Ad hoc announcement pursuant to Art. 53 LR

Basilea announces acquisition of novel clinical-stage antifungal for treatment of *Aspergillus* mold infections

- **New compound added to Basilea's clinical pipeline; upon successful completion of preclinical profiling, start of phase 2 study planned for H1 2025**
- **Upfront payments of USD 2 million**

Allschwil, Switzerland, October 19, 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 asset purchase agreement with privately owned Gravitas Therapeutics Inc. for GR-2397, a clinical-stage antifungal compound with a novel mechanism of action, targeting invasive mold infections caused by *Aspergillus* species.

David Veitch, Chief Executive Officer of Basilea, stated: "This is the first transaction in the implementation of our strategy to expand our clinical-stage anti-infectives pipeline and to complement our portfolio of marketed products, Cresemba and Zevtera. We are looking forward to developing this asset."

Dr. Marc Engelhardt, Chief Medical Officer of Basilea, added: "With GR-2397, now referred to as BAL2062, we are adding an antifungal compound to our pipeline that has already completed a clinical phase 1 study. Based on its novel mechanism of action which results in rapid fungicidal activity in vitro, BAL2062 could become a valuable treatment option against difficult-to-treat invasive mold infections. To define the optimal positioning and the most efficient clinical development path, we will initiate a focused preclinical profiling program. Upon successful completion of the preclinical profiling, we are planning to move directly into phase 2 clinical development in the first half of 2025."

BAL2062 (formerly GR-2397) is a first-in-class antifungal, derived from a natural product, and has demonstrated fungicidal activity against clinically important molds such as *Aspergillus* spp., including azole-resistant strains.[1] Safety and tolerability have been demonstrated in a previously completed phase 1 study with single and multiple ascending intravenous (i.v.) doses.[2] The drug candidate has Qualified Infectious Disease Product (QIDP), Orphan Drug and Fast Track designation from the US Food & Drug Administration (FDA) for invasive aspergillosis.

Basilea is paying USD 2 million in upfront payments. Under the asset purchase agreement with Gravitas, Basilea assumes the rights and obligations under a license agreement with Astellas Pharma Inc. who owns patents relating to BAL2062 (formerly GR-2397) and takes over an agreement with Fresh Tracks Therapeutics Inc., who previously owned the asset that was acquired by Gravitas. Upon achievement of defined milestones, Basilea will make total pre-approval milestone payments of up to USD 1.75 million and up to USD 67 million in total approval and commercialization milestone payments. In addition, Basilea will pay tiered royalties on sales starting in the low single-digit percentage range, going to the mid-single-digit percentage range.

About invasive aspergillosis

Invasive aspergillosis is a life-threatening mold infection that predominantly affects immunocompromised patients, such as patients with hematologic malignancies (blood cancer). The infection is associated with high morbidity and mortality.

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.

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This ad hoc announcement can be downloaded from www.basilea.com.

References

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2. ClinicalTrials.gov identifier NCT02956499: M. P. Mammen, D. Armas, F. H. Hughes et al. First-in-Human Phase 1 Study To Assess Safety, Tolerability, and Pharmacokinetics of a Novel Antifungal Drug, VL-2397, in Healthy Adults. Antimicrobial Agents and Chemotherapy 2019 (63), e00969-19