# FY 2022 results

# webcast

February 24, 2023



### Disclaimer

This presentation 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 "estimate," "next," "encouraging," "initial," "atm," "feasible," "potential," "will," "on track," "towards," and "roadmap," as well similar expressions. Forward-looking statements contained herein include, but are not limited to, the guidance from management regarding our financial results. expected operational use of cash, and estimated peak sales for Jyseleca® during the 2023 financial year, statements regarding our strategic and capital allocation priorities, statements and analyses related to our CAR-T delivery model and related therapeutics, statements regarding preliminary, interim and topline data from the EUPLAGIA-1, ATALANTA-1, DIVERSITY, MANGROVE, and TORTUGA studies and any other analyses related to our portfolio, and our plans and strategy with respect to the foregoing, statements regarding the acquisitions of CellPoint and AboundBio, including statements regarding anticipated benefits of these acquisitions and their integration into our portfolio and plans, statements regarding the timing and likelihood of business development projects and external innovation, statements regarding our strategic re-evaluation, including our oncology vision 2028 roadmap, statements regarding our regulatory outlook, statements regarding our R&D plans, strategy and outlook, including progress on our immunology or oncology portfolio, CAR-T-portfolio and SIKi portfolio, and any potential changes in such strategy, statements regarding our pipeline and complementary technology platforms facilitating future growth, statements regarding the expected timing, design and readouts of our ongoing and planned preclinical studies and clinical trials, including, but not limited to, with (i) filgotinib in RA, UC and AxSpA, (ii) GLPG3667 in SLE and DM, (iii) with compounds from our SIKi portfolio, (iv) GLPG2737 in ADPKD, (v) GLPG5101 in NHL and rSLE, (vi) GLPG5201 in CLL and SLL, (vii) GLPG5301 in MM, and (viii) the next-generation CAR-Ts and bispecific antibodies, including recruitment for trials and topline results for trials and studies in our portfolio, statements regarding our expectations on commercial sales of filootinib and any of our product candidates (if approved), statements regarding the global R&D collaboration with Gilead for the commercialization and development of filgotinib, as amended, statements regarding the amount and timing of potential future milestones and other payments, statements relating to interactions with regulatory authorities, the timing or likelihood of additional regulatory authorities' approval of marketing authorization for filootinib for RA, UC or any other indication for filootinib in Europe, Great Britain, Japan, or the U.S., the timing or likelihood of pricing and reimbursement interactions for filootinib, statements regarding EMA's safety review of JAK inhibitors used to treat certain inflammatory disorders, including filootinib, initiated at the request of the European Commission under article 20 of Regulation (EC) No 726/2004, and regarding the hereto related PRAC and CHMP opinion, statements regarding the CHMP opinion for filootinib about the European label update based on testicular function safety data from the MANTA/Ray studies, statements regarding our commercialization efforts for filootinib, our product candidates, and any of our future approved products, statements relating to the development of our commercial organization, statements and expectations regarding the rollout of our products or products (if approved) in Europe, statements related to the expected reimbursements for Jyseleca<sup>®</sup>, statements regarding the timing for the start of a study in AXSpA, and for the Phase 3 topline results from such study, statements regarding patient enrollment for our study with GLPG3667, and the timing for the start of a study in DM and SLE, statements regarding the timing of clinical development with GLPG5101 in rSLE, statements regarding the progress of patient recruitment efforts in the European sites in the ATALANTA-1 study with GLPG5101, and in the EUPLAGIA-1 study with GLPG5201, as well as the timing for Phase 1 topline results from such studies, statements regarding the timing for expansion of, and patient enrollment in, the CAR-T portfolio with GLPG5301, and the timing for Phase 2 topline results from our study with GLPG2737, statements regarding the changes in our leadership and expected resulting benefits, and statements regarding our strategy, portfolio goals, business plans and focus.

