Galapagos announces first half-year 2023 financial results

- **Half-year 2023 key financials**
  - **Group revenues of €328.8 million**
  - **Jyseleca® net sales of €54.3 million**
  - **Cash and current financial investments of €3.9 billion on 30 June 2023**
- **Full year 2023 net sales guidance for Jyseleca® lowered to €100-€120 million – 2023 cash burn guidance of €380-€420 million reiterated**
- **Oncology pipeline update – continued progress with point-of-care manufactured CAR-T candidates in hemato-oncology, including approval of the clinical trial application in Europe for BCMA CAR-T candidate in multiple myeloma**
- **Immunology pipeline update – start of Phase 3 study with filgotinib in axial spondyloarthritis; start of Phase 2 study with GLPG3667 in dermatomyositis; clinical trial application in Europe for CAR-T candidate in refractory systemic lupus erythematosus**
- **Implemented R&D strategy focused on best-in-class medicines to accelerate innovation and time-to-patients – over 10 differentiated discovery programs across multiple modalities in immunology and oncology initiated**
- **Appointed Thad Huston as Chief Financial Officer (CFO) and Chief Operating Officer (COO)**
- **Appointed Dr. Susanne Schaffert as non-executive independent Director to the Board of Directors**

Webcast presentation tomorrow, 4 August 2023, at 14:00 CET / 8:00 am ET, www.glpg.com

Mechelen, Belgium; 3 August 2023, 22:01 CET; regulated information – Galapagos NV (Euronext & NASDAQ: GLPG) today announced its first half-year 2023 financial results, a year-to-date business update and its outlook for the remainder of 2023. The results are further detailed in the H1 2023 financial report available on the financial reports section of the corporate website.

"The market and competitive landscape for the JAK class in Europe has changed significantly over the past six months, negatively impacting net sales of Jyseleca® and leading us to revise our 2023 net sales guidance for Jyseleca® in rheumatoid arthritis and ulcerative colitis from €140-€160 million to €100-€120 million. In response to that, we are in the process of evaluating various strategic options for Jyseleca®. We have a strong cash position of €3.9 billion and we will continue to deploy our resources in our strategic areas of immunology and oncology, including externally sourced innovative product candidates, to further build and expand our portfolio. Despite lower than anticipated net sales for Jyseleca®, we reiterate our cash burn guidance of €380-€420 million," said Thad Huston, CFO and COO of Galapagos.

Dr. Paul Stoffels[1], CEO and Chairman of Galapagos added: "Our commitment to providing transformational medicines to patients worldwide remains our core focus. We have successfully implemented our R&D strategy focused on best-in-class medicines to accelerate innovation, aiming to generate short and long-term value for all our stakeholders. We are actively building a differentiated discovery pipeline of best-in-class small molecules, CAR-T cell therapies and biologicals in our core areas of immunology and oncology. In addition, our ongoing clinical programs across our therapeutic areas are progressing well, and we are optimistic about the global potential of our point-of-care CAR-T cell therapy portfolio in hematological malignancies. Furthermore, in immunology, we have continued to expand our clinical pipeline of small molecules, while leveraging our CAR-T capabilities to start clinical development in refractory systemic lupus erythematosus with a CD19 CAR-T candidate."

Half-Year 2023 operational performance

Immunology portfolio

- **Jyseleca® (filgotinib) (JAK1)**
  - Jyseleca® is reimbursed for rheumatoid arthritis (RA) and ulcerative colitis (UC) in 19 and 18 countries respectively. Sobi[2], our distribution and commercialization partner in Eastern and

[1] Throughout this press release, 'Dr. Paul Stoffels' should be read as 'Dr. Paul Stoffels, acting via Stoffels IMC BV'
[2] Swedish Orphan Biovitrum AB

