



DARWIN 2 24-week monotherapy data in RA confirm previous results and support best-in-class potential for filgotinib

- **ACR50 responses up to 45 % as once-daily monotherapy**
- **DAS28(CRP) low disease activity up to 50 %**
- **Similar efficacy at 100 and 200 mg**
- **Safety profile in DARWIN 2 consistent with previous filgotinib RA studies**
- **These data complete the delivery of the final data package to AbbVie; triggers the licensing decision period**

Webcast presentation of the results to be held on 11 August 2015, 16.00 CET/10 AM EDT/ 8 AM PDT, +32 2 404 0660, access code 1973880, more call number info further down

Mechelen, Belgium; 10 August 2015: Galapagos NV (Euronext & NASDAQ: GLPG) announced today that the selective JAK1 inhibitor filgotinib as once-daily monotherapy at week 24 showed further improvements in signs and symptoms of moderately to severe, active rheumatoid arthritis (RA) in the DARWIN 2 Phase 2B study. Filgotinib was well tolerated in this study. Hemoglobin levels increased. These final 24-week study results are consistent with the efficacy and safety profile of filgotinib observed in prior clinical studies. With these final results, the data package for AbbVie is complete, which triggers the start of the licensing decision period.

DARWIN 2 is a 24-week, double-blind, placebo-controlled evaluation of filgotinib, as once-daily administration (QD dosing) at 3 dose levels. Results were reported for 283 patients with moderate to severe rheumatoid arthritis who showed an inadequate response to methotrexate. Filgotinib or placebo was given as monotherapy. The patients were evaluated up to 24 weeks.

Summary of the ACR responses and DAS28(CRP) changes at 24 weeks of once-daily monotherapy:

	50 mg (W0-24) <i>n</i> =72	100 mg (W0-24) <i>n</i> =70
ACR20 responders, NRI, %	57	77
ACR50 responders, NRI, %	32	40
ACR70 responders, NRI, %	19	26
DAS28(CRP), LOCF, mean change from baseline	-1.9	-2.6

ACR responses based on intent to treat (ITT) analysis, with non-responder imputation (NRI). Placebo was only given for a maximum duration of 12 weeks, so no comparisons were possible at Week 24. Mean baseline DAS28(CRP) varied between 6.0 and 6.2. The DAS28(CRP) is analyzed by ITT with last observation carried forward (LOCF).

The results from this study show a rapid onset of efficacy, as of week 1 for ACR and DAS28(CRP) responses. Maximum ACR20 and ACR50 responses were obtained at week 8 and week 12 respectively. Additional gain was reported for ACR70 and DAS28(CRP) during the second half of the study. In the highest dose groups, up to 50% of the patients reached low disease activity or remission. The 100 mg and 200 mg QD doses achieve similar levels of efficacy.

Over all dose groups including placebo, 3.9% of patients stopped treatment during the study for safety reasons. A higher discontinuation rate for safety was observed for placebo (5.6%) during the first 12 weeks of the study compared to filgotinib treated patients (2.5%) up to week 24. Similar incidence of serious and non-serious treatment-emergent adverse events was reported, evenly spread over the dose groups including placebo. A higher rate of infections was observed in filgotinib (19% over 24 weeks) compared to placebo (10% up to week 12), with serious infections remaining limited (1.4% of filgotinib patients). No malignancies, TB, MACE, opportunistic infections, or death were reported. Consistent with its selective JAK1 inhibition, filgotinib treatment led to an improvement in hemoglobin (up to 0.4 g/dL, or 3.6% increase from baseline). Neutrophil levels remained stable after initial decline to mid-normal range at week 4. There was no impact on lymphocytes or liver function tests. The similar increases in LDL and HDL were maintained.

"The DARWIN 2 24-week data clearly show the efficacy of this compound in rheumatoid arthritis. In addition, the safety profile is quite notable. The increase in hemoglobin and lack of lymphocyte reduction suggest that there can be differentiation of various safety signals among different JAK inhibitors," said Professor Arthur Kavanaugh, MD, Professor of Medicine at the University of California, San Diego (UCSD) School of Medicine, and Principal Investigator for DARWIN 2.

"These final 24-week monotherapy data of DARWIN 2 confirm previous results and we believe these support the best-in-class potential of filgotinib, our oral, once a day, JAK1 selective treatment in RA," said Dr Piet Wigerinck, Chief Scientific Officer of Galapagos. "We experience a lot of enthusiasm from the medical community, to make filgotinib broadly available to patients with other inflammatory diseases. We very much look forward to Abbvie's in-licensing decision."