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 statements. Such risks include, but are not limited to, the risk that our beliefs, guidance, and expectations regarding our 2023 revenues, operating expenses, cash burn and other financial results may be incorrect (including because one or more of its 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 developments, clinical trials, recruitment of patients, product development activities and regulatory approval reguirements (including the risk that data from our ongoing and planned clinical research programs in RA, UC, AxSpA, SLE, DM, ADPKD, rSLE, NHL, CLL, SLL, MM, or any other indications or diseases, may not support registration or further development of its 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 these acquisitions, the inherent risks and uncertainties associated with target discovery and validation, and drug discovery and development activities, the risk that the initial and topline data from the ATALANTA-1, MANGROVE, TORTUGA, and EUPLAGIA-1 studies may not be reflective of the final data, risks related to our reliance on collaborations with third parties (including Gilead and Lonza), the risks related to the implementation of the European commercialization responsibility of filootinib from Gilead to us, including the transfer of the supply chain, the risk that the transition will not have the currently expected results for our business and results of operations and our expectations regarding the costs and revenues associated with the transfer of European commercialization rights to filocotinib 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 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 disruption in our operations, supply chain or ongoing studies due to the conflict between Russia and Ukraine, risks related to continued regulatory review of filoptinib following approval by relevant regulatory authorities and the EMA's safety review of JAK inhibitors used to treat certain inflammatory disorders, 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 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 results, performance, 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 hereof. We expressly disclaim any obligation to update any such forward-looking statements herein 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.

Except for filgotinib's approval as Jyseleca<sup>®</sup> for the treatment of RA and UC by the European Commission, Great Britain's Medicines and Healthcare Products Regulatory Agency, and the 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.

Under no circumstances may any copy of this presentation, if obtained, by retained, copied or transmitted.





#### **Commercial & financial update**

Paul Stoffels CEO

#### Bart Filius President & COO

Q&A

Michele Manto, CCO Daniele D'Ambrosio, Head of Immunology





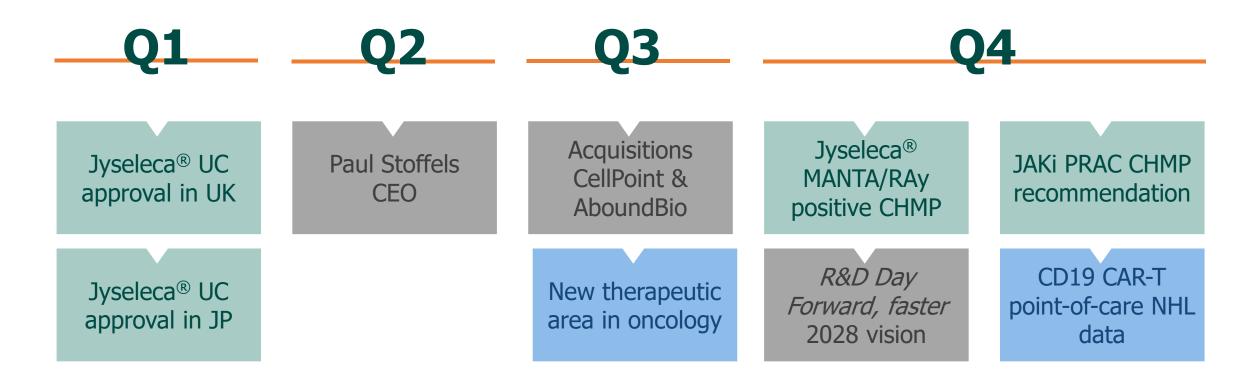
### **Commercial & financial update**

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Michele Manto, CCO Daniele D'Ambrosio, Head of Immunology





Immunology 📃 Oncology 🔳 Corporate development

CHMP, Committee for Medicinal Products for Human Use; JP, Japan; NHL, non-Hodgkin lymphoma; PRAC, Pharmacovigilance Risk Assessment Committee; UC, ulcerative colitis; UK, United Kingdom. Throughout this presentation, 'Paul Stoffels' should be read as 'Paul Stoffels, acting via Stoffels IMC BV'



