Galapagos demonstrates commitment to immunology with new data in rheumatoid arthritis at EULAR 2023

- **9 poster presentations and 3 abstracts publications reinforce Galapagos' commitment to immunology and the rheumatoid arthritis (RA) patient and healthcare professional community**
- **New analyses will be presented from long-term extension studies providing insights into filgotinib's effectiveness and safety**
- **Interim baseline characteristics, effectiveness and safety outcomes will be published online from the real-world FILOSOPHY study in RA patients**

Mechelen, Belgium; 22 May 2023, 22:01 CET; Galapagos NV (Euronext & NASDAQ: GLPG) will present a broad range of abstracts, including analysis from randomized controlled trials (RCTs) and real-world evidence (RWE) studies at the European League Against Rheumatism (EULAR) annual congress taking place from 31 May to 3 June 2023 in Milan.

"We are focused on advancing treatment options for chronic, debilitating immune-mediated diseases such as RA and are excited to present further analyses on filgotinib's efficacy and safety profile at this year's EULAR congress," said Daniele D'Ambrosio, MD, PhD, Therapeutic Area Head, Immunology, at Galapagos. "Our presence at EULAR underscores our firm commitment to develop transformational therapies to improve the lives of patients around the world."

A number of abstracts will present trial data analyses on filgotinib, a once-daily oral preferential JAK-1 inhibitor, for the treatment of moderate to severe active RA. Key presentations include long-term efficacy and integrated safety data, post hoc analysis identifying distinct trajectories of treatment responses in patients with RA receiving filgotinib, the long-term clinical profile of filgotinib in patients with RA by cardiovascular (CV) risk factors, and the added value of filgotinib on pain relief in patients with RA achieving remission in the Phase 3 FINCH 1, 2 and 3 studies (NCT02889796, NCT02873936 and NCT02886728). Additionally, interim results from 500 patients on baseline characteristics as well as effectiveness and safety outcomes from the FILOSOPHY real-world evidence study (NCT04871919), which has now enrolled over 1000 patients in RA, will be published online.

Furthermore, Galapagos is hosting a symposium: "**JAK to reality: seeking clarity in RA**", which will focus on key considerations when selecting treatments for RA patients, efficacy and safety of JAK inhibitors, and the practical use of JAK inhibitors in the treatment of RA patients. An interactive meet-the-expert session: "**Burning questions: the practical use of JAK inhibitors in RA**", will feature an expert faculty sharing insights and answers to audience questions on recent developments in the RA treatment landscape and the potential implications for clinical practice. In addition to exhibiting an interactive booth that attendees can explore at the congress, Galapagos is also hosting a media roundtable discussion featuring experts, including a patient representative, discussing the real-life impact of RA and exploring solutions to overcome and manage the burden of the disease.

Scientific abstracts include:

