Q3 2023 financial results

03 Nov 2023

Galápagos

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 "vision", "progress", "accelerate", "believe", "anticipate", "plan", "continue", "forward", "goal", "should", "expect", "deliver", "further", "estimate," "next," "encouraging," "aim," "potential," and "will," and "initiate," as well as any similar expressions. Forward-looking statements contained herein include, but are not limited to, the guidance from management regarding our financial results, including our expected operational use of cash during financial year 2023 and the adjusted net sales guidance for Jyseleca® during financial year 2023, statements related to the contemplated transaction between Galapagos and Alfasigma, including potential cost savings, milestone payments, and the planned reduction in force, 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 our studies, including, but not limited to, the EUPLAGIA-1, and ATALANTA-1, statements regarding the expected timing, design and readouts of our ongoing and planned preclinical studies and clinical trials, including the recruitment for such studies and trials, and our plans and strategy with respect to the such studies and trials, statements regarding our regulatory outlook, statements regarding our regulatory outlook, respect to the such studies and trials, strategy and outlook, including progress on our immunology or oncology portfolio, and AR-T-portfolio, and any potential changes in such strategy, statements regarding our repetition efforts for filgotinib, our product candidates, and any of our future growth, statements regarding our commercial sales of filgotinib, our product candidates (if approved), statements regarding the rollout candidates (if approved).

We caution the reader that forward-looking statements are based on our management's current beliefs and expectations and are not guarantees of future performance. Forward-looking statements may involve any 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, net sales, and other financial results may be incorrect (including because one or more of its assumptions underlying our revenue, expense, cash burn, sales or result 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, 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 risk that the contemplated transaction with Alfasigma may not be completed on the currently anticipated timeline or at all, the risk that we may not realize the anticipated benefits of the contemplated transaction with Alfasigma, 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, AxSpA, SLE, DM, NHL, CLL, 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 any other reasons), 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 our trials and studies, including, but not limited to, the ATALANTA-1 and EUPLAGIA-1 studies, may not be reflective of the final data, risks related to our reliance on collaborations with third parties (including, but not limited to, Gilead and Lonza), the risk that the transition of the European commercialization responsibility of filgotinib from Gilead to us, will not have the currently expected results for our business and results of operations, the risk that estimates regarding our filgotinib development program and the commercial potential of our product candidates and our expectations regarding the revenues and costs associated with the transfer of European commercialization rights to filgotinib may be incorrect, the risk that we will not be able to continue to execute on our currently contemplated business plan and/or will revise our business plan, 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, including the risk that we may not achieve the anticipated benefits of such transformation on the currently envisaged timeline or not 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 due to the conflict between Russia and Ukraine and the conflict in Israel and Gaza, and risks related to continued regulatory review of filgotinib following approval by relevant regulatory authorities, including the EC and EMA, and the EMA's safety review of JAK inhibitors used to treat certain inflammatory disorders, 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 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® 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.

Agenda

Introduction & outcome

Jyseleca® strategic exercise

Dr. Paul Stoffels*, CEO

2 Operational & financial update

Thad Huston, CFO & COO

R&D update – CAR-T programs

Jeevan Shetty, M.D.,

Head Clinical Development Oncology

4 Outlook & conclusion

Dr. Paul Stoffels*, CEO

5 Q&A

All

Agenda

Introduction & outcome Jyseleca® strategic exercise

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² Operational & financial update

