

## **GALAPAGOS REPORTS PRIMARY ENDPOINT FOR THE ONGOING FILGOTINIB MANTA AND MANTA-RAY SAFETY STUDIES**

- **8.3% patients on placebo and 6.7% patients on filgotinib had a 50% or more decline in sperm concentration at week 13**
- **No new safety findings were identified**
- **Data will be submitted to the relevant regulatory authorities**

**Mechelen, Belgium, 4 March 2021, 07.40 CET, regulated information –Galapagos NV (Euronext & Nasdaq: GLPG) today announced interim results from MANTA and MANTA-RAY, two ongoing safety studies investigating the effect of Jyseleca® (filgotinib) on sperm parameters in males with inflammatory bowel disease (MANTA) or rheumatic conditions (MANTA-RAY).**

In total, 248 patients were randomized 1:1 to receive filgotinib 200 mg once daily or placebo for an initial 13-week, double-blind treatment period. The primary endpoint in both trials was the proportion of patients who had a reduction of 50% or more in sperm concentration at Week 13. Patients who met this endpoint discontinued study treatment at Week 13, were switched to standard of care treatment and were monitored for reversibility every 13 weeks for up to 52 weeks.

Out of the 248 randomized patients, 240 reached Week 13 with two evaluable semen samples at baseline and Week 13. Of those, 18 patients showed a  $\geq 50\%$  decline in sperm concentration, with 10/120 (8.3%) patients on placebo and 8/120 (6.7%) patients on filgotinib. These studies, which were designed with the input of the relevant health authorities, are not powered for statistical comparison between groups. These data will now be submitted to relevant regulatory authorities.

Beyond the double-blind, placebo-controlled, 13-week period, for which MANTA and MANTA-RAY results are pooled, patients who did not meet the primary endpoint of 50% or more decline in sperm motility or morphology could continue under their respective trial protocol on blinded treatment, receive open-label filgotinib or receive standard of care therapy based on disease response, for another 13 weeks before entering a long-term extension period. At any point, patients exhibiting a predetermined sperm decline enter a monitoring phase in which they are assessed every 13 weeks for reversibility for up to 52 weeks.

As the MANTA and MANTA-RAY trials are ongoing, and to maintain data integrity, Galapagos and Gilead intend to report additional results only after all patients in the monitoring phase have completed the protocol-defined observation period.

"We are pleased the interim results reported today will be submitted to the relevant regulatory authorities," said Dr. Walid Abi-Saab, CMO of Galapagos.

When the MANTA and MANTA-RAY trials are completed, Galapagos and Gilead intend to submit the full results for publication in a peer-reviewed medical journal.

### **About filgotinib**

Filgotinib is approved and marketed as Jyseleca (200 mg and 100 mg tablets) in Europe, Great Britain and Japan for the treatment of adults with moderately to severely active RA who have responded inadequately or are intolerant to one or more disease modifying anti-rheumatic drugs

(DMARDs). Filgotinib may be used as monotherapy or in combination with methotrexate (MTX). The European Summary of Product Characteristics for filgotinib, which includes contraindications and special warnings and precautions, is available at [www.ema.europa.eu](http://www.ema.europa.eu). The interview form from the Japanese Ministry of Health, Labour and Welfare is available at [www.info.pmda.go.jp](http://www.info.pmda.go.jp). Filgotinib was submitted to the European Commission for an extended indication for the treatment of adults with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic agent.

*With the exception of filgotinib's approval for the treatment of RA by the European Commission and Japanese Ministry of Health, Labour and Welfare, all of our drug candidates are investigational; their efficacy and safety have not been fully evaluated by any regulatory authority and they are not yet approved for any use outside of clinical trials.*

### **About the MANTA and MANTA-RAY Studies**

MANTA is a Phase 2 safety study being conducted by Gilead in men with moderate/severe active ulcerative colitis (UC) or Crohn's disease (CD) to assess semen parameters while taking filgotinib. MANTA-RAY is a similar study being conducted by Galapagos outside the US, in men with rheumatic diseases. The results of both studies have been pooled in the interim results of the primary endpoint.

### **About Galapagos**

Galapagos NV discovers, develops and commercializes small molecule medicines with novel modes of action, several of which show promising patient results and are currently in late-stage development in multiple diseases. Our pipeline comprises discovery through Phase 3 programs in inflammation, fibrosis and other indications. Our ambition is to become a leading global biotech company focused on the discovery, development and commercialization of innovative medicines. More information at [www.glp.com](http://www.glp.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 press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, that are subject to risks, uncertainties and other factors that could cause actual results to differ materially from those referred to in the forward-looking statements and, therefore, the reader should not place undue reliance on them. These risks, uncertainties and other factors include, without limitation, the inherent risks associated with clinical trial and product development activities, competitive developments, and regulatory approval requirements, including the risk that data from the ongoing and planned clinical research programs (including but not limited to the data from the up to 52 weeks monitoring phase of the MANTA and MANTA-RAY trials) with filgotinib may not support registration or further development due to safety, efficacy or other reasons, the timing or likelihood of additional regulatory authorities approval of marketing authorization for filgotinib, such additional regulatory authorities requiring additional studies, Galapagos' reliance on collaborations with third parties, including the collaboration with Gilead for filgotinib, the uncertainty regarding estimates of the commercial potential of filgotinib, the timing of and the risks related to completing and implementing the amendment of our arrangement with Gilead for the commercialization and development of Jyseleca (filgotinib), as well as those risks and uncertainties identified in our Annual Report on Form 20-F for the year ended 31 December 2019 and our subsequent filings with the SEC. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. The forward-looking statements contained herein are based on management's current expectations and beliefs and speak only as of the date hereof, and Galapagos makes no commitment to update or publicly release any revisions to forward-looking statements in order to reflect new information or subsequent events, circumstances or changes in expectations.*

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