Abstract Title	Authors	Presentation details
Integrated safety analysis of filgotinib in patients with moderate to severe active rheumatoid arthritis with a maximum exposure of 8.3 years	Kevin Winthrop, Daniel Aletaha, Roberto Caporali, Yoshiya Tanaka, Tsutomu Takeuchi, Paul Van Hoek, Pieter-Jan Stiers, Vijay Rajendran, Katrien Van Beneden, Jacques-Eric Gottenberg, Gerd R. Burmester	Poster Number: POS0844 Date: 01 June 2023, 14:45–15:45 CET
Distinct treatment responses in patients with rheumatoid arthritis receiving filgotinib 200 mg over 12 months: A post hoc analysis of FINCH 1	Peter C. Taylor, Yoshiya Tanaka, Emily Aiello, Thomas Debray, Chris Watson, Kristina Harris, Gerd Rüdiger Burmester	Poster Number: POS0843 Date: 01 June 2023, 14:45–15:45 CET
What trade-offs are acceptable to rheumatoid arthritis patients during treatment selection?	Rieke Alten, Juan Carlos Nieto Gonzalez, Peggy Jacques, Carlomaurizio Montecucco, Robert Moots, Helga Radner, Sebastian Heidenreich, Chiara Whichello, Nicolas Krucien, Monia Zignani, Harald Vonkeman, Katrien Van Beneden	Poster Number: POS0600-HPR Date: 31 May 2023, 15:30–16:30 CET
Safety and efficacy of filgotinib: an update from the DARWIN 3 Phase 2 long-term extension with a maximum of 8.2 years of exposure	Rene Westhovens, Rieke Alten, Lorenzo Dagna, Arthur Kavanaugh, Kevin L. Winthrop, Jane Barry, Robin Besuyen, Claudio Corallo, Dick de Vries, Nicolas Martin, Chris Watson, Mark C. Genovese, Alberto Spindler, Mykola Stanislavchuk, Maria Greenwald, Paul Emery	Poster Number: POS0829 Date: 01 June 2023, 14:45–15:45 CET
Long-term clinical profile of filgotinib (FIL) in patients (pts) with rheumatoid arthritis (RA) by cardiovascular (CV) risk factors: a post hoc subgroup analysis	Maya H Buch, Jose A Gómez-Puerta, Gerd Rüdiger Burmester, Bernard G Combe, Vijay Rajendran, Pieter-Jan Stiers, Paul Van Hoek, Katrien Van Beneden, Jacques-Eric Gottenberg, Yoshiya Tanaka, Daniel Aletaha, René Westhovens, Roberto Caporali	Poster Number: POS0308 Date: 03 June 2023, 10:00–11:30 CET Poster tour - discussion session: 10:05–10:10 CET
Real-world experience with filgotinib (FIL) for rheumatoid arthritis (RA) in Germany: A retrospective chart review	Olaf Schultz, Christoph Fiehn, Christian Kneitz, Nils Picker, Daniel Kromer, Monia Zignani, Francesco De Leonardis, Hans-Dieter Orzechowski, Margot Gurrath, Klaus Krüger	Poster Number: POS0851 Date: 01 June 2023, 14:45–15:45 CET
Efficacy of filgotinib (FIL) in patients (pts) with rheumatoid arthritis (RA): Week (W) 156 results from a long-term extension (LTE) study	Maya H Buch, Daniel Aletaha, Roberto Caporali, Bernard G Combe, Hendrik Schulze-Koops, Jacques-Eric Gottenberg, Yoshiya Tanaka, Ricardo Blanco, Tsutomu Takeuchi, Edmund V Ekoka Omoruyi, Katrien Van Beneden, Vijay Rajendran, Chris Watson, Francesco De Leonardis, Paul Emery	Poster Number: POS0853 Date: 01 June 2023, 14:45–15:45 CET
Cardiovascular (CV) and malignancy events in the filgotinib (FIL) rheumatoid arthritis (RA) clinical development program up to 8.3 years	Xavier Mariette, Sven Borchmann, Sandrine Aspeslagh, Jaime Calvo-Alén, Richard Moriggl, Zoltan Szekanecz, Francesco De Leonardis, Nadia Verbruggen, Paul Van Hoek, Marc Schmalzing, Andreas Stallmach, Christina Charles-Schoeman, Vijay Rajendran, Christine Rudolph, Chris Watson, Yoshiya Tanaka, Ernest Choy	Poster Number: POS0824 Date: 01 June 2023, 14:45–15:45 CET

Interim update on baseline characteristics and effectiveness from a prospective observational study of patients with rheumatoid arthritis (RA) treated with filgotinib (FILOSOPHY)	Roberto Caporali, Jérôme Avouac, Karen Bevers, Gerd Burmester, Thomas P.A. Debray, Francesco De Leonardis, Kristina Harris, Neil Betteridge, Susana Romero Yuste, Patrick Verschueren, Monia Zignani, James Galloway	Poster Number: POS0466 Date: 31 May 2023, 15:30–16:30 CET Session: Poster view Poster discussion session: NA
Safety outcomes in patients (pts) with rheumatoid arthritis (RA) treated with filgotinib (FIL) in FILOSOPHY: interim results from a prospective observational study	Patrick Verschueren, Jérôme Avouac, Karen Bevers, Susana Romero Yuste, Roberto Caporali, Thomas P.A. Debray, Francesco De Leonardis, James Galloway, Monia Zignani, Gerd Burmester	**Abstract publication** Abstract number: AB0191
Effect of filgotinib on pain in patients with rheumatoid arthritis in the Phase 3 FINCH 1, 2 and 3 studies	Peter C. Taylor, Arthur Kavanaugh, Peter Nash, Janet Pope, Georg Pongratz, Bruno Fautrel, Rieke Alten, Ken Hasegawa, Shangbang Rao, Dick de Vries, Pieter-Jan Stiers, Chris Watson, Rene Westhovens	**Abstract publication** Abstract number: AB0290
Safety of filgotinib in patients with RA: Laboratory analysis results from a long-term extension study *(encore from ACR 2022)*	Ennio Giulio Favalli, Maya H Buch, James Galloway, Arnaud Constantin, Patrick Durez, Paul Van Hoek, Christopher Watson, Pieter-Jan Stiers, Vijay Rajendran, Katrien Van Beneden, Tsutomu Takeuchi, Bernard Combe	**Abstract publication** Abstract number: AB0454