# Solution Positioned for accelerated growth & value creation



Focused pipeline in immunology & oncology



**Established Jyseleca® franchise in Europe** 



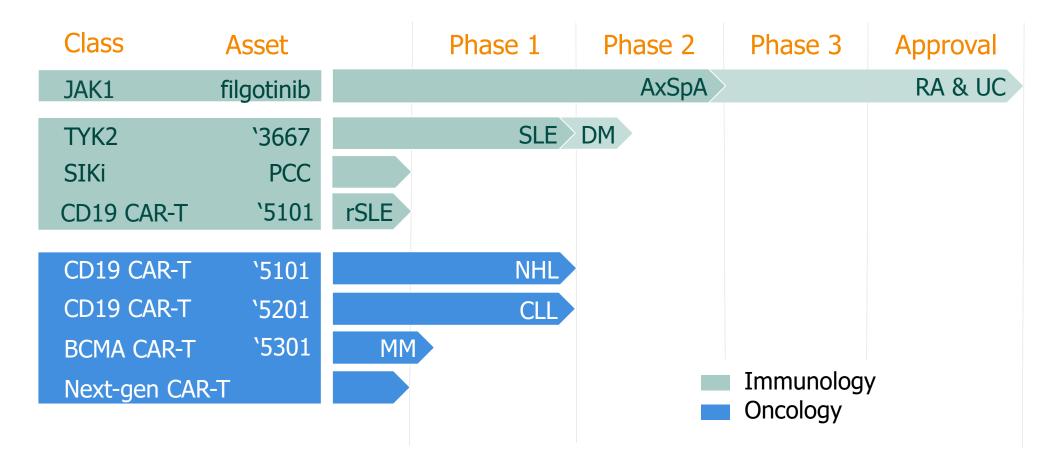
Long-term GILD collaboration



**€4.1B\* cash & cash equivalents** 



# Portfolio focus on immunology & oncology



Note: filgotinib is approved for RA and UC in EU, Great Britain and Japan.

AxSpA, axial spondyloarthritis; CLL, chronic lymphocytic leukemia; DM, dermatomyositis; MM, multiple myeloma; NHL, non-Hodgkin lymphoma; rSLE, refractory systemic lupus erythematosus; SLE, systemic lupus erythematosus; RA, rheumatoid arthritis; UC, ulcerative colitis.



