## SAPHIRA 1 topline shows competitive clinical results in G551D patients

- First potentiator after Kalydeco<sup>®1</sup> to show comparable results in G551D patients
- GLPG1837 was generally well tolerated when dosed up to 500 mg twice daily for 14 days
- Statistically significant and dose dependent decreases in sweat chloride observed
- Clinical validation of *in vitro* predictive platform

Webcast presentation tomorrow (21 Dec) at 15.00 CET/9 AM ET, <u>www.glpg.com</u>, + 32 2 404 0659, code 6588087

Mechelen, Belgium; 20 December 2016 – Galapagos NV (Euronext & NASDAQ: GLPG) reports topline results from its SAPHIRA 1 Phase 2 study in cystic fibrosis patients with potentiator GLPG1837.

The SAPHIRA 1 trial included 26 patients with the G551D mutation in CFTR each receiving three sequential doses of GLPG1837. Of these, 25 patients were on stable Kalydeco treatment at screening and agreed to a one week washout prior to the start of dosing GLPG1837. One patient was naïve to Kalydeco. All subjects received GLPG1837 125 mg bid (twice-daily) for 7 days, immediately followed by 250 mg bid for 7 days and subsequently by 500 mg bid for 14 days.

A statistically significant dose dependent decrease in sweat chloride concentration was observed. At the 500 mg bid dose, sweat chloride decreased from a mean value of 98 mmol/L at baseline to 66 mmol/L (p <0.0001). For those patients exceeding the predicted target concentration, sweat chloride changed from a mean value of 94 mmol/L at baseline to 52 mmol/L.

25 patients were on stable treatment with Kalydeco prior to this study. For these patients, mean percent predicted FEV1 (ppFEV1) levels were 74% at screening (prior to Kalydeco washout). The one week wash-out resulted in a 5.4% mean decrease in absolute ppFEV1. At the end of treatment with GLPG1837, the ppFEV1 levels returned to the Kalydeco pre-washout levels.

Overall GLPG1837 was well tolerated, with observed treatment emergent adverse events being predominantly mild or moderate, and typical for a CF patient population. One patient dropped out of the study due to an increase in non-cardiac creatine phosphokinase.

"The success of this trial is an important milestone in two regards; firstly, GLPG1837 has shown safety and significant efficacy as a novel CFTR potentiator. Secondly, it demonstrates that the CF community is committed to the further development of CFTR modulators despite the complexities related to evolving standards of care," commented Prof Jane Davies of the Royal Brompton & Harefield NHS Trust in London and principal investigator for SAPHIRA 1.

"The SAPHIRA 1 results show this is the first new potentiator since Kalydeco to demonstrate competitive results in patients harboring the G551D mutation. Galapagos has a suite of potentiators in development. Galapagos and AbbVie will further study the data before deciding which potentiator will be included in the triple combination," said Dr Piet Wigerinck, CSO of Galapagos. "The clinical validation of our *in vitro* systems reinforces our belief in our approach to get to a triple combination therapy."

\_

 $<sup>^{\</sup>rm 1}$  Kalydeco $^{\rm (\!\! R \!\!\!)}$  is marketed drug of Vertex Pharmaceuticals

## Conference call and webcast presentation

Galapagos will conduct a conference call and webcast open to the public tomorrow (21 December 2016) at 15:00 Central European Time (CET) or 9 AM ET. To participate in the conference call, please call one of the following numbers ten minutes prior to commencement:

CODE: 6588087

UK: +44 330 336 9105

Netherlands: +31 20 721 9251

France: + 33 1 76 77 22 74

Belgium: + 32 2 404 0659

USA: +1 719 325 4746

A question and answer session will follow the presentation of the results. Go to <a href="www.glpg.com">www.glpg.com</a> to access the live audio webcast. The archived webcast will also be available for replay shortly after the close of the call.

# **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. Our pipeline comprises a pipeline of Phase 3, Phase 2, Phase 1, pre-clinical, and discovery programs in cystic fibrosis, inflammation, fibrosis, osteoarthritis and other indications. We have discovered and developed filgotinib: in collaboration with Gilead we aim to bring this JAK1-selective inhibitor for inflammatory indications to patients all over the world. Galapagos is focused on the development and commercialization of novel medicines that will improve people's lives. The Galapagos group, including fee-for-service subsidiary Fidelta, has approximately 480 employees, operating from its Mechelen, Belgium headquarters and facilities in The Netherlands, France, and Croatia. More information at <a href="https://www.glpq.com">www.glpq.com</a>.

#### **Contacts**

Elizabeth Goodwin VP IR & Corporate Communications +1 781 460 1784

Paul van der Horst Director IR & Business Development +31 6 53 725 199 ir@qlpg.com

This press release contains inside information within the meaning of Regulation (EU) No 596/2014 of the European Parliament and of the Council of 16 April 2014 on market abuse (market abuse regulation).

## Forward-looking statements

This release may contain forward-looking statements, including statements regarding the potential activity of GLPG1837, the anticipated timing of clinical studies with GLPG1837, the progression and results of such studies, and statements regarding a potential triple combination therapy. 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 the ongoing and planned clinical research programs in cystic fibrosis may not support registration or further development of GLPG1837 due to safety, efficacy or other reasons), Galapagos' reliance on collaborations with third parties (including its collaboration partner for cystic fibrosis, AbbVie), 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 (SEC) filings and reports, including in Galapagos' most recent annual report on form 20-F filed with the SEC and subsequent filings and reports filed by Galapagos with the SEC. 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.