

## **Galapagos announces first patient enrolled in FILOSOPHY study to advance understanding of Jyseleca (filgotinib) effectiveness and safety in a real-world setting**

*Study uses mobile device technology to support capture of patient-reported outcomes during early and ongoing use of study treatment amongst patients with rheumatoid arthritis*

**Mechelen, Belgium; 18 May 2021; 22.01 CET; – Galapagos NV (Euronext & Nasdaq: GLPG) today announced that the first patient has been enrolled in the FILOSOPHY Phase 4 European real-world outcomes study. The goal of the FILOSOPHY study is to advance understanding of the effectiveness and safety of filgotinib as it is used with patients with rheumatoid arthritis (RA) in clinical practice.**

The study, with target enrollment of 1500 patients across Europe, will evaluate the effectiveness, safety, and patient-reported outcomes (PROs) in patients with moderate to severe active RA while receiving filgotinib in a real-world setting for up to two years. Mobile device technology will play a central role in collection of PROs, allowing data collection to begin within the first weeks of treatment. This may also prove to be an effective tool during the pandemic, while in-person clinic visits are harder to achieve.

FILOSOPHY will enable the gathering of comprehensive real-world data in a population that may not be fully represented in clinical trials, as randomized, placebo-controlled trials require strict patient inclusion criteria. These data will expand the evidence base to support the appropriate use of filgotinib in clinical practice.

Dr. Walid Abi-Saab, Chief Medical Officer of Galapagos said, "This study can enhance our understanding about the effectiveness and safety of filgotinib from the experiences of RA patients who are prescribed the treatment in a real-world healthcare setting. We aim to improve disease management and outcomes for people living with this debilitating condition."

Professor Gerd Burmester, Director Department of Rheumatology and Clinical Immunology, Charité, Universitätsmedizin, Berlin and FILOSOPHY Steering Committee Member, added, "We expect that use of remote devices to collect treatment outcomes data will give us more comprehensive insights into early treatment effects in relation to patient reported outcomes, including pain and fatigue. In addition, we are interested to understand how long patients stay on treatment and how this could be affected by patient characteristics or treatment effects."

### **About Rheumatoid Arthritis**

RA is a chronic inflammatory disease. In RA a person's immune system attacks healthy cells, causing painful swelling in affected parts of the body, primarily in the joints.<sup>1</sup> RA can cause tissue damage resulting in chronic pain, unsteadiness and physical disability.<sup>1</sup> More than 2.3 million individuals are living with RA in Europe<sup>2</sup> and women are 2 – 3 times more likely to develop RA<sup>3</sup>. The onset of disease is typically between 30 and 50 years of age<sup>4</sup>.

### **About the FILOSOPHY Phase 4 study**

FILOSOPHY (FILgotinib Observational Study Of Patient Health related outcomes over 2 Years), is a prospective, non-interventional cohort study enrolling approximately 1500 patients across Europe. Data will be collected by the clinical sites and patients using an electronic case report form (eCRF) and mobile devices. Each enrolled patient will be followed for 24 months or until

discontinuation of study, whichever occurs first. Baseline assessments may be collected within 30 days prior to the first dose of filgotinib.

The primary objective of the study is to evaluate the treatment persistence rate at 24 months, defined as the rate of patients continuing to receive filgotinib 24 months from treatment initiation. Secondary and exploratory objectives include effectiveness, evaluation of the effect of filgotinib on patient reported outcomes (PROs) including on pain, fatigue and work productivity, rate of adverse events (AEs) and serious adverse events (SAEs) as well as adverse events of interest, including serious and opportunistic infections (including herpes zoster), major adverse cardiovascular events (MACE), venous thromboembolism (VTE), hyperlipidemia, malignancies, non-melanoma skin cancer (NMSC), and gastrointestinal (GI) perforation.

For more information go to [ClinicalTrials.gov Identifier](https://clinicaltrials.gov/ct2/show/study/NCT04871919): NCT04871919

