Galapagos' JAK1 inhibitor filgotinib (GLPG0634) meets primary and other key efficacy endpoints after 12 weeks of treatment in DARWIN 1 Phase 2B study

- **ACR20 scores up to 80% at 12 weeks**
- **Statistically significant ACR50 and DAS28(CRP) scores with all doses**
- **Patient-reported improvements observed after one week of treatment**
- **Safety profile is consistent with previous filgotinib RA studies**

Webcast presentation of the results to be held on 15 April 2015, 16.00 CET/10 AM EDT/7 AM PDT, ***+32 2 789 2126, access code 5188327*****,** *morecall number info further down*

Mechelen, Belgium; 14 April 2015: Galapagos NV (Euronext: GLPG)announced today that the selective JAK1 inhibitor filgotinib showed improvements in signs and symptoms of active rheumatoid arthritis and met key efficacy endpoints after 12 weeks of treatment with filgotinib as an add-on to methotrexate, or MTX, in the DARWIN 1 Phase 2B study. The study achieved its primary endpoint with a statistically significant improvement in ACR20 score versus placebo after 12 weeks of treatment at a daily dose of 200 mg. Statistically significant ACR50 scores were achieved with all dose levels and dose regimens. Statistically significant improvement in DAS28(CRP) was seen within one week. In this study, filgotinib was well tolerated. Hemoglobin levels increased. The total cholesterol over HDL ratio improved with dose. These first results in the ongoing 24 week study are consistent with the efficacy/safety profile of filgotinib observed in the prior 4-week clinical studies.

DARWIN 1 is an ongoing, 24 week, double-blind, placebo-controlled evaluation of filgotinib, as once- and twice-daily administration (QD and BID dosing) at 3 daily dose levels. Results were reported for 594 patients with moderate to severe rheumatoid arthritis who showed an inadequate response to methotrexate and who remained on their background therapy of methotrexate. These patients received filgotinib or placebo and were evaluated up to 12 weeks, the time of the primary endpoint of the study. Galapagos expects to report the full 24 week results for DARWIN 1 around the middle of the year.

Summary of the ACR/DAS28(CRP) scores at 12 weeks treatment:

		Once-daily dosing			Twice-daily dosing		
	Placebo *n=86*	50 mg *n=82*	100 mg *n=85*	200 mg *n=86*	25 mg *n=86*	50 mg *n=85*	100 mg *n=84*
ACR20 responders, NRI, %	45	56	62	69*	57	59	80***
ACR50 responders, NRI, %	15	32*	39**	43***	28*	34*	55***
ACR70 responders, NRI, %	8	16	20	24*	14	19	31**
DAS28(CRP), mean change from baseline, LOCF §	-1.2	-1.8*	-2.2***	-2.5***	-1.9**	-2.1***	-2.8***

* p< 0.05 vs. placebo; ** p<0.01 vs. placebo; *** p<0.001 vs. placebo; ACR scores based on intent to treat (ITT) analysis, with non-responder imputation (NRI).
§ Mean baseline DAS28(CRP) varied between 6.0 and 6.2. The DAS28(CRP) is analyzed on a last observation carried forward (LOCF) basis.

Overall, there were no statistically relevant differences for the once-daily and twice-daily dosing regimens. The results suggest a rapid onset of activity, already after one week of treatment.

Over all dose groups including placebo, 1.7% of patients stopped treatment during the study for safety reasons. Because of the low number of discontinuations, the actual distribution across treatment groups is not disclosed to prevent individual treatment unblinding while the study is still ongoing. Serious (1.3% overall) and non-serious treatment-emergent adverse events were evenly

spread over the dose groups including placebo. The rare frequency adverse events remain blinded for the treatment group and include 3 cases (0.5% of patients) of serious infections. Consistent with its selective JAK1 inhibition, filgotinib treatment led to a dose-dependent improvement in hemoglobin (up to 0.4 g/dL, or 3.7% increase from baseline). All lipid fractions including HDL and LDL increased, with the largest percentage increase in HDL leading to an improved total cholesterol over HDL ratio (atherogenic index) at 200 mg/day.

"The last decade saw an important progress in RA treatment with biologicals," said Prof. René Westhovens from the University of Leuven, Belgium, and Principal Investigator for DARWIN 1. "The current data with this oral drug spell hope for a potential future treatment option that combines fast onset of action and ease of administration. I am particularly impressed by the rapid improvement reported by the patients. Also the increase in hemoglobin is important for my patients, as this may lessen fatigue and enhance their overall well-being."

"I am very pleased to see that filgotinib treatment in DARWIN 1, one of the largest Phase 2 studies in RA to date, shows consistent efficacy with fast onset of action. Its selective inhibition of JAK1 also leads to a differentiated safety profile, as measured by an improvement in hemoglobin and overall lipid profile. Today's results with 12 weeks' treatment with filgotinib met the key efficacy endpoints and are in line with what Galapagos showed in two previous 4-week studies in RA patients. Based on these 12-week results in RA, we believe that filgotinib has a promising future to address a significant medical need. We look forward to seeing the DARWIN 2 monotherapy results in just a few weeks," said Dr Piet Wigerinck, Chief Scientific Officer of Galapagos.

About the DARWIN 1 trial and its measures
The primary endpoint of the DARWIN 1 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 1 study, at week 12, subjects on placebo or lower doses of filgotinib who have not achieved 20% improvement in swollen joint count and tender joint count will be re-randomized automatically to another treatment arm with either a 50 mg (twice daily) or 100mg (once daily) dose. Subjects in the other groups will 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.

The improvement of rheumatoid arthritis can be assessed using composite scores as recommended by the American College of Rheumatology, or ACR. The ACR criteria measure improvement in tender and swollen joint counts and include other parameters which take into account the patient's and physician's assessment of disease, pain, and an anti-inflammatory biomarker. These clinical and laboratory disease activity parameters are combined to form a composite score and are expressed as percentages of clinical response that are known as ACR20, ACR50, and ACR70. An ACR20 score represents at least a 20% improvement in these criteria and is considered a modest improvement in a patient's disease. An ACR50 and ACR70 represent a minimal 50% and 70% improvement in the response criteria, respectively, and each is considered evidence of a substantial improvement in a patient's disease.

The DAS28(CRP), or the Disease Activity Score, considers 28 tender and swollen joint counts, general health, plus levels of an inflammatory biomarker. DAS28(CRP) is used to give an overall picture of the disease state, resulting in a score on a scale from 0 to 10 indicating current RA disease activity, whereby remission is less than or equal to 2.6, low disease activity is less than or equal to 3.2, moderate disease activity is less than or equal to 5.1, and high disease activity is >5.1.

Conference call and webcast presentation

Galapagos will conduct a conference call open to the public tomorrow, 15 April 2015, at 16:00 CET/10 AM EDT/7 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: 5188327

London, United Kingdom:	+44 20 3427 1903
Toll free - United Kingdom:	0800 279 4977
New York, United States of America:	+1646 254 3366
Toll free - United States of America:	1877 280 1254
Amsterdam, Netherlands:	+31 20 716 8256
Toll free - Netherlands:	0800 020 2577
Brussels, Belgium:	+32 2 789 2126
Toll free - Belgium:	0800 58032
Paris, France:	+33 1 76 77 22 24
Toll free - France:	0805 631 579

A question and answer session will follow the presentation of the results. Go to www.glpg.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 (Euronext: GLPG; OTC: GLPYY) 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 offilgotinib. 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. 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 Fidelta, has approximately 400 employees, operating from its Mechelen, Belgium headquarters and facilities in The Netherlands, France, and Croatia. Further information at: www.glpg.com

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