PRESS RELEASE

Debiopharm International SA Announces Dosing of First Patient in a Combination Trial of Debio 1143 and Avelumab in Patients with Solid Tumors Including Non-Small Cell Lung Cancer (NSCLC)

The clinical trial is in collaboration with the Merck-Pfizer Alliance

Lausanne, Switzerland – November 6, 2017 – Debiopharm International SA (Debiopharm – www.debiopharm.com), part of Debiopharm Group™, a Swiss-based global biopharmaceutical company, today announced the dosing of the first patient in a Phase Ib study of Debio 1143, an oral, small molecule inhibitor of IAPs (Inhibitor of Apoptosis Proteins), in combination with avelumab*, a human anti-PD-L1 IgG1 monoclonal antibody, in patients with advanced solid tumors including non-small cell lung cancer (NSCLC). The trial is being conducted under a clinical collaboration agreement announced last year between Debiopharm International SA and the Merck-Pfizer Alliance.

"We are very excited to conduct this Phase Ib study to evaluate the potential of combining our Debio 1143 molecule with avelumab", said Sergio Szyldergemajn, Medical Director in Oncology at Debiopharm International SA. "This is the first time this combination is being investigated in patients and we are looking forward to assessing the therapeutic potential of our compound in the Immuno-oncology space."

The clinical trial, a phase-Ib dose-finding study of the Second Mitochondrial-derived Activator of Caspases (SMAC) mimetic Debio 1143 when given in combination with the anti-PD-L1 antibody avelumab to patients with advanced solid malignancies and, in an expansion cohort, to patients with locally advanced or metastatic Non-Small Cell Lung Cancer (NSCLC), is a multi-center, open-label study designed to evaluate the safety and potential efficacy of the combination of Debio 1143 and avelumab, in patients with advanced NSCLC who have not previously received immunotherapy. The design of the trial consists of an adaptive dose-escalation phase to determine the recommended Phase II dose of Debio 1143 in combination with a standard dose of avelumab, followed by an expansion phase to enroll up to a total of 37 patients with NSCLC. (NCT03270176).

* Avelumab is jointly developed by Merck and Pfizer. Avelumab is under clinical investigation for the treatment of advanced solid tumors or NSCLC and has not been demonstrated to be safe and effective for these indications. There is no guarantee that avelumab will be approved for advanced solid tumors or NSCLC by any health authority worldwide.

About Debio 1143

Debio 1143 is a potent, orally available, inhibitor of IAPs (Inhibitor of Apoptosis Proteins) that displays immunomodulatory properties making it a natural candidate for combination with Immune Checkpoint Inhibitors. In addition, like other members of the class, Debio 1143 promotes apoptosis of cancer cells by mimicking the activity of the natural Second Mitochondrial-derived Activator of Caspases (SMAC). Through this dual mode of action, Debio 1143 is expected to improve cancer patient treatment outcomes in combination with immunotherapy, chemotherapy and/or radiotherapy.

About Avelumab

Avelumab is a human programmed death ligand-1 (PD-L1) blocking antibody. Avelumab is designed to potentially engage both the adaptive and innate immune systems. By binding to PD-L1, avelumab is thought to prevent tumor cells from using PD-L1 for protection against white blood cells, such as T cells, exposing them to anti-tumor responses. Avelumab has been shown to induce antibody-dependent cell-mediated cytotoxicity in vitro. In November 2014, Merck and Pfizer announced a strategic alliance to co-develop and co-commercialize avelumab.

Approved Indications in the US
The US Food and Drug Administration (FDA) granted accelerated approval for avelumab (BAVENCIO®) for the treatment of (i) metastatic Merkel cell carcinoma (mMCC) in adults and pediatric patients 12 years and older and (ii) patients with locally advanced or metastatic urothelial carcinoma (UC) who have disease progression during or following platinum-containing chemotherapy, or who have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy. These indications were approved under accelerated approval based on tumor response rate and duration of response. Continued approval for these indications may be contingent upon verification and description of clinical benefit in confirmatory trials.

Important Safety Information from the US FDA Approved Label
The warnings and precautions for avelumab (BAVENCIO®) include immune-mediated adverse reactions (such as pneumonitis, hepatitis, colitis, endocrinopathies, nephritis and renal dysfunction and other adverse reactions), infusion-related reactions and embryo-fetal toxicity.

Common adverse reactions (reported in at least 20% of patients) in patients treated with avelumab for mMCC and patients with locally advanced or metastatic UC include fatigue, musculoskeletal pain, diarrhea, nausea, infusion-related reaction, peripheral edema, decreased appetite/hypophagia, urinary tract infection and rash.

About Debiopharm International SA
Part of Debiopharm Group™ – a Swiss-headquartered global biopharmaceutical group including five companies active in the life science areas of drug development, GMP manufacturing of proprietary drugs, diagnostic tools and investment management – Debiopharm International SA is focused on the development of prescription drugs that target unmet medical needs. The company in-licenses and develops promising drug candidates. The products are commercialized by pharmaceutical out-licensing partners to give access to the largest number of patients worldwide.
For more information, please visit www.debiopharm.com

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Cautionary Note on Forward-Looking Statements
This press release contains forward-looking statements reflecting the current beliefs and expectations of management. Words such as “may,” “believe,” “will,” “expect,” “plan,” “anticipate,” “estimate,” “intend” and similar expressions, as well as other words or expressions referencing future events, conditions or circumstances, are intended to identify forward-looking statements. Forward-looking statements contained in this press release include statements about expectations related to a Phase Ib clinical trial for the Company’s lead monoclonal antibody, Debio 1143. Forward-looking statements in this press release involve substantial risks and uncertainties that could cause our performance or achievements to differ significantly from those expressed or implied by the forward-looking statements, including as a result of the inherent challenges in clinical development. All forward-looking statements are based on Debiopharm’s expectations and assumptions as of the date of this press release, and actual results may differ materially. Except as required by law, Debiopharm expressly disclaims any responsibility to update any forward-looking statement contained herein, whether as a result of new information, future events or otherwise.

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