### **About filgotinib**

Filgotinib is approved and marketed as Jyseleca (200mg and 100mg tablets) in the Europe Union, Great Britain and Japan for the treatment of adults with moderate to severe active rheumatoid arthritis (RA) who have responded inadequately or are intolerant to one or more disease modifying anti-rheumatic drugs (DMARDs). Filgotinib may be used as monotherapy or in combination with methotrexate (MTX). The European Summary of Product Characteristics for filgotinib, which includes contraindications and special warnings and precautions, is available at [www.ema.europa.eu](http://www.ema.europa.eu). The interview form from the Japanese Ministry of Health, Labour and Welfare is available at [www.info.pmda.go.jp](http://www.info.pmda.go.jp). The Great Britain Summary of Product Characteristics is available at [www.medicines.org.uk/emc](http://www.medicines.org.uk/emc). Applications have been submitted to the European Medicines Agency (EMA), the UK's Medicines and Healthcare products Regulatory Agency (MHRA), and Japan's Pharmaceuticals and Medical Devices Agency (PMDA) for the treatment of adults with moderately to severely active ulcerative colitis (UC) who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic agent and are currently under review. Filgotinib is not approved in any other jurisdictions.

### **About the filgotinib collaboration**

Gilead and Galapagos NV are collaborative partners in the global development and commercialization of filgotinib. Galapagos will be responsible for the commercialization of filgotinib in Europe (transition anticipated to be completed by end of 2021), while Gilead will remain responsible for filgotinib outside of Europe, including in Japan, where filgotinib is co-marketed with Eisai. Filgotinib in UC has been filed in Europe and Japan and a global Phase 3 program is ongoing in Crohn's Disease. More information about clinical trials can be accessed at [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

### **About Galapagos**

Galapagos NV discovers, develops and commercializes small molecule medicines with novel modes of action, several of which show promising patient results and are currently in late-stage development in multiple diseases. Our pipeline comprises discovery through Phase 3 programs in inflammation, fibrosis and other indications. Our ambition is to become a leading global biotech company focused on the discovery, development and commercialization of innovative medicines. More information at [www.glp.com](http://www.glp.com).

1. Centers for Disease Control and Prevention. Rheumatoid Arthritis (RA). Available at: <https://www.cdc.gov/arthritis/basics/rheumatoid-arthritis.html>. Accessed September 2020.
2. National Rheumatoid Arthritis Society. The Burden of Rheumatoid Arthritis across Europe a Socioeconomic Survey (BRASS). Summary Report. Available at: [https://www.nras.org.uk/data/files/Publications/Surveys%20Reports/UoC\\_HCD\\_BRASS%20Summary%20Report%20FINAL.pdf](https://www.nras.org.uk/data/files/Publications/Surveys%20Reports/UoC_HCD_BRASS%20Summary%20Report%20FINAL.pdf). Accessed September 2020
3. Arthritis Foundation. Arthritis by the Numbers. Available at: <https://www.arthritis.org/getmedia/e1256607-fa87-4593-aa8a-8db4f291072a/2019-abtn-final-march-2019.pdf>. Accessed September 2020.
4. Wasserman, A. Diagnosis and Management of Rheumatoid Arthritis. *American Family Physician*. 2011;84(11):1245-1252.

## Contacts

### Investors:

Elizabeth Goodwin  
VP Investor Relations  
+1 781 460 1784

Sofie Van Gijssel  
Senior Director Investor Relations  
+32 485 19 14 15  
[ir@glpg.com](mailto:ir@glpg.com)

### Media:

Carmen Vroonen  
Global Head of Communications & Public Affairs  
+32 473 824 874

Anna Gibbins  
Senior Director Therapeutic Areas Communications  
+44 7717 801900  
[communications@glpg.com](mailto:communications@glpg.com)

### Forward-looking statements

*This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, that are subject to risks, uncertainties and other factors that could cause actual results to differ materially from those referred to in the forward-looking statements and, therefore, the reader should not place undue reliance on them. These risks, uncertainties and other factors include, without limitation, the inherent risks associated with clinical trial and product development activities, including the FILOSOPHY study, competitive developments, and regulatory approval requirements, the risk that the results of the FILOSOPHY study will not support continued approval of Jyseleca for the treatment of adults with moderate to severe active rheumatoid arthritis (RA) who have responded inadequately or are intolerant to one or more disease modifying anti-rheumatic drugs (DMARDs) due to safety, efficacy or other reasons, Galapagos' reliance on collaborations with third parties, including the collaboration with Gilead for filgotinib, risks related to the implementation of the transition of European commercialization responsibility to us, as well as those risks and uncertainties identified in our Annual Report on Form 20-F for the year ended 31 December 2020 and our subsequent filings with the SEC. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. The forward-looking statements contained herein are based on management's current expectations and beliefs and speak only as of the date hereof, and Galapagos makes no commitment to update or publicly release any revisions to forward-looking statements in order to reflect new information or subsequent events, circumstances or changes in expectations.*