# Our oncology Vision 2028 roadmap

Towards 3 next-generation cell therapies in 3 years

#### 2022-23

#### **Short term**

Validate the **decentralized CAR-T** delivery model with proven therapies

#### 2023-25

#### **Medium term**

Build a pipeline of **Best-in-Class** cell therapies

Global scalable decentralized CAR-T platform

#### 2025 - 2028+

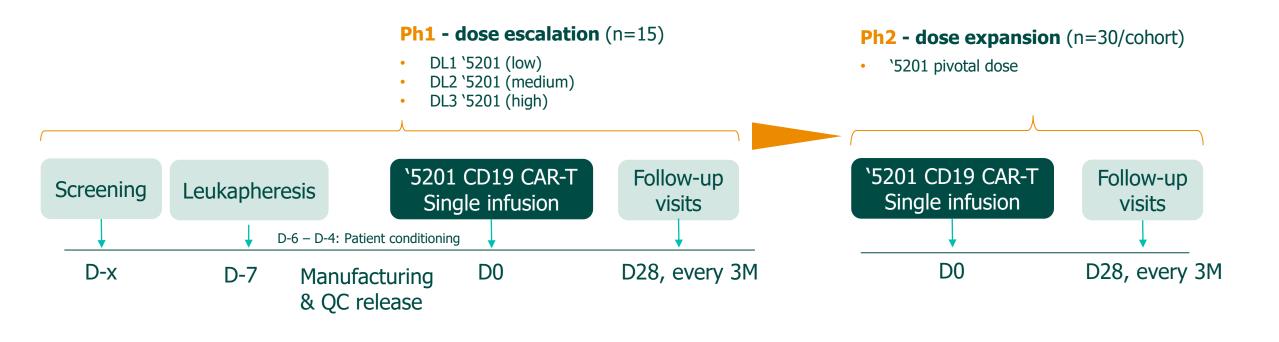
#### Longer term

**Leverage capabilities** to rapidly address unmet needs in oncology



# EUPLAGIA CD19 CAR-T Ph1/2a in r/rCLL

With or without Richter's transformation

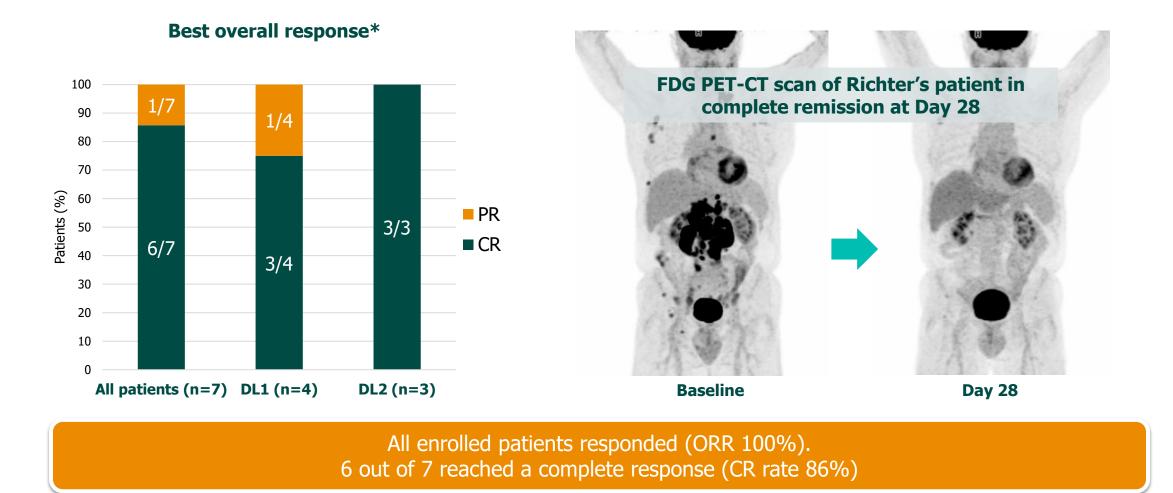


Aim for Ph1 topline data mid 2023

DL, dose level; r/rCLL, relapsed/refractory chronic lymphocytic leukemia



# **Encouraging first patient data with `5201**

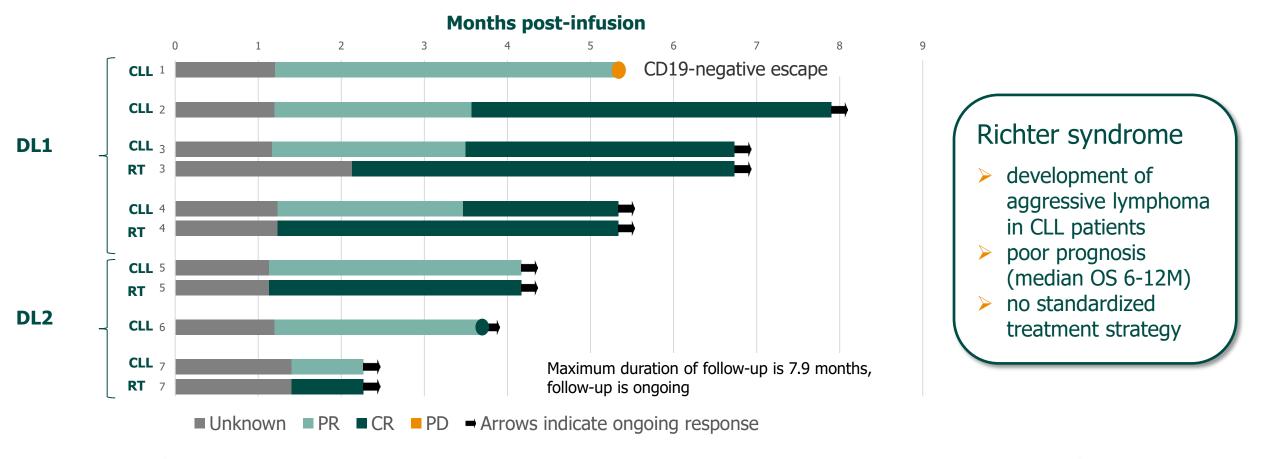


\*For patients with CLL + Richter's transformation, best response of the Richter's transformation is plotted. Response data are assessed by the investigator and are under review.

