# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 6-K				
UNDER THE SECURITIES EXCHANGE ACT OF 1934  For the Month of September 2015				
Commission File Number: 001-37384				
GALAPAGOS NV (Translation of registrant's name into English)				
Generaal De Wittelaan L11 A3 2800 Mechelen, Belgium (Address of principal executive offices)				
Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.				
Form 20-F ⊠ Form 40-F □				
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** 

Date: September 25, 2015

99.1 Press Release dated September 25, 2015

# **SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

# **GALAPAGOS NV**

By: /s/ Xavier Maes

Xavier Maes Company Secretary

## Galapagos to advance filgotinib to Phase 3 in rheumatoid arthritis

- Galapagos regains all unencumbered rights to filgotinib
- Filgotinib is the most selective JAK1 inhibitor
- Best-in-class efficacy and safety in RA in 24-week Phase 2B studies in 877 patients
- Phase 3 start in RA expected in early 2016

Galapagos to hold a conference call open to the public today at 17.15 CET/11:15 AM EDT

CODE: 830162

UK: +44 330 336 6025 USA: +1 719 325 2556 Belgium: +32 2400 6966 +31 207 940454 NL: +33 176 7722 61 France:

Mechelen, Belgium; 25 September 2015: Galapagos NV (Euronext & NASDAQ: GLPG) announced today that the Company will be moving filgotinib, its highly selective JAK1 inhibitor, into Phase 3 in rheumatoid arthritis by early 2016. Filgotinib has shown best-in-class efficacy and safety in the DARWIN Phase 2B studies in rheumatoid arthritis and is now fully owned by Galapagos.

Galapagos has demonstrated that high selectivity for JAK1 results in excellent efficacy and safety in rheumatoid arthritis patients. Based on our own human whole blood assays comparing ABT-494 to filgotinib, filgotinib is three-fold more JAK1 selective than ABT-494. Galapagos reported best-in-class efficacy and safety in 24-week Phase 2B studies in 877 patients with filgotinib. Furthermore, Galapagos has more than 700 patient-years of treatment experience with filgotinib in RA patients, of which more than 500 years at the highest 200 mg dose, all with a clean safety profile consistent with JAK1 inhitbition: filgotinib showed a clear dose dependent increase in hemoglobin concentration without any impact on NK cells and lymphocyte counts.

"We see a rapid path forward in development for filgotinib, which we will be taking into Phase 3. Galapagos is currently in advanced discussions with a substantial number of large pharma companies to partner filgotinib. We anticipate starting Phase 3 in rheumatoid arthritis with filgotinib early in 2016 and we are expecting data from our Phase 2B FITZROY study with filgotinib in Crohn's disease by yearend, "said Onno van de Stolpe, CEO of Galapagos.

On efficacy, Galapagos consistently has reported ACR scores using the most conservative NRI approach. The table below shows the ACR scores for the DARWIN 1 study at 24-weeks on the LOCF basis, for comparison purposes :

DARWIN1 (MTX-IR)	ACR20	ACR50	ACR70
		35 <sup>**</sup>	22*
			38***
200mg, once-daily	78***	55***	31 <sup>**</sup>
25mg, twice-daily	62 <sup>*</sup>	38 <sup>**</sup>	22*
50mg, twice-daily	66 <sup>*</sup>		25 <sup>*</sup>
100mg, twice-daily	87***	62***	43 <sup>***</sup>
placebo	45	16	9

<sup>\*</sup> p< 0.05 vs. placebo; \*\* p<0.01 vs. placebo; \*\*\* p<0.001 vs. placebo; ACR scores based on LOCF analysis

#### AbbVie notified Galapagos today of termination of the agreement on filgotinib.

#### Conference call and webcast presentation

Galapagos will conduct a conference call open to the public today (25 September 2015) at 17:15 CET/11:15 AM EDT. To participate in the conference call, please call one of the following numbers ten minutes prior to commencement:

**CODE: 830162** 

UK: +44 330 336 6025 USA: +1 719 325 2556 Belgium: +32 2400 6966 NL: +31 207 940454 France: +33 176 7722 61

#### **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. 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. In the field of cystic fibrosis, AbbVie and Galapagos signed a collaboration agreement 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**

Galapagos NV Elizabeth Goodwin, Head of Corporate Communications & IR Tel: +31 6 2291 6240 <u>ir@glpg.com</u>

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

This release may contain forward-looking statements, including without limitation statements regarding the possibility and timing of the initiation of Phase 3 activities in rheumatoid arthritis with filgotinib, the possibility of partnering filgotinib with a third partyand filgotinib's safety and/or efficacy profile. Galapagos cautions the reader that forward-looking statements are not quarantees 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, and estimating the commercial potential of Galapagos' product candidates. A further list and description of these risks, uncertainties and other risks can be found in Galapagos' Securities and Exchange Commission filing and reports, including in Galapagos' prospectus filed with the SEC on May 14, 2015 and future filings and reports by Galapagos. Given these uncertainties, the reader is advised not to place any undue reliance on such forwardlooking 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.