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OUR VISION

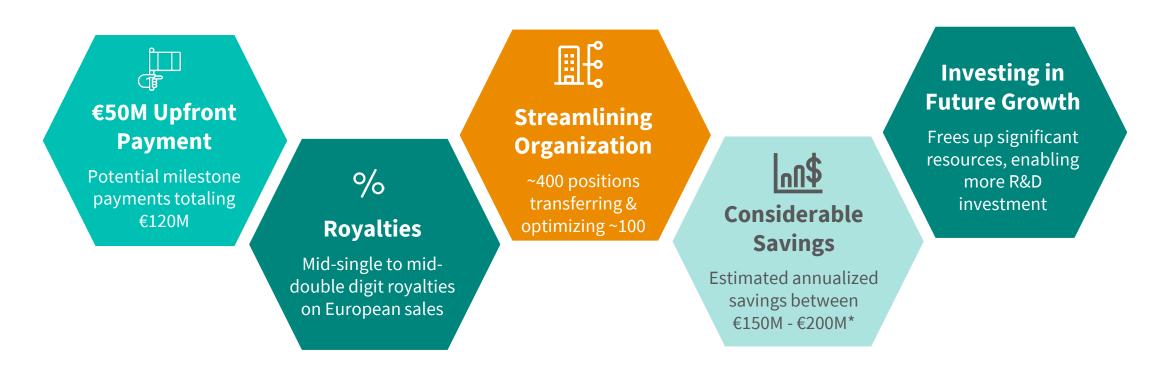
Galapagos' vision is to
transform patient outcomes
through life-changing
science and innovation for more
years of life and quality of life.

OUR MISSION

We accelerate
transformational innovation
through the relentless pursuit of
groundbreaking science, our
entrepreneurial spirit and a
collaborative mindset.

Divestment of Jyseleca® to Alfasigma

Strategically and financially compelling transaction



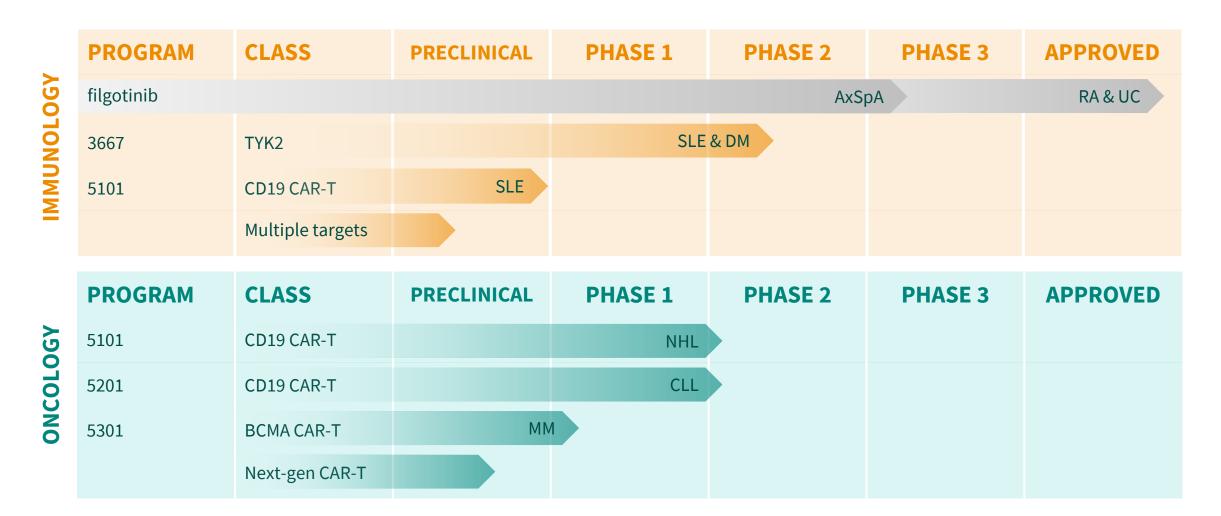
Delivering on commitment to take action for Jyseleca®



Final agreement and completion of transaction of Jyseleca® are subject to customary conditions, including consultations with works councils and other employee representative bodies. Completion and of the contemplated transaction are is also subject to the execution of a definitive agreement with Alfasigma and an amendment to the agreement with Gilead.

*starting in 2025. Potential milestone payments, employee transfers and cost savings are based on current Galapagos estimates.

