Galapagos and Gilead Announce Global Partnership to Develop Filgotinib for the Treatment of Rheumatoid Arthritis and Other Inflammatory Diseases

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Galapagos Webcast presentation of the partnership to be held on 17 December, 17.00 CET/11 AM EDT/8 AM PST, +1 646 254 3361, access code 5852445, more call number info further down

MECHELEN, Belgium & FOSTER CITY, Calif.--(BUSINESS WIRE)--Dec. 17, 2015-- Galapagos NV (Euronext & NASDAQ:GLPG) and Gilead Sciences, Inc. (NASDAQ:GILD) today announced that the companies have entered into a global partnership for the development and commercialization of the JAK1-selective inhibitor filgotinib for inflammatory disease indications. Galapagos will receive an upfront payment of $725 million consisting of a license fee of $300 million and a $425 million equity investment in Galapagos. In addition, Galapagos is eligible for payments up to $1.35 billion in milestones, with tiered royalties starting at 20% and a profit split in co-promotion territories.

Phase 2 trial data show that filgotinib has the potential to be an effective and well-tolerated oral therapy for patients with rheumatoid arthritis (RA) (DARWIN studies) and Crohn’s disease (FITZROY study). The companies will start Phase 3 trials in RA and Crohn’s in 2016 pending the successful outcome of discussions with regulatory authorities.

“We are excited about the potential of filgotinib in RA and other diseases with a strong partner like Gilead, which shares our goal of rapidly delivering these therapies for patients,” said Onno van de Stolpe, Chief Executive Officer of Galapagos. “Furthermore, we look forward to the perspective of working together worldwide across other possible indications. The co-development and co-promotion aspects of this collaboration bring us into the next phase of the company’s evolution.”

“This partnership represents an opportunity to add complementary clinical programs to our growing inflammation research and development efforts,” said Norbert Bischofberger, PhD, Gilead’s Executive Vice President, Research and Development and Chief Scientific Officer. “We look forward to working with Galapagos to advance this program forward as quickly as possible.”

Under the terms of the agreement, the companies will collaborate jointly on the global development of filgotinib starting with the initiation of Phase 3 trials in RA. Galapagos will co-fund 20 percent of global development activities and Gilead will be responsible for manufacturing and worldwide marketing and sales activities. Galapagos has the option to co-promote filgotinib in the UK, Germany, France, Italy, Spain, Belgium, the Netherlands and Luxembourg, in which case the companies will share profits equally. If Galapagos exercises its option to co-promote in Belgium, the Netherlands or Luxembourg, it will also book sales in these countries.

Galapagos will receive an upfront license fee of $300 million and Gilead will make a $425 million equity investment in Galapagos by subscribing for shares at a price of €58 per share, which represents a 20% premium as compared to the average share price over the last 30 days. After the issuance of the shares, Gilead will own approximately 15% of the outstanding share capital of Galapagos depending on the $/€ exchange rate at closing. Galapagos is eligible to receive further development, regulatory and commercial milestone payments up to $1.35 billion, plus tiered royalties on global sales starting at 20%, with the exception of the co-promotion territories where profits will be shared equally.

This transaction has been approved by the boards of both companies, and is subject to customary closing conditions and clearances under the Hart-Scott Rodino Antitrust Improvements Act.

Galapagos Conference Call and Webcast

Galapagos will conduct a conference call open to the public on 17 December 2015 at 17:00 Central European Time/11 AM Eastern US/8 AM Pacific US, which will also be webcast. To participate in the conference call, please call one of the following numbers ten minutes prior to commencement:
A question and answer session will follow the presentation of the results. Go to www.glpg.com to access the live audio webcast. An archived webcast and PDF of the slides will be available on the Galapagos website later in the day.

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 three Phase 2, three Phase 1, five pre-clinical, and 20 discovery studies in cystic fibrosis, inflammation, fibrosis, osteoarthritis and other indications. We are 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 400 employees, operating from its Mechelen, Belgium headquarters and facilities in The Netherlands, France, and Croatia. More information at www.glpg.com.

About Gilead

Gilead Sciences is a biopharmaceutical company that discovers, develops and commercializes innovative therapeutics in areas of unmet medical need. The company’s mission is to advance the care of patients suffering from life-threatening diseases worldwide. Gilead has operations in more than 30 countries worldwide, with headquarters in Foster City, California. http://www.gilead.com

Galapagos Forward-Looking Statements

This release may contain forward-looking statements, including, among other things, statements regarding the expected timing of closing of the partnership with Gilead, the amount and timing of potential future milestone and/or royalty payments by Gilead, statements regarding the expected timing, design and readouts of ongoing and planned clinical trials with filgotinib in rheumatoid arthritis (Phase 3) and Crohn’s disease (Phase 2), the future development, regulatory approval and commercialization of filgotinib and the commercial potential of filgotinib. Galapagos cautions the reader that forward-looking statements are not guarantees of future performance. In particular it should be noted that the positive results of the DARWIN 1 and DARWIN 2 Phase 2B and FITZROY Phase 2 trials of filgotinib may not be indicative of future results, either on a stand-alone basis or as part of a combination therapy. 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 Galapagos’ ongoing and planned clinical research programs with filgotinib may not support registration or further development of filgotinib due to safety, efficacy or other reasons), any applicable antitrust clearance requirements, Galapagos’ reliance on collaborations with third parties (including its collaboration partner, Gilead), 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’ prospectus filed with the SEC on 14 May 2015 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.

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 risks that the parties will be unable to develop and commercialize filgotinib for the treatment of rheumatoid arthritis or any other indications; the expected timing of the completion of the transaction; and the ability of the parties to complete the transaction considering the transaction is subject to closing conditions. 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 September 30, 2015, 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.


Source: Gilead Sciences, Inc.

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