Central Europe, Portugal, Greece, and the Baltic countries, launched Jyseleca® in Czech Republic and Poland in UC and in Croatia in RA. The commercial launch of Jyseleca® in Poland resulted in a €1 million milestone receivable for us in the first half of 2023.
  - The European Commission endorsed the recommendation of the Pharmaceutical Risk Assessment Committee (PRAC) to add measures to minimize risks of serious side effects with the JAK inhibitor class of medicines used for chronic inflammatory disorders. The product information for all JAK inhibitors has been updated accordingly to include these recommendations and warnings.
  - We dosed the first patients in the pivotal Phase 3 OLINGUITO study in axial spondyloarthritis (AxSpA).
  - Based on the topline results from the Phase 3 DIVERSITY study in Crohn's disease (CD), we decided not to submit a Marketing Authorization Application (MAA) in Europe in this indication and not to proceed with the MAA for filgotinib in UC in Switzerland.
  - We presented various data abstracts at the annual ECCO and EULAR congresses in Europe.
- **Our pipeline assets**
  - First patients dosed in the Phase 2 GALARISSO study with oral, selective tyrosine kinase 2 (TYK2) inhibitor, GLPG3667, in dermatomyositis (DM).
  - Clinical trial application (CTA) filed to start clinical development of a CD19 CAR-T candidate in patients with refractory systemic lupus erythematosus (rSLE).
  - Multiple small molecules programs initiated to further build our research pipeline.

Oncology portfolio

- We are encouraged by the initial safety, efficacy and point-of-care feasibility results we have observed in the Phase 1/2 studies with our CD19 CAR-T candidates, GLPG5101 and GLPG5201, which underscore the potential global transformational impact our differentiated approach to CAR-T cell therapy could have on patients.

GLPG5101 in relapsed/refractory non-Hodgkin's lymphoma (rrNHL)

  - We are in the final stages of the Phase 1 part of the ongoing Phase 1/2 ATALANTA-1 study, which enrolled patients with diffuse large B cell lymphoma, mantle cell lymphoma and indolent lymphoma. To generate a robust data package that is informative for further development, we have decided to include more patients of certain subpopulations in the Phase 1 dose-escalation cohort of ATALANTA-1.
  - The first patients with indolent lymphoma and mantle cell lymphoma in the Phase 2 dose-expansion part of ATALANTA-1 have been dosed.

GLPG5201 in relapsed/refractory chronic lymphocytic leukemia (rrCLL), with or without Richter's transformation (RT)

  - We presented promising interim safety, efficacy and point-of-care manufacturing data from 7 eligible patients[3] of the ongoing Phase 1/2 EUPLAGIA-1 study at two major scientific meetings in Europe: objective response rate of 100%; no cytokine release syndrome higher than grade 2, or immune effector cell-associated neurotoxicity syndrome observed.[4]
  - We are recruiting the last patients in the Phase 1 dose-escalation part of EUPLAGIA-1 and preparations to start the Phase 2 dose-expansion cohort of the study are ongoing.
- We initiated multiple programs spanning various drug modalities, including biologicals, CAR-T cell therapies and small molecules, to further build our research pipeline.

Corporate update

- At the Annual General Meeting held on 25 April 2023, all proposed resolutions were approved.
- The Board of Directors created 1,975,000 subscriptions rights under new subscription right plans.
- Thad Huston was appointed as Chief Financial Officer (CFO) and Chief Operating Officer (COO), succeeding Bart Filius, per 1 July 2023.
- The Board of Directors appointed Dr. Susanne Schaffert as non-executive independent Director by way of co-optation on 12 June 2023, replacing Dr. Rajesh Parekh who stepped down on 10 June 2023.

[3] Cut-off date for efficacy and safety analysis: 9 January 2023

[4] As published in the press release of February 9, 2023: Galapagos presented encouraging initial safety and efficacy data at 2023 EBMT-EHA for point-of-care manufactured CAR-T candidate, GLPG5201, in rrCLL

- We completed the integrated drug discovery collaboration transaction with NovAliX on 30 June 2023, effective as from 1 July 2023. Under the terms of the agreement, Galapagos' drug discovery and research activities conducted in Romainville, France, and Galapagos' employees in Romainville, which are exclusively dedicated to the operation of these activities, are transferred to NovAliX who will assume all ongoing research and discovery activities in Romainville. In return, Galapagos is committed to utilizing the research capabilities and expertise of NovAliX through a five year-collaboration and within the context of the company's R&D portfolio.