Focus on accelerating our pipeline





Important progress in our oncology TA

Delivering on CAR-T programs with point-of-care manufacturing

Strong data in CLL & NHL

With '5201 and '5101

Tech transfer to 1st US site initiated

With Boston-based Landmark Bio



Initiating MM study with '5301

3rd clinical study

Increasing point-of-care footprint

Signing on additional sites

Strengthening capabilities

Key hires across TAs

3 Poster Presentations & KOL Event at ASH in Dec 2023

We have a clear path outlined for value creation

Strong fundamentals to build a global innovative biotech



Accelerate early-stage pipeline

build on renewed discovery portfolio



Broaden solid latestage pipeline

combine internal & external innovation



Execute on oncology strategy

progress trials & expand pointof-care network



Jyseleca divestment

free up significant resources



Strengthen capabilities

build team of top experts



Disciplined cash use

prioritize to maximize value creation



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Key financials YTD Q3 2023

€489M

Revenues & other income

- €186M revenue recognition for filgotinib development
- €173M revenue recognition for platform
- €82M sales, €1M sales milestones & €7M royalties for Jyseleca®

-€494M

Operating costs

Decrease in R&D and SG&A costs; total opex €72M down (-13%)
 vs last year

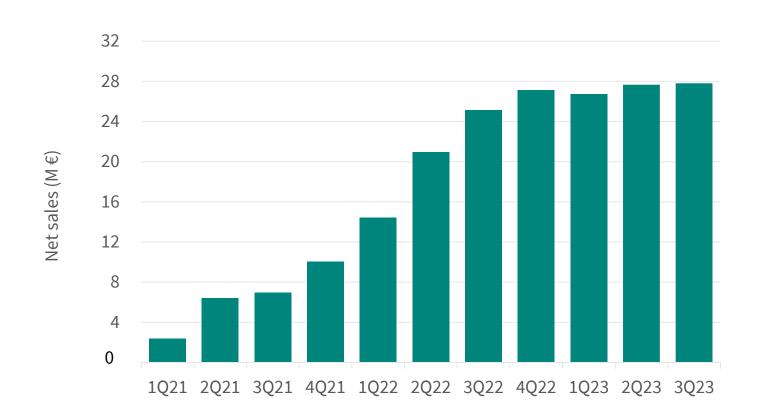
€54M

Net profit

• €87M net financial income

Jyseleca® European net sales of €28M in Q3 2023

YTD sales of €82M; reiterating FY guidance of €100-€120M



JAKi class under pressure following Article 20

UC launch progressing

Reimbursement status

- 22 countries in RA
- 20 in UC

Cash & current financial investments and cash burn guidance

Cash position of ~€3.8B end of September 2023

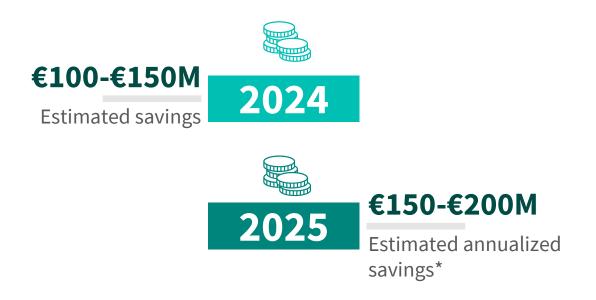
€344M

Cash burn YTD

€380-420M

Re-iterating guidance for FY 2023

With expected increase in interest income & grants in Q4



Disciplined business development to accelerate pipeline

Actively pursuing multiple deals in oncology & immunology



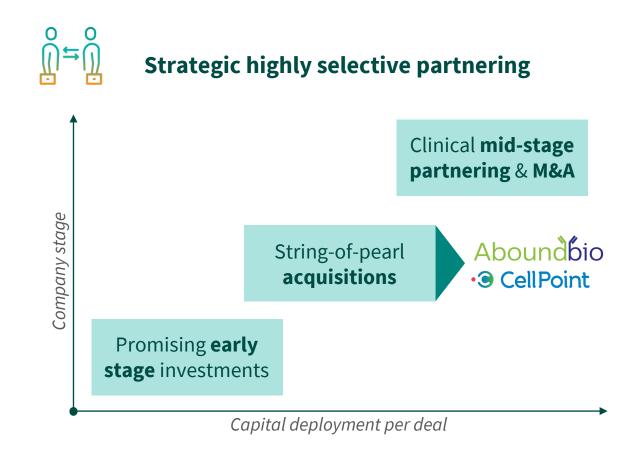
Scientific excellence

Financial capacity

Unique **expertise**

Our value proposition

- Deep expertise in small molecules, biologics and CAR-T
- Broad industry network
- Strong balance sheet
- Strategic Gilead partnership
- Highly experienced BD team
- Strong European ecosystem presence
- Agile decision making



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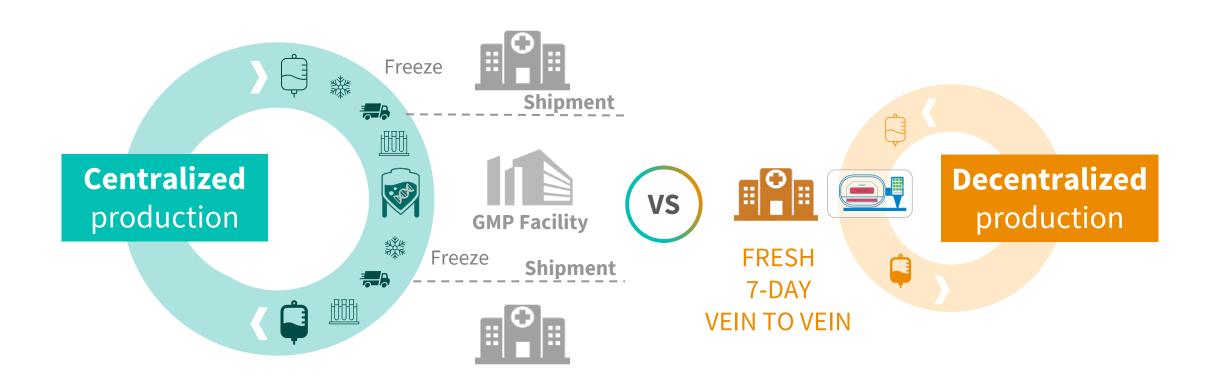
5 Q&A

All



The Galapagos Platform

Our point-of-care manufacturing model

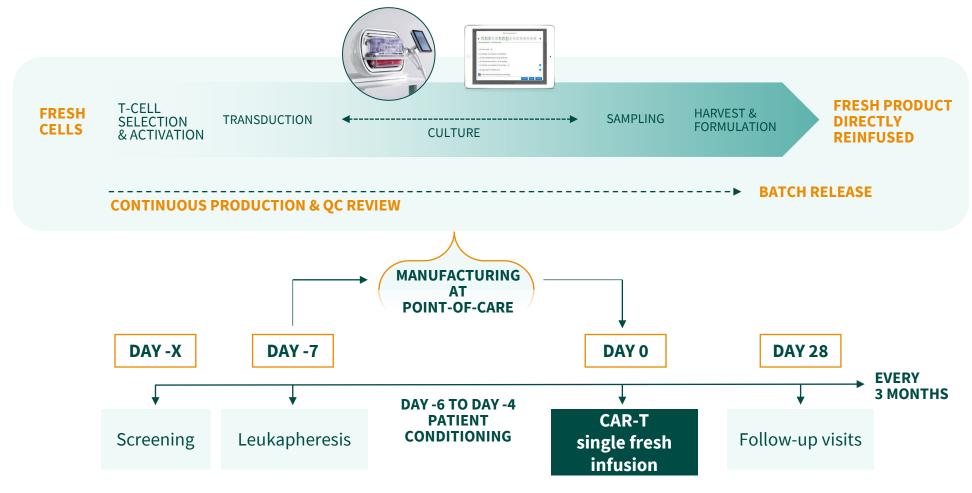




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7-day vein-to-vein, fresh-to-fresh

