

# Pipeline and capital for growth

## Key 2020 events:

- Jyseleca approved for rheumatoid arthritis (RA) in Europe & Japan
- Gilead decided not to pursue the RA indication in the U.S. as a result of Complete Response Letter (CRL) from the Food and Drug Administration (FDA)
- Galapagos to assume commercialization of Jyseleca in Europe by the end of 2021, first sales achieved
- Primary endpoint achieved in SELECTION Phase 3 trial in ulcerative colitis (UC) with Jyseleca, submitted for approval in UC in Europe
- Positive topline results in PINTA Phase 2 trial with '1205 in idiopathic pulmonary fibrosis (IPF);
   no signal with '1972 in ROCCELLA Phase 2b trial in osteoarthritis (OA)
- Initiation of five Proof-of-Concept studies with Toledo program lead candidate '3970, a SIK2/3 inhibitor
- Sale of fee-for-service business Fidelta to Selvita
- Business development deals to complement the inflammation & fibrosis pipelines

### **Financial results:**

- Group revenues & other income from continuing operations of €530 million, compared to €886 million in 2019
- Net loss of €305 million, compared to a net profit of €150 million in 2019
- Operational cash burn<sup>i</sup> of €517 million, within the guided range
- Strong balance sheet with cash and current financial investments of €5.2 billion and €2.8 billion in deferred revenues

Audio webcast presentation tomorrow, 19 February 2021 at 14.00 CET/8 AM ET, +32 (0)2 793 3847, code 8873918, https://www.qlpq.com/webcasts

Mechelen, Belgium; 18 February 2021, 22.01 CET, regulated information – Galapagos NV (Euronext & NASDAQ: GLPG) presents financial results 2020 and reviews the key events for the full year 2020.

"We are turning the page on an eventful 2020," said Onno van de Stolpe, CEO of Galapagos. "We received the very disappointing CRL from the FDA for Jyseleca for RA, and as a result, our partner Gilead will not commercialize Jyseleca in the U.S. in this indication. That being said, 2020 is also marked by our first ever approval in both Europe and Japan, and with the renegotiated agreement with Gilead, we are excited to bring Jyseleca to patients throughout Europe. Moreover, following the positive Phase 3 results in UC, we are looking forward to potentially adding a second indication in Europe in 2021.

Our earlier inflammation pipeline continues to advance, including our Toledo program, where we currently are conducting 5 patient trials with our SIK2/3 inhibitor '3970, with read-outs of three Proof-of-Concept trials (PoCs) expected mid this year.

In our fibrosis portfolio we made progress last year, with the positive topline results in our PINTA trial in IPF, preclinical candidate nomination of a new Toledo compound directed toward IPF, and the inlicensing of exciting new molecules. We recently discontinued all development with ziritaxestat due to an insufficient risk-benefit profile observed in the ISABELA Phase 3 program.



Given the recent setbacks in our late stage portfolio, we aim to assess lessons learned and will continue to reassess the R&D portfolio in light of this learning."

Bart Filius, COO and CFO of Galapagos, added: "We ended 2020 with again a very strong balance sheet, providing us with the capital to leverage our R&D engine to execute on our novel target based programs. We remain focused on investing in our maturing clinical pipeline of candidates. We landed our operational cash burn<sup>i</sup> in 2020 in line with our guidance at €517 million, including the milestones received for the approval of Jyseleca in Europe and Japan. Following the very recent discontinuation of the ziritaxestat trials, we aim to review our plans for 2021, after which we expect to give cash burn guidance for 2021."

## **Key figures (consolidated)**

(€ millions, except basic & diluted income/loss (-) per share)

	31 Dec 2020 Group total	31 Dec 2019 Group total (*)
Revenues and other income	530.3	885.8
R&D expenditure	-523.7	-420.1
G&A <sup>ii</sup> and S&M expenses <sup>iii</sup>	-185.2	-97.0
Operating profit / loss (-)	-178.6	368.7
Fair value re-measurement of financial instruments	3.0	-181.6
Other financial result	-134.2	-38.6
Income taxes	-1.2	0.2
Net profit / loss (-) from continuing operations	-311.0	148.7
Net profit from discontinued operations	5.6	1.1
Net profit / loss (-) of the year	-305.4	149.8
Basic income / loss (-) per share (€)	-4.69	2.60
Diluted income / loss (-) per share (€)	-4.69	2.49
Current financial investments and cash and cash equivalents at year-end	5,169.3	5,780.8

<sup>(\*)</sup> The 2019 comparatives have been restated to consider the impact of classifying the Fidelta business as discontinued operations in 2020.



#### **Details of the financial results**

We previously held two operating segments. Due to the completion of the sale of our fee-for-service business (Fidelta) to Selvita on the 4<sup>th</sup> January 2021 for an enterprise value of €31.2 million (plus the customary adjustments for net cash and working capital), the results of Fidelta are presented as "Net results from discontinued operations" in our consolidated income statements for the year 2020 and 2019.