About rheumatoid arthritis (RA)

Rheumatoid arthritis (RA) is an autoimmune inflammatory disease that primarily causes pain, stiffness and swelling in the joints. RA often follows a painful, progressively debilitating course, depriving patients of the ability to continue their daily lives and leading to physical disability. Despite current treatments, RA continues to pose a substantial burden to people living with the disease, comprised of the daily health issues directly related to their RA, such as pain, and the complications of managing comorbid conditions.[1,2,3]

About filgotinib

Filgotinib is marketed as Jyseleca® in Europe and Japan for the treatment of adults with moderate to severe active RA who have responded inadequately or are intolerant to one or more disease modifying anti-rheumatic drugs. Filgotinib is also marketed as Jyseleca® in Europe and Japan for the treatment of adult patients with moderate to severe 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® 100mg and 200mg are registered in the above-mentioned territories. 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,

[1] Taylor PC, Moore A, Vasilescu R, Alvir J, Tarallo M. A structured literature review of the burden of illness and unmet needs in patients with rheumatoid arthritis: a current perspective. Rheumatology International. 2016;36(5):685-95.
[2] Radner H, et al. Comorbidity affects all domains of physical function and quality of life in patients with rheumatoid arthritis Rheumatology 2011 Feb;50(2):381-8.
[3] An J, et al. Prevalence of comorbidities and their associations with health-related quality of life and healthcare expenditures in patients with rheumatoid arthritis Clin Rheumatol. 2019; 38(10):2717-2726.

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 moderate to severe active 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 Galapagos

Galapagos is a fully integrated biotechnology company united around a single purpose: to transform patient outcomes through life-changing science and innovation for more years of life and quality of life. We focus on the key therapeutic areas of immunology and oncology, where we have developed a deep scientific expertise in multiple drug modalities, including small molecules and cell therapies. Our portfolio comprises discovery through to commercialized programs and our first medicine for rheumatoid arthritis and ulcerative colitis is available in Europe 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 not always, made through the use of words or phrases such as "will," "commit," "potential," "continue," "develop," and "advance," as well as any similar expressions. Forward-looking statements contained in this release include, but are not limited to, statement regarding preliminary, interim and topline data from our studies, including, but not limited to, the FILOSOPHY and Phase 3 FINCH 1, 2 and 3 studies, and any other analyses related to our portfolio, and statements regarding the expected timing, design and readouts of our ongoing studies and trials, and our plans and strategy with respect to filgotinib and such studies and trials. Any forward-looking statements in this release are based on our 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 our actual results, performance or achievements to be materially different from any historic or future results, performance or achievements expressed or implied by such statements. These risks, uncertainties and other factors include, without limitation, the risk that ongoing and future clinical studies with filgotinib (including the FILOSOPHY study) may not be completed in the currently envisaged timelines or at all, the inherent risks and uncertainties associated with competitive developments, clinical trials, recruitment of patients, product development activities and regulatory approval requirements (including that data from ongoing and planned clinical research programs, including, without limitation, the data from the ongoing FILOSOPHY study, may not support the further development of filgotinib due to safety, efficacy or other reasons and that data readouts in the future may not reflect interim data results), *and the* risk that we will not be able to continue to execute on our currently contemplated business plan and/or will need to revise our business plan. A further list of these risks, uncertainties and other risks can be found in our filings and report with the Securities and Exchange Commission (SEC), including in our most recent Annual Report on Form 20-F filed with the 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 our 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 hereof. We expressly disclaim any obligation to update any such statements in this release, unless required by law or regulation.