

# **Galapagos initiates Phase 1 trial for second Toledo compound**

- Second generation compound of novel target class with dual action in inflammatory disorders
- Discovered and validated on Galapagos' target discovery platform

Mechelen, Belgium; 24 September 2019, 22.01 CET — Galapagos NV (Euronext & NASDAQ: GLPG) started a Phase 1 trial with GLPG3970, a second generation compound against a novel and undisclosed inflammation target class discovered by Galapagos.

The Toledo platform delivers small molecule inhibitors of Toledo targets with different selectivity profiles. GLPG3970 is a second-generation, more selective, compound for which preclinical activity has already been observed in a number of inflammatory indications, including in inflammatory bowel diseases, rheumatoid arthritis, and psoriasis.

The Phase 1 trial is a double-blind, placebo-controlled study evaluating the efficacy, safety, tolerability, and PK/PD¹ of GLPG3970 single and multiple ascending doses in up to 52 adult healthy male subjects, and, in a next step, in 20 psoriasis patients.

A Phase 1 trial with our first generation Toledo compound, GLPG3312, was announced early 2019, with results expected early next year. The Phase 2 trial in ulcerative colitis patients is now scheduled to start in H1 2020.

"We are excited with the rapid progress of our second Toledo compound into the clinic," said Dr. Piet Wigerinck, Chief Scientific Officer at Galapagos. "With the start of this trial, we are on track to potentially launch multiple proof of concept studies in parallel in 2020, in a range of inflammatory diseases. Thanks to its unique mechanism of action, the Toledo program has the potential to become a new paradigm in the treatment of inflammatory diseases."

## **About Toledo**

"Toledo" is a code name for a novel class discovered by Galapagos. The target family has a dual mode of action on inflammation by stimulating anti-inflammatory cytokines and inhibiting pro-inflammatory cytokines. Galapagos has observed unprecedented activity<sup>2</sup> in various inflammatory preclinical models with compounds targeting the class. Galapagos is executing on a broad program to discover and develop multiple series of compounds acting on Toledo, aimed at activity across several inflammatory conditions.

GLPG3312 and GLPG3970 are investigational drugs and their efficacy and safety have not been established.

For more information about Toledo in our R&D Update 2018: <a href="www.glpg.com/webcasts">www.glpg.com/webcasts</a>. For information about the clinical trial with GLPG3312 and GLPG3970: <a href="www.clinicaltrials.gov">www.clinicaltrials.gov</a>.

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<sup>&</sup>lt;sup>1</sup> Pharmacokinetics/pharmacodynamics

<sup>&</sup>lt;sup>2</sup> Data on file



#### **About Galapagos**

Galapagos (Euronext & NASDAQ: GLPG) discovers and develops small molecule medicines with novel modes of action, three of which show promising patient results and are currently in late-stage development in multiple diseases. The company's pipeline comprises Phase 3 through to discovery programs in inflammation, fibrosis, osteoarthritis and other indications. Galapagos' ambition is to become a leading global biopharmaceutical company focused on the discovery, development and commercialization of innovative medicines. More information at <a href="https://www.glpg.com">www.glpg.com</a>.

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#### Forward-looking statements

This release may contain forward-looking statements, including, among other things, statements regarding Galapagos' strategic ambitions, the mechanism of action and potential activity of Toledo compounds including GLPG3312 and GLPG3970; the anticipated timing of clinical trials and proof-of-concept studies with GLPG3312 and GLPG3970; the progression and results of such trials, and future regulatory submissions and Galapagos' interactions with regulatory authorities. 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 GLPG3312 and GLPG3970 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 Galapagos' ongoing clinical research programs may not support registration or further development of Toledo compounds including GLPG3312 and GLPG3970 due to safety, efficacy or other reasons), Galapagos' reliance on collaborations with third parties, and estimating the commercial potential of Toledo. 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.