CLL, chronic lymphocytic leukemia; CR, complete response; DL1, dose level 1; DL2, dose level 2; FDG, fluorodeoxyglucose; ORR, objective response rate; PET-CT, positron emission tomography-computed tomography; PR, partial response. Presented at EBMT-EHA 2023: February 9

Galápagos

# Encouraging first patient data with `5201



Rapid complete responses observed with a 100% OR rate in heavily pre-treated r/rCLL patients, with or without Richter's transformation

CLL, chronic lymphocytic lymphoma; OS, overall survival; CR, complete response; PD, partial disease; PR, partial response; RT, Richter transformation. Cancer Research UK; Rossi et al, Front Oncol, 2022; Wang et al., Haematologica, 2020. Presented at EBMT-EHA 2023: February 9



# No CRS Grade ≥3 and ICANS at DL1 and DL2

	All patients N=7	DL1 (low) N=4	DL2 (medium) N=3
Patients with any grade CRS, n (%)	4 (57)	2 (50)	2 (67)
Grade 1/2	4	2	2
Grade ≥3	0	0	0
Median time to onset (days)	4	4.5	2.5
Median duration (days)	7	5.5	7
Neurotoxicity (ICANS), n (%)			
Any grade	0	0	0

### Initial data '5201 show encouraging safety profile in r/rCLL

r/rCLL, refractory/relapsed chronic lymphocytic leukemia; CRS, cytokine release syndrome; DL, dose level; ICANS, Immune effector cell-associated neurotoxicity syndrome. Presented at EBMT-EHA 2023: February 9



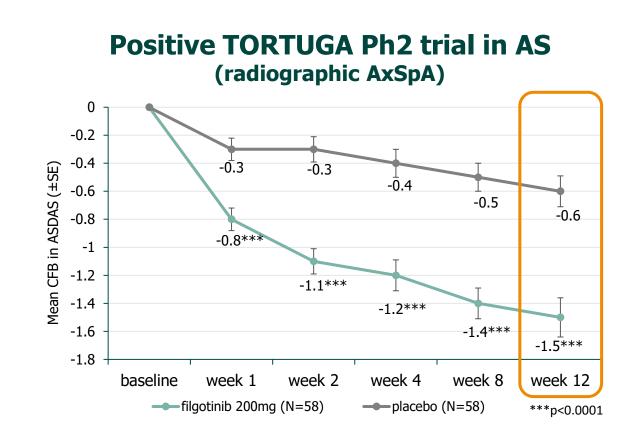
# **Phase 3 DIVERSITY in Crohn's Disease**

- Topline results
  - **Induction**: two cohorts missed the co-primary endpoints of clinical remission & endoscopic response at W10
  - Maintenance: filgotinib 200mg achieved the co-primary endpoints of clinical remission & endoscopic response at W58
- Safety data generally consistent with the known profile of filgotinib
- No MAA submission in Europe
- Fully committed to filgotinib in approved indications, RA & UC, and development in AxSpA





- Rheumatology indication:
  inflammation in spine & sacroiliac joints;
  heterogenous clinical features
- Young population, significant burden with disability outcome if left untreated
  - only 15-20% achieves remission
  - limited options available (TNFi, IL-17i, JAKi)
  - no new MOAs expected in next years

