

Galapagos demonstrates regulatory and commercial progress in Q1 2022

- **First three months 2022 financial results:**
 - **Jyseleca[®] net sales reached €14.4 million**
 - **Group revenues +20% to €136.3 million**
 - **Operating loss -58% to €21.1 million**
 - **Cash and current financial investments of €4.6 billion on 31 March 2022**
- **Jyseleca approved in Great Britain and Japan for the treatment of ulcerative colitis (UC); commercial roll-out in the EU in rheumatoid arthritis (RA) and UC progressing well with 15 countries reimbursed for RA**
- **Dr. Paul Stoffelsⁱ appointed as Chief Executive Officer (CEO), effective as of 1 April 2022**

[Webcast presentation tomorrow, 6 May 2022, at 14.00 CET / 8 AM ET, \[www.glpq.com\]\(http://www.glpq.com\), + 32 \(0\)2 793 38 47, code 9523309](http://www.glpq.com)

Mechelen, Belgium; 5 May 2022, 22.01 CET; regulated information – Galapagos NV (Euronext & NASDAQ: GLPG) today announced its first quarter 2022 financial results, a year-to-date business update and its outlook for the remainder of 2022. The results are further detailed in the Q1 2022 financial report available on the financial reports section of the [website](#).

“It is an honor to address you for the first time as CEO of Galapagos. I want to express my respect and appreciation to previous CEO and founder Onno van de Stolpe, who successfully built Galapagos from a start-up to an independent, established publicly listed company. Since I joined a few weeks ago, I have been working closely with the board and the teams across the entire organization to thoroughly review our R&D product portfolio, shape our business strategy and lay the foundations for accelerated growth,” said Dr. Paul Stoffels, CEO of Galapagos. “Our mission is to bring novel medicines to patients around the world and to help them live longer, better lives by adding years of life and improving quality of life. We have the people, the science, the R&D capabilities, the commercial infrastructure, and financial resources to realize that ambition. There are exciting opportunities ahead of us and I look forward to sharing my vision and strategy for the future later this year.”

“In the first quarter of this year, the launch of our Jyseleca franchise continued to gain momentum with robust sales growth,” added Bart Filius, President, COO and CFO of Galapagos. “Following the recent approval of filgotinib in UC in Great Britain and Japan, we are very excited to also bring Jyseleca to patients in this indication, while further progressing our roll-out in RA and UC throughout the European Union. We continue to focus on operational excellence and reiterate our cash burnⁱⁱ guidance of €450-€490 million, including anticipated net sales for Jyseleca of €65-€75 million, compared to the cash burn of €564.8 million over the same period in 2021.”

First quarter 2022 and recent business update

Commercial & regulatory progress with filgotinib in RA and UC:

- Strong progress with the roll-out by our own commercial organization across Europe, with reimbursements in 15 countries and a fast uptake in RA and now in UC since the approval by EMA (European Medicines Agency) in November 2021
- Sobi, our distribution and commercialization partner in Eastern and Central Europe, Portugal, Greece, and the Baltic countries, launched Jyseleca in RA in the Czech Republic, resulting in a €1 million milestone payment to Galapagos
- The MHRA (Medicines and Healthcare products Regulatory Agency) in Great Britain and the MHLW (Ministry of Health, Labour and Welfare) in Japan approved filgotinib 200mg for the treatment of moderate to severe UC
- Nine presentations at ECCO (European Crohn's and Colitis Organisation), including 4 new analyses from the Phase 3 SELECTION and SELECTION long-term extension studies in UC. Initial results from European real-world survey demonstrated the importance of taking an innovative holistic approach to the management of UC
- Article 20 pharmacovigilance procedure ongoing, investigating the safety data of all JAK inhibitors used to treat certain chronic inflammatory disorders

Pipeline and corporate update:

- Multiple Phase 1 studies are being finalized with data read-outs expected before year-end
- Dr. Paul Stoffels appointed as Chief Executive Officer, effective as of 1 April 2022
- Third installment of €50 million received from Gilead in Q1 as part of the revised filgotinib agreement as announced in December 2020, following payments of earlier instalments totalling €110 million in 2021
- Raised €2.2 million through the exercise of subscription rights
- Received a transparency notification from EcoR1 Capital indicating that its shareholding in Galapagos increased and crossed the 5% threshold, to 5.2% of the current outstanding Galapagos shares
- Created 2 new subscription rights plans within the framework of the authorized capital, intended for certain new members of the personnel of Galapagos or any of its subsidiaries

Post-period events:

