Galapagos reports Q3 2020 results

- **First nine months 2020 financial results:**
  - **Group revenues and other income of €368.6 million**
  - **Operating loss of €163.2 million**
  - **Net loss of €247.6 million**
  - **Cash and current financial investments of €5.3 billion on 30 September 2020**
- **Approval for filgotinib in rheumatoid arthritis (RA) in Europe and Japan, Complete Response Letter (CRL) received in the U.S.**
- **Positive topline results with ziritaxestat in systemic sclerosis**
- **No signal observed with GLPG1972 in osteoarthritis**
- **First dosing of patients with Toledo compound GLPG3970**

Webcast presentation tomorrow, 06 November 2020, at 14.00 CET / 8 AM ET, www.glpg.com, +32 2 793 38 47, code 8542327

Mechelen, Belgium; 5 November 2020, 22.01 CET; regulated information – Galapagos NV (Euronext & NASDAQ: GLPG) announces its unaudited Q3 results and operational highlights, which are further detailed in its Q3 2020 report available on the Galapagos website, www.glpg.com.

"We closed a turbulent third quarter with an approved first drug in Europe and Japan, but also a CRL in the U.S. As we work with Gilead to adequately address the CRL, we stand ready for commercial launch in our co-promotion countries in Europe. We continue to work through the clinical programs from our pipeline, as we execute on our strategy to develop a portfolio of novel mechanism therapies in inflammation and fibrosis," said Onno van de Stolpe, CEO of Galapagos.

Bart Filius, COO and CFO added, "We ended the third quarter with a strong cash balance, positioning us well to further grow our pipeline and deliver on the anticipated commercial launch of filgotinib. We maintain our 2020 operational cash burn guidance of €490-€520 million."

Key figures third quarter report 2020 (unaudited)
(€ millions, except basic & diluted gain/loss (-) per share)

	30 September 2020 group total	30 September 2019 group total
Revenues and other income	**368.6**	**752.5**
R&D expenditure	(398.1)	(298.2)
S&M[i] expenses	(44.1)	(9.7)
G&A[ii] expenses	(89.5)	(51.5)
Operating loss (-)/operating profit	**(163.2)**	**393.0**
Fair value re-measurement of share subscription agreement and warrants	(8.1)	(142.3)
Net other financial result	(75.2)	(2.1)
Taxes	(1.1)	16.7
Net result for the period	**(247.6)**	**265.3**
Basic loss (-)/ gain per share (€)	(3.81)	4.77
Diluted loss (-)/gain per share (€)	(3.81)	4.59
Current financial investments and cash and cash equivalents	**5,308.6**	**5,599.8**

Revenues and other income

Revenues and other income for the first nine months of 2020 decreased to €368.6 million compared to €752.5 million in the first nine months of 2019, due to one-time recognition in revenue in the first nine months of 2019 of the upfront payment received from Gilead related to ziritaxestat for €667.0 million. The revenues from the Gilead collaboration in the first nine months of 2020 amount to €316.6 million and consist of (i) the access and option rights to our drug discovery platform (€170.7 million), and (ii) the filgotinib revenue recognition (€145.9 million).

Due to the approval of filgotinib by both the Japanese and European authorities on 25 September 2020, we achieved a total milestone of $105.0 million (€90.2 million) from Gilead that will be recognized in revenue over time until the end of the development plan.

As a result of the upfront payment received from Gilead in the third quarter of 2019, our deferred income on 30 September 2020 includes €2.0 billion allocated to our drug discovery platform that is recognized linearly over 10 years, and €0.7 billion allocated to filgotinib (2015 filgotinib contract and recent revised collaboration combined, and additional milestones) that is recognized over a period of 4 to 5 years.

Results

We realized a net loss of €247.6 million for the first nine months of 2020, compared to a net profit of €265.3 million for the first nine months of 2019.

We reported an operating loss amounting to €163.2 million for the first nine months of 2020, compared to an operating profit of €393.0 million for the first nine months of 2019.

The net profit and operating profit for the first nine months of 2019 was mainly due to one-time recognition in revenue in the first nine months of 2019 of the upfront payment received from Gilead related to ziritaxestat for €667.0 million.

