

## Galapagos presents roadmap for pipeline and commercial growth at its R&D Day 2022

- **Guiding principles for a sustainable future:**
  - Invest in strategic therapeutic areas of oncology and immunology
  - Rebuild and accelerate portfolio of transformational medicines in high unmet medical needs
  - Combine internal with external innovation
- **Capital allocation:**
  - Discontinue fibrosis and kidney disease to further invest in oncology
  - Leverage strong balance sheet through disciplined cash management and smart business development
- **Oncology roadmap:**
  - Validate point-of-care CAR-T delivery model with proven CD19<sup>1</sup> and BCMA<sup>2</sup>
  - Develop next-generation, best-in-class oncology candidates
- **Immunology roadmap:**
  - Evaluate potential of filgotinib in axial spondyloarthritis
  - Execute on TYK2i clinical program with '3667
  - Continue to invest in deep portfolio across modes of action, with JAKi, TYK2i and SIKi programs
- **Commercial roadmap:**
  - Jyseleca® 2022 net sales guidance further upped to €80-€90 million
  - Leverage commercial infrastructure for future launches

*[Webcast replay available at www.glpq.com](http://www.glpq.com)*

**Mechelen, Belgium; 4 November 2022, 21.01 CET; Galapagos NV (Euronext & NASDAQ: GLPG) today held its R&D Day 2022, featuring presentations of key opinion leaders and company management on the strategic, scientific, and commercial progress at the company. The company also presented its financial results for the third quarter of 2022.**

Paul Stoffels<sup>3</sup>, CEO and Chairman of the Board of Directors of Galapagos, commented: "Today we presented our strategic vision for our future as a financially sustainable biopharma company. Building on our strong fundamentals, we are convinced that we are taking the right steps to deliver on our core mission: adding years of life and improving the quality of life of patients globally.

Focusing on our strategic therapeutic areas, we strive to push forward our deep, differentiated portfolio in immunology, build out our oncology franchise, and execute on business development opportunities with the aim to accelerate innovation and speed up time-to-patients, while creating long-term value for our stakeholders."

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<sup>1</sup> Cluster of differentiation 19

<sup>2</sup> B-cell maturation antigen

<sup>3</sup> Acting via Stoffels IMC BV

## Strategic update

Building on our strong fundamentals, we aim to build a financially sustainable biopharma company, accelerating cutting-edge therapies to market to address unmet medical needs in our core key therapeutic areas of oncology and immunology.

Our renewed focus on two strategic therapeutic areas goes hand in hand with redirecting our resources. To further streamline our portfolio, we have decided to discontinue activities in fibrosis and kidney disease to allow for increased investments in our oncology franchise.

To shape our portfolio of innovative drugs with accelerated time-to-market, we intend to combine internal innovation with smart business development and apply deep clinical expertise to push programs through an optimal development process.

Based on these guiding principles, we presented our *Vision 2028* portfolio outlook. Over the course of the next five years, we aim to build a portfolio comprising:

- over 10 assets in lead optimization and five in preclinical development across different modalities (small molecules, cell therapy, biologics),
- five pivotal-stage candidates forming a solid late-stage pipeline in immunology and cell therapy, and
- a growing commercial presence with additional marketed indications for Jyseleca® and one CAR-T therapy approved in multiple indications.

## Financial vision

Aligned with our *Vision 2028*, we presented our financial outlook and capital allocation strategy at our R&D Day 2022. Discontinuation of our fibrosis and kidney efforts allows for reinvesting in oncology.

With Jyseleca® potentially breaking even in 2024, and projected peak sales of €500 million in Europe and first oncology revenues potentially contributing to our topline later this decade, we are committed to building a sustainable financial future, with a significantly reduced cash burn by 2028.

## Oncology

We also presented our *Vision 2028* roadmap for oncology at our R&D Day 2022. Our core mission in the field is to broaden patient access and improve clinical outcomes by bringing best-in-class medicines to patients.

With the combined acquisitions of CellPoint and AboundBio announced earlier this year, we positioned ourselves in the cell therapy space, combining the potentially disruptive manufacturing and delivery model of CellPoint (Lonza's Cocoon®, a closed, automated manufacturing platform for cell therapy) with the ability to develop next-generation CAR-Ts, small molecules and biologics. Short term, our aim is to validate the decentralized CAR-T delivery model with proven CAR-T therapies, and we announced the addition of a BCMA Phase 1/2 trial on the Cocoon® platform. This complements the currently ongoing CD19 Phase 1/2 programs in recurring/refractory Non-Hodgkin Lymphoma (rrNHL; ATALANTA study) and recurring/refractory Chronic Lymphocytic Leukemia (rrCLL; EUPLAGIA study).

