Galapagos reports commercial and operational progress at Q3 financial results

- **First nine months 2021 financial results:**
  - **Group revenues of €317.9 million**
  - **Operating loss of €175.7 million**
  - **Net loss of €119.6 million**
  - **Cash and current financial investments of €4.9 billion on 30 September 2021**
- **Filgotinib launch in RA on track with reimbursement secured in 14 countries**
- **Reduced 2021 cash burn guidance by €50 million to €530-€570 million**

Webcast presentation tomorrow, 5 November 2021, at 13.00 CET / 8 AM ET, www.glpg.com, +32 2 793 38 47, code 4987105

Mechelen, Belgium; 4 November 2021, 22.01 CET; regulated information – Galapagos NV (Euronext & NASDAQ: GLPG) is pleased to report on its commercial launch of filgotinib in Europe. The company is moving forward with its revised R&D strategy and operational restructuring announced in May, resulting in a downward adjustment of the cash burn by €50 million. The unaudited Q3 financial and operational results are further detailed in the Q3 2021 report available on the website, www.glpg.com.

"This quarter we achieved key steps in our growing commercial business in Europe, while moving earlier-stage R&D programs forward. We continue to deliver on our revised strategy, accelerating the savings program announced at the first quarter results. We are focused on nominating a successor to lead our company going forward following my eventual retirement as CEO," said Onno van de Stolpe, CEO of Galapagos. "Supported by our strong balance sheet and long-term R&D collaboration with Gilead, we believe that Galapagos remains well-positioned for future growth."

"After years of hard work by so many, we are very excited to bring Jyseleca to market as a new treatment option for people living with rheumatoid arthritis (RA). As per 30 September 2021, we booked €6.1 million in net sales for Jyseleca, for a total of €15.8 million together with Gilead. Encouraged by these sales of our first commercial product and its positioning in the growing JAK market in Europe, we are confident in the commercial potential of our Jyseleca franchise in Europe. Following the positive CHMP opinion for filgotinib for the treatment of patients with ulcerative colitis (UC), we expect a decision by the European Commission (EC) before year-end, and if granted, we are ready to go full steam ahead with the commercial roll-out in a second indication," added Bart Filius, President and COO of Galapagos. "Following our strategic operational review in March 2021, we implemented a cost savings program of €150 million on a full year basis. As a result of an acceleration of this program, we revise our guidance for full year 2021 operational cash burn[i] from €580 to €620 million to €530 to €570 million."

Key figures third quarter report 2021 (unaudited)
(€ millions, except basic & diluted loss per share)

	30 September 2021 group total	30 September 2020 group total (*)
Product net sales	6.1	-
Collaboration revenues	311.7	321.9
Total revenues	**317.9**	**321.9**
Cost of sales	(0.7)	-
R&D expenditure	(378.0)	(392.2)
G&A[ii] and S&M[iii] expenses	(151.3)	(132.4)
Other operating income	36.3	35.0
Operating loss	**(175.7)**	**(167.7)**
Fair value re-measurement of financial instruments	3.0	(8.1)
Net other financial result	30.6	(75.3)
Income taxes	0.3	(0.7)
Net loss from continuing operations	**(141.8)**	**(251.8)**
Net profit from discontinued operations	22.2	4.2
Net loss of the period	**(119.6)**	**(247.6)**
Basic and diluted loss per share (€)	(1.83)	(3.81)
Current financial investments and cash and cash equivalents	**4,874.2**	**5,308.6**

(*) The 2020 comparatives have been restated to consider the impact of classifying the Fidelta business as discontinued operations in 2020.

Details of the financial results
Due to the sale of our fee-for-service business (Fidelta) to Selvita on 4 January 2021 for a total consideration of €37.1 million (including customary adjustments for net cash and working capital), the results of Fidelta are presented as "Net profit from discontinued operations" in our unaudited condensed consolidated income statements for the nine months ended 30 September 2021 and 30 September 2020.

