Galapagos announces strategy to accelerate innovation and reports strong third quarter 2022 results

- **Clear path forward for accelerated growth and value creation**
- **Reshape innovation model and build fit-for-purpose organization in key strategic therapeutic areas: immunology and oncology**
- **Jyseleca® 2022 net sales guidance further increased to €80-€90 million from €75-€85 million at H1 2022**
- **First nine months 2022 financial results:**
  - **Strong performance of Jyseleca franchise with €60.5 million in net sales**
  - **Group revenues of €410.2 million**
  - **Operating loss of €135.1 million**
  - **Cash and current financial investments of €4.4 billion on 30 September**

R&D and Strategy Webcast presentation at R&D Update tomorrow in New York, 4 November 2022, 13.00 – 15.30 CET / 8 am – 10.30 am EDT, www.glpg.com

Mechelen, Belgium; 3 November 2022, 21.01 CET; regulated information – Galapagos NV (Euronext & NASDAQ: GLPG) today announced its strategy for accelerated growth and value creation, its financial results for the first nine months of 2022, and the outlook for the remainder of 2022. The results are further detailed in the Q3 2022 financial report available on the financial reports section of the website.

***Forward, Faster* strategy to accelerate innovation**

"Guided by our purpose to bring transformational medicines to patients around the world to help them live longer and healthier lives, we today announce our *Forward, Faster* strategy to accelerate growth and value creation by reshaping the way we innovate and operate. This strategy provides a clear path forward based on three key pillars. First, we will shift from novel target-based discovery to patient-centric medical need research and development with a focus on our key therapeutic areas of immunology and oncology. Second, we will build on our current capabilities and derisk R&D through multiple drug modalities, including CAR-T, and by focusing on best-in-disease validated targets in our strategic therapeutic areas with shorter time-to-patient potential. Third, we will increase our business development efforts to complement our pipeline and continue to work with our collaboration partner Gilead to bring more medicines to patients worldwide," said Dr. Paul Stoffels[1], CEO and Chairman of the Board of Directors of Galapagos.

"Our new fit-for-purpose organizational structure and operating model will focus on accelerating our pipeline in immunology and oncology, supported by externally sourced opportunities, and we will discontinue our activities in fibrosis and kidney disease[2].

As a result of our new strategic direction, we intend to reduce our workforce by approximately 200 positions across our sites in Europe to create room to reinvest in new capabilities and programs in our oncology franchise. This is a difficult but necessary decision, and we will follow all applicable processes with respect for our people.

[1] Acting via Stoffels IMC BV
[2] The study with ‘2737 in polycystic kidney disease is ongoing with topline results expected in the first half of 2023. If successful, we aim to outlicense the program.

Third quarter financial performance

"Jyseleca continues to perform very well with a growing European base and a solid €60.5 million in net sales as of 30 September. As a result, we further increase our 2022 net sales guidance to €80-€90 million from our initial guidance of €65-€75 million. We ended the third quarter of the year with a strong balance sheet of €4.4 billion in cash and current financial investments, which provides us with the necessary means to invest in immunology and oncology and execute on smart business development. We reiterate our cash burn[i] guidance of €480-€520 million for the full year 2022," added Bart Filius, President, COO and CFO of Galapagos."

Q3 2022 operational review and recent events

Jyseleca commercial & regulatory progress

- Strong adoption across Europe with reimbursement for rheumatoid arthritis (RA) in 15 countries and for ulcerative colitis (UC) in 10 countries
- Marketing Authorization Application (MAA) submitted for the treatment of UC to Swissmedic, the regulatory authority in Switzerland
- Article 20 pharmacovigilance procedure ongoing by the European Medicines Agency (EMA)

Pipeline update

- Preparations advanced to start Phase 2 of GLPG3667 (TYK2 inhibitor) in dermatomyositis, with the aim to recruit the first patients around year-end

Corporate update

- Received various transparency notifications from FMR LLC, indicating that its shareholding in Galapagos changed, without crossing below the 5% threshold, to 5.65% of the current outstanding Galapagos shares
- Raised €6.7 million year-to-date through the exercise of subscription rights