In the coming years, we intend to build a pipeline of best-in-class cell therapies for hematologic malignancies and leverage our capabilities to rapidly address unmet needs in oncology.

Today, we showcased the robust process performance of the Cocoon® system as well as first encouraging biomarker patient data of the CAR-T expansion profile with a 7 day-point-of-care vein-

to-vein treatment. Topline Phase 1 results of both the rrNHL and rrCLL study are expected in the first half of 2023, followed by initial data of the BCMA study later in the year.

Next year, we also aim to broaden the studies to include U.S. patients, and we plan to submit Investigational New Drug (IND) applications for both the CD19 and BCMA CAR-T programs with the FDA.

## Immunology

We have built up over 20 years of expertise in immunology, resulting in a deep and growing pipeline with multiple modes-of-action candidate medicines across all phases of development, from preclinical to Phase 4.

We are excited about our selective TYK2 inhibitor, '3667, for which we presented new data elucidating its potentially differentiating selectivity and potency profile. *Ex vivo* and *in vivo* data show that '3667 fully blocks the INF $\alpha$  pathway with once-daily dosing, while in our assays JAK2 and JAK1/3 dependent pathways are not affected. Further, no effects on hematological parameters, lipids and creatine phosphokinase (CPK) were observed, suggesting that '3667 does not show JAKi 'fingerprints' at therapeutic doses. Also based on the positive results in psoriasis patients, we presented our development plan for '3667, confirming the start of a Phase 2 study in dermatomyositis (GALARISSO) around year-end and the intention to start a Phase 2 study in systemic lupus erythematosus (SLE) in 2023.

We also presented an update on our SIKi portfolio, a potential novel mode-of-action in immunology. With targeted investments, we continue to make important progress in developing next-generation best-in-class candidates that reach optimal target coverage, teasing apart selectivity profiles that indicate the potential of SIK3i for rheumatological indications and SIK2/3i for inflammatory bowel disease. Our most advanced candidate, SIK3 inhibitor '4399, has shown strong preclinical evidence for potential in rheumatoid arthritis (RA) (*EULAR 2022*<sup>4</sup>), with a promising pharmacological and safety profile. We are planning to start a proof-of-mechanism study in RA patients with '4399 mid 2023.

For filgotinib, our selective JAK1 inhibitor, we are completing a Phase 3 program in Crohn's disease (CD), with results expected in the first half of 2023. Given the sales momentum and supportive long-term safety and efficacy data generated for filgotinib, we are currently exploring additional indications for filgotinib, and plan to start a Phase 3 study in axial spondyloarthritis (AxSpA) in 2023.

## Commercial progress

Since becoming European marketing authorization holder (MAH) of Jyseleca®, we successfully set up our own commercial capabilities and are currently operational throughout Europe in the current approved indications RA and ulcerative colitis (UC).

The financial results for the third quarter of 2022 show continued strong sales momentum for Jyseleca®, and we further raise our net sales guidance 2022 from €75-€85 million at H1 2022 to €80-€90 million.

In the future, we aim to leverage our European commercial infrastructure beyond Jyseleca®, in line with our *Vision 2028*, to have at least one CAR-T cell therapy on the market within five years.

*Jyseleca® is a trademark of Galapagos NV and Gilead Sciences, Inc. or its related companies. Except for filgotinib's approval as Jyseleca® for the treatment of moderately to severely RA and UC*

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<sup>4</sup> Poster presented at EULAR (European Alliance of Associations for Rheumatology) 2022, POS0442

by the relevant regulatory authorities in the European Union, Great Britain, and Japan, our drug candidates are investigational; their efficacy and safety have not been fully evaluated by any regulatory authority.

## 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.glp.com](http://www.glp.com) or follow us on [LinkedIn](#) or [Twitter](#).

## Contact

### Investors:

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

Sandra Cauwenberghs  
Director Investor Relations  
+32 495 58 46 63  
[ir@glpg.com](mailto:ir@glpg.com)

### Media:

Marieke Vermeersch  
Head of Corporate Communication  
+32 479 490 603  
[media@glpg.com](mailto:media@glpg.com)

## 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," "expect," "intend," "plan," "future," "estimate," "may," "potential," "forward," "next," "continue," "promise," "encouraging," "aim," "explore," "further" as well as similar expressions. These statements include, but are not limited to, statements made in the sections captioned "strategic update," "financial vision," "commercial progress,"; 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 our 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 JAKi, TYK2i and SIKi programs, and potential changes in such strategy, statements regarding our pipeline and complementary technology platforms driving future growth, 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 topline results for trials and studies in our portfolio, statements about the expected topline results from the DIVERSITY Phase 3 study in CD, 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, rRHL, rCLL, CD, UC, axial spondyloarthritis, dermatomyositis, systemic lupus erythematosus, 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 European Medicines Agency's (EMA) 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.*