Revenues from continuing operations
Our revenues from continuing operations for the first nine months of 2021 amounted to €317.9 million compared to €321.9 million in the first nine months of 2020.

We reported net sales of Jyseleca for the first nine months of 2021 amounting to €6.1 million (€5.7 million in the third quarter of 2021), which reflects the sales booked by Galapagos after the transition from Gilead. Total sales of Jyseleca in Europe by both companies for the first nine months of 2021 is €15.8 million.

Collaboration revenues amounted to €311.7 million for the first nine months of 2021, compared to €321.9 million for the same period last year. This was mainly driven by the recognition of upfront

consideration and milestone payments received in the scope of the collaboration with Gilead for filgotinib, amounting to €136.4 million for the first nine months of 2021 (€145.9 million for the same period last year). The decrease in revenue recognition was primarily due to a negative cumulative catch up of revenue triggered by the recent agreement under which Galapagos will assume operational and financial responsibility for the ongoing DIVERSITY clinical study. This decrease was partly compensated by additional consideration from Gilead related to the renegotiated collaboration, when compared to the same period last year. The revenue recognition related to the exclusive access rights for Gilead to our drug discovery platform amounted to €173.3 million for the first nine months of 2021 (€170.7 million for the same period last year).

Our deferred income balance on 30 September 2021 includes €1.8 billion allocated to our drug discovery platform that is recognized linearly over 10 years, and €0.7 billion allocated to the filgotinib development that is recognized over time until the end of the development period.

Results from continuing operations

We realized a net loss from continuing operations of €141.8 million for the first nine months of 2021, compared to a net loss of €251.8 million for the first nine months of 2020.

We reported an operating loss amounting to €175.7 million for the first nine months of 2021, compared to an operating loss of €167.7 million for the same period last year.

Cost of sales related to Jyseleca net sales in the first nine months of 2021 amounted to €0.7 million.

Our R&D expenditure in the first nine months of 2021 amounted to €378.0 million, compared to €392.2 million for the first nine months of 2020. This decrease was primarily explained by winding down of our ziritaxestat (IPF), MOR106 (atopic dermatitis), and GLPG1972 (OA) programs and by reduced spend on our other programs. This was partly offset by costs increases for our filgotinib and Toledo (SIKi) programs, on a nine months comparison basis. Personnel costs increased primarily because of an increased average headcount compared to the same period last year, and increased costs of our subscription right plans.

Our S&M and G&A expenses were respectively €46.6 million and €104.7 million in the first nine months of 2021, compared to respectively €44.1 million and €88.3 million in the first nine months of 2020. This increase was primarily due to an increase in personnel costs and other operating expenses mainly driven by the commercial launch of filgotinib in Europe. This increase was partly compensated by higher cost recharges from us to Gilead in the scope of our commercial cost sharing for filgotinib in Europe.

Other income (€36.3 million vs €35.0 million for the same period last year) increased, mainly driven by higher grant income.

We reported a non-cash fair value gain from the re-measurement of initial warrant B issued to Gilead, amounting to €3.0 million, mainly due to the decreased implied volatility of the Galapagos share price and its evolution between 31 December 2020 and 30 September 2021.

Net other financial income in the first nine months of 2021 amounted to €30.6 million, compared to net other financial loss of €75.3 million for the first nine months of 2020, which was primarily attributable to €54.9 million of currency exchange gain on our cash and cash equivalents and current financial investments in U.S. dollars, to €10.1 million of negative changes in (fair) value of

current financial investments and financial assets and to €8.5 million of interest expenses. The other financial expenses also contained the effect of discounting our long term deferred income of €7.2 million.

Results from discontinued operations
The net profit from discontinued operations for the nine months ended 30 September 2021 consisted of the gain on the sale of Fidelta, our fee-for-services business, for €22.2 million.