First half-year 2023 financial highlights (unaudited)
(€ millions, except basic & diluted income/loss (-) per share)

	Six months ended 30 June		Change
	2023	2022	
Product net sales	54.3	35.4	+54%
Collaboration revenues	274.5	238.6	+15%
Total net revenues	**328.8**	**274.0**	**+20%**
Cost of sales	(7.8)	(5.5)	+41%
R&D expenditure	(211.9)	(249.5)	-15%
G&A[ii] and S&M[iii] expenses	(121.6)	(134.0)	-9%
Other operating income	23.8	17.6	+35%
Operating profit/loss (-)	**11.3**	**(97.5)**	
Fair value adjustments and net currency exchange differences	0.2	71.9	
Net other financial result	30.4	(4.3)	
Income taxes	(13.6)	(2.5)	
Net profit/loss (-) of the period	**28.3**	**(32.3)**	
Basic and diluted income/loss (-) per share (€)	0.43	(0.49)	
Current financial investments and cash and cash equivalents	**3,874.9**	**4,429.0**	

Details of the first half-year 2023 financial results

Total net revenues for the six months ended 30 June 2023 was €328.8 million, compared to €274.0 million for the six months ended 30 June 2022, and consisted of:

- **Product net sales** of Jyseleca® in Europe for the first six months of 2023 amounting to €54.3 million (€35.4 million in the first half-year of 2022).
- **Collaboration revenues** of €274.5 million for the first six months of 2023, compared to €238.6 million for the first six months of 2022.

Collaboration revenues increased mainly due to revenue recognition related to the collaboration agreement with Gilead for the filgotinib development amounting to €154.9 million in the first six months of 2023 compared to €115.3 million for the same period last year. This increase is primarily driven by a positive catch up of revenue explained by a decrease in the total estimated remaining costs to complete the filgotinib development. This was a consequence of the topline results from Phase 3 DIVERSITY trial of filgotinib in CD and our decision not to submit a Marketing Authorization Application in Europe.

Our deferred income balance on 30 June 2023 includes €1.4 billion allocated to our drug discovery platform that is recognized linearly over the remaining period of our 10-year collaboration, and €0.3 billion allocated to the filgotinib development that is recognized over time until the end of the development period.

Total operating profit for the six months ended 30 June 2023 was €11.3 million, compared to total operating loss of €97.5 million for the first six months ended 30 June 2022.

- **Cost of sales** related to Jyseleca® net sales in the first six months of 2023 amounted to €7.8 million (€5.5 million in the first half-year of 2022).
- **R&D expenditure** in the first six months of 2023 amounted to €211.9 million, compared to €249.5 million for the first six months of 2022. This decrease was primarily explained by an impairment recorded in the first six months of 2022 of €26.7 million of previously capitalized upfront fees related to our collaboration with Molecure on the dual chitinase inhibitor OATD-01 (GLPG4716), as well as by decreased personnel and subcontracting costs.
- **S&M and G&A expenses** amounted to €121.6 million in the first six months of 2023, compared to €134.0 million in the first six months of 2022. This decrease was primarily due to a decrease in personnel costs and agency deliverables.
- **Other operating income** amounted to €23.8 million in the first six months of 2023, compared to €17.6 million for the same period last year.

Net financial income in the first six months of 2023 amounted to €30.6 million, compared to net financial income of €67.7 million for the first six months of 2022.

- **Fair value adjustments and net currency exchange differences** in the first six months of 2023 amounted to €0.2 million, compared to fair value adjustments and net currency exchange gains of €71.9 million for the first six months of 2022, and were primarily attributable to €11.4 million of unrealized currency exchange losses on our cash and cash equivalents and current financial investments at amortized cost in U.S. dollars, offset by €12.7 million of positive changes in (fair) value of current financial investments.
- **Net other financial income** in the first six months of 2023 amounted to €30.4 million, compared to net other financial expenses of €4.3 million for the first six months of 2022, and was primarily attributable to €33.4 million of interest income, which increased significantly due to the increase in interest rates.

We reported a **group net profit** for the first six months of 2023 of €28.3 million, compared to a group net loss of €32.3 million for the first six months of 2022.

Cash position

Current financial investments and cash and cash equivalents totaled €3,874.9 million on 30 June 2023, as compared to €4,094.1 million on 31 December 2022.

Total net decrease in cash and cash equivalents and current financial investments amounted to €219.1 million during the first six months of 2023, compared to a net decrease of €274.2 million during the first six months of 2022. This net decrease was composed of (i) €224.3 million of operational cash burn, (ii) €9.3 million of mainly negative exchange rate differences, offset by (iii) €1.8 million of cash proceeds from capital and share premium increase from exercise of subscription rights in the first six months of 2023, and (iv) €12.7 million positive changes in (fair) value of current financial investments.