Post-period events

- On 27 October 2022, the Pharmacovigilance Risk Assessment Committee (PRAC) of the European Medicines Agency (EMA) concluded the safety review (Article 20 procedure) of all JAK inhibitors approved in the EU for the treatment of inflammatory diseases. On 28 October 2022, the PRAC recommended the harmonization of all labels and concluded that JAK inhibitors should remain indicated for the treatment of patients with RA who have responded inadequately to or who cannot tolerate disease modifying anti-rheumatic drugs (DMARDs) therapy, and for patients with UC who have responded inadequately to or who cannot tolerate conventional therapy or biologics. The PRAC also recommended to update all product labels to include a precautionary approach for use of JAK inhibitors in patients with identified risk factors only if no suitable treatment alternative is available (*Section 4.4 - Warning and Precautions*). The PRAC recommendations will now be considered by the Committee for Medicinal Products for Human Use (CHMP) for an opinion
- Abstract accepted for poster presentation at the Annual Society of Hematology (ASH) conference taking place 10-13 December 2022 on the initial data from the ATALANTA-1 Phase 1/2 study in recurring/refractory Non-Hodgkin Lymphoma (rrNHL) evaluating the feasibility, safety and efficacy of the CD19 CAR-T candidate manufactured at point-of-care
- New *post hoc* analyses from SELECTION Phase 3 data set with filgotinib in UC patients presented at the United European Gastroenterology (UEG) Week
- Received positive CHMP opinion for Jyseleca European label update based on testicular function safety data from MANTA/RAy studies

Financial highlights for the first nine months of 2022 (unaudited)
(€ millions, except basic & diluted loss per share)

	30 September 2022 group total	30 September 2021 group total	Variance
Product net sales	60.5	6.1	54.3
Collaboration revenues	349.7	311.7	38.0
Total net revenues	**410.2**	**317.9**	**92.3**
Cost of sales	(7.9)	(0.7)	(7.3)
R&D expenditure	(364.1)	(378.0)	14.0
G&A[ii] and S&M[iii] expenses	(202.7)	(151.3)	(51.4)
Other operating income	29.5	36.3	(6.9)
Operating loss	**(135.1)**	**(175.7)**	**40.7**
Net financial result	127.5	33.6	93.8
Income taxes	(3.2)	0.3	(3.5)
Net loss from continuing operations	**(10.8)**	**(141.8)**	**131.0**
Net profit from discontinued operations	-	22.2	(22.2)
Net loss of the period	**(10.8)**	**(119.6)**	**108.8**
Basic and diluted loss per share (€)	(0.16)	(1.83)	
Basic and diluted loss per share from continuing operations (€)	(0.16)	(2.16)	
Current financial investments and cash and cash equivalents	**4,362.1**	**4,874.2**	

Q3 2022 financial results
We reported product net sales of Jyseleca in Europe for the first nine months of 2022 amounting to €60.5 million (€6.1 million in the first nine months of 2021). Our counterparties for the sales of Jyseleca were mainly hospitals and wholesalers located across Europe.

Cost of sales related to Jyseleca net sales in the first nine months of 2022 amounted to €7.9 million.

Collaboration revenues amounted to €349.7 million for the first nine months of 2022, compared to €311.7 million for the first nine months of 2021.

Revenues recognized related to the collaboration agreement with Gilead for the filgotinib development were €166.8 million in the first nine months of 2022 compared to €136.4 million for the same period last year. This increase was due to a higher increase in the percentage of completion, as well as a higher revenue recognition of milestone payments, strongly influenced by the milestone achieved related to the regulatory approval in Japan for UC in the first nine months of 2022. The revenue recognition related to the exclusive access rights for Gilead to our drug discovery platform amounted to €172.6 million for the first nine months of 2022 (€173.3 million for the same period last year).

We have recognized royalty income from Gilead for Jyseleca for €8.2 million in the first nine months of 2022 (compared to €1.9 million in the same period last year) of which €3.6 million royalties on milestone income for UC approval in Japan.

