

Galapagos initiates Nanocort[®] Phase II clinical trial for multiple sclerosis

Mechelen, Belgium; 17 November 2009 – [Galapagos NV](#) (Euronext: GLPG) announced today that it has started a Phase II clinical study to evaluate Nanocort's effectiveness in treating flares in multiple sclerosis (MS). Nanocort combines less frequent treatment with lower dosage and potentially more effective delivery than other MS flare treatments.

Nanocort is a novel pharmaceutical for the treatment of inflammatory conditions such as MS and rheumatoid arthritis. The Phase II trial will involve 90 MS patients experiencing flares, episodes of increased neurological dysfunction. In the study, a single administration of Nanocort will be compared to the standard steroid treatment of three methylprednisolone infusions, with the aim to evaluate the efficacy and safety of Nanocort in treating MS flares. This study will take place in Belgium and Germany over a period of one to two years, with an interim readout after treatment of the first 20 patients.

This Phase II trial follows a Phase I/II study concluded in 2008, which demonstrated safety as well as faster and more pronounced decrease in rheumatoid arthritis flare symptoms as compared to standard steroid treatments. Since the completion of the Phase I/II study, the production and formulation were optimized in preparation for the Phase II studies. In the first half of 2010 Galapagos plans to initiate a small Phase II study to measure targeting of Nanocort to the inflamed joints of RA patients.

"After the positive outcome of the Phase I/II study last year, we have evaluated Nanocort's product profile and decided to pursue MS as a first indication. Pre-clinical studies indicate Nanocort's efficacy, and the product shows distinct advantages over conventional corticosteroid use," said Onno van de Stolpe, CEO of Galapagos. "We are proud that the start of this trial marks Galapagos' entry into Phase II studies, and the third program in clinical trials this year."

About Nanocort

Nanocort is a novel candidate drug composed of prednisolone, a widely used corticosteroid, enclosed in a small lipid vesicle (liposome). Although corticosteroids are a common treatment for many other inflammatory disorders, their use as a free drug is limited due to systemic side effects. In the Nanocort treatment, the corticosteroid is largely confined to the liposome in the blood stream. After administration, the Nanocort liposomes selectively accumulate at sites of inflammation where they deliver long-lasting high concentrations of corticosteroid. As a result, Nanocort may be able to significantly reduce frequency of administration and the toxicities of the steroid compared to other therapies.

About multiple sclerosis

Multiple sclerosis (MS) is an autoimmune disease where the body's immune system mistakenly attacks the nervous system. MS affects the ability of nerve cells in the brain and spinal cord to communicate with each other. The myelin sheath surrounding these nerve cells is usually the first to be injured, causing symptoms such as vision loss, balance issues, fatigue, numbness and tingling. Once the myelin sheath is damaged, flares, or exacerbations of the disease can occur,

which involves either the appearance of new symptoms or the reappearance of previous symptoms. MS flares can last from a few days to a few weeks and are currently treated with corticosteroids, which reduce the severity of the symptoms, but can cause severe systemic side effects. The World Health Organization estimates that over 2.5 million people suffer from multiple sclerosis worldwide and that women are twice as likely to be affected by the disease.

About Galapagos

[Galapagos](#) (Euronext: GLPG; OTC: GLPYY) is a drug discovery and development company with small molecule programs in bone and joint diseases, bone metastasis, cachexia, anti-infectives and metabolic diseases. It has established risk sharing alliances with GSK, Janssen Pharmaceutica, Lilly and Merck&Co. Through an alliance with MorphoSys, Galapagos also develops new antibody therapies in bone and joint diseases. Its division BioFocus offers a full suite of target-to-drug discovery products and services to pharmaceutical and biotech companies and to patient foundations, encompassing target discovery and validation, screening and drug discovery through to delivery of pre-clinical candidates. Galapagos currently employs 495 people and operates facilities in six countries, with global headquarters in Mechelen, Belgium. More info at: www.glpj.com.

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