PRESS RELEASE

Basilea announces collaboration to study derazantinib and atezolizumab (Tecentriq®) in urothelial cancer

Basel, Switzerland, January 24, 2019 – Basilea Pharmaceutica Ltd. (SIX: BSLN) announced today that it entered into a collaboration with Roche (SIX: RO, ROG) to explore a combination of Basilea's derazantinib and Roche's PD-L1-blocking immune-checkpoint inhibitor atezolizumab (Tecentriq®) in patients with urothelial cancer. Basilea expects to start a biomarker-driven multi-cohort phase 1/2 study mid-2019.

Dr. Marc Engelhardt, Chief Medical Officer of Basilea, said: "We are very pleased with this collaboration. This is an important study as it explores a novel targeted treatment approach that addresses the high medical need of patients with urothelial cancer." He added: "The combination of derazantinib and atezolizumab is based on a sound scientific rationale. In addition to its effects on FGFR kinases, derazantinib also inhibits the colony-stimulating factor-1-receptor kinase (CSF1R). CSF1R inhibition has the potential to enhance the response to atezolizumab's immune-checkpoint inhibition. The combination of inhibiting FGFR while, at the same time, enhancing T cell-mediated antitumor effects through CSF1R inhibition is potentially a promising new treatment approach in patients with urothelial cancer."

The planned study will assess the safety, tolerability and efficacy of the derazantinib-atezolizumab combination in patients with advanced urothelial cancer and confirmed FGFR genomic aberrations. Basilea will be the sponsor of the study and Roche will provide clinical supply of atezolizumab for the study.

About derazantinib

Derazantinib (BAL087, formerly ARQ 087) is an investigational orally administered small molecule inhibitor of the FGFR family of kinases with strong activity against FGFR1, 2, and 3. Therefore, it is called a panFGFR kinase inhibitor. FGFR kinases are key drivers of cell proliferation, differentiation and migration. FGFR alterations, e.g. gene fusions, overexpression or mutations, have been identified as potentially important therapeutic targets for various cancers, including intrahepatic cholangiocarcinoma (iCCA), urothelial (bladder), breast, gastric and lung cancers.[1] Current scientific literature suggests that FGFR alterations exist in a range of 5% to 30% in these cancers.[2] In addition, derazantinib inhibits the colony-stimulating-factor-1-receptor kinase (CSF1R). CSF1R-mediated signaling is important for the maintenance of tumor-promoting macrophages and therefore has been identified as a potential target for anti-cancer drugs.[3] Moreover, pre-clinical data has shown that tumor macrophage depletion through CSF1R blockade renders tumors more responsive to T-cell checkpoint immunotherapy, including approaches targeting PD-L1/PD-1.[3, 4, 5] Basilea in-licensed derazantinib from ArQule Inc. in April 2018. The drug candidate has demonstrated favorable clinical data in previous clinical studies, including a biomarker-driven Phase 1/2 study in iCCA patients.[6] Derazantinib has U.S. and EU orphan drug designation for this disease.

About urothelial cancer

Urothelial cancer is the sixth most common cancer in the U.S. These cancers start in the urothelial cells that line the inside of the bladder. 80,000 new cases of bladder cancer have been estimated in the U.S. for 2017. Up to 20 percent of patients will have muscle-invasive disease and

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present with or will later develop metastases.[7] For patients with metastatic disease, outcomes can be poor due to the often rapid progression of the tumor and the lack of efficacious treatments, especially in relapsed or refractory disease.

About Basilea

Basilea Pharmaceutica Ltd. is a commercial stage biopharmaceutical company, focused on the development of products that address the medical challenges in the therapeutic areas of oncology and anti-infectives. With two commercialized drugs, the company is committed to discovering, developing and commercializing innovative pharmaceutical products to meet the medical needs of patients with serious and life-threatening conditions. Basilea Pharmaceutica Ltd. is headquartered in Basel, Switzerland and listed on the SIX Swiss Exchange (SIX: BSLN). Additional information can be found at Basilea's website www.basilea.com.

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

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