- Our distribution partner Sobi recently launched Jyseleca in RA in Portugal
- AbbVie announced that a Phase 2 Proof-of-Concept study evaluating a triple combination therapy in cystic fibrosis (CF) did not meet the prespecified criteria. The company plans to start a Phase 2 study with a new triple combo, including the existing C1 corrector and potentiator licensed from Galapagos, early next year. In the event AbbVie receives regulatory approval and realizes commercial sales in CF, Galapagos is eligible to receive royalties ranging from single digit to low teens
- All proposed resolutions regarding the extraordinary and annual shareholders' meetings held on 26 April 2022 have been adopted by the shareholders, including the implementation of a *one-tier* governance structure in accordance with the Belgian Companies and Associations Code, the appointment of Stoffels IMC BV (permanently represented by Dr. Paul Stoffels) as director and the appointments of Jérôme Contamine and Dr. Dan Baker as independent directors of the board. Subsequently, the (new) unitary board has appointed Stoffels IMC BV (permanently represented by Dr. Paul Stoffels) as chair of the board of directors

First quarter 2022 financial highlights (unaudited)
(€ millions, except basic & diluted income/loss per share)

	31 March 2022 group total	31 March 2021 group total	Variance
Product net sales	14.4	0.1	14.3
Collaboration revenues	121.9	113.8	8.1
Total net revenues	136.3	113.9	22.4
Cost of sales	(2.9)	-	(2.9)
R&D expenditure	(99.9)	(130.0)	30.1
G&A ⁱⁱⁱ and S&M ^{iv} expenses	(62.3)	(45.0)	(17.3)
Other operating income	7.7	10.3	(2.6)
Operating loss	(21.1)	(50.8)	29.7
Fair value re-measurement of financial instruments	(0.2)	2.0	(2.2)
Net other financial result	9.7	36.2	(26.5)
Income taxes	(1.7)	(0.2)	(1.5)
Net loss from continuing operations	(13.3)	(12.8)	(0.5)
Net profit from discontinued operations	-	22.2	(22.2)
Net profit/loss (-) of the period	(13.3)	9.4	(22.7)
Basic and diluted income/loss (-) per share (€)	(0.2)	0.14	
Basic and diluted loss per share from continuing operations (€)	(0.2)	(0.2)	
Current financial investments and cash and cash equivalents	4,643.4	5,114.7	

Q1 2022 financial results

We reported product net sales of Jyseleca in Europe for the first three months of 2022 amounting to €14.4 million (€0.1 million in the first quarter of 2021). Our counterparties for the sales of Jyseleca were mainly hospitals and wholesalers located in Belgium, the Netherlands, France, Italy, Spain, Germany, the United Kingdom, Ireland, Austria, Norway, Sweden and Finland.

Cost of sales related to Jyseleca net sales in the first three months of 2022 amounted to €2.9 million.

Collaboration revenues amounted to €121.9 million for the first three months of 2022, compared to €113.8 million for the first three months of 2021.

Revenues recognized related to the collaboration agreement with Gilead for the filgotinib development were €59.0 million in the first three months of 2022 compared to €55.3 million for the same period last year. This slight increase was mainly due to higher revenue recognition of milestone payments, strongly influenced by the milestone achieved related to the regulatory approval in Japan for UC in the first quarter of 2022. The revenue recognition related to the exclusive access rights for Gilead to our drug discovery platform amounted to €57.3 million for the first three months of 2022 (€57.8 million for the same period last year).

We have recognized royalty income from Gilead for Jyseleca for €4.6 million in the first three months of 2022 (compared to €0.7 million in the same period last year) of which €3.6 million royalties on milestone income for UC approval in Japan.

Additionally, we recorded a milestone of €1.0 million triggered by the first sale of Jyseleca in the Czech Republic by our distribution and commercialization partner Sobi, in the first quarter of 2022.

Our deferred income balance on 31 March 2022 includes €1.7 billion allocated to our drug discovery platform that is recognized linearly over the remaining period of our 10 year collaboration, and €0.6 billion allocated to the filgotinib development that is recognized over time until the end of the development period.

Our R&D expenditure in the first three months of 2022 amounted to €99.9 million, compared to €130.0 million for the first three months of 2021. This decrease was primarily explained by a decrease in subcontracting costs from €73.0 million in the first quarter of 2021 to €41.7 million in the first quarter of 2022, primarily due to the winding down of the ziritaxestat (IPF) program and reduced spend on our Toledo (SIKi) and other programs. This was partly offset by cost increases for our filgotinib program, on a three months basis compared to the same period in 2021.