## Revenues and other income from continuing operations

Our revenues and other income from continuing operations for 2020 amounted to  $\in$ 530.3 million, compared to  $\in$ 885.8 million in 2019. Revenues ( $\in$ 478.1 million in 2020 compared to  $\in$ 834.9 million in 2019) were lower due to the one-time revenue recognition in 2019 of the upfront payment received from Gilead in August 2019 related to ziritaxestat for  $\in$ 667.0 million. In 2020, our revenues from the Gilead collaboration ( $\in$ 473.9 million) related to (i) the exclusive access to our drug discovery platform ( $\in$ 229.6 million) and (ii) the filgotinib revenue recognition ( $\in$ 228.1 million). Additionally we have recognized royalty income from Gilead for Jyseleca for  $\in$ 16.2 million.

Due to the approval of Jyseleca by both the Japanese and European authorities on 25 September 2020, we received a total milestone of \$105.0 million (€90.2 million) from Gilead. As a consequence of the recently renegotiated collaboration for filgotinib, we also have accrued for a €160 million payment expected from Gilead in our 2020 financial statements. Both amounts are recognized in revenue over time until the end of the development period.

Our deferred income balance on 31 December 2020 includes €2.0 billion allocated to our drug discovery platform that is recognized linearly over 10 years, and €0.8 billion for the filgotinib development (including considerations for the previous and the renegotiated collaboration combined) that is recognized over time until the end of the development period.

Other income (€52.2 million vs €50.9 million for the same period last year) mainly consists of incentives income from the government for our R&D activities.

## Results from continuing operations

We realized a net loss from continuing operations in 2020 of €311.0 million, compared to a net profit of €148.7 million in 2019.

We reported a net operating loss in 2020 of €178.6 million, compared to a net operating profit of €368.7 million in 2019.

Our R&D expenditure increased by 25% in 2020 to €523.7 million compared to €420.1 million in 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 Jyseleca in Europe, contributed to the increase in our S&M and G&A expenses which were respectively €66.5 million and €118.8 million in 2020, compared to €24.6 million and €72.4 million in 2019.



We reported a non-cash fair value gain amounting to €3.0 million resulting from the remeasurement of initial warrant B issued to Gilead, primarily due to the evolution of the Galapagos share price and its implied volatility.

Net other financial loss in 2020 amounted to €134.2 million, compared to net other financial loss of €38.6 million in 2019, and was primarily attributable to €106.4 million of unrealized exchange loss on our cash and cash equivalents and current financial investments in U.S. dollars (€10.6 million of unrealized exchange loss in 2019), and to €15.9 million of negative changes in (fair) value of current financial investments (€3.1 million of net negative changes in (fair) value in 2019).

## Group net results

We reported a group net loss in 2020 of €305.4 million, compared to a group net profit of €149.8 million in 2019.

# Cash position

Current financial investments and cash and cash equivalents totaled €5,169.3 million on 31 December 2020, as compared to €5,780.8 million on 31 December 2019.

The net decrease comprises (i) €517.4 million of operational cash burn, within the guided range, (ii) offset by €28.3 million of cash proceeds from capital and share premium increase from the exercise of subscription rights in 2020, and (iii) €106.4 million of unrealized negative exchange rate differences and €15.9 million of negative changes in (fair) value of current financial investments.

Furthermore, our balance sheet on 31 December 2020 held a receivable from the French government (*Crédit d'Impôt Recherche*<sup>iv</sup>) and a receivable from the Belgian Government for R&D incentives, for a total of both receivables of €135.7 million.

#### Outlook 2021

We anticipate a year filled with announcements on regulatory developments with Jyseleca as well as progress in our deep pipeline of novel target-based candidates.

In early 2021, Jyseleca received a recommendation by NICE in the UK for use in moderate to severe active RA patients. This is a landmark decision, as Jyseleca is the first JAK inhibitor and first advanced therapy recommended by NICE in the moderate disease population. Going forward, we anticipate reimbursement decisions in most key European markets for Jyseleca in RA this year, as we complete the transition to a full European commercial operation by year end. We anticipate a Committee for Medicinal Products for Human Use (CHMP) opinion and a European Commission (EC) approval decision for Jyseleca in UC, as well as Gilead's submission for approval of Jyseleca in UC in Japan. We expect to update the markets on the MANTA/RAy semen parameter studies, which determines the path forward for inflammatory bowel disease (IBD) indications with Jyseleca in the U.S. We expect that our collaboration partner Gilead will complete recruitment for the global DIVERSITY Phase 3 trial in Crohn's disease this year.

Within our broader inflammation portfolio, we expect to report topline results from several trials this year, including a Phase 1b trial with TYK2 inhibitor '3667 in psoriasis, a Phase 1b trial with JAK1 inhibitor '555 via intra-articular injection in OA, and three proof-of-concept studies with lead Toledo candidate SIK2/3 inhibitor '3970 in psoriasis, UC and RA.



