PRESS RELEASE

Basilea presents first phase 1 data from its novel anti-cancer drug BAL101553 at ASCO conference

Basel, Switzerland, June 4, 2013 – Basilea Pharmaceutica Ltd. (SIX: BSLN) reported today the presentation of interim data of its oncology drug BAL101553 from its ongoing phase 1 study in patients with advanced solid tumors at the Annual Meeting of the American Society of Clinical Oncology (ASCO), held in Chicago, Illinois (USA) from May 31 to June 4.

The presented data demonstrated that intravenously administered BAL101553 was well tolerated at the doses studied thus far and provided first evidence of anti-tumor activity. Among the 18 patients treated, one patient experienced a partial response (decrease in tumor lesion size) and an additional five patients reported stable disease of which two patients showed stable disease for more than 16 weeks. The main side effects observed were nausea/vomiting and transient blood pressure elevations which were well manageable. Dose escalation continues to determine the maximum tolerated dose.

Pharmacokinetic profiles from the study indicated dose-proportionality; initial pharmacodynamic analyses showed vascular disrupting and anti-proliferative effects in post-treatment tumor biopsies.

Prof. Achim Kaufhold, Basilea's Chief Medical Officer, commented: "Resistance to currently available anti-cancer drugs remains a major challenge in the treatment of cancer patients. These interim results from our investigational drug BAL101553 are encouraging, with first evidence of anti-tumor activity in patients who failed to respond to standard treatment. In addition, the observed safety profile of BAL101553 is promising."

Dr. Heidi Lane, Head of Cancer Biology Basilea, added: "Once the maximum tolerated dose is established, the study will be extended to enlarge patient numbers and identify tumor types likely to respond to this novel anti-cancer compound. In parallel we are actively exploring novel biomarkers for patient stratification to determine which patients will potentially benefit most from treatment."

BAL101553 is a highly water-soluble pro-drug of Basilea's small molecule BAL27862, a novel anti-cancer drug targeting the intracellular microtubule network critical for tumor cell proliferation. It was previously shown that the drug has a dual mode of action directly attacking drug-refractory tumor cells as well as disrupting tumor blood supply.

Poster on BAL101553
A first-in-human (FIH) dose-escalation study of the safety, pharmacokinetics (PK), and pharmacodynamics (PD) of intravenous BAL101553, a novel microtubule inhibitor, in adult patients with advanced solid tumors – A.H. CALVERT, M. GONZALEZ, S. GANGULI, M. NG, S. BENAFIF, M. CAPELAN, R. GOLDSTEIN, K. SHAH, C. JARVIS, M. FLYNN, M. FORSTER, S. ANDERSON, A. SCHMITT-HOFFMANN, H. LANE, M. ENGELHARDT, A.L. HANNAH, A. TZANKOV, F. BACHMANN, L. R. MOLIFE, R. KRISTELEIT; A 2566

For further information please visit http://chicago2013.asco.org/.

Basilea Pharmaceutica Ltd. • Grenzacherstrasse 487 • PO Box • 4005 Basel • Switzerland • www.basilea.com

About Basilea

Basilea Pharmaceutica Ltd. is headquartered in Basel, Switzerland, and listed on the SIX Swiss Exchange (SIX: BSLN). Through the fully integrated research and development operations of its Swiss subsidiary Basilea Pharmaceutica International Ltd., the Company focuses on innovative pharmaceutical products in the therapeutic areas of bacterial infections, fungal infections and oncology, targeting the medical challenge of rising resistance and non-response to current treatment options.

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For further information, please contact:

Media Relations	Investor Relations
Peer Nils Schröder, PhD Head Public Relations & Corporate Communications +41 61 606 1102 media_relations@basilea.com	Barbara Zink, PhD, MBA Head Corporate Development +41 61 606 1233 investor_relations@basilea.com

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