Galapagos to present encouraging initial data from FILOSOPHY real-world arthritis study at ACR Convergence 2022

- Preliminary results from real-world FILOSOPHY, *FILgotinib Observational Study Of Patient Health-related outcomes*, in the first 200 patients with moderately to severely active rheumatoid arthritis (RA)
- Data showed that filgotinib induced rapid relief in pain and fatigue as early as Week 1 as well as improvements in disease activity[1] at Month 1
- 7 additional presentations encompassing key analyses of filgotinib, including long term, integrated safety data and safety data in specific subpopulations, demonstrating Galapagos' commitment to the RA patient and HCP community

Mechelen, Belgium; 8 November 2022, 22.01 CET, Galapagos NV (Euronext & NASDAQ: GLPG) will present new data on filgotinib at the American College of Rheumatology (ACR) Convergence 2022 meeting taking place in Philadelphia, Pennsylvania from 10-14 November 2022.

Dr. Walid Abi-Saab, Chief Medical officer, at Galapagos said, "We are excited to present data at ACR which highlights our continued commitment to patients and the healthcare provider community, in particular initial data from our first international, real-world arthritis study. We believe that it's not only important to control disease activity to prevent long term irreparable disability, but also to take a comprehensive approach to the disease by aiming at improving quality of life of patients and their families. These initial results are encouraging, and we look forward to seeing further results as the study continues."

Over the last two decades, disease activity in rheumatoid arthritis (RA) has improved, yet fatigue and pain continue to hinder patients' quality of life (QOL), and ability to function.[2,3] Less than 30% of patients are satisfied with their pain levels and 40-80% of RA patients are affected by fatigue.[4,5] Pain and fatigue have negative impacts on mental and physical QOL, including social functioning.[6]

Interim data from the FILOSOPHY study of patients aged ≥18 years with moderately to severely active RA, who are prescribed filgotinib for the first time, showed rapid improvements in pain (VAS scale) and fatigue as early as week 1, with mean changes from baseline in VAS pain score of -11.9 and -22.2 at Week 1 and Month 1, respectively, and from baseline in FACIT-F[7] score of 3.7 and 6.8 at Week 1 and Month 1, respectively.[1] The FILOSOPHY study also showed improvements in disease activity, with a mean change from baseline in Clinical Disease Activity Index (CDAI) score of -13.7 at Month 1.[1] The interim results are based on data from 200 patients enrolled in Germany, the United Kingdom, the Netherlands, Belgium, and Italy, representing real-world patients with moderately to severely active RA.[1]

Other abstracts being presented at ACR Convergence 2022 include analyses of filgotinib safety, and clinical outcomes, in adult patients with RA with up to 8.2 years of exposure to filgotinib, including the most recent integrated safety data from 7 clinical trials (pooled phase 2 and 3 clinical

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[1] Galloway J, Bevers K, Vershueren P, et al. Presented at: ACR Convergence 2022; November 10-14, 2022; Philadelphia, Pennsylvania.
[2] Nieuwenhuis WP, de Wit MP, Boonen A, *et al*. Changes in the clinical presentation of patients with rheumatoid arthritis from the early 1990s to the years 2010: earlier identification but more severe patient reported outcomes. *Annals of the Rheumatic Diseases*. 2016;**75**:2054-2056.
[3] Gossec L, Steinberg G, Rouanet S, Combe B. Fatigue in rheumatoid arthritis: quantitative findings on the efficacy of tocilizumab and on factors associated with fatigue. The French multicentre prospective PEPS Study. *Clin Exp Rheumatol*. 2015;**33(5)**:664-70.
[4] Santos EJF, Duarte C, da Silva JAP, Ferreira RJO. The impact of fatigue in rheumatoid arthritis and the challenges of its assessment. *Rheumatology (Oxford)*. 2019;**58(Suppl 5)**:v3-v9.
[5] Taylor P, Manger B, Alvaro-Gracia J, *et al*. Patient perceptions concerning pain management in the treatment of rheumatoid arthritis. *J Int Med Res*. 2010;**38(4)**:1213-24.
[6] Wysocka-Skurska I, Sierakowska M, Kułak W. Evaluation of quality of life in chronic, progressing rheumatic diseases based on the example of osteoarthritis and rheumatoid arthritis. *Clin Interv Aging*. 2016;**11**:1741-1750.
[7] The FACIT Fatigue Scale is a short, 13-item tool that measures an individual's level of fatigue during their usual daily activities over the past week.

data) that looked at the overall RA population as well as at subgroups of patients with risk factors for cardiovascular events, and another abstract describing laboratory results from a long-term Phase 3 extension study. Two encore abstracts will be presented on the effect of filgotinib on body weight and BMI, and insights from a post-hoc analysis of filgotinib integrated safety data.

