



Debiopharm Presented Results at the ASCO 2012 Annual meeting - Results of Phase I study with Debio 0932, an oral HSP90 inhibitor in patients with solid tumours -

Lausanne, Switzerland – June 6, 2012 – Debiopharm Group[™] (Debiopharm), a Swiss-based global biopharmaceutical group of companies with a focus on the development of prescription drugs that target unmet medical needs and companion diagnostics, presented results of a Phase I open-label dose-escalation study with Debio 0932, an oral Heat Shock Protein 90 (HSP90) inhibitor in clinical development as an anti-cancer agent. The study was designed to determine the maximum tolerated dose of Debio 0932. On June 2, during the ASCO Annual meeting in Chicago, Dr Nicolas Isambert (Centre Georges-François Leclerc, Dijon, France) presented a poster (abstract # 3026) describing the study results.

During the study, Debio 0932 was administered orally every other day or once daily at a starting dose of 50mg. Patients receiving a daily dose remained on treatment for an average of 81 days, the former for 76 days. Debio 0932 monotherapy was generally well tolerated in doses up to 1600mg every other day and 1000mg daily. It showed promising signs of anti-tumour activity in patients with advanced solid tumours, especially lung cancer.

"We are encouraged by such positive results. For these first 50 patients, we have met the objective of the Phase I trial, demonstrating safety of Debio 0932," said Rolland-Yves Mauvernay, President and founder of Debiopharm Group TM . "We are extremely pleased that this data could be presented at the ASCO meeting."

"This phase I trial demonstrates that the safety and efficacy of Debio 0932 meets our expectations. This can only encourage Debiopharm to investigate the drug further for the treatment of lung cancer for example, which remains one of the leading causes of cancer death in both men and women," added Nicolas Isambert.

During the study, adverse events observed included constipation, diarrhea, nausea, vomiting, asthenia, and decreased appetite, however there was no apparent relation between the dose of Debio 0932 and the occurrence of these adverse events. No ocular or cardiac toxicity was observed.

Out of the 50 patients enrolled in the study, 45 were evaluable for anti-tumour activity assessment. Partial responses were observed in a patient with non-small cell lung cancer (NSCLC) and in a patient with breast cancer. Among seven other patients with lung cancer, four had stable disease and three had progressive disease.

The recommended dose for the Phase 2 study has been established at 1000mg per day and will be tested in an additional 30 patients in an on-going expansion study. A Phase I-II study of Debio 0932 in combination with standard of care in the first- and second-line treatment of non-small cell lung cancer is planned.

About HSP90 and Debio 0932

HSP90 is a chaperone protein that controls the folding and processing of certain client proteins. HSP90 clients include many proteins that drive tumour development and progression, such as EGFR, HER2, c-MET, AKT, KIT, FLT3, and VEGFR. Inhibition of HSP90 leads to degradation of client proteins targeting multiple oncogenic signalling pathways.

Debio 0932 is an oral second-generation HSP90 inhibitor, which has shown extended tumour retention, blood-brain-barrier penetration, and promising anti-tumour activity both as monotherapy and in combination against a broad range of tumours in pre-clinical models.

Debio 0932 potently inhibits tumour growth in subcutaneous xenograft models of a number of solid and haematological malignancies, including models of NSCLC which harbour mutations conferring acquired or primary erlotinib resistance. Furthermore, Debio 0932 is able to extend animal survival in models of brain metastasis due to its ability to cross the blood-brain barrier, and it enhances the activity of several standard-of-care agents in animal models of cancer.

About Debiopharm Group™

Debiopharm Group™ (Debiopharm) is a Swiss-based global biopharmaceutical group of companies with a focus on the development of prescription drugs that target unmet medical needs. The group inlicenses, develops and/or co-develops promising biological and small molecule drug candidates having reached clinical development phases I, II or III, as well as earlier stage candidates. It develops its products for global registration and maximum commercial potential. The products are out-licensed to pharmaceutical partners for sales and marketing. Debiopharm is also active in the field of companion diagnostics with a view to progressing in the area of personalised medicine. Debiopharm independently funds the worldwide development of all of its products while providing expertise in preclinical and clinical trials, manufacturing, drug delivery and formulation, and regulatory affairs.

For more information on Debiopharm Group™, please visit: www.debiopharm.com.

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