Our R&D expenditure in the first nine months of 2020 amounted to €398.1 million, compared to €298.2 million for the first nine months of 2019. This planned increase was mainly due to an increase in subcontracting costs primarily related to our filgotinib program, our Toledo program and other clinical programs. Furthermore, personnel costs increased explained by a planned headcount increase following the growth in our R&D investments, and increased cost of the subscription right plans. This factor, and the increased cost of the commercial launch of filgotinib in Europe, contributed to the increase in our S&M and G&A expenses, which were respectively €44.1 million and €89.5 million in the first nine months of 2020, compared to respectively €9.7 million and €51.5 million in the first nine months of 2019.

We reported a non-cash fair value loss from the re-measurement of initial warrant B issued to Gilead, amounting to €8.1 million, as result of the increased implied volatility of the Galapagos share price and its evolution between 31 December 2019 and 30 September 2020.

Net other financial loss in the first nine months of 2020 amounted to €75.2 million, compared to net other financial loss of €2.1 million for the first nine months of 2019, which was primarily attributable to €51.2 million of unrealized exchange loss on our cash and cash equivalents and current financial investments in U.S. dollars, and to €13.3 million of negative changes in (fair) value of current financial investments.

Cash position

Current financial investments and cash and cash equivalents totaled €5,308.6 million on 30 September 2020.

A total net decrease of €472.2 million in cash and cash equivalents and current financial investments was recorded during the first nine months of 2020, compared to a net increase of €4,309.0 million during the first nine months of 2019. This net decrease was composed of (i) €433.3 million of operational cash burn[iii], (ii) offset by €25.7 million of cash proceeds from capital and share premium increase from exercise of subscription rights in the first nine months of 2020, and (iii) €13.3 million negative changes in (fair) value of current financial investments and €51.3 million of unrealized negative exchange rate differences.

Finally, our balance sheet on 30 September 2020 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 €122.9 million.

Outlook 2020

Our collaboration partner Gilead is in direct dialogue with the Food and Drug Administration on filgotinib's new drug application following receipt of the CRL for filgotinib in RA in the U.S., and we expect more clarity in the coming months. With the MANTA and MANTA-RAy studies fully recruited, we expect to have key results available in the first half of 2021.

In the fourth quarter we expect to report topline data from the PINTA Phase 2 study with GLPG1205 in IPF. Furthermore there have been over 1,200 patients recruited in our global landmark ISABELA Phase 3 program with ziritaxestat in IPF. We remain on track to announce the futility analysis in the first half of 2021.

To further evaluate the broad potential of our most advanced Toledo compound, SIK2/3 inhibitor GLPG3970, in inflammatory diseases, we anticipate first dosing in the LADYBUG (RA) and SEA TURTLE (UC) proof-of-concept studies.

We retain our operational cash burn guidance of €490 to €520 million for full year 2020.

Third quarter report 2020
Galapagos' financial report for the first nine months ended 30 September 2020, 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, 06 November 2020, at 14:00 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: 8542327

Standard International:	+44 (0) 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

18 February 2021	Full year 2020 results (webcast 19 February 2021)

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 rheumatoid arthritis 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.

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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, the guidance from management (including guidance regarding the expected operational cash burn during financial year 2020), financial results, timing and/or results of clinical trials, mechanisms of action and potential commercialization of our product candidates, interaction with regulators, the timing or likelihood of additional regulatory authorities' approval of marketing authorization for filgotinib, such additional regulatory authorities requiring additional studies, statements relating to the build-up of our commercial organization 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 Galapagos' expectations regarding its 2020 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 may not support registration or further development of its product candidates due to safety, efficacy or other reasons), Galapagos' reliance on collaborations with third parties (including our collaboration partner for filgotinib and ziritaxestat, Gilead, and our collaboration partner for GLPG1972, Servier), and estimating the commercial potential of our product candidates 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.

[i] Sales and marketing

[ii] General and administrative

[iii] 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:

i. the net proceeds, if any, from share capital and share premium increases included in the net cash flows generated / used (–) in financing activities
ii. 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 / 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 2020 amounted to €433.3 million and can be reconciled to our cash flow statement by considering the increase in cash and cash equivalents of €262.1 million, adjusted by (i) the cash proceeds from capital and share premium increase from the exercise of subscription rights by employees for €25.7 million and (ii) the net sale of current financial investments amounting to €669.7 million.

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