Outlook 2023

Financial outlook

- In response to the changing market dynamics and the competitive landscape for the JAK class in Europe, we are in the process of evaluating various strategic options for Jyseleca® and have lowered our net 2023 sales guidance for Jyseleca® in RA and UC to €100-€120 million, compared to €140-160 million initially guided in our full year 2022 results in February.
- Despite the lower than anticipated net sales for Jyseleca®, we reiterate our full year 2023 cash burn guidance in the range of €380-€420 million. We will continue to focus on expanding our portfolio and will deploy our resources in our strategic core areas of immunology and oncology.

R&D outlook

- **Immunology portfolio**
  - We expect to announce Phase 4 results from the FILOSOPHY real-world evidence study of filgotinib in patients with RA at a future scientific conference (subject to abstract acceptance) and to initiate the Phase 2 pediatric study in patients with juvenile arthritis later this year.
  - We aim to start dosing patients with SLE in the Phase 2 GALACELA study of oral, selective TYK2 inhibitor, GLPG3667.
  - Following the potential approval of the CTA submitted in Europe for CD19 CAR-T candidate, GLPG5101, in patients with rSLE, we expect to open the clinical centers in the coming months.
- **Oncology portfolio**
  - As we continue to build a solid data package, we aim to release an update on the ATALANTA-1 and EUPLAGIA-1 Phase 1 studies with GLPG5101 and GLPG5201 in rrNHL and rrCLL respectively later this year. We intend to present detailed data at a forthcoming hematology scientific conference (subject to abstract acceptance) before year-end.
  - The Phase 1 part of EUPLAGIA-1 study with GLPG5201 is close to completion and we aim to initiate the Phase 2 dose-expansion cohort in the first half of 2024.
  - In the first half of 2024, we anticipate submitting an investigational new drug application (IND) in the US to start clinical development with our CD19 CAR-T program.

- We expect to start the Phase 1/2 PAPILIO-1 study with BCMA CAR-T candidate, GLPG5301, in relapsed/refractory multiple myeloma (rrMM) after summer[5].

Business development

- We continue to explore additional business development opportunities to further leverage our internal capabilities and expand our portfolio in our core areas of growth and value creation.

First half-year 2023 financial report

Galapagos' financial report for the first six months ended 30 June 2023, including details of the unaudited consolidated results, is accessible on the financial reports section of our website.

Conference call and webcast presentation

We will host a conference call and webcast presentation tomorrow 4 August 2023, at 14:00 CET / 8:00 am ET. To participate in the conference call, please register in advance using this link, after which the dial-in numbers will be provided. The conference call can be accessed 10 minutes prior to the start by using the conference access information provided in the email after registration, or by selecting the "call me" feature.

The live webcast is available on glpg.com or via the following link. The archived webcast will be available for replay shortly after the close of the call on the investor section of the website.

Financial calendar 2023

2 November 2023	Third quarter 2023 results	(webcast 3 November 2023)
22 February 2024	Full year 2023 results	(webcast 23 February 2024)

About Galapagos

Galapagos is a fully integrated biotechnology company united around a single purpose: to transform patient outcomes through life-changing science and innovation for more years of life and quality of life. We focus on the key therapeutic areas of immunology and oncology, where we have developed deep scientific expertise in multiple drug modalities, including small molecules and cell therapies. Our portfolio comprises discovery through to commercialized programs and our first medicine for rheumatoid arthritis and ulcerative colitis is currently available in Europe 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 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," "believe," "progress," "further," "expect," "encouraging," "long-term," "plan," "could," "estimate," "will," "continue," "aim," "intend," "future," "guidance," "outlook," "progress," "forward" as well as similar expressions. Forward-looking statements contained in this release include, but are not limited to, statements made in the sections captioned "Half-Year 2023 operational performance" and "Outlook 2023", the guidance from management regarding our financial results (including guidance regarding the expected operational use of cash and adjusted net sales guidance for Jyseleca® during the financial year 2023), statements regarding our strategy and plans, including our strategic and capital allocation priorities, statements regarding the transfer of our drug and research activities and employees exclusively dedicated to the activities in Romainville (France), statements regarding the five year-collaboration between Galapagos and NovAliX, statements regarding the global R&D collaboration with Gilead, statements regarding the amount and timing of potential future milestones, and other payments, statements regarding our strategic R&D plans, including progress on our immunology or oncology portfolio, our CAR-T-portfolio and our SIKi-portfolio, and potential