Potential for rapid, automated and scalable CAR-T treatment



Incidence of high-risk CLL and Richter's transformation



CLL

~20,000 new patients in US and ~20,000 in E5 p.a.*1,2,3



High-risk CLL

 \sim 2,100 new patients in US and \sim 1,800 in E5 p.a.*4



DLBCL-RT

No standard of care available

Overall survival: 5-8 months

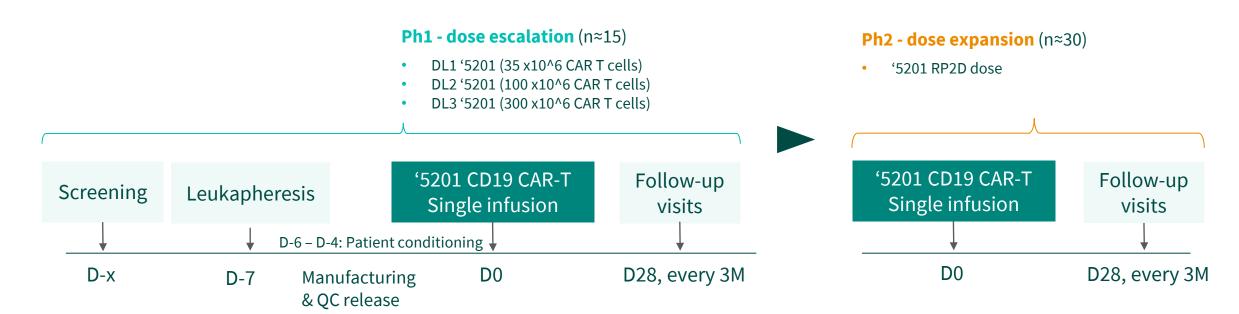
~1,900 new patients in US and

~2,000 in E5 p.a.*5,6

Overall CLL incidence	US		E 5	
	2023	2035	2023	2035
# new patients [in K]	20	24	19	22
population [in M]	340	360	322	321
incidence rate per 100k	5.77	6.76	5.91	6.97



EUPLAGIA-1 CD19 CAR-T Ph1/2a in r/rCLL & RT



Study population

- CD19+ CLL or SLL
- ≥ 2 prior lines of therapy
- Richter's Transformation allowed with ≥1 prior line of therapy
- Incl. transplant ineligible
- No prior CD19-targeted therapy allowed



EUPLAGIA-1 patient baseline characteristics

Heavily pretreated population of CLL & RT patients

	All patients (N=12)
Age, median (range), years	66 (58-71)
Male, n (%)	8 (66.7)
Disease subtype, n (%)	
CLL alone	5 (41.7)
CLL with RT	7 (58.3)
No. of prior therapy lines, median (range)	4 (2-10)
Prior BTKi, n (%)	10 (83.3)
Prior venetoclax, n (%)	9 (75.0)
Prior allo-HSCT, n (%)	1 (8.3)
Prior R-CHOP, n (% of RT patients)	5 (71.4)
High-risk features, n (%)	
TP53 abberations	7 (58.3)
Unmutated IGHV	11 (91.7)
Complex karyotype	2 (16.7)



Good safety profile with '5201

EUPLAGIA-1 preliminary results in critically ill patient population

	All patients N=12	
Patients with any grade CRS, n (%)	6 (50)	
Grade 1/2	6 (50)	
Grade ≥3	0	
Neurotoxicity (ICANS), n (%)		
Any grade	0	

