

## **Topline interim results of FALCON trial Part 1 in CF**

**Mechelen, Belgium; 24 October 2018; 22.01 CET; regulated information – Galapagos NV (Euronext & NASDAQ: GLPG) announces topline interim results of Part 1 of the FALCON trial in cystic fibrosis (CF).**

The FALCON trial is a phase 1b, multi-center, open-label, non-randomized, multiple cohorts study to assess the safety, tolerability, pharmacokinetics, and efficacy of a novel combination treatment of GLPG2451 and GLPG2222, with and without GLPG2737, in up to 24 adult patients with CF.

The trial is designed in two parts, with Part 1 being all adult CF patients homozygous for the Class II F508del mutation (n=10). The FALCON study's primary objectives include safety and PK. Secondary objectives include changes in pharmacodynamic biomarkers for CFTR activity (sweat chloride concentration and ppFEV1). The FALCON trial is being conducted in multiple sites in Europe.

Preliminary results from Part 1 of the trial show that the dual and triple combinations of GLPG2451 and GLPG2222 with and without GLPG2737, respectively, were generally well tolerated during the dosing phase. The longer-term safety follow-up is currently ongoing. All adverse events were mild to moderate. There were no deaths and no serious adverse events reported. One patient was prematurely removed from the trial during the dual combination treatment period following the development of rash (allergic skin reaction).

PK results for all components were in line with expectations based on previous data observed in healthy subjects and/or CF patients. The addition of GLPG2737 did not impact the exposure of GLPG2451 and GLPG2222.

Two weeks' treatment with the dual combination (GLPG2451 and GLPG2222) resulted in mean decrease from baseline in sweat chloride concentration of approximately 25 mmol/L and a mean increase in ppFEV1 of approximately 3%. Subsequent two-week treatment with the triple combination (GLPG2451, GLPG2222 and GLPG2737) did not result in additional enhancement of CFTR activity.

After completion of the safety follow-up, expected in Q1 2019, the full data set is expected to be assessed prior to a decision to initiate Part 2 of the trial.

### **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. Galapagos' pipeline comprises Phase 3 through to discovery programs in inflammation, fibrosis, osteoarthritis and other indications. Our target discovery platform has delivered three novel mechanisms showing promising patient results in, respectively, inflammatory diseases, idiopathic pulmonary fibrosis and atopic dermatitis. Our ambition is to become a leading global biopharmaceutical company, focused on the development and commercialization of innovative medicines that will improve people's lives. The Galapagos group, including fee-for-service subsidiary Fidelta, has approximately 675 employees, operating from its Mechelen, Belgium headquarters and facilities in the Netherlands, France, Switzerland, the US and Croatia. More information at [www.glpg.com](http://www.glpg.com).

**Contact**

**Investors:**

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

Sofe Van Gijssel  
Director IR  
+32 485 191415  
[ir@glpg.com](mailto:ir@glpg.com)

**Media:**

Evelyn Fox  
Director Communications  
+31 6 53 591 999  
[communications@glpg.com](mailto:communications@glpg.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 GLPG2737; the anticipated timing of clinical studies with, and plans related to, GLPG2222, GLPG2451, and GLPG2737 (or any combinations thereof); the timing, progression and/or results (including the reporting thereof) of such studies and plans, including the potential initiation of Part 2 of the FALCON trial; statements regarding potential triple combination therapies, including the timing of potential studies thereof; statements regarding the CF collaboration between Galapagos and AbbVie; and statements regarding interactions with regulatory authorities. 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 CF may not support registration or further development of GLPG2222, GLPG2451, or GLPG2737 (or any combinations thereof), or potential triple combination therapies, due to safety, efficacy or other reasons), Galapagos' reliance on collaborations with third parties (including its collaboration partner for CF, AbbVie), and estimating the commercial potential of CF 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.*