

Ad hoc announcement pursuant to Art. 53 LR

## **Basilea announces FDA approval of Investigational New Drug application for novel oncology drug candidate BAL0891**

- **Phase 1 study in patients with advanced solid tumors planned to start in the first quarter of 2022**

**Basel, Switzerland, December 17, 2021**

Basilea Pharmaceutica Ltd. (SIX: BSLN), a commercial-stage biopharmaceutical company committed to meeting the needs of patients with cancer and infectious diseases, announced today that the U.S. Food and Drug Administration (FDA) has approved the company's Investigational New Drug (IND) application for the novel kinase inhibitor BAL0891, a potential first-in-class mitotic checkpoint inhibitor (MCI) that drives aberrant tumor cell division leading to tumor cell death.

Dr. Laurenz Kellenberger, Chief Scientific Officer of Basilea, said: "We are excited about the FDA approval of the IND for BAL0891, allowing us to proceed with the phase 1 clinical study, which we are planning to initiate in the first quarter of 2022. The drug candidate offers the potential for a targeted development strategy in multiple cancers. BAL0891 is differentiated through its unique kinase inhibition profile targeting both threonine tyrosine kinase and polo-like kinase 1. This may be the key factor driving its potent single agent activity seen in preclinical studies. We are looking forward to adding this potential first-in-class mitotic checkpoint inhibitor to our clinical oncology pipeline."

The IND approval triggers a milestone payment of CHF 1.85 million to the Dutch precision medicine company, NTRC, from which Basilea in-licensed BAL0891 in 2018. Under the terms of the agreement, NTRC remains eligible to receive development, regulatory and commercial milestone payments and royalties on global sales.

### **About BAL0891**

BAL0891 is a first-in-class mitotic checkpoint inhibitor that pushes cells through mitosis without adequate time for correct chromosome segregation. This results in aberrant tumor cell division leading to tumor cell death. The compound is a unique dual inhibitor of threonine tyrosine kinase (TTK) and polo-like kinase 1 (PLK1). Both kinases collaborate in activating the mitotic spindle assembly checkpoint (SAC), a cell division mechanism regulating correct chromosome alignment and segregation. The dual action of BAL0891 leads to a rapid disruption of the SAC driving cells through mitosis before the chromosomes are properly aligned leading to premature cell division and tumor cell death. BAL0891 has shown anti-proliferative activity across diverse

tumor cell lines in vitro and single agent efficacy in in-vivo models of solid human cancers. BAL0891 was in-licensed from NTRC in 2018.

### **About NTRC**

NTRC is a privately owned biotech company based in Oss in the Netherlands that has two subsidiary companies: NTRC Therapeutics B.V. and Oncolines B.V.

NTRC Therapeutics is a precision medicine company that is specialized in discovery and development of innovative kinase inhibitors to treat cancer patients. Using its proprietary EPriL platform NTRC Therapeutics is now developing next-generation kinase inhibitors to treat acquired drug resistance observed in cancer patients treated with first generation inhibitors. Please visit [ntrctx.com](http://ntrctx.com).

Oncolines is a precision medicine services company in oncology and cancer immunotherapy. Oncolines helps to bring improved and novel therapies to the right patient population faster by offering a set of complimentary services to enable clients to characterize their compounds, and to determine activities, selectivities and mechanism of action. Please visit [oncolines.com](http://oncolines.com)

### **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 cancer and infectious diseases. We have successfully launched two hospital brands, Cresemba for the treatment of invasive fungal infections and Zevtera for the treatment of severe bacterial infections. We are conducting clinical studies with two targeted drug candidates for the treatment of a range of cancers and have a number of preclinical assets in both cancer and infectious diseases in our portfolio. Basilea is listed on the SIX Swiss Exchange (SIX: BSLN). Please visit [basilea.com](http://basilea.com).

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