PRESS RELEASE

New research data highlight the potential of Basilea’s BAL101553 as a novel oncology drug candidate

Basel, Switzerland, April 5, 2011 - New research data on Basilea’s antitumor drug candidate BAL101553 (prodrug of BAL27862) was presented at the American Association of Cancer Research (AACR) Annual Meeting in Orlando, Florida, USA. This novel small-molecule agent has a unique mode of action and elicits broad anticancer activity also in tumor models resistant to standard of care treatments. BAL101553 can be administered intravenously and orally.

Despite progress in the development of agents with antitumor activity, cancer remains a significant challenge in healthcare. There is an increasing medical need for novel agents with new mechanisms of action that overcome drug resistance, such as in taxane- or vinca alkaloid-refractory human cancer.

A unique mode of action with efficacy in resistant cancer models

The synthetic small molecule BAL101553 exhibits broad antitumor activity also against models refractory to agents such as taxanes and vinca alkaloids. Potent induction of cell death in cancer cells through a unique destabilizing effect on microtubules suggests a novel mechanism of action. Microtubules are one of the components of the intracellular scaffold and are a well established target for anticancer therapy.

Data presented at the AACR outline the work which resulted in developing the highly water-soluble lysine prodrug BAL101553. BAL101553 is effectively converted to the active drug BAL27862 in tumor models. Prodrug administration facilitated a higher tumor exposure to the active agent, associated with more profound responses in some tumor models. In addition, dose fractionation of BAL101553 resulted in similar antitumor efficacy suggesting a flexible dosing potential. (J. Pohlmann et al., poster #1347)

To further investigate the novel mode of action of this anticancer compound, Basilea also selected tumor cell-lines for resistance to BAL27862. The data presented show that development of resistance is difficult. Unlike taxanes and vinca alkaloids, resistance development is not associated with enhanced expression levels of the P-glycoprotein (Pgp) drug efflux pump, an event often linked to multidrug resistance in cancer. Furthermore, BAL27862 does not bind to the vinca alkaloid tubulin-binding site, consistent with a distinct effect on microtubules and a different antitumor profile across resistant models. Ongoing efforts to identify the changes associated with BAL27862 resistance will facilitate patient stratification during clinical development of BAL101553. (F. Bachmann et al., poster #743)

Basilea is currently preparing for a phase I clinical development program to investigate BAL101553 in humans.
Posters on BAL101553/BAL27862 at the AACR 102nd Annual Meeting

- Development of tumor models resistant to the novel microtubule destabilizer BAL27862 (active moiety of the prodrug BAL101553) - F. Bachmann, F. Danel, K. Burger, R. Martinez, S. Reinelt, M. Page, M. Steinmetz, H.A. Lane; poster abstract #743

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). Its fully integrated research and development operations are focused on antibiotics, antifungals and oncology drugs, as well as on the development of dermatology drugs, targeting the medical challenge of resistance and non-response to current treatment options in the hospital and specialty care setting.

Basilea is currently marketing Toctino® (alitretinoin), the only approved treatment for severe chronic hand eczema unresponsive to potent topical corticosteroids, in Denmark, Finland, France, Germany, Switzerland and the United Kingdom and has appointed distributors for Toctino® in other selected European markets, Canada, Israel and Mexico. Furthermore, a phase III clinical program on alitretinoin for the treatment of severe chronic hand eczema is ongoing in the U.S. 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 global partnership with Astellas Pharma Inc. In addition, Basilea is developing ceftobiprole, a late-stage novel anti-MRSA broad-spectrum cephalosporin antibiotic, for the first-line treatment of potentially life-threatening resistant bacterial infections. Ceftobiprole has broad coverage of both Gram-positive bacteria, including methicillin-resistant Staphylococcus aureus (MRSA), and many clinically important Gram-negative bacteria such as Pseudomonas spp.

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