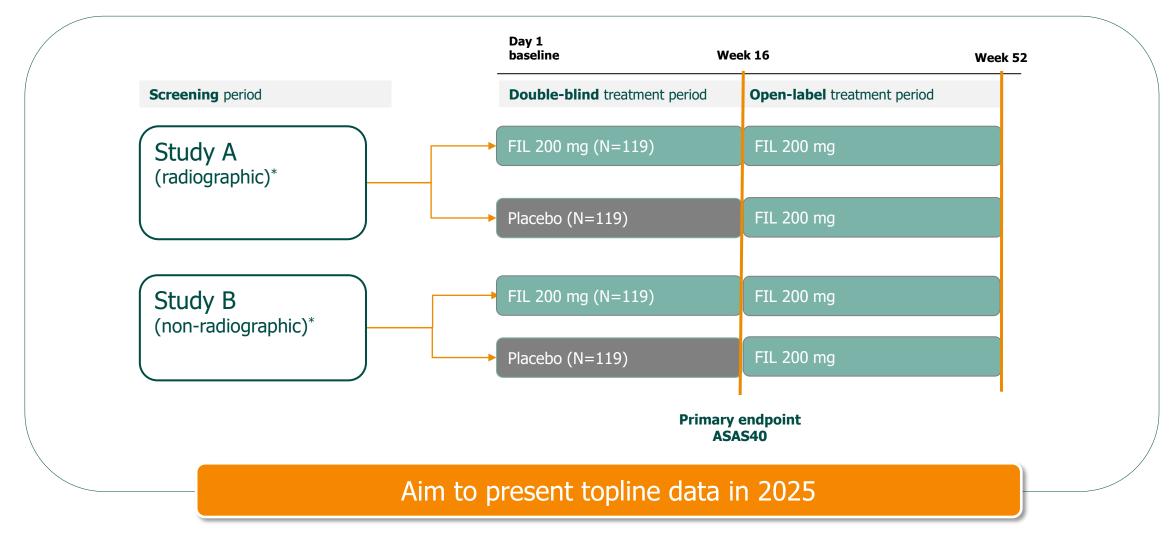


AS, ankylosing spondylitis; ASDAS, Ankylosing Spondylitis Disease Activity Score; axSpA, axial spondyloarthritis; CFB, change from baseline; IL, interleukin; JAKi, Janus kinase inhibition; MOA, mode of action; TNFi, tumour necrosis factor inhibition; SE, standard error.

Van der Heijde D, et al. Lancet 2018; Van der Heijde D, et al. Lancet 2019; Deodhar, et al. Annals of the Rheumatic Diseases 2021.



# Start Ph3 study in AxSpA with filgotinib in Q2



\*Up to 25% may be bDMARD(s)-IR; AxSpA, axial spondyloarthritis; bDMARD, biologic disease-modifying antirheumatic drug; ASAS, Assessment of SpondyloArthritis international Society





Paul Stoffels CEO

#### **Commercial & financial update**

Bart Filius President & COO Q&A

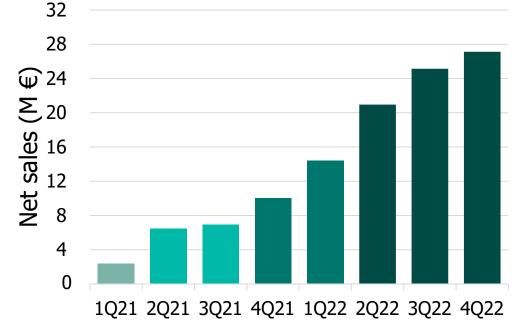
Michele Manto, CCO Daniele D'Ambrosio, Head of Immunology



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# Jyseleca European net sales of €88M in 2022

- Approved for RA & UC
  - ➢ ~85% RA, ~15% UC
  - strong UC launch
- Treating ~18,000 patients
- MANTA/RAy label positive CHMP opinion
- CHMP Article 20 outcome

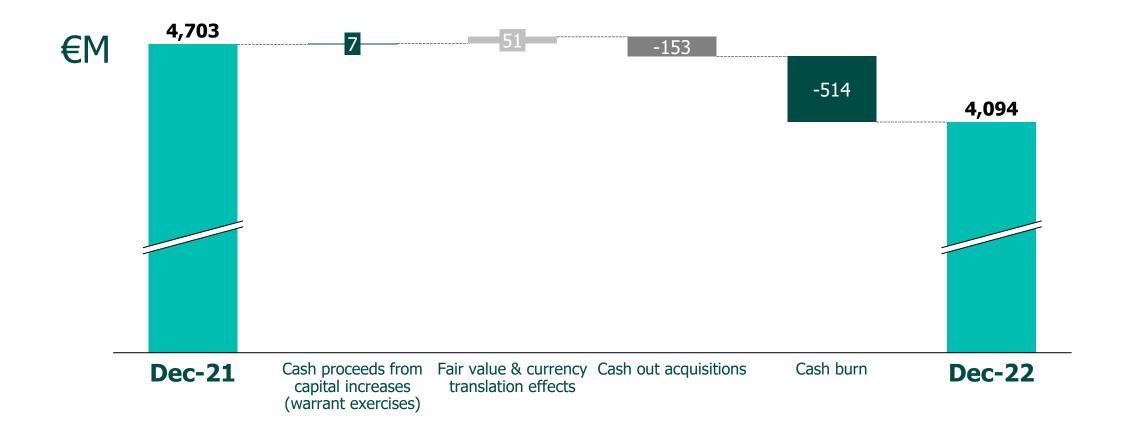


Jyseleca net sales guidance for 2023 €140-160M

Guidance on European net sales based on Galapagos management projections. Original guidance for FY22 was €65-75M; updated at H1 update to €75-85M and updated at Q3 to €80-90M.



