

Press release

# Galapagos announces new Phase 2 Proof-of-Concept study with filgotinib in cutaneous lupus erythematosus

Mechelen, Belgium; 25 April 2017, 22.00 CET — Galapagos NV (Euronext & NASDAQ: GLPG) announces a new Phase 2 Proof-of-Concept study investigating filgotinib and another investigational agent in cutaneous lupus erythematosus (CLE). This study is being led by filgotinib collaboration partner Gilead Sciences, Inc.

"We are very excited with the initiation of this Proof-of-Concept study with filgotinib in CLE. This is the first time we evaluate filgotinib in an autoimmune skin disorder, and specifically, one with a significant unmet need," said Dr. Walid Abi-Saab, Chief Medical Officer of Galapagos. "This study represents another cornerstone in Gilead and Galapagos' efforts to explore filgotinib in inflammation. We look forward to seeing whether filgotinib can impact signs and symptoms of CLE."

Galapagos and Gilead entered into a global collaboration for the development and commercialization of filgotinib in inflammatory indications. This study in CLE is in addition to the ongoing Phase 2 studies in Sjögren's syndrome, ankylosing spondylitis (TORTUGA), and psoriatic arthritis (EQUATOR), as well as the ongoing FINCH Phase 3 program in rheumatoid arthritis, the DIVERSITY Phase 3 study in Crohn's disease (also Phase 2 in small bowel and fistulizing Crohn's disease), and the SELECTION Phase 2b/3 study in ulcerative colitis.

Filgotinib is an investigational drug and its efficacy and safety have not been established. For information about the studies with filgotinib: www.clinicaltrials.gov
For more information about filgotinib: www.glpg.com/filgotinib

## Filgotinib in CLE

The Phase 2 study will be a multi-center, randomized, double-blind, placebo-controlled study in adult female patients with active CLE. Approximately 50 patients are planned to be randomized in 18 centers in the US and Canada to receive either filgotinib, another investigational drug or placebo, administered once daily. The primary endpoint will be change the change from baseline in Cutaneous Lupus Erythematosus Disease Area and Severity Index (CLASI) activity score at Week 12.

## **About CLE**

Lupus is an autoimmune disease affecting multiple organs and systems in the body, resulting in a wide variety of signs and symptoms. CLE is a form of lupus in the skin which can be triggered or exacerbated by exposure to sunlight. CLE is most commonly diagnosed in women 20-50 years of age, although it may occur at any age. Approximately 1/3 of women who are diagnosed with CLE also develop systemic lupus erythematosus (SLE). Overall, therapeutic options for CLE are limited, and there are limited clinical trial data in CLE for the biologic and synthetic DMARDs that have been approved for other indications.

## **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. Our pipeline comprises Phase 3, Phase 2, Phase 1, pre-clinical, and discovery programs in cystic fibrosis, inflammation, fibrosis, osteoarthritis and other indications. We have discovered and developed filgotinib: in collaboration with Gilead we aim to bring this JAK1-selective inhibitor for inflammatory indications to patients all over the world. 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 510 employees, operating from its



Mechelen, Belgium headquarters and facilities in The Netherlands, France, and Croatia. More information at www.glpg.com.

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#### **Forward-Looking Statements**

This release may contain forward-looking statements, including statements regarding Galapagos' strategic ambitions, the anticipated timing of clinical studies with filgotinib and the progression and results of such studies. Galapagos cautions the reader that forward-looking statements are not quarantees 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 the inherent uncertainties associated with competitive developments, clinical trial and product development activities and regulatory approval requirements (including that data from the ongoing and planned clinical research programs may not support registration or further development of filgotinib due to safety, efficacy or other reasons), Galapagos' reliance on collaborations with third parties (including its collaboration partner for filgotinib, Gilead), 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 subsequent 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.