• '5201 is well-tolerated

No Grade 3 CRS

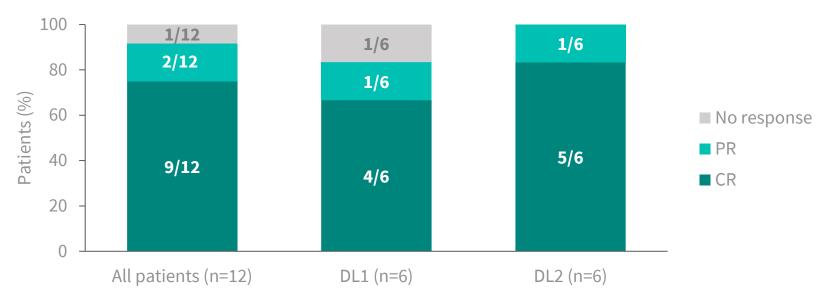
No ICANS reported

No deaths occurred

High clinical activity observed in r/rCLL & RT

EUPLAGIA-1 preliminary results in heavily pretreated population

Best objective response*



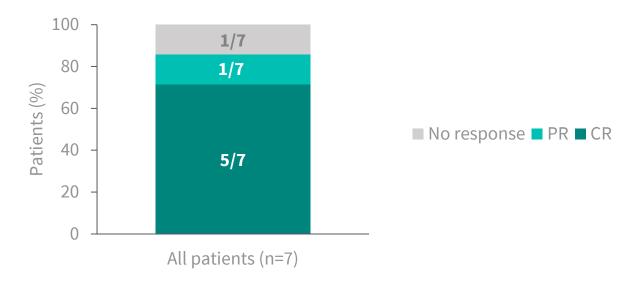
11 of 12 patients responded (ORR 92%) 9 of 12 reached a complete response (CRR 75%) 5 of 6 on DL2 reached a complete response (CRR 83%)



High clinical activity observed in RT subset

EUPLAGIA-1 preliminary results in RT patients

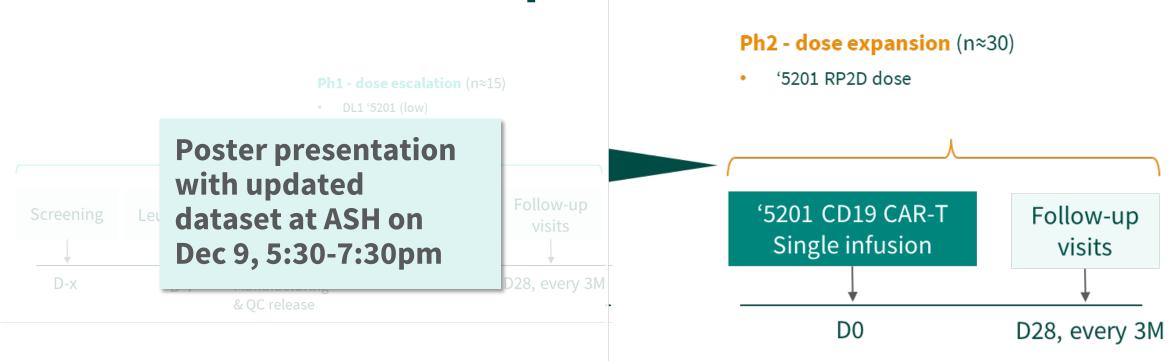
Best objective response* in RT patients



6 of 7 patients with RT responded (ORR 86%)
5 of 7 patients with RT reached a complete response (CRR 71%)