Group net results
We reported a group net loss for the first nine months of 2021 of €119.6 million, compared to a group net loss of €247.6 million for the first nine months of 2020.

Cash position
Current financial investments and cash and cash equivalents totaled €4,874.2 million on 30 September 2021, as compared to €5,169.3 million on 31 December 2020.

Total net decrease in cash and cash equivalents and current financial investments amounted to €295.2 million during the first nine months of 2021, compared to a net decrease of €472.2 million during the first nine months of 2020. This net decrease was composed of (i) €376.7 million of operational cash burn, (ii) offset by €2.7 million of cash proceeds from capital and share premium increase from exercise of subscription rights in the first nine months of 2021, (iii) €7.2 million negative changes in (fair) value of current financial investments and €57.3 million of mainly positive exchange rate differences, (iv) €28.7 million cash in from disposal of subsidiaries, net of cash disposed.

Our balance sheet on 30 September 2021 also held a receivable from the French government (Crédit d'Impôt Recherche[iv]) and a receivable from the Belgian Government for R&D incentives, for a total of both receivables of €149.3 million.

Outlook 2021
Going forward, we continue to build our filgotinib franchise throughout Europe, and remain on track to complete the transition of the full European commercial operations for filgotinib from our collaboration partner Gilead to us by year-end. We anticipate an approval decision from the EC and Great Britain's Medicines and Healthcare products Regulatory Agency (MHRA) for filgotinib for the treatment of UC, which, if approved, would add a second indication to our growing commercial footprint in Europe.

Following the positive topline Phase 1b data from our TYK2 inhibitor GLPG3667, we are running an extended dose escalation study in healthy volunteers, and we are preparing to launch a Phase 2b trial in Psoriasis and a Phase 2 trial in UC in 2022.

We are advancing our SIK3 inhibitor GLPG4399 in healthy volunteers this year, and we aim to move a follow-up SIK2/3 preclinical candidate into the clinic in 2022.

By year-end we also intend to finalize recruitment into the GLPG2737 Phase 2a trial in autosomal dominant polycystic kidney disease (ADPKD), an indication with important unmet medical need.

Meanwhile we continue to apply lessons learned from the strategic exercise announced at Q1 to the development of our deep pipeline, and we diligently evaluate business development opportunities in our core therapeutic areas of inflammation and fibrosis.

Following our strategic review of operations in March 2021, we implemented a cost savings program of €150 million on a full year basis. As a result of an acceleration of this program, we revise our guidance for full year 2021 operational cash burn from €580 to €620 million to €530 to €570 million.

Third quarter report 2021
Galapagos' financial report for the first nine months ended 30 September 2021, including details of the unaudited consolidated results, is accessible via www.glpg.com/financial-reports.

Conference call and webcast presentation
Galapagos will conduct a conference call open to the public tomorrow, 5 November 2021, at 13:00 CET / 8 AM ET, which will also be webcasted. To participate in the conference call, please call one of the following numbers ten minutes prior to commencement:

CODE: 4987105

Standard International:	+44 2071 928338
USA:	+1 646 741 3167
UK:	+44 844 481 9752
Netherlands:	+31 207 95 66 14
France:	+33 1 70 70 0781
Belgium:	+32 2 793 38 47

A question and answer session will follow the presentation of the results. Go to www.glpg.com to access the live audio webcast. The archived webcast will also be available for replay shortly after the close of the call.

Financial calendar
24 February 2022 Full year 2021 results (webcast 25 February 2022)

About Galapagos
Galapagos NV discovers, develops, and commercializes small molecule medicines with novel modes of action. 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 rheumatoid arthritis by the European Commission, Great Britain's Medicines and Healthcare products Regulatory Agency 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.

Jyseleca® is a trademark of Galapagos NV and Gilead Sciences, Inc. or its related companies.