Our S&M and G&A expenses were respectively €29.0 million and €33.4 million in the first three months of 2022, compared to respectively €14.5 million and €30.4 million in the first three months of 2021. This increase was primarily due to an increase in personnel costs mainly driven by higher average FTEs on a three months comparison basis following the commercial launch of filgotinib in Europe, as well as higher costs for RSU plans. The increase was also explained by the termination of our 50/50 co-commercialization cost sharing agreement with Gilead for filgotinib in 2022, while in the first quarter of 2021 such costs were still shared with Gilead.

Other operating income (€7.7 million vs €10.3 million for the same period last year) decreased, mainly driven by lower grant and R&D incentives income.

Net other financial income in the first three months of 2022 amounted to €9.7 million, compared to net other financial income of €36.2 million for the first three months of 2021. Net other financial income in the first three months of 2022 was primarily attributable to €13.8 million of unrealized currency exchange gains on our cash and cash equivalents and current financial investments at amortized cost in U.S. dollars, to €0.2 million of negative changes in (fair) value of current financial investments and to €2.1 million of interest expenses. The other financial expenses also contained the effect of discounting our long term deferred income of €1.9 million.

We realized a net loss from continuing operations of €13.3 million for the first three months of 2022, compared to a net loss of €12.8 million for the first three months of 2021.

The net profit from discontinued operations for the three months ended 31 March 2021 consisted of the gain on the sale of Fidelta, our fee-for-services business, for €22.2 million.

We reported a group net loss for the first three months of 2022 of €13.3 million, compared to a group net profit of €9.4 million for the first three months of 2021.

Cash position

Current financial investments and cash and cash equivalents totaled €4,643.4 million on 31 March 2022, as compared to €4,703.2 million on 31 December 2021.

Total net decrease in cash and cash equivalents and current financial investments amounted to €59.8 million during the first three months of 2022, compared to a net decrease of €54.6 million during the first three months of 2021. This net decrease was composed of (i) €77.4 million of operational cash burn, (ii) offset by €2.2 million of cash proceeds from capital and share premium increase from exercise of subscription rights in the first three months of 2022, and (iii) €0.2 million negative changes in (fair) value of current financial investments and €15.6 million of mainly positive exchange rate differences.

Outlook 2022

Financial guidance:

For 2022, we anticipate a significantly lower cash burn compared to 2021 of €450-€490 million, including anticipated net sales for Jyseleca between €65 and €75 million.

Expected regulatory events:

We expect reimbursement decisions in most key European markets for Jyseleca in UC this year and anticipate that Sobi will further progress with reimbursement discussions in RA and UC in Eastern and Central Europe, Greece, and the Baltic countries. Following the ongoing article 20 pharmacovigilance procedure on all JAK inhibitors, we expect that the EMA will give its opinion by end of September 2022.

Anticipated R&D milestones:

We expect the read out from a Phase 1b trial with JAK1 inhibitor GLPG0555 and a Phase 1 trial with JAK1/TYK2i GLPG3121 in healthy volunteers. In addition, we aim to progress TYK2 inhibitor GLPG3667 into a Phase 2 program, considering the current regulatory and competitive landscape for TYK2 as a class, and to advance selected compounds with optimized pharmacology and selectivity from our SIKi portfolio into the clinic. Furthermore, we are evaluating the start of a Phase 2 trial with chitinase inhibitor GLPG4716 in lung fibrosis.

While we push forward our internal programs and further roll-out Jyseleca in RA and UC, we continue to diligently scout for external opportunities. We are confident that in 2022 we will make significant progress to accelerate our innovative pipeline with the aim to address unmet medical needs, and we look forward to presenting an in-depth update on our future plans later this year.

First quarter 2022 financial report

Galapagos' financial report for the first three months ended 31 March 2022, including details of the unaudited consolidated results, is accessible on the financial reports section of our [website](#).

Conference call and webcast presentation

Management will host a conference call and webcast presentation with Q&A tomorrow 6 May 2022, at 14:00 CET / 8 AM ET. To participate in the conference call, please dial one of the following numbers ten minutes prior to the start:

CODE: 9523309

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

The live webcast can be accessed on the investors section of the Galapagos [website](#), and a replay will be made available shortly after the close of the call.

Financial calendar 2022

4 August 2022	Half year 2022 results	(webcast 5 August 2022)
3 November 2022	Third quarter 2022 results	(webcast 4 November 2022)
23 February 2023	Full year 2022 results	(webcast 24 February 2023)

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.glpq.com.

Except for filgotinib's approval for the treatment of rheumatoid arthritis and ulcerative colitis 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.

