

## Positive topline results with GLPG1972 in osteoarthritis patients

**Mechelen, Belgium; 7 January 2018, 22.00 CET – Galapagos NV (Euronext & NASDAQ: GLPG) reports positive preliminary topline results with a Phase 1b study in osteoarthritis (OA) patients in the United States.**

Galapagos evaluated GLPG1972 in a randomized, placebo-controlled, double-blind Phase 1b study in 30 patients aged 50 to 75 years with diagnosis of knee and/or hip osteoarthritis, in the United States. Patients were given one of three doses of GLPG1972 or placebo for a total of 4 weeks, with a 3 week follow-up period. Primary objectives were to evaluate safety, tolerability, and pharmacokinetics of GLPG1972 in patients. A secondary objective was to measure the reduction of ARGS neopeptide, an important cartilage breakdown biomarker.

The mechanism of action of GLPG1972, which targets a cartilage degrading enzyme called ADAMTS-5, was confirmed in two animal models. An earlier Phase 1 study in healthy volunteers met all its safety and pharmacokinetic targets and also demonstrated that GLPG1972 reduced the blood level of ARGS neopeptide by up to more than 50% within two weeks.

In this Phase 1b study in patients, GLPG1972 was well tolerated. There was one treatment discontinuation with reversible abnormal liver function test on Day 15 in the highest dose cohort. The pharmacokinetics of GLPG1972 in a population of elderly individuals with OA were similar to those in healthy volunteers, potentially supporting once-daily oral treatment.

Patients on treatment achieved a dose-dependent, reduction of ARGS neopeptide versus placebo:

	Placebo (n=6)	Low dose (n=8)	Medium dose (n=8)	High dose (n=8)
Average % reduction in ARGS neopeptide compared to baseline, Day 29, in % (mean $\pm$ se)	-3.64 ( $\pm$ 5.95)	38.43 ( $\pm$ 2.91)	44.93 ( $\pm$ 4.46)	50.43 ( $\pm$ 4.47)

"We are pleased that this study extends our findings of more than 50% reduction in cartilage breakdown biomarker in healthy subjects to patients with osteoarthritis in a sustained way over a 4-week period," said Dr. Piet Wigerinck, Chief Scientific Officer of Galapagos. "We are working diligently with our collaboration partner Servier to prepare a global Phase 2 program expected to start later this year, and to further develop GLPG1972 as a potentially disease-modifying molecule for OA."

OA is a highly prevalent and disabling pathology. So far, no treatment is available to counteract disease progression, patients being left with only symptomatic treatments. As a result, OA represents an important unmet medical need. Since 2010, Servier<sup>1</sup> and Galapagos joined their expertise to tackle this problem, leading to the development of GLPG1972, a first-in-class and potentially disease-modifying investigational molecule. Galapagos has full US commercial rights to GLPG1972. Under the terms of the agreement, Galapagos is also eligible to receive development, regulatory and other milestone payments plus royalties upon commercialization outside the US.

<sup>1</sup> Servier is an international pharmaceutical company governed by a non-profit foundation, with its headquarters in France.

GLPG1972 is an investigational candidate drug and its safety and efficacy have not yet been established.

### **About Galapagos**

Galapagos (Euronext & NASDAQ: GLPG) is a clinical-stage biotechnology company specialized in the discovery and development of small molecule medicines with novel modes of action. Galapagos' pipeline comprises Phase 3 through to discovery programs in cystic fibrosis, inflammation, fibrosis, osteoarthritis and other indications. Our target discovery platform has delivered three novel mechanisms showing promising patient results in, respectively, inflammatory diseases, idiopathic fibrosis and atopic dermatitis. Galapagos is focused on the development and commercialization of novel medicines that will improve people's lives. The Galapagos group, including fee-for-service subsidiary Fidelta, has approximately 578 employees, operating from its Mechelen, Belgium headquarters and facilities in the Netherlands, France, and Croatia. More information at [www.glpg.com](http://www.glpg.com).

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### **Galapagos forward-looking statements**

*This release may contain forward-looking statements, including, among other things, statements regarding the mechanism of action and profile of, and timing and results of clinical trials with, and potential commercialization of, GLPG1972. Galapagos cautions the reader that forward-looking statements are not guarantees of future performance. Forward-looking statements involve known and unknown risks, uncertainties and other factors which might cause the actual results, financial condition and liquidity, performance or achievements of Galapagos, or industry results, to be materially different from any historic or future results, financial conditions and liquidity, performance or achievements expressed or implied by such forward-looking statements. In addition, even if Galapagos' results, performance, financial condition and liquidity, and the development of the industry in which it operates are consistent with such forward-looking statements, they may not be predictive of results or developments in future periods. Among the factors that may result in differences are that Galapagos' expectations regarding its GLPG1972 development program may be incorrect, the inherent uncertainties associated with competitive developments, clinical trial and product development activities and regulatory approval requirements (including that data from the ongoing clinical research programs may not support registration or further development of GLPG1972 due to safety, efficacy or other reasons), Galapagos' reliance on collaborations with third parties (including its collaboration partner for OA Servier), and estimating the commercial potential of Galapagos' product candidates. A further list and description of these risks, uncertainties and other risks can be found in Galapagos' Securities and Exchange Commission (SEC) filings and reports, including in Galapagos' most recent annual report on Form 20-F filed with the SEC and other filings and reports filed by Galapagos with the SEC. Given these uncertainties, the reader is advised not to place any undue reliance on such forward-looking statements. These forward-looking statements speak only as of the date of publication of this document. Galapagos expressly disclaims any obligation to update any such forward-looking statements in this document to reflect any change in its expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements, unless specifically required by law or regulation.*