# **Cash & current financial investments**



Cash burn of €514M; cash position ~€4.1B end of 2022

# **Key financials 2022**



#### **Revenues & other income**

- €174M revenue recognition for filgotinib development
- €230M revenue recognition for platform
- €88M sales, €11M royalties & €2M sales milestones for Jyseleca



#### **Operating costs**

Increase in S&M costs and in R&D costs



#### **Net loss**

• Including €52M net other financial income



# **Guidance for 2023**

# €140-160M



#### Jyseleca net sales guidance

- Reflects current growth trends in RA and UC
- Includes further UC launches throughout Europe

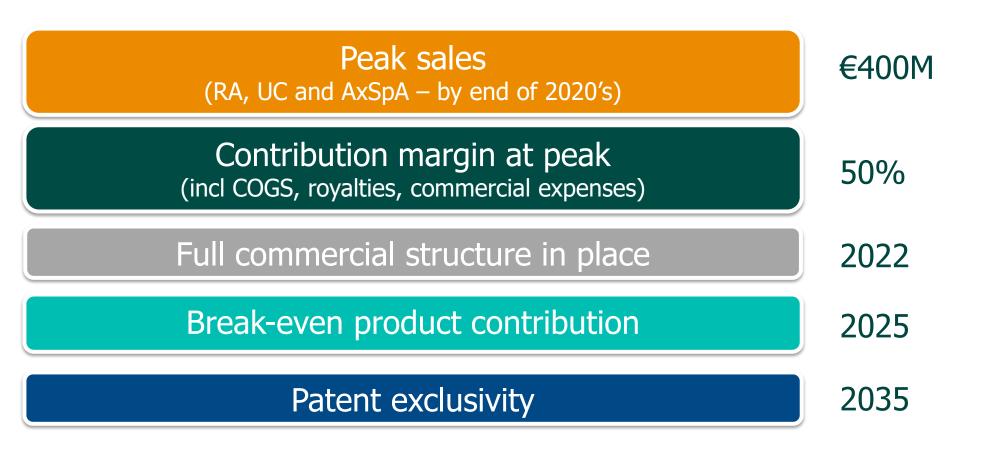
#### **Cash burn guidance**

- Represents cash burn reduction >€100M
- Resulting from program discontinuations, Jyseleca performance, organizational restructuring and interest income, partly offset by oncology build-up



# Jyseleca (filgotinib) in Europe

On track towards a profitable business case



Note: Galapagos estimates

Subject to approval of AxSpA by applicable regulatory authorities; P&L break-even including commercial & R&D expenses



Estimates

# **Outlook 2023**

### **Key topline results**

- `5101 CD19 CAR-T Ph1b NHL
- `5201 CD19 CAR-T Ph1b CLL

### **Regulatory progress**

- CD19 IND submission
- BCMA CTA approval

### **Trial initiations**

- Filgotinib Ph3 AxSpa
- `3667 (TYK2i) Ph2 DM & SLE
- `5101 CD19 CAR-T Ph1b rSLE
- CD19 CAR-T NHL/CLL expansion cohorts
- `5301 BCMA CAR-T Ph1b MM

#### Aim to execute on additional business development deals

AxSpA, axial spondyloarthritis; CLL, chronic lymphocytic leukemia; CTA, clinical trial application; DM, dermatomyositis; IMPD, Investigational Medicinal Product Dossier; IND, Investigational New Drug; MM, multiple myeloma; NHL, non-Hodgkin lymphoma; rSLE, refractory systemic lupus erythematosus; SLE, systemic lupus erythematosus.



**Commercial & financial update** Bart Filius

President & COO

Paul Stoffels CEO

#### Q&A

Michele Manto, CCO Daniele D'Ambrosio, Head of Immunology

