PRESS RELEASE

Basilea presents new research data on a biomarker for its novel oncology drug candidate BAL101553 at AACR

Basel, Switzerland, April 4, 2012 – Research data on a potential biomarker predicting response to Basilea’s novel microtubule-targeting phase I oncology drug candidate BAL101553 were presented at the American Association of Cancer Research (AACR) Annual Meeting in Chicago, Illinois, USA.

BAL101553 is a novel small molecule that arrests tumor cell proliferation and induces tumor cell death through a characteristic destabilizing effect on microtubules, an intracellular network essential for cell division.

Anti-cancer activity of BAL101553 has been demonstrated across a broad panel of preclinical models of human cancer, including those resistant against conventional microtubule-targeting drugs such as taxanes or vinca alkaloids. The injectable form of BAL101553 is currently being tested in a phase I clinical program with patients suffering from advanced solid tumors. Phase I data are expected in the second half of 2012.

Results of collaborative studies between the Basilea research group and the team of Dr. Michael Boutros, Deutsches Krebsforschungszentrum (DKFZ), Heidelberg, Germany, were presented at AACR. These preclinical studies demonstrate that BubR1 protein kinase function is required for the antiproliferative action of BAL27862 (the active moiety of BAL101553) in tumor cells. BubR1 plays a key regulatory role in the assembly of the microtubule mitotic spindle required for cell division. Using small interfering RNA (siRNA) approaches and diverse cancer models, it was found that susceptibility to BAL27862 correlated with BubR1 expression levels. The work presented at AACR provides a robust dataset across tumor types, supportive of the further evaluation of BubR1 as a potential marker of tumor response to BAL101553.

“The identification of BubR1 as a potential predictive biomarker, based on the demonstrated correlation between BubR1 expression and sensitivity of cancer cells to BAL101553, is a result of Basilea’s strategy to ultimately optimize treatment of cancer patients by selecting as early as possible those most likely to benefit from this novel drug,” said Dr. Laurenz Kellenberger, Basilea’s Chief Scientific Officer.

Poster on BAL101553/BAL27862 at the AACR Annual Meeting 2012

- BubR1 function is required for the antiproliferative activity of the novel microtubule-targeting drug BAL27862 (active moiety of the prodrug BAL101553) – H. Lane, K. Burger, F. Bachmann, A. Tzankov, M. Boutros, D. Gilbert; poster/abstract #3795

For further information please visit www.aacr.org

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,
oncology and skin diseases, targeting the medical challenge of rising resistance and non-response to current treatment options in the hospital and specialty care setting. The Basilea group includes affiliates in European countries as well as in China.

Basilea is currently marketing Toctino® (oral alitretinoin), approved in European countries, Canada and Israel for the treatment of adults with severe chronic hand eczema unresponsive to potent topical corticosteroids, in Denmark, Finland, France, Germany, Norway, Switzerland and the United Kingdom and has appointed distributors for Toctino® in other selected European markets, Canada, Israel, Mexico and the Republic of Korea. In the U.S., oral alitretinoin is an investigational drug. Topline data from the U.S. phase III study (HANDEL) on oral alitretinoin have been recently reported. The results are consistent with previous randomized international studies.

For its phase III compound isavuconazole, a potential best-in-class azole antifungal for the treatment of life-threatening invasive fungal infections, the company has entered into a license, co-development and co-promotion agreement with Astellas Pharma Inc.

In addition, Basilea is developing ceftobiprole, a late-stage novel anti-MRSA (methicillin-resistant Staphylococcus aureus) broad-spectrum cephalosporin antibiotic, for the first-line treatment of potentially life-threatening resistant bacterial infections. Ceftobiprole has a broad coverage of both Gram-positive bacteria, including MRSA, and many clinically important Gram-negative bacteria such as Pseudomonas spp.

Basilea’s BAL30072, a novel investigational antibiotic for the treatment of resistant Gram-negative infections, and the oncology drug candidate BAL101553 for the treatment of drug-resistant cancers are in phase I clinical testing.

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