

## **Galapagos announces that Gilead received a complete response letter for filgotinib for the treatment of moderately to severely active rheumatoid arthritis**

**Mechelen, Belgium; 19 August 2020, 01.25 CET; regulated information** – Galapagos (Euronext & Nasdaq: GLPG) announces today that Gilead Sciences, Inc. (Nasdaq: GILD) received a complete response letter (CRL) from the U.S. Food and Drug Administration (FDA) for the New Drug Application (NDA) for filgotinib, an investigational treatment for moderately to severely active rheumatoid arthritis (RA). The FDA issues CRLs to indicate that the review cycle for an application is complete and that the application is not ready for approval in its present form. Gilead is the market authorization holder for filgotinib in the United States and is responsible for potential commercialization in the U.S.

The FDA has requested data from the MANTA and MANTA-RAy studies before completing its review of the NDA. The MANTA and MANTA-RAy studies are designed to assess whether filgotinib has an impact on sperm parameters. The FDA also has expressed concerns regarding the overall benefit/risk profile of the filgotinib 200 mg dose.

“We are disappointed in this outcome and will evaluate the points raised in the CRL for discussion with the FDA. We continue to believe in the benefit/risk profile of filgotinib in RA, which has been demonstrated in the FINCH Phase 3 clinical program,” said Merdad Parsey, MD, PhD, Chief Medical Officer, Gilead Sciences.

“This CRL issued by the FDA is very disappointing given the robust and comprehensive data package provided. Despite today’s news, we continue to believe filgotinib has the potential to provide an effective, new treatment option for patients with rheumatoid arthritis, where there remains a significant unmet need,” said Dr. Walid Abi-Saab, Chief Medical Officer, Galapagos.

The MANTA and MANTA-RAy studies are fully recruited, with topline results anticipated in the first half of 2021. Filgotinib is currently under review by regulatory authorities around the world. Filgotinib recently received a positive opinion from the European Medicines Agency’s Committee for Medicinal Products for Human Use, recommending marketing authorization for filgotinib in the EU for the treatment of adults with moderate to severe RA who have responded inadequately or are intolerant of one or more disease-modifying anti-rheumatic drugs.

Under the terms of the agreement with Gilead, Galapagos is entitled to an approval milestone of \$100 million for the approval of filgotinib in the US, which was included in the Galapagos cash burn guidance. Following this CRL, Galapagos revises its full year 2020 operational cash burn guidance to between €490 and €520 million.

### **About the Filgotinib Collaboration<sup>1</sup>**

Gilead and Galapagos NV are collaborative partners in the global development and commercialization of filgotinib in rheumatoid arthritis, and other inflammatory indications. The companies have multiple clinical study programs for filgotinib in inflammatory diseases, including the FINCH Phase 3 program in rheumatoid arthritis, the Phase 3 SELECTION trial in ulcerative colitis, the DIVERSITY Phase 3 trial in Crohn’s disease, the Phase 3 PENGUIN trials in psoriatic arthritis, as well as Phase 2 studies in uveitis and in small bowel and fistulizing Crohn’s disease. More information about clinical trials with filgotinib can be accessed at: [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

### **About Galapagos**

Galapagos NV discovers and develops small molecule medicines with novel modes of action, three 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, osteoarthritis and other indications. Our ambition is to become a leading global biopharmaceutical company focused on the discovery, development and commercialization of innovative medicines. More information at [www.glpg.com](http://www.glpg.com).

### **About Gilead Sciences**

Gilead Sciences, Inc. is a research-based biopharmaceutical company that discovers, develops and commercializes innovative medicines in areas of unmet medical need. The company strives to transform and simplify care for people with life-threatening illnesses around the world. Gilead has operations in more than 35 countries worldwide, with

headquarters in Foster City, California. For more information on Gilead Sciences, please visit the company's website at [www.gilead.com](http://www.gilead.com).

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### **Galapagos 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 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 with filgotinib may not support registration or further development of filgotinib due to safety, efficacy or other reasons), whether or when regulatory authorities would approve marketing authorization for filgotinib after receipt of data from MANTA and MANTA RAY studies or whether regulatory authorities will require additional studies, Galapagos' reliance on collaborations with third parties (including its collaboration partner for filgotinib, Gilead), the uncertainty regarding estimating the commercial potential of filgotinib, that Galapagos' expectations regarding its operational cash burn for financial year 2020 may be incorrect, as well as those risks and uncertainties identified in our Annual Report on Form 20-F for the year ended December 31, 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.

*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).*

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<sup>1</sup> Gilead & Galapagos Filgotinib Clinical Program Trial Details: FINCH 1 ([NCT02889796](https://clinicaltrials.gov/ct2/show/study/NCT02889796)); FINCH 2 ([NCT02873936](https://clinicaltrials.gov/ct2/show/study/NCT02873936)); FINCH 3 ([NCT02886728](https://clinicaltrials.gov/ct2/show/study/NCT02886728)); SELECTION ([NCT02914522](https://clinicaltrials.gov/ct2/show/study/NCT02914522)); DIVERSITY ([NCT02914561](https://clinicaltrials.gov/ct2/show/study/NCT02914561)); PENGUIN 1 ([NCT04115748](https://clinicaltrials.gov/ct2/show/study/NCT04115748)); PENGUIN 2 ([NCT04115839](https://clinicaltrials.gov/ct2/show/study/NCT04115839))