Scientific Abstracts:

Abstract Title	Authors	Presentation date/time
Galapagos-driven original abstracts		
Baseline characteristics of and early outcomes in the first 200 patients with RA treated with filgotinib in a prospective observational study	James Galloway, Karen Bevers, Patrick Verschueren, Roberto F. Caporali, Susana Romero Yuste, Jérôme Avouac, Emilia Gvozdenovic, Kristina Harris, Monia Zignani, Gerd Burmester	Poster Number: 0276 Date: 12 November 2022, 1:00–3:00 PM Session: RA – Treatment poster I
Malignancy events in the filgotinib rheumatoid arthritis and ulcerative colitis clinical development programs	Xavier Mariette, Sandrine Aspeslagh, Richard Moriggl, Vijay Rajendran, Christine Rudolph, Paul Van Hoek, Nadia Verbruggen, Chris Watson, Sven Borchmann, Andreas Stallmach	Poster Number: 0277 Date: 12 November 2022, 1:00–3:00 PM Session: RA – Treatment poster I
Exploratory analysis of filgotinib safety data in patients with moderately to severely active RA and an increased risk of cardiovascular events: data from phase 2 and 3 clinical trials	Maya H. Buch, Gerd R. Burmester, Xavier Mariette, Christina Charles-Schoeman, Vijay Rajendran, Pieter-Jan Stiers, Agustin Cerani, Paul Van Hoek, Katrien Van Beneden, Yoshiya Tanaka, Hendrik Schulze-Koops, René Westhovens, Ennio Giulio Favalli	Poster Number: 0275 Date: 12 November 2022, 1:00–3:00 PM Session: RA – Treatment poster I
Safety of filgotinib in patients with RA: Laboratory analysis results from a long-term extension study	Maya Buch, James Galloway, Ennio Giulio Favalli, Arnaud Constantin, Patrick Durez, Paul Van Hoek, Christopher Watson, Pieter-Jan Stiers, Vijay Rajendran, Katrien Van Beneden, Tsutomu Takeuchi, Bernard Combe	Poster Number: 0280 Date: 12 November 2022, 1:00–3:00 PM Session: RA – Treatment poster I
Clinical outcomes of filgotinib in patients with RA aged ≥65 years: A post hoc subgroup analysis of phase 2 and 3 clinical trials and ongoing long-term extensions	Maya Buch, Bernard Combe, Jose A. Gómez-Puerta, Roberto Caporali, Jacques-Eric Gottenberg, Paul Van Hoek, Vijay Rajendran, Pieter-Jan Stiers, Katrien Van Beneden, Daniel Aletaha, Gerd Burmester, René Westhovens, Yoshiya Tanaka	Poster Number: 0281 Date: 12 November 2022, 1:00–3:00 PM Session: RA – Treatment poster I
An update on the integrated safety analysis of filgotinib in patients with moderately to severely active RA	Kevin Winthrop, Daniel Aletaha, Roberto F. Caporali, Yoshiya Tanaka, Tsutomu Takeuchi, Paul Van Hoek, Chris Watson, Pieter-Jan Stiers, Vijay Rajendran, Katrien Van Beneden, Jacques-Eric Gottenberg, Gerd R. Burmester	Poster Number: 0273 Date: 12 November 2022, 1:00–3:00 PM Session: RA – Treatment poster I

Galapagos-driven encore abstracts		
The use of exposure-adjusted event rates versus exposure-adjusted incidence rates in adverse event reporting: Insights from filgotinib integrated safety data in RA *(EULAR 2022 encore)*	Patrick Durez, Eugen Feist, Ricardo Blanco, Vijay Rajendran, Nadia Verbruggen, Katrien Van Beneden, James Galloway	Poster Number: 0278 Date: 12 November 2022, 1:00–3:00 PM Session: RA – Treatment poster I
Effect of filgotinib on body weight and BMI and effect of baseline BMI on the efficacy and safety of filgotinib in RA *(EULAR 2022 encore)*	Alejandro Balsa, Siegfried Wassenberg, Anne Tournadre, Hans-Dieter Orzechowski, Katrien Van Beneden, Vijay Rajendran, Udo Lendl, Pieter-Jan Stiers, Chris Watson, Roberto Caporali, Patrick Verschueren	Poster Number: 0279 Date: 12 November 2022, 1:00–3:00 PM Session: RA – Treatment poster I

About filgotinib
Filgotinib is marketed as Jyseleca in the European Union (incl. Norway), Great Britain, and Japan for the treatment of adults with moderately to severely active rheumatoid arthritis (RA) who have responded inadequately or are intolerant to one or more disease modifying anti-rheumatic drugs (DMARDs). Filgotinib is also marketed as Jyseleca in the European Union (incl. Norway), Great Britain, and Japan for the treatment of adult patients 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. Jyseleca (filgotinib) 100mg and 200mg are registered in the above-mentioned territories. A global Phase 3 program with filgotinib is ongoing in Crohn's Disease. More information about clinical trials can be accessed at https://www.clinicaltrials.gov.

