

Regulated information

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Galapagos candidate cachexia drug, GLPG0492, shows good safety and profile suitable for once-daily oral dosing

- Successful completion of first-in-human trial for GLPG0492
- Plans to initiate extended dose and Proof of Concept studies in 2011

Mechelen, Belgium; 2 December 2010 – Galapagos NV (Euronext: GLPG) announced today that it has successfully completed the first-in-human trial for GLPG0492, its candidate drug for cachexia (loss of weight and muscle mass) and potentially other indications, such as Duchenne muscular dystrophy. The candidate drug showed good safety in healthy volunteers and a pharmacokinetic (PK) profile which supports oncedaily oral dosing.

In this first-in-human trial, healthy volunteers were given increasing doses of candidate drug GLPG0492 by oral administration. Safety data were favorable with no severe adverse events or changes in vital signs and laboratory parameters reported. Changes in biomarker levels lasting more than 24 hours were consistent with once-daily oral dosing. Similar positive safety and dosing results were seen for elderly volunteers. Galapagos plans to conduct a second Phase I trial in healthy volunteers in the course of 2011 to assess the safety and tolerability of GLPG0492 over at least 14 consecutive days. Based on this trial, a Proof of Concept study is scheduled for late 2011.

"We are encouraged by the promising results of this first clinical trial for GLPG0492," said Piet Wigerinck, Galapagos' SVP Development. "Comparable safety and PK profiles were seen for younger and elderly volunteers, the latter being particularly relevant for a therapeutic aimed at improving muscle function."

Details of the first-in-human clinical trial

The primary endpoints of the first-in-human trial were to determine the safety, tolerability and pharmacokinetics of the candidate drug GLPG0492. The double-blind, single ascending dose study was conducted in 16 young healthy human volunteers, with 12 receiving ascending doses of GLPG0492 (ranging 0.5 to 120 mg) and four receiving placebo. Another group of 12 elderly subjects (> 60 years) received three single 100 mg doses once weekly over a three week period, to compare the PK profile of the oral solution and capsule formulation.

About GLPG0492 and cachexia

GLPG0492 is an orally available small molecule that Galapagos has developed in its selective androgen receptor modulator (SARM) program. In pre-clinical studies, GLPG0492 has shown efficacy in the treatment of cachexia, the involuntary loss of weight and muscle mass which can affect patients with diseases such as cancer, chronic obstructive pulmonary disease (COPD) and AIDS. It is estimated that worldwide more than two million people die annually from the consequences of cancer-related cachexia¹.

Candidate drug GLPG0492 has been shown to improve muscle mass in animal models, with minimal cardiovascular, prostate, or virility side effects traditionally seen in androgen therapies. Galapagos aims for once-a-day oral dosing that improves muscle mass and function, with

¹ Muscaritoli et al, Asia Pac J Clin Nutr 2008;17 (S1):387-390



minimal effects on hormonal status in patients. With the support of two foundations - Charley's Fund and the Nash Avery Foundation - Galapagos is currently evaluating the potential effectiveness of GLPG0492 in pre-clinical models of Duchenne muscular dystrophy.

Galapagos aims to complete the Proof of Concept study for GLPG0492 in the course of 2011 before out-licensing the program.

About Galapagos

Galapagos (Euronext: GLPG; OTC: GLPYY) is a mid-size biotechnology company specialized in the discovery and development of small molecule and antibody therapies with novel modes-of-action. The Company is progressing one of the largest pipelines in biotech, with six clinical and over 50 small molecule discovery/pre-clinical programs. Through risk/reward-sharing alliances with GlaxoSmithKline, Lilly, Janssen Pharmaceutica, Merck & Co., Roche and Servier, Galapagos is eligible to receive up to €3.3 billion in downstream milestones, plus royalties. The Galapagos Group has over 800 employees and operates facilities in seven countries, with global headquarters in Mechelen, Belgium. More info at: www.glpg.com

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