Within our fibrosis portfolio, we expect to progress early clinical compounds with novel mechanisms of action, casting a wide net with the aim to develop novel treatments to help patients suffering from this debilitating disease.

Following the very recent discontinuation of the ziritaxestat trials, we aim to review our plans for 2021, after which we expect to give cash burn guidance for 2021.

### **Annual report 2020**

Galapagos is currently finalizing its financial statements for the year ended 31 December 2020. The auditor has confirmed that his audit procedures, which are substantially completed, have not revealed any material corrections required to be made to the financial information included in this press release. Should any material changes arise during the audit finalization, an additional press release will be issued. Galapagos expects to be able to publish its fully audited annual report for the full year 2020 on or around 25 March 2021.

## Conference call and webcast presentation

Galapagos will conduct a conference call open to the public tomorrow, 19 February 2021, 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 scheduled start of the call:

Confirmation Code: 8873918

Belgium: +32 2 793 3847 France: +33 1 70 700 781 Netherlands: +31 20 795 6614 United Kingdom: +44 2071 928338 United States: +1 646 741 3167

A question and answer session will follow the presentation of the results. Go to <a href="https://www.glpg.com/webcasts">https://www.glpg.com/webcasts</a> to access the live audio webcast. The archived webcast will also be available for replay shortly after the close of the call.

#### **Financial calendar**

25 March 2021 Publication Annual Report and 20-F 2020

28 April 2021 Annual Shareholders' meeting in Mechelen, Belgium

6 May 2021 First quarter 2021 results (webcast 7 May) 5 August 2021 Half year 2021 results (webcast 6 August)

4 November 2021 Third quarter 2021 results (webcast 5 November) Full year 2021 results (webcast 25 February)

#### **About Galapagos**

Galapagos (Euronext & NASDAQ: GLPG) discovers and develops small molecule medicines with novel modes of action, several of which showed promising patient results and are currently in late-stage development in multiple diseases. Galapagos' pipeline comprises discovery programs through Phase 3 programs in inflammation, fibrosis, osteoarthritis and other indications. The Company's ambition is to become a leading global biopharmaceutical company focused on the discovery, development and commercialization of innovative medicines.



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

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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 and regarding the amendment of our arrangement with Gilead for the commercialization and development of Jyseleca (filgotinib), including Gilead's recruitment in the Phase 3 trial in Crohn's disease, the amount and timing of potential future milestones, opt-in and/or royalty payments by Gilead, Galapagos' strategic R&D ambitions and potential changes of such ambitons, the quidance from management (including the timing and/or outcome of the review of our plans for 2021, and of the guidance regarding the expected operational cash burn during financial year 2021), commercialization of Jyseleca, including in Europe, financial results, timing and/or results of clinical trials, including trials with our SIK2/3 inhibitor '3970 (Toledo), TYK2 inhibitor '3667, JAK1 inhibitor '555, and ziritaxestat and the MANTA/MANTA-RAy trials with filgotinib, 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 for RA, UC or any other indication, including UC and IBD indication for Jyseleca in Europe, Japan, and the US, such additional regulatory authorities requiring additional studies, the timing or likelihood of reimbursement decisions for filgotinib, including in key European markets, statements relating to the build-up of our commercial organization for filaotinib, the expected impact of COVID-19, and our strategy, business plans and focus. Galapagos cautions the reader that forwardlooking 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 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



# Galápagos

uncertainties associated with competitive developments, clinical trial and product development activities and regulatory approval requirements (including that data from Galapagos' ongoing clinical research programs may not support registration or further development of its product candidates due to safety, efficacy or other reasons, including ziritaxestat for IPF, systemic sclerosis or any other indication), Galapagos' reliance on collaborations with third parties (including our collaboration partner for filgotinib and ziritaxestat, Gilead), that Galapagos' expectations regarding 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) and Galapagos' expectations regarding the costs and revenues associated with the transfer of European commercialization rights to filgotinib may be incorrect, and the inherent uncertainty associated with estimating the commercial potential of our product candidates, including Galapagos' estimates regarding the commercial potential of ziritaxestat, and the possibility that Galapagos and Gilead may make a strategic decision to discontinue development of ziritaxestat and that ziritaxestat may as a result never be successfully commercialized, including unanticipated expenses in connection with such decision and the potential effects on Galapagos' revenues and earnings, 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 forwardlooking 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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<sup>i</sup> 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 2020 amounted to €517.4 million and can be reconciled to our cash flow statement by considering the increase in cash and cash equivalents of €352.0 million, adjusted by (i) the cash proceeds from capital and share premium increase from the exercise of subscription rights by employees for €28.3 million and (ii) the net sale of current financial investments amounting to €841.1 million.

- ii General and administrative
- iii Sales and marketing
- V Crédit d'Impôt Recherche refers to an innovation incentive system underwritten by the French government.