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Forward-looking statements

This release may contain forward-looking statements, including, among other things, statements regarding the global R&D collaboration with Gilead, the amount and timing of potential future milestones, opt-in and/or royalty payments by Gilead, Galapagos' strategic R&D ambitions, including progress on our fibrosis portfolio and SIK platform, and potential changes of such ambitions, the guidance from management (including guidance regarding the expected operational use of cash during financial year 2021), financial results, statements regarding the expected timing, design and readouts of ongoing and planned clinical trials, including recruitment for trials and topline results for our trials and studies in our inflammation portfolio, statements regarding the strategic re-evaluation, statements relating to interactions with regulatory authorities, the timing or likelihood of additional regulatory authorities' approval of marketing authorization for filgotinib for RA, UC or any other indication, including UC and IBD indications for filgotinib in Europe, Great-Britain, Japan, and the U.S., such additional regulatory authorities requiring additional studies, statements regarding changes in our management board and key personnel, our ability to effectively transfer knowledge during this period of transition, the search and recruitment of a suitable successor to lead our organization and a CSO, the risk that Galapagos will be unable to successfully achieve the anticipated benefits from its leadership transition plan, the possibility that Galapagos will encounter challenges retaining or attracting talent, the timing or likelihood of pricing and reimbursement interactions for filgotinib, statements relating to the build-up of our commercial organization, statements and expectations regarding commercial sales for filgotinib, the expected impact of COVID-19, and our strategy, business plans and focus. 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 that our expectations regarding our 2021 revenues and financial results and our 2021 operating expenses may be incorrect (including because one or more of its assumptions underlying its expense expectations may not be realized), Galapagos' expectations regarding its development programs may be incorrect, the inherent uncertainties associated with competitive developments, clinical trial and product development activities and regulatory approval requirements (including the risk that data from Galapagos' ongoing and planned clinical research programs in rheumatoid arthritis, Crohn's disease, ulcerative colitis, idiopathic pulmonary fibrosis, osteoarthritis, other inflammatory indications and kidney disease may not support registration or further development of its product candidates due to safety or efficacy concerns or other reasons), Galapagos' reliance on collaborations with third parties (including our collaboration partner Gilead), the timing of and the risks related to the implementation of the transition of the European commercialization responsibility of filgotinib from Gilead to us, the risk that the transition will not be completed on the currently contemplated timeline or at all, including the transfer of the supply chain, and the risk that the transition will not have the currently expected results for our business and results of operations, estimating the commercial potential of our product candidates and Galapagos' expectations regarding the costs and revenues associated with the transfer of European commercialization rights to filgotinib may be incorrect, the risk that Galapagos will not be able to continue to execute on its currently contemplated business plan and/or will revise its business plan, and the uncertainties

relating to the impact of the COVID-19 pandemic. 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 other 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.

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[i] The operational cash burn (or operational cash flow if this performance measure is positive) is equal to the increase or decrease in our cash and cash equivalents (excluding the effect of exchange rate differences on cash and cash equivalents), minus:

- the net proceeds, if any, from share capital and share premium increases included in the net cash flows generated from/used in (-) financing activities
- the net proceeds or cash used, if any, in acquisitions or disposals of businesses; the movement in restricted cash and movement in current financial investments, if any, included in the net cash flows generated from/used in (-) investing activities.

This alternative performance measure is in our view an important metric for a biotech company in the development stage.
The operational cash burn for the nine months ended 30 September 2021 amounted to €376.7 million and can be reconciled to our cash flow statement by considering the increase in cash and cash equivalents of €650.7 million, adjusted by (i) the cash proceeds from capital and share premium increase from the exercise of subscription rights by employees for €2.7 million, (ii) the net sale of current financial investments amounting to €996.0 million, and (iii) the cash in from sale of subsidiaries, net of cash disposed, of €28.7 million.

[ii] General and administrative

[iii] Sales and marketing

[IV] *Crédit d'Impôt Recherche* refers to an innovation incentive system underwritten by the French government