Additionally, we recorded milestones of €2.0 million triggered by the first sales of Jyseleca in the Czech Republic and Portugal by our distribution and commercialization partner Sobi, in the first nine months of 2022.

Our deferred income balance on 30 September 2022 includes €1.6 billion allocated to our drug discovery platform that is recognized linearly over the remaining period of our 10-year collaboration, and €0.5 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 nine months of 2022 amounted to €364.1 million, compared to €378.0 million for the first nine months of 2021. This decrease was primarily explained by a decrease in subcontracting costs from €189.1 million in the first nine months of 2021 to €158.5 million in the first nine months of 2022, primarily due to the winding down of the ziritaxestat (IPF) program and reduced spend on our SIKi and TYK2 programs. This was partly offset by cost increases for our filgotinib program, on a nine month basis compared to the same period in 2021. Personnel costs decreased from €134.3 million in the first nine months of 2021 to €130.0 million for the same period this year. Depreciation and impairment amounted to €35.6 million for the first nine months of 2022 (€14.1 million for the same period last year). This increase was primarily due to an impairment of €26.7 million of previously capitalized upfront fees related to our collaboration with Molecure on the dual chitinase inhibitor OATD-01 (GLPG4716) recorded in Q2 2022.

Our G&A and S&M expenses amounted to €202.7 million in the first nine months of 2022, compared to €151.3 million in the first nine months of 2021. This increase was primarily due to the termination of our 50/50 filgotinib co-commercialization cost sharing agreement with Gilead for filgotinib in 2022. The cost increase was also explained by an increase in personnel costs for the first nine months of 2022 compared to the same period last year explained by an increase in the commercial work force driven by the commercial launch of filgotinib in Europe.

Other operating income (€29.5 million vs €36.3 million for the same period last year) decreased, mainly driven by lower grant and R&D incentives income.

Net financial income in the first nine months of 2022 amounted to €127.5 million, compared to net financial income of €33.6 million for the first nine months of 2021. Net financial income in the first nine months of 2022 was primarily attributable to €102.1 million of unrealized currency exchange gains on our cash and cash equivalents and current financial investments at amortized cost in U.S. dollars, and to €26.0 million of positive changes in (fair) value of current financial investments. The financial expenses also contained the effect of discounting our long term deferred income of €5.7 million.

We realized a net loss from continuing operations of €10.8 million for the first nine months of 2022, compared to a net loss of €141.8 million for the first nine months of 2021.

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.

We reported a group net loss for the first nine months of 2022 of €10.8 million, compared to a group net loss of €119.6 million for the first nine months of 2021.

Cash position
Current financial investments and cash and cash equivalents totaled €4,362.1 million on 30 September 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 €341.1 million during the first nine months of 2022, compared to a net decrease of €295.2 million during the first nine months of 2021. This net decrease was composed of (i) €343.1 million of operational cash burn, (ii) offset by €6.7 million of cash proceeds from capital and share premium increase from exercise of subscription rights in the first nine months of 2022, (iii) €26.0 million positive changes in (fair) value of current financial investments and €105.6 million of mainly positive exchange rate differences, and (iv) the cash out from the acquisitions of CellPoint and AboundBio, net of cash acquired, of €136.4 million.

Acquisitions of CellPoint and AboundBio
The preliminary accounting of the acquisitions of CellPoint and AboundBio are included in our Q3 2022 condensed consolidated financial statements. To date, we have performed a preliminary fair value analysis of the business combinations. We expect the provisional amount of goodwill to change significantly upon the completion of the purchase price allocation, resulting from the valuation of the different assets and liabilities acquired.

Near term outlook

Immunology – an area in which we have built deep scientific know-how and expertise since our founding

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. We also expect to report initial results from the FILOSOPHY Real-World Evidence Phase 4 trial in RA later this year, and topline results from the DIVERSITY Phase 3 study in Crohn's disease (CD) in the first quarter of 2023. Before the end of this year, we anticipate a CHMP opinion following the PRAC Article 20 recommendation issued on 28 October 2022.

