

Galapagos candidate metastasis drug shows good safety and biomarker response

- **Successful conclusion of first clinical trial for GLPG0187**
- **Plans to initiate clinical trial in cancer patients this year**

Mechelen, Belgium; 19 January 2010 – Galapagos NV (Euronext: GLPG) announced results from the first-in-human trial with candidate drug GLPG0187. GLPG0187 offers a new approach to treat metastases, a severe complication of many cancers. The candidate drug showed good safety and a promising biomarker profile in healthy volunteers. Based on the results from the trial, Galapagos plans to initiate a second Phase I trial including cancer patients later this year.

“We are excited that our candidate drug demonstrated a clear biological response in healthy volunteers. With these promising biomarker data and the favorable safety profile, we believe GLPG0187 has strong potential as a cancer drug,” said Onno van de Stolpe, CEO of Galapagos. “Therefore, we have decided to broaden the therapeutic focus to metastatic cancer, which is more prevalent than bone metastasis.”

In the double-blind, placebo-controlled trial, 27 healthy volunteers were given escalating doses of candidate drug GLPG0187 by either subcutaneous injection (17.5 to 315 mg) or oral administration (50 to 1200 mg). For both routes of administration, systemic safety data were favorable with no severe adverse events or changes in vital signs or laboratory parameters observed. Local reactions occurring at or near the injection site were not attributable to the candidate drug. A biomarker relevant to bone metastasis (serum CTX, collagen telopeptide) showed a response lasting 24 hours. Although bioavailability for the oral formulation was low, a clear biomarker response was observed with two oral doses (300 and 1200 mg). Given these results, Galapagos plans to initiate a second Phase I trial including cancer patients later this year. Galapagos is also working to improve the injectable formulation and the bioavailability of the oral formulation.

About GLPG0187

GLPG0187, an integrin receptor antagonist (IRA), blocks five integrin receptors known to be present in many metastatic cancers, affording a unique anti-integrin profile. In animal studies, oral administration of GLPG0187 as a single agent has been shown to inhibit multiple processes involved in the spread and growth of metastatic tumors.

About metastatic cancer

Metastatic cancer is a cancer that has spread from its primary site (such as the breast or prostate) to other parts of the body. Once in the bloodstream, metastatic cancer can spread throughout the body, but the most common sites of metastases are the lungs, bones, liver and brain. According to the American Cancer Society, an estimated half million cancer-related deaths occur annually in the U.S. and metastases are responsible for the majority of these cases. Once cancer has metastasized, it is rarely curable, but treatment options can increase the length and quality of patient lives.

About Galapagos

[Galapagos](#) (Euronext: GLPG; OTC: GLPYY) is a drug discovery and development company with small molecule programs in bone and joint diseases, metastatic cancer, cachexia, anti-infectives and metabolic diseases. It has established risk sharing alliances with GlaxoSmithKline, Janssen Pharmaceutica, Eli Lilly, Merck & Co. and Roche. Through an alliance with MorphoSys, Galapagos is also developing 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 has more than 500 employees and operates facilities in six countries, with global headquarters in Mechelen, Belgium. More info at: www.glpj.com

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