The European Summary of Product Characteristics for filgotinib, which includes contraindications and special warnings and precautions, is available at www.ema.europa.eu. The Great Britain Summary of Product Characteristics for filgotinib can be found at www.medicines.org.uk/emc and the Northern Ireland Summary of Product Characteristics for filgotinib can be found at www.emcmedicines.com/en-GB/northernireland, respectively. The interview form from the Japanese Ministry of Health, Labour and Welfare is available at www.info.pmda.go.jp.

Jyseleca® is a trademark of Galapagos NV and Gilead Sciences, Inc. or its related companies. Except for filgotinib's approval as Jyseleca for the treatment of moderately to severely RA and UC by the relevant regulatory authorities in the European Union, Great Britain, and Japan, our drug candidates are investigational; their efficacy and safety have not been fully evaluated by any regulatory authority.

About FILOSOPHY
FILOSOPHY (*FILgotinib Observational Study Of Patient Health-related outcomes*), is a prospective, observational, non-interventional cohort Phase 4 study enrolling approximately 1500 patients aged ≥ 18 years with moderately to severely active RA across Europe. Data will be collected by the clinical sites and patients using an electronic case report form (eCRF) and electronic patient reported outcomes (ePRO) via mobile devices. Each enrolled patient will be followed for 24 months or until discontinuation of the study, whichever occurs first.

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 objectives include effectiveness, evaluation of the effect of filgotinib on patient reported

outcomes (PROs) including on pain, fatigue and work productivity, and rate of adverse events (AEs) and serious adverse events (SAEs) as well as adverse events of interest. More information is available on clinicaltrials.gov, identifier NCT04871919.

About Galapagos

Galapagos is a fully integrated biotechnology company focused on discovering, developing, and commercializing innovative medicines. We are committed to improving patients' lives worldwide by targeting diseases with high unmet needs. Our R&D capabilities cover multiple drug modalities, including small molecules and cell therapies. Our portfolio comprises discovery through to Phase 4 programs in immunology, oncology and other indications. Our first medicine for rheumatoid arthritis and ulcerative colitis is available in the European Union, Norway, Great Britain, and Japan. For additional information, please visit www.glpg.com or follow us on LinkedIn or Twitter.

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Forward Looking Statements

This press release includes forward-looking statements, all of which involve certain risks and uncertainties. These statements are often, but are not always, made through the use of words or phrases such as "may," "upcoming," "future," "potential," "will," and "plan," as well as similar expressions. Forward-looking statements contained in this release include, but are not limited to, statements regarding interim data from the FILOSOPHY study and other analyses of filgotinib and Galapagos' plans and strategy with respect to Jyseleca and the FILOSOPHY study. Of note, the FILOSOPHY study is ongoing and these interim results may not continue or be confirmed upon completion of the study. Any forward-looking statements in this release are based on Galapagos management's current expectations and beliefs and are not guarantees of future performance. Forward-looking statements involve known and unknown risks, uncertainties and other factors which might cause Galapagos' actual results, performance or achievements to be materially different from any historic or future results, performance or achievements expressed or implied by such forward-looking statements. These risks, uncertainties and other factors include, without limitation, the risk that ongoing and future clinical studies with filgotinib may not be completed in the currently envisaged timelines or at all, the inherent risks associated with clinical trial and product development activities, including the filgotinib clinical program and the FILOSOPHY study, the inherent risks and 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, including but not limited to the data from the ongoing FILOSOPHY study, may not support registration or further development of filgotinib due to safety, efficacy or other reasons), the risks related to continued regulatory review of filgotinib following approval by relevant regulatory authorities, including EMA's safety review of JAK inhibitors used to treat certain inflammatory disorders, the risks that regulatory authorities may require additional post-approval trials of filgotinib or any other product candidates that are approved in the future, Galapagos' reliance on collaborations with third parties (including our collaboration partner for filgotinib, Gilead) and that Galapagos' estimations regarding its filgotinib development program and regarding the commercial potential of filgotinib may be incorrect, the risk that Galapagos will not be able to continue to execute on its currently contemplated business plan and/or will need to revise its business plan, and risks related to the ongoing COVID-19 pandemic, as well as those risks and uncertainties identified in our most recent Annual Report on Form 20-F filed with the U.S. Securities and Exchange Commission (SEC), as supplemented and/or modified by any other filings and reports that we have made or will make with the SEC in the future. Given these risks and uncertainties, the reader is advised not to place any undue reliance on such forward-looking statements. In addition, even if Galapagos' results, performance or achievements are consistent with such forward-looking statements, they may not be predictive of results, performance or achievements in future periods. These forward-looking statements speak only as of the date of publication of this release.

Galapagos expressly disclaims any obligation to update any such forward-looking statements in this release unless required by law or regulation.