About the DARWIN 2 trial and its measures

The primary endpoint of the DARWIN 2 study is efficacy in terms of percentage of subjects achieving an ACR20 response after 12 weeks of treatment. In accordance with the protocol for the DARWIN 2 study, at week 12, all subjects on placebo and those who received 50 mg once-daily filgotinib but did not achieve a 20% improvement in swollen joint count and tender joint count have been re-randomized to a 100 mg once-daily dose. Other subjects maintain their randomized treatment until week 24. Secondary trial objectives include efficacy in terms of the percentage of subjects achieving an ACR20 response at week 24, ACR50 and ACR70 response and other disease activity measures, as well as safety and tolerability and effects on fatigue and quality of life.

Conference call and webcast presentation

Galapagos will conduct a conference call open to the public tomorrow, 11 August 2015, at 16:00 CET/10 AM EDT/8 AM PDT, which will also be webcast. To participate in the conference call, please call one of the following numbers ten minutes prior to commencement:

Confirmation Code:

1973880

London, UK:	+44 20 3427 1901
Toll free - UK:	0800 279 5736
New York, USA:	+1 646 254 3360
Toll free - USA:	+1 877 280 1254
Amsterdam, Netherlands:	+31 20 721 9158

Toll free - Netherlands:	0800 020 2576
Brussels, Belgium:	+32 2 404 0660
Toll free - Belgium:	0800 58032
Paris, France:	+33 1 76 77 22 28
Toll free - France:	0805 631 579

A question and answer session will follow the presentation of the results. Go to www.glpq.com to access the live audio webcast. The archived webcast, PDF of the slides, and a transcript will also be available on the Galapagos website later in the day.

About Galapagos

[Galapagos](http://www.glpq.com) (Euronext & NASDAQ: GLPG) is a clinical-stage biotechnology company specialized in the discovery and development of small molecule medicines with novel modes of action, with a pipeline comprising three Phase 2 programs, two Phase 1 trials, five pre-clinical studies, and 20 discovery small-molecule and antibody programs in cystic fibrosis, inflammation, and other indications. In the field of inflammation, AbbVie and Galapagos signed a collaboration agreement for the development and commercialization of [filgotinib](#). Filgotinib is an orally-available, selective inhibitor of JAK1 for the treatment of rheumatoid arthritis and potentially other inflammatory diseases, currently in Phase 2B studies in RA and in Phase 2 in Crohn's disease. Galapagos reported good activity and a favorable safety profile in both the DARWIN 1 and 2 trials in RA. AbbVie and Galapagos also signed a collaboration agreement in cystic fibrosis to develop and commercialize molecules that address mutations in the CFTR gene. Potentiator [GLPG1837](#) is currently in a Phase 1 trial, and corrector GLPG2222 is at the pre-clinical candidate stage. [GLPG1205](#), a first-in-class inhibitor of GPR84 and fully-owned by Galapagos, is currently being tested in a Phase 2 proof-of-concept trial in ulcerative colitis patients. [GLPG1690](#), a fully proprietary, first-in-class inhibitor of autotaxin, has shown favorable safety in a Phase 1 trial and is expected to enter Phase 2 in idiopathic pulmonary fibrosis. The Galapagos Group, including fee-for-service subsidiary Fidelia, has approximately 400 employees, operating from its Mechelen, Belgium headquarters and facilities in The Netherlands, France, and Croatia. More info at www.glpq.com

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Galapagos forward-looking statements

This release may contain forward-looking statements, including statements regarding filgotinib's potential for a best-in-class profile, the statements by Prof. Kavanaugh and Dr. Wigerinck on the second page of the release, and statements on AbbVie's potential licensing decision regarding filgotinib. 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 the inherent uncertainties associated with competitive developments, clinical trial and product development activities and regulatory approval requirements (including that data from Galapagos' ongoing DARWIN and FITZROY programs with filgotinib 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, AbbVie, who may not in-license filgotinib or, if it does, may not devote sufficient resources to the development and commercialization of filgotinib), and estimating the commercial potential of our product candidates. A further list and description of these risks, uncertainties and other risks can be found in the company's Securities and Exchange Commission filing and reports, including in the company's prospectus filed with the SEC on May 14, 2015 and future filings and reports by the company. 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.