We aim to recruit the first patients in a Phase 2 study of our TYK2 inhibitor product candidate, GLPG3667, in dermatomyositis around year-end, and we intend to start a Phase 2 study in patients with Systemic Lupus Erythematosus (SLE) in 2023. Finally, we continue to advance select compounds with optimized pharmacology and selectivity from our SIKi portfolio.

Oncology portfolio – an area where we will continue to grow and invest

We will present the initial data from the ATALANTA-1 Phase 1/2 study of the CD19 CAR-T product candidate in patients with rrNHL at the annual ASH conference in December. The objectives of the ATALANTA-1 study are to evaluate the feasibility, safety and efficacy of the CD19 CAR-T candidate manufactured at point-of-care and will provide initial clinical validation of the CAR-T decentralized supply model.

The recruitment of the ongoing Phase 1/2 studies of the CD19 CAR-T candidate in patients with rrNHL (ATALANTA study) and relapsed/refractory Chronic Lymphocytic Leukemia (rrCLL) (EUPLAGIA study) is progressing well, and we are on track to report topline results of the dose escalation cohorts in the first half of 2023, which will be followed by one or more dose expansion cohorts.

Financial guidance and *Forward, Faster* strategy presentation
For the full year 2022, we reiterate our net cash burn of €480-€520 million, including the acceleration in oncology, and we further increase our net sales guidance for Jyseleca to €80-€90 million.

A detailed update of the strategy, portfolio and pipeline goals and commercial progress will be presented by Galapagos management and key opinion leaders at the company's R&D Day 2022 which will be held tomorrow, Friday, 4 November 2022, from 8:00 am to 10:30 am EDT (13:00 to 15:30 CET) in New York.

The event will include a live webcast on the Investors section of the company's website and a replay will be available on the Galapagos website within 48 hours after the event. Presentations showcased during the event will be featured on the Presentations section of the company's website.

To participate in the conference call, please register in advance using this link. Upon registration, the dial-in numbers will be provided. The conference call can be accessed 10 minutes prior to the start time by using the conference access information provided in the e-mail received at the point of registering, or by selecting the *call me* feature.

Third quarter 2022 financial report
Galapagos' financial report for the first nine months ended 30 September 2022, including details of the unaudited consolidated results, is accessible on the financial reports section of our website.

Financial calendar 2023

23 February 2023	Full year 2022 results	(webcast 24 February 2023)
23 March 2023	Annual report 2022	
25 April 2023	Annual Shareholders' meeting	
4 May 2023	First quarter 2023 results	(webcast 5 May 2023)
3 August 2023	Half year 2023 results	(webcast 4 August 2023)
2 November 2023	Third quarter 2023 results	(webcast 3 November 2023)

About Galapagos
Galapagos is a fully integrated biotechnology company focused on discovering, developing, and commercializing innovative medicines. We are committed to improving patients' lives worldwide by targeting diseases with high unmet needs. Our R&D capabilities cover multiple drug modalities, including small molecules and cell therapies. Our portfolio comprises discovery through to Phase 4 programs in immunology, oncology, and other indications. Our first medicine for rheumatoid arthritis and ulcerative colitis is available in the European Union, Norway, Great Britain, and Japan. For additional information, please visit www.glpg.com or follow us on LinkedIn or Twitter.