Contact

Investors:

Sofie Van Gijsel
Head of Investor Relations
+1 781 296 1143

Sandra Cauwenberghs
Director Investor Relations
+32 495 58 46 63
ir@glpg.com

Media:

Marieke Vermeersch
Head of Corporate Communication
+32 479 490 603
media@glpg.com

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 2022), 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 related to the EMA's planned safety review of JAK inhibitors used to treat certain inflammatory disorders, including filgotinib, initiated at the request of the European Commission (EC) under article 20 of Regulation (EC) No 726/2004, 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 board of directors, and key personnel, our ability to effectively transfer knowledge during this period of transition, the search and recruitment

of 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 2022 revenues and financial results and our 2022 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, the risk that Galapagos will be unable to successfully achieve the anticipated benefits from its leadership transition plan, the risk that Galapagos will encounter challenges retaining or attracting talent, risks related to disruption in our operations due to the conflict between Russia and Ukraine, the risks related to continued regulatory review of filgotinib following approval by relevant regulatory authorities and the EMA's planned safety review of JAK inhibitors used to treat certain inflammatory disorders, including the risk that the EMA and/or other regulatory authorities determine that additional non-clinical or clinical studies are required with respect to filgotinib, the risk that the EMA may require that the market authorization for filgotinib in the EU be amended, the risk that the EMA may impose JAK class-based warnings, the risk that the EMA's planned safety review may negatively impact acceptance of filgotinib by patients, the medical community and healthcare payors and the risks and 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.

This release may contain forward-looking statements, all of which involve certain risks and uncertainties. These statements are often, but are not always, made through the use of words or phrases such as "anticipate," "expect," "intend," "plan," "may," "will," "continue," "aim," "future," "guidance," "outlook," "progress," "forward" as well as similar expressions. Forward-looking statements contained in this release include, but are not limited to, statements regarding the global R&D collaboration with Gilead, statements regarding the amount and timing of potential future milestones, opt-in and/or royalty payments by Gilead, statements regarding our strategic R&D plans, including progress on our fibrosis portfolio and SIK platform, and potential changes of such plans, statements regarding the guidance from management regarding our financial results (including guidance regarding the expected operational use of cash during financial year 2022), statements regarding our regulatory and R&D outlook, 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., and such additional regulatory authorities requiring additional studies, , statements regarding 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, and statements regarding our strategy, business plans and focus. Any forward-looking statements in this release are based on management's current expectations and beliefs and are not guarantees of future performance. Forward-looking statements involve known and unknown risks, uncertainties and other factors which might cause our actual results, financial condition and liquidity, performance or achievements 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. Such risks include, but are not limited to, the risk that our expectations regarding our 2022 revenues and financial results and our 2022 operating expenses may be incorrect (including because one or more of our assumptions underlying our expense expectations may not be realized), the risk that our

expectations regarding our development programs may be incorrect, the inherent risks and uncertainties associated with competitive developments, clinical trial and product development activities and regulatory approval requirements (including the risk that data from our 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 our product candidates due to safety or efficacy concerns or other reasons), risks related to our reliance on collaborations with third parties (including, but not limited to, our collaboration partner Gilead), 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, the risk that our estimates of the commercial potential of our product candidates and our expectations regarding the costs and revenues associated with the transfer of European commercialization rights to filgotinib may be incorrect, the risk that we will not be able to continue to execute on our currently contemplated business plan and/or will revise our business plan, risks related to our ability to effectively transfer knowledge during this period of transition, the risk that we will be unable to successfully achieve the anticipated benefits from our leadership transition plan, the risk that we will encounter challenges retaining or attracting talent, risks related to potential disruptions in our operations due to the conflict between Russia and Ukraine, and the risks and uncertainties relating to the impact of the COVID-19 pandemic. A further discussion of these risks, uncertainties and other risks can be found in our filings and reports with the Securities and Exchange Commission (SEC), including in our 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 risks and uncertainties, the reader is advised not to place any undue reliance on such forward-looking statements. In addition, even if our results, performance, financial condition and liquidity, and the development of the industry in which we operate are consistent with such forward-looking statements, they may not be predictive of results or developments in future periods. These forward-looking statements speak only as of the date of publication of this release. We expressly disclaim any obligation to update any such forward-looking statements in this release unless required by law or regulation.

ⁱ Acting via Stoffels IMC BV

ⁱⁱ The operational cash burn (or operational cash flow if this liquidity 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 liquidity measure is in our view an important metric for a biotech company in the development stage.

The operational cash burn for the three months ended 31 March 2022 amounted to €77.4 million and can be reconciled to our cash flow statement by considering the decrease in cash and cash equivalents of €995.4 million, adjusted by (i) the cash proceeds from capital and share premium increase from the exercise of subscription rights by employees for €2.2 million, and (ii) the net purchase of current financial investments amounting to €920.2 million

ⁱⁱⁱ General and administrative

^{iv} Sales and marketing