PRESS RELEASE

Debiopharm expands its Immuno-Oncology development program for Debio 1143, with the first IAP inhibitor/nivolumab combination trial

First patient enrolled in SMARTPLUS-106, a Phase Ib/II study in patients failing prior PD-1/PD-L1 treatment in selected solid tumors

Lausanne, Switzerland – May 21, 2019 – Debiopharm (www.debiopharm.com) announced today the first patient enrolled in SMARTPLUS-106, an exploratory study investigating the safety and efficacy of Debio 1143, a first-in-class oral IAP (Inhibitor of Apoptosis Proteins) inhibitor, in combination with the Immune Checkpoint Inhibitor (ICI), nivolumab, in patients with advanced solid tumors, such as small cell lung cancer (SCLC) or squamous cell carcinoma of the head & neck (SCCHN), who have progressed during or immediately after anti-PD-1/PD-L1 treatment.

Despite improved progression-free survival and overall survival rates observed with ICIs in some patients, most either do not respond to treatment or ultimately develop resistance to therapy, with only 10-30% of patients showing a durable treatment response.[1][2][3]The combination of ICIs with Debio 1143 has strong therapeutic potential through its dual mode of action, fostering anti-tumor immunity and promoting programmed cell death in tumor cells.

Debio 1143 has demonstrated synergy with PD-1/PD-L1 ICIs, including nivolumab, promoting tumor immunity in pre-clinical models of cancer. Therefore the compound is expected to offer an immune-sensitizing effect and enhance patient response to ICIs. With SMARTPLUS-106, part of the broadest immune-oncology IAP clinical research program, Debiopharm hopes to extend the reach of current immunotherapy.

"As IAP inhibition has shown synergistic potential in combination with immunotherapeutic agents, this study is of critical importance to document the clinical efficacy of this new treatment combination in patients not responding to ICIs."
- Angela Zubel, Chief Development Officer, Debiopharm International SA.

About Debio 1143

Debio 1143 is a IAPs inhibitor with a dual mode of action, promoting programmed cell death and fostering anti-tumor immunity. Currently in clinical development in a broad range of cancer types, the compound is being tested combination with chemo-radiotherapy or with ICIs (PD-1/PD-L1), with reported data consistently showing a favorable and manageable safety profile. Over 200 patients have been treated so far with Debio 1143, in indications such as non-small cell lung cancer and Head & Neck cancer.

Trial information:

- Gastrointestinal cancers: patients.debiopharm.com/gastrointestinal-cancers/
- Gynecologic cancers: patients.debiopharm.com/gynecologic-cancer/
- Small cell lung cancers: patients.debiopharm.com/small-cell-lung-cancer-sclc/
- Head & neck cancers: patients.debiopharm.com/head-and-neck-cancer/

[1] Brahmer JR et al. J Clin Oncol. 2010;28(19):3167-75
[2] Antonia SJ et al. Lancet Oncol. 2016;17(7):883-95
[3] Ferris RL et al. Oral Oncol. 2018 Jun;81:45-51

Debiopharm's commitment to cancer patients
Debiopharm aims to develop innovative therapies that target high unmet medical needs in oncology. Bridging the gap between disruptive discovery products and real-world patient reach, we identify high-potential compounds for in-licensing, clinically demonstrate their safety and efficacy and then select large pharmaceutical commercialization partners to maximize patient access globally.

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