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NICE recommends Jyseleca®▼ (filgotinib) on NHS in landmark decision for rheumatoid arthritis

- **NICE guidance, for the first time in the UK, supports access to an advanced therapy for people with moderate as well as severe rheumatoid arthritis (RA) - aiming to avoid irreversible damage as early as possible[1]**
- **More than 400,000 people across the UK live with RA[2] and around 70% have moderate or severe disease[3]**

Mechelen, Belgium, 21 January 2021, 08:05 CET – Galapagos NV (Euronext & Nasdaq: GLPG) today welcomed the news that the *National Institute for Health and Care Excellence* (NICE) has issued a final appraisal determination (FAD) recommending the use of the daily oral pill, JYSELECA®▼ (filgotinib) on the National Health Service (NHS) in England for the treatment of eligible adult patients with moderate to severe active rheumatoid arthritis (RA).[1] It is the first time in the UK that an advanced therapy has been recommended in people with moderate RA, offering thousands more the potential to achieve remission earlier - potentially slowing the irreversible damage and life-limiting symptoms RA can cause.[2] RA is a degenerative auto-immune disease that can cause life-threatening complications.[4] The sooner treatment begins, the better the chance of slowing disease progression.[2] With thousands of people potentially eligible, the recommendation could help improve many lives as well as lessen the significant societal burden RA has in England.[5,6]

"We are delighted with the NICE recommendation for Jyseleca today. For patients with moderate to severe RA in England this decision represents a significant new opportunity and especially for those with moderate symptoms who can now receive an advanced treatment earlier," said Onno van de Stolpe, Galapagos CEO.

Filgotinib is a once daily oral pill that can be given on its own (as a monotherapy) or used alongside another common RA medicine, called methotrexate.[7] Eligible patients with moderate or severe RA will have responded inadequately to intensive therapy with 2 or more conventional disease-modifying antirheumatic drugs (DMARDs).[1] Eligible patients with severe disease will also have wider access to filgotinib in line with criteria defined by NICE. Filgotinib is an advanced therapy which, in RA, is a term used to describe biologic DMARDs and targeted synthetic DMARDs.[1]

More than 400,000 people in the UK live with RA (around 380,000 in England), and it is recognised as a condition that can cause debilitating physical pain, affect mental health and require chronic care.[2] Studies have shown that RA shortens life expectancy, with some estimates putting this at around 10 years.[8] Nearly 50% of patients diagnosed with RA suffer from mental health issues with 1 in 6 people having a major depressive disorder.[6,9] RA is also a significant burden on the UK economy. Around a third of people diagnosed with RA stop work within two years of diagnosis[10] and the combined cost of workdays lost due to osteoarthritis and RA in the UK was estimated at £2.58 billion in 2017 – estimated to rise to £3.43

billion by 2030.[5]

NICE guidance covers England. Wales and Northern Ireland are expected to follow the guidance with timelines for implementation currently under consideration. Filgotinib will be reviewed separately by the *Scottish Medicines Consortium* for use on the NHS in Scotland.

Under a new arrangement between Gilead and Galapagos, announced in December 2020, Galapagos will assume sole responsibility for filgotinib in Europe, including the UK. Through a phased transition the majority of activities supporting filgotinib in Europe are expected to be assumed by Galapagos by the end of 2021.

About filgotinib[7]

Filgotinib is a Janus-kinase (JAK) inhibitor and works by preferentially targeting JAK1, part of a specific pathway involved in inflammation – an immune response of the body that causes symptoms of RA. In clinical studies, filgotinib has been shown to significantly improve the chance of disease remission (a DAS28-CRP score of <2.6, indicating few or no symptoms).[7] In the FINCH 1 study of 1,755 patients with RA who had an inadequate response to methotrexate, 34% of patients given filgotinib 200mg + methotrexate (n=475) achieved disease remission after just 12 weeks, compared to 9% of a group given placebo (n=475). After 24 weeks, 48% of patients in this group had achieved remission vs. 16% of those on placebo and these response levels were sustained through 52 weeks. In many cases, responses were seen within two weeks (measured using an ACR20 score).

Data supporting filgotinib include more than 3,800 patients treated across the Phase 3 FINCH and Phase 2 DARWIN programmes. In the FINCH studies, filgotinib consistently achieved ACR20/50/70 criteria, with improvements in all individual ACR components compared with placebo or methotrexate.

Across the FINCH and DARWIN trials, the most common adverse reactions were nausea, upper respiratory tract infection, urinary tract infection and dizziness. Rates of herpes zoster and pneumonia were uncommon. The frequency of serious infections in the filgotinib 200mg group was 1.0 percent compared with 0.6 percent in the placebo group. In an integrated safety analysis in seven clinical trials the rates of major adverse cardiac events (MACE) and venous thromboembolism (VTE) with filgotinib were comparable to placebo. The rates of serious infections remained stable with long-term exposure.

About Galapagos

Galapagos NV discovers and develops 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 biopharmaceutical company focused on the discovery, development and commercialization of innovative medicines. More information at www.glpg.com.

Except for filgotinib's approval for the treatment of RA by the European Commission and Japanese Ministry of Health, Labour and Welfare, 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.

▼ The black triangle next to JYSELECA® means that it is subject to additional monitoring. This is to allow quick identification of new safety information. Patients can help with this by reporting any side effects that they experience. More information can be found online at https://www.mhra.gov.uk/yellowcard

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 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 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, the timing or likelihood of additional guidance or final appraisal determinations for filgotinib, 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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