# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

|       | FORM 6-K  |
|-------|---|
| RI    | EPORT OF FOREIGN PRIVATE ISSUER   |
| P     | PURSUANT TO RULE 13a-16 OR 15d-16   |
| UNDER | THE SECURITIES EXCHANGE ACT OF 1934   |
|       | For the Month of June 2015  |
|       |   |
|       | Commission File Number: 001-37384   |
|       | Commission File Number: 001-37384  GALAPAGOS NV (Translation of registrant's name into English)                   |
|       | GALAPAGOS NV (Translation of registrant's name into English)  Generaal De Wittelaan L11 A3                        |
|       | GALAPAGOS NV (Translation of registrant's name into English)  |
|       | GALAPAGOS NV (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 June 18, 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**

Date: June 19, 2015

By: /s/ Bart Filius

Bart Filius

Chief Financial Officer



Regulated information 18 June 2015

# Galapagos completes recruitment for ORIGIN Phase 2 trial with GLPG1205 in ulcerative colitis patients

Mechelen, Belgium; 18 June 2015 – Galapagos NV (Euronext & NASDAQ: GLPG) announced today it has completed recruitment for the Phase 2 Proof-of-Concept study in ulcerative colitis with GPR84 inhibitor GLPG1205, a potential novel treatment for inflammatory bowel diseases. Topline results from this study are now expected in Q1 2016. GPR84 was identified as a target for these diseases through Galapagos' target discovery platform and GLPG1205 is fully proprietary to Galapagos.

GLPG1205 ('1205) inhibits GPR84, a novel mechanism of action for the treatment of inflammatory bowel diseases (IBD). GPR84 is upregulated in IBD patients. Galapagos has shown that '1205, a selective inhibitor of GPR84, is very effective in pre-clinical models for IBD. In Phase 1 studies, once-daily oral '1205 showed good safety, full blockage of GPR84, and favorable drug-like properties.

"We are pleased that recruitment for the ORIGIN study has gone so well, which means we can report topline results one quarter earlier than planned," said Dr Piet Wigerinck, Chief Scientific Officer of Galapagos. "We look forward to finding out if this novel mode of action opens a new approach towards the treatment of ulcerative colitis patients."

## Details of ORIGIN, the clinical Proof-of-Concept study in ulcerative colitis

The Proof-of-Concept Phase 2 trial for '1205 was initiated in January 2015 and involves approximately 60 patients with moderate to severe ulcerative colitis. The aim is to evaluate the efficacy, safety, tolerability and pharmacokinetics of '1205, and to explore the effects of '1205 on selected biomarkers in this patient population. Patients receive oral doses of either 100 mg of '1205 or placebo (2:1 ratio) once-daily, for a period of twelve weeks. The primary endpoint is the change in Mayo scores versus baseline after 8 weeks of treatment, which includes endoscopic confirmation on improvement of ulceration. This randomized, double-blind study recruited patients in multiple sites in 6 countries: Belgium, Czech Republic, Germany, Hungary, Poland, and Russia. The trial will deliver top line data in Q1 2016.

#### About ulcerative colitis

Ulcerative colitis is one of the forms of inflammatory bowel disease. It is a chronic, relapsing inflammatory disease of the colon, characterized by ulcers in the colon and rectum. Symptoms may include abdominal pain, malnutrition and diarrhea, often bloody. Ulcerative colitis has a prevalence of 200-250 cases per 100,000 individuals per year and a peak incidence between the ages of 15 and 25 years. This chronic condition is without a medical cure and commonly requires a lifetime of care. Current drug treatment includes anti-inflammatory steroids and immunosuppressive agents such as TNF inhibitors. Over the long term, up to 25-30% of the patients will require surgery to remove the inflamed parts of the bowels.

#### **About GPR84**

G-coupled protein receptor 84 (GPR84) is involved in the regulation of macrophages, monocytes, and neutrophils in the human immune system. Galapagos identified GPR84 as playing a key role in inflammation, using its proprietary target discovery platform. GPR84 is over-expressed in patients with both forms of IBD - UC and Crohn's disease. Galapagos has demonstrated in pre-clinical



# Galápagos

trials that GPR84 inhibition prevents neutrophil and macrophage chemotaxis induced by specific triggers, and that '1205 prevents IBD disease progression in animal models. '1205 is also the first inhibitor of GPR84 to be tested in humans; it has shown good safety, inhibition of GPR84, and favorable drug-like properties in Phase 1 studies.

# **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 at 12 weeks 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 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.