



## European Medicines Agency Validates Marketing Application for Filgotinib for the Treatment of Rheumatoid Arthritis

August 15, 2019

FOSTER CITY, Calif. & MECHELEN, Belgium--(BUSINESS WIRE)--Aug. 15, 2019-- Gilead Sciences, Inc. (NASDAQ: GILD) and Galapagos NV (Euronext & NASDAQ: GLPG) today announced that the Marketing Authorization Application (MAA) for filgotinib, an investigational, oral, selective JAK1 inhibitor, for the treatment of adults with rheumatoid arthritis (RA) has been validated and is now under evaluation by the European Medicines Agency (EMA).

This press release features multimedia. View the full release here: <https://www.businesswire.com/news/home/20190815005605/en/>

"We are excited about the validation of this application which is an important milestone in our ongoing work to improve the lives of people living with rheumatoid arthritis and other inflammatory conditions," said John Sundy, MD, PhD, Senior Vice President, Inflammation and Respiratory Diseases, Gilead Sciences.

The MAA for filgotinib is supported by 24-week data from the Phase 3 FINCH clinical trials in which once-daily treatment with filgotinib achieved improvements in clinical signs and symptoms, achievement of low disease activity and remission, and inhibition of structural damage for different sub-populations of patients living with RA. Across the FINCH program, safety data were consistent with previously reported results.

"We are very happy with the validation of the filgotinib MAA by the EMA, as this represents the latest step forward in our partnership with Gilead to bring filgotinib as a new treatment option to RA patients across Europe," said Dr. Walid Abi-Saab, Chief Medical Officer at Galapagos.

The filgotinib filing will be reviewed by the EMA under the centralized licensing procedure for all 28 member states of the European Union, as well as Norway, Iceland and Liechtenstein. In early July, Gilead announced plans to submit a New Drug Application (NDA) for filgotinib for the treatment of RA in the United States before the end of the year.

Filgotinib is an investigational agent and is not approved anywhere globally. Its efficacy and safety have not been established by any regulatory authorities.

### 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).

### About the Galapagos – Gilead Collaboration

Galapagos and Gilead entered into a global collaboration for the development and commercialization of filgotinib in inflammatory indications. The FINCH studies are among several clinical trials of filgotinib in inflammatory diseases, including the EQUATOR Phase 2 study in psoriatic arthritis, the TORTUGA Phase 2 study in ankylosing spondylitis, the DIVERSITY Phase 3 trial in Crohn's disease (also small bowel and fistulizing Crohn's disease Phase 2 studies) and the Phase 3 SELECTION trial in ulcerative colitis.

### About Galapagos

Galapagos (Euronext & NASDAQ: GLPG) 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. Its pipeline comprises Phase 3 through to discovery programs in inflammation, fibrosis, osteoarthritis and other indications. Galapagos' ambition is to become a leading global biopharmaceutical company focused on the discovery, development and commercialization of innovative medicines. More information at [www.glgp.com](http://www.glgp.com).

### Gilead Forward-Looking Statement

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that are subject to risks, uncertainties and other factors, including the risk that EMA, the European Commission and other regulatory agencies may not approve filgotinib for the treatment of RA, and any marketing approvals, if granted, may have significant limitations on its use. As a result, filgotinib may never be successfully commercialized. There is also the possibility that Gilead may be unable to file an NDA for filgotinib in the United States in the currently anticipated timelines. Further, there is the possibility of unfavorable results from ongoing and additional clinical trials involving filgotinib. These risks, uncertainties and other factors could cause actual results to differ materially from those referred to in the forward-looking statements. The reader is cautioned not to rely on these forward-looking statements. These and other risks are described in detail in Gilead's Quarterly Report on Form 10-Q for the quarter ended June 30, 2019, as filed with the U.S. Securities and Exchange Commission. All forward-looking statements are based on information currently available to Gilead, and Gilead assumes no obligation to update any such forward-looking statements.

### Galapagos Forward-Looking Statements

This release may contain forward-looking statements with respect to Galapagos, including statements regarding Galapagos' strategic ambitions, the mechanism of action and potential safety and efficacy of filgotinib, the progression and results of clinical studies with filgotinib, the regulatory pathway for filgotinib and the timing of regulatory filings. 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 may not support registration or further development of filgotinib due to safety, efficacy or other reasons), Galapagos' reliance on collaborations with third parties (including its collaboration partner for filgotinib, Gilead), and estimating the commercial potential of filgotinib. 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.

*For more information on Gilead Sciences, please visit the company's website at [www.gilead.com](http://www.gilead.com), follow Gilead on Twitter (@GileadSciences) or call Gilead Public Affairs at 1-800-GILEAD-5 or 1-650-574-3000.*

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