial agent

- Exclusive license to evaluate tonabacase in preclinical studies
- Exclusive option to license tonabacase at pre-agreed terms

**Allschwil, Switzerland, October 31, 2023**

Basilea Pharmaceutica Ltd, Allschwil (SIX: BSLN), a commercial-stage biopharmaceutical company, committed to meeting the needs of patients with severe bacterial and fungal infections, announced today that it has entered into an exclusive evaluation license and option agreement for tonabacase, with iNtRON Biotechnology, Inc. (KOSDAQ: 048530), a company based in the Republic of Korea. Tonabacase is a potential first-in-class clinical-stage antibacterial of the endolysin class. Over the course of 2024, Basilea will investigate various hypotheses in a number of preclinical studies to determine the optimal future clinical development program for tonabacase. Upon successful completion of the preclinical evaluation phase, Basilea will have the exclusive option to license tonabacase for further clinical development and commercialization.

The use of endolysins represents a novel and innovative approach in the treatment of bacterial infections. Endolysins are recombinant proteins derived from bacteriophages, i.e. viruses that infect bacteria. They cause a rapid destabilization of the bacterial cell wall, leading to the death of bacteria. In addition, endolysins have shown significant advantages over conventional antibiotic treatments including activity against biofilms, a frequent cause of persistent and recurring infections, synergy with other antibiotics and a low risk of resistance development.<sup>1</sup>

Tonabacase has shown activity in vitro and in preclinical animal models of infection against methicillin-resistant and methicillin-susceptible *Staphylococcus aureus* (MRSA and MSSA) as well as in-vitro activity against coagulase-negative staphylococci.<sup>2,3</sup> In phase 1 studies, tonabacase single and multiple dose administrations were shown to be well-tolerated.<sup>4,5</sup>

Dr. Marc Engelhardt, Chief Medical Officer of Basilea, stated: “There continues to be a high medical need for new treatment options for patients with persistent infections caused by Gram-positive bacteria and tonabacase is an exciting and innovative asset for us to evaluate over the coming months. If the outcome of our evaluation is positive and we enter into a full license agreement, we may be able to start directly a phase 2 clinical study in 2025.”

Under the terms of the agreement, Basilea is making an undisclosed upfront payment to iNtRON and will make one additional payment if Basilea decides to exercise its exclusive option



and execute the license agreement at pre-agreed financial terms. This transaction has no impact on Basilea's financial guidance for 2023, provided on August 15, 2023.

### **About Basilea**

Basilea is a commercial-stage biopharmaceutical company founded in 2000 and headquartered in Switzerland. We are committed to discovering, developing and commercializing innovative drugs to meet the needs of patients with severe bacterial and fungal infections. We have successfully launched two hospital brands, Cresemba for the treatment of invasive fungal infections and Zevtera for the treatment of bacterial infections. In addition, we have an R&D portfolio of anti-infective assets. Basilea is listed on the SIX Swiss Exchange (SIX: BSLN). Please visit [basilea.com](http://basilea.com).

### **Disclaimer**

This communication expressly or implicitly contains certain forward-looking statements, such as "believe", "assume", "expect", "forecast", "project", "may", "could", "might", "will" or similar expressions concerning Basilea Pharmaceutica Ltd, Allschwil and its business, including with respect to the progress, timing and completion of research, development and clinical studies for product candidates. 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, Allschwil to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Basilea Pharmaceutica Ltd, Allschwil 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.

For further information, please contact:

#### **Peer Nils Schröder, PhD**

Head of Corporate Communications & Investor Relations  
Basilea Pharmaceutica Ltd, Allschwil  
Hegenheimermattweg 167b  
4123 Allschwil  
Switzerland

Phone +41 61 606 1102

E-mail [media\\_relations@basilea.com](mailto:media_relations@basilea.com)  
[investor\\_relations@basilea.com](mailto:investor_relations@basilea.com)

This ad hoc announcement can be downloaded from [www.basilea.com](http://www.basilea.com).

## References

1. H. Liu, Z. Hu, M. Li et al. Therapeutic potential of bacteriophage endolysins for infections caused by Gram-positive bacteria. *Journal of Biomedical Science* 2023 (30), 29
2. N.-H. Kim, W. B. Park, J. E. Cho et al. Effects of Phage Endolysin SAL200 Combined with antibiotics on *Staphylococcus aureus* infection. *Antimicrobial Agents and Chemotherapy* 2018 (62), e00731-18
3. D. B. Huang, H. S. Sader, P. R. Rhomberg et al. Anti-staphylococcal lysin, LSVT-1701, activity: In vitro susceptibility of *Staphylococcus aureus* and coagulase-negative staphylococci (CoNS) clinical isolates from around the world collected from 2002 to 2019. *Diagnostic Microbiology and Infectious Disease* 2021 (101), 115471
4. Single ascending dose phase 1 study: [ClinicalTrials.gov identifier NCT01855048](https://clinicaltrials.gov/ct2/show/study/NCT01855048)  
S. Y. Jun, I. J. Jang, S. Yoon et al. Pharmacokinetics and Tolerance of the Phage Endolysin-Based Candidate Drug SAL200 after a Single Intravenous Administration among Healthy Volunteers. *Antimicrobial Agents and Chemotherapy* 2017 (61), e02629-16
5. Single and multiple ascending dose phase 1 study: [Clinicaltrials.gov identifier NCT03446053](https://clinicaltrials.gov/ct2/show/study/NCT03446053)  
M. B. Wire, S. Y. Jun, I.-J. Jang et al. A Phase 1 Study To Evaluate Safety and Pharmacokinetics following Administration of Single and Multiple Doses of the Antistaphylococcal Lysin LSVT-1701 in Healthy Adult Subjects. *Antimicrobial Agents and Chemotherapy* 2022 (66), e01842-21