[5] CTA for GLPG5301 in BCMA was approved in May 2023

changes of such plans, statements regarding our pipeline and complementary technology platforms facilitating future growth, statements regarding the expected timing, design and readouts of ongoing and planned preclinical studies and clinical trials, including but not limited to (i) filgotinib in RA, UC and AxSpA, (ii) with SIKi compounds, including GLPG3667 in SLE and DM, (iii) GLPG5101 in rrNHL and rSLE, (iv) GLPG5201 in rrCLL and rrSLL, and (v) GLPG5301 in rrMM, including recruitment for trials and topline results for our trials and studies in our portfolio, 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 for filgotinib, statements regarding our commercialization efforts for filgotinib, our product candidates, and any of our future approved products, statements regarding our expectations on commercial sales of filgotinib and any of our product candidates (if approved), 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 and regarding the related CHMP opinion and EC's decision, statements regarding the timing or likelihood of pricing and reimbursement interactions for filgotinib, statements relating to the development of our commercial organization, statements and expectations regarding commercial sales for filgotinib, statements regarding our plans and strategy related to the development of our CD19 CAR-T candidates, GLPG5101 and GLPG5201, including patient enrollment for the Phase 1/2 ATALANTA-1 study and the EUPLAGIA-1 study, and the timing for topline results from such studies, statements regarding the timing for initiation of, the Phase 1/2 PAPILIO-1 study with BCMA CAR-T candidate, GLPG5301, statements regarding the timing and likelihood of business development projects and external innovation, and statements regarding the changes in our leadership and expected resulting benefits. 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 2023 revenues, operating expenses, cash burn and other financial results may be incorrect (including because one or more of our assumptions underlying our revenue and 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 developments, clinical trials, recruitment of patients, product development activities and regulatory approval requirements (including the risk that data from our ongoing and planned clinical research programs in RA, UC, DM, SLE, AxSpA, refractory/relapsed NHL, rrCLL, refractory/replapsed small lymphocytic lymphoma, rrMM and other immunologic indications or any 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, risks related to the transfer of the drug discoveries and research activities conducted in Romainville (France) and employees exclusively dedicated to these activities to NovAliX, the inherent risks and uncertainties associated with target discovery and validation and drug discovery and development activities, the risk that the preliminary and topline data from the OLINGUITO, ATALANTA-1, EUPLAGIA-1, GALARISSO, PAPILIO-1, FILOSOPHY, and GALACELA-studies may not be reflective of the final data, risks related to our reliance on collaborations with third parties (including, but not limited to, our collaboration partner Gilead, Sobi and Lonza), risks related to the implementation of the transition of the European commercialization responsibility of filgotinib from Gilead to us, 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 plans with respect to our CAR-T programs may not be achieved on the currently anticipated timeline or at all, the risk that our estimates of the commercial potential of our product candidates or expectations regarding the costs and revenues associated with the commercialization rights may be inaccurate, 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, the risks related to our strategic transformation, 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 be unable to successfully achieve the anticipated benefits from our leadership transition, the risk that we will encounter challenges retaining or attracting talent, risks related to potential disruptions in our operations, supply chain or ongoing studies due to the conflict between Russia and Ukraine, the risk that the EMA may impose JAK class-based warnings, and the risk that the EMA's safety review may negatively impact acceptance of filgotinib by patients, the medical community, and healthcare payors, the risk that regulatory authorities may require additional post-approval trials of filgotinib or any other product candidates that are approved in the future, 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] 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, 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 six months ended 30 June 2023 amounted to €224.3 million and can be reconciled to our cash flow statement by considering the decrease in cash and cash equivalents of €409.8 million, adjusted by (i) the cash proceeds from capital and share premium increase from the exercise of subscription rights by employees for €1.8 million, and (ii) the net purchase of current financial investments amounting to €187.2 million.

[ii] General and administrative

[iii] Sales and marketing