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Forward-looking statements

This press release contains 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 "believe," "anticipate," "expect," "intend," "plan," "seek," "upcoming," "future," "estimate," "may," "will," "could," "would," "potential," "forward," "goal," "next," "stand to," "continue," "should," "encouraging," "aim," "explore," "further" as well as similar expressions. These statements include, but are not limited to, statements made in the sections captioned "Q3 2022 operational review and recent events" and "Near term outlook", the guidance from management (including the guidance regarding the expected operational use of cash during the 2022 fiscal year, the expected financial results and our strategic and capital allocation priorities), statements regarding the acquisitions of CellPoint and AboundBio, including statements regarding anticipated benefits of the acquisitions and the integration of CellPoint and AboundBio into our portfolio and strategic plans, statements regarding our regulatory and R&D outlook, statements regarding expected financial results, statements regarding the amount and timing of potential future milestones, opt-in and/or royalty payments, our R&D strategy, including progress on our immunology or oncology portfolio or our SIKi platform, and potential changes in such strategy, statements regarding our pipeline and complementary technology platforms driving future growth, statements regarding the strategic re-evaluation, statements regarding our expectations on commercial sales of filgotinib, statements regarding the global R&D collaboration with Gilead and the amendment of our arrangement with Gilead for the commercialization and development of filgotinib, statements regarding the expected timing, design and readouts of ongoing and planned clinical trials, including recruitment for trials and topline results for trials and studies in our portfolio, statements regarding the expected topline results from the DIVERSITY Phase 3 study in CD, statements related to the EMA's 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 other indications for filgotinib in Europe, Great Britain, Japan, and the U.S., such additional regulatory authorities requiring additional studies, the timing or likelihood of pricing and reimbursement interactions for filgotinib, statements relating to the build-up of our commercial organization, commercial sales for filgotinib and rollout in Europe, statements related to the expected reimbursement for Jyseleca, and statements regarding our strategy (including our strategic transformation exercise), portfolio goals, business plans, focus, and plans for a sustainable future. We caution the reader that forward-looking statements are based on our management's current expectations and beliefs and are not guarantees of future performance. Forward-looking statements may involve known and unknown risks, uncertainties and other factors which might cause our actual results, financial condition and liquidity, performance or achievements, or the industry in which we operate, to be materially different from any historic or future results, financial conditions, 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 or our 2022 operating expenses may be incorrect (including because one or more of our assumptions underlying our revenue or expense expectations may not be realized), the risk that ongoing and future clinical trials may not be completed in the currently envisaged timelines or at all, the inherent risks and uncertainties associated with competitive development, clinical trial, recruitment of patients for trials and product development activities and regulatory approval requirements (including, but not limited to, the risk that data from our ongoing and planned clinical research programs in RA, rrNHL, rrCLL, CD, UC, other immunologic indications or other indications or diseases, may not support registration or further development of our product candidates due to safety, or efficacy concerns, or other reasons), risks related to the acquisitions of CellPoint and AboundBio, including the risk that we may not achieve the anticipated benefits of the acquisitions of CellPoint and AboundBio, the inherent risks and uncertainties associated with target discovery and validation and drug discovery and development activities, risks related to our reliance on collaborations with third parties (including our collaboration partner for filgotinib, 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 transition 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 our expectations regarding the costs and revenues associated with the transfer of the 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, including the risk that our plans with respect to CAR-T may not be achieved on the currently anticipated timeline or at all, the risk that our projections and expectations regarding the commercial potential of our product candidates or expectations regarding the costs and revenues associated with the commercialization rights may be inaccurate, the risks related to our strategic transformation exercise, including the risk that we may not achieve the anticipated benefits of such exercise on the currently envisaged timeline or at all, the risk that we will encounter challenges retaining or attracting talent, risks related to disruption in our operations, supply chain or ongoing studies (including our DIVERSITY 1 study) 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 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 safety review may negatively impact acceptance of filgotinib by patients, the medical community, and healthcare payors and the risks and uncertainties related to the impact of the COVID-19 pandemic. A further list and description 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 our subsequent filings and reports filed 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 the result of our operations, financial condition and liquidity, or the industry in which we operate, are consistent with such forward-looking statements, they may not be predictive of results, performance or achievements 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 to reflect any change in our 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 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, related to the acquisitions or disposals of businesses; the movement in restricted cash and movement in current financial investments, if any, the cash advances and loans given to third parties, if any, included in the net cash flows generated from/used in (-) investing activities
- the cash used for other liabilities related to the acquisition of businesses, if any, included in the net cash flows generated from/used in (-) operating 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 nine months ended 30 September 2022 amounted to €343.1 million and can be reconciled to our cash flow statement by considering the decrease in cash and cash equivalents of €1,583.9 million, adjusted by (i) the cash proceeds from capital and share premium increase from the exercise of subscription rights by employees for €6.7 million, (ii) the net purchase of current financial investments amounting to €1,111.1 million, and (iii) the cash out from acquisition of subsidiaries, net of cash acquired, of €136.4 million

[ii] General and administrative

[iii] Sales and marketing