# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

	FORM 6-K
	EPORT OF FOREIGN PRIVATE ISSUER
	PURSUANT TO RULE 13a-16 OR 15d-16 THE SECURITIES EXCHANGE ACT OF 1934
	For the Month of July 2015
	Commission File Number: 001-37384
	GALAPAGOS NV (Translation of registrant's name into English)
	(Translation of registrant's name into English)  Generaal De Wittelaan L11 A3 2800 Mechelen, Belgium
licate by check mark whether the registrant files on	(Translation of registrant's name into English)  Generaal De Wittelaan L11 A3 2800 Mechelen, Belgium

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):  $\Box$ 

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):  $\Box$ 

### **EXHIBITS**

Exhibit Description

99.1 Press Release dated July 29, 2015

**SIGNATURES** 

Pursuant to the requirements of the Securities Exchange Act of 193	4, the registrant has duly caused this report to be signed on its behalf by the
undersigned, thereunto duly authorized.	

**GALAPAGOS NV** 

Date:  $\underbrace{\text{July 31, 2015}}_{\text{Bart Filius}}$  By:  $\underbrace{\text{/s/ Bart Filius}}_{\text{Bart Filius}}$ 

Chief Financial Officer



Regulated information 29 July 2015

Galapagos' selective JAK1 inhibitor filgotinib meets key efficacy endpoints, shows ACR70 responses up to 39%, and maintains safety profile after 24 weeks of treatment in DARWIN 1 Phase 2B study

- Up to 64% of patients achieved DAS28(CRP) remission or low disease state, all doses and regimens statistically significant at week 24
- Safety profile consistent with data at week 12: increased hemoglobin, higher increases in HDL than LDL, no change to lymphocyte
  counts

Webcast presentation of the results to be held on 30 July 2015, 16.00 CET/10 AM EDT/7 AM PDT, +32 2 789 2126, access code 6868513, more call number info further down

Mechelen, Belgium; 29 July 2015: Galapagos NV (Euronext: GLPG) announced today that at week 24, patients treated with the selective JAK1 inhibitor filgotinib showed further improvement in signs and symptoms of rheumatoid arthritis activity, as demonstrated by improved ACR responses, DAS28(CRP), and other scores, compared to week 12 in the DARWIN 1 Phase 2B methotrexate add-on study. In this study, filgotinib was well tolerated. The initial increase in hemoglobin levels was sustained to week 24. The higher relative increase in HDL compared to LDL remained stable over 24 weeks. Lymphocyte counts were not impacted by filgotinib. These 24 week results are consistent with the efficacy/safety profile of filgotinib previously observed.

DARWIN 1 was a 24 week, double-blind, placebo-controlled evaluation of filgotinib, as once- and twice-daily administration (QD and BID dosing) at 3 daily dose levels. Final results are reported for all 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 24 weeks.

Summary of the ACR/DAS28(CRP) scores at week 24:

		Once–daily dosing			Twice-daily dosing		
	Placebo	50 mg	100 mg	200 mg	25 mg	50 mg	100 mg
	_n=86_	n=82	n=85	n=86	n=86	n=85	n=84
ACR20 responders, NRI, %	42	55	60	73***	56	60	80***
ACR50 responders, NRI, %	17	35*	46***	50***	35*	35*	55***
ACR70 responders, NRI, %	9	22*	33**	29**	21*	24*	39***
DAS28(CRP)£3.2, LOCF, %	19	33*	51***	51***	40**	38*	64***

<sup>\*</sup> 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). The DAS28(CRP) is analyzed on a last observation carried forward (LOCF) basis. Subjects who switch treatment at week 12 are handled as if they discontinued at week 12.



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Overall, there was no statistically relevant difference between the once-daily and twice-daily dosing regimens.

Since this is the final analysis, the 24-week DARWIN 1 safety data are unblinded. Over all dose groups including placebo, 3.9% of patients stopped treatment during the study for safety reasons. Patients reporting serious (2.5% overall) and non-serious treatment-emergent adverse events were evenly spread over the dose groups including placebo. Serious infections were reported in 6 patients, including one death on active treatment in the second half of the study and for which the DSMB (Data Safety Monitoring Board) did not see a reason to pause or change the study. No opportunistic infections were reported. Herpes zoster infection occurred in 5 patients, equally spread over placebo and filgotinib groups. Consistent with its selective JAK1 inhibition, filgotinib treatment led to an improvement in hemoglobin (up to 0.5 g/dL, or 4% increase from baseline). All lipid fractions including HDL and LDL increased, with the largest percentage increase in HDL. Lymphocytes were not impacted by treatment with filgotinib in this study. No clinically significant changes or discontinuations were observed for male reproductive hormones.

"These 6-month data confirm the strong efficacy already observed after 3 months. Furthermore, for the parameters most relevant to patients, such as ACR70 and DAS28 remission, increased responses were reported. Importantly, placebo patients switching to the mid dose quickly responded. On top of this, the good safety profile was sustained," said Prof. René Westhovens from the University of Leuven, Belgium, and Principal Investigator for DARWIN 1.

"Galapagos is extremely pleased with the final data in the DARWIN 1 study, which show promising efficacy and the potential for a differentiated safety profile. It is especially gratifying to see these results with filgotinib after 10 years of work on the JAK1 target, and we look forward to confirming these results in the Phase 3 RA studies," said Dr Piet Wigerinck, Chief Scientific Officer of Galapagos. "We anticipate the DARWIN 2 week 24 results in just a few weeks, the AbbVie licensing decision after that, and the FITZROY Crohn's disease Phase 2 study 10 week interim results before year end."

#### About the DARWIN 1 study and its measures

The primary endpoint of the DARWIN 1 study was 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 did not achieve 20% improvement in swollen joint count and tender joint count were re-randomized automatically to another treatment arm with either a 50 mg (twice daily) or 100mg (once daily) dose. Subjects in the other groups maintained their randomized treatment until week 24. Secondary trial objectives included 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, 30 July 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:	6868513
London, United Kingdom:	+44 20 3427 1908
Toll free - United Kingdom:	0800 279 4977
New York, United States of America:	+1 646 254 3364
Toll free - United States of America:	1 877 280 2342
Amsterdam, Netherlands:	+31 20 713 2790
Toll free - Netherlands:	0800 020 2577
Brussels, Belgium:	+32 2 789 2126
Toll free - Belgium:	0800 58033
Paris, France:	+33 1 70 80 17 65
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 & 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 DARWIN 2 studies 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 Fidelta, has approximately 400 employees, operating from its Mechelen, Belgium headquarters and facilities in The Netherlands, France, and Croatia. More info at <a href="https://www.glpg.com">www.glpg.com</a>

#### CONTACT

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#### **Galapagos forward-looking statements**

This release may contain 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 "believes," "anticipates," "expects," "intends," "plans," "seeks," "estimates," "may," "will," "could," "stands to," "continues," "we believe," "we intend," as well as similar expressions. Such forward-looking statements may involve known and unknown risks, uncertainties and other factors which might cause the actual results, financial condition, performance or achievements of Galapagos, or industry results, to be materially different from any historic or future results, financial conditions, performance or achievements expressed or implied by such forward-looking statements. Among the factors that may result in differences are the inherent uncertainties associated with competitive developments, clinical trial and product development activities, regulatory approval requirements 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, unless required by law or regulation.