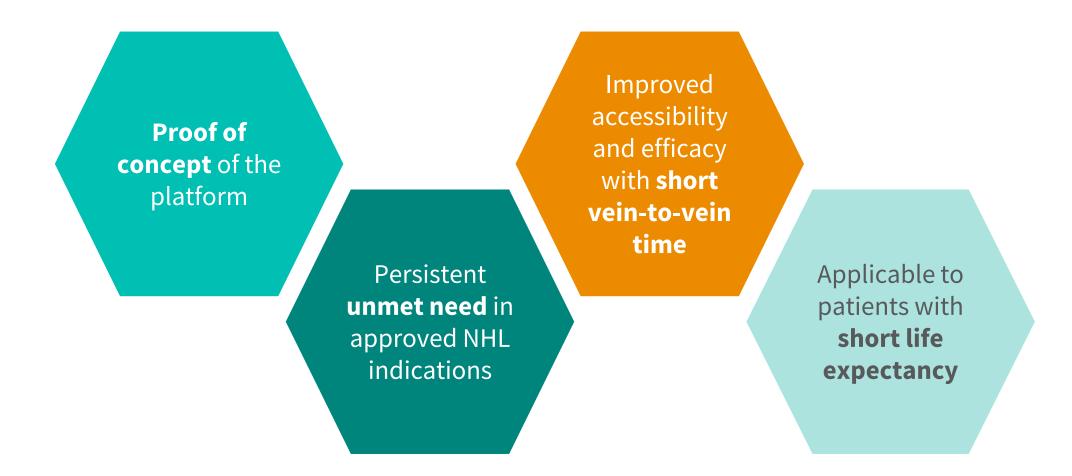


EUPLAGIA-1 next steps



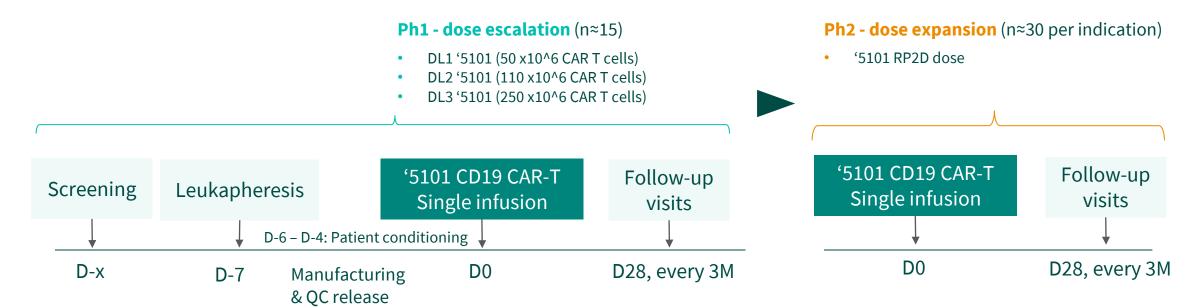
- Select DL2 as recommended Phase 2 dose (RP2D)
- DL3 not necessary
- Initiate Ph2 expansion cohorts in high-risk CLL and RT
- Initiate tech transfer to 1st US site –Landmark Bio, Boston (MA)

NHL program



ATALANTA-1 CD19 CAR-T Ph1/2a in r/rNHL

'5101 basket trial in DLBCL, MCL, MZL, FL



Study population

- r/r DLBCL, MCL, MZL, FL
- ≥ 2 prior lines of therapy, or primary refractory DLBCL
- Incl. transplant ineligible
- No prior CD19-targeted therapy allowed

ATALANTA-1 patient baseline characteristics

Heavily pretreated population of NHL patients

	All patients (N=14)	
Age, median (range), years	65 (50-77)	
Male, n (%)	11 (78.6)	
Disease subtype, n (%)		
DLBCL	7 (50.0)	
FL	3 (21.4)	
MCL	3 (21.4)	
MZL	1 (7.1)	
No. of prior therapy lines, median (range)	4 (1-8)	



Encouraging safety profile with '5101

ATALANTA-1 preliminary results in critically ill patient population

	All doses N=14
Patients with any grade CRS, n (%)	7 (50)
Grade 1-2	6
Grade 3	1

Neurotoxicity (ICANS), n (%)	6 (43)
Grade 1	6
Grade ≥2	0

- ICANS Grade 1
 - 6 patients
- Only 1 case of Grade 3 CRS
 - All other Grade 1-2
- 2 deaths
 - 1 intra-abdominal hemorrhage* in patient previously diagnosed with prior thromboembolic disease on LMWH
 - 1 urosepsis >6 months post-infusion**

Data to be presented at ASH 2023 (Kersten MJ, et al.). ASH poster #2113, 9 Dec 2023 5:30-7:30 PM. Cut-off date: 2 May 2023 CRS, cytokine release syndrome; ICANS, Immune effector cell-associated neurotoxicity syndrome; LMWH, low-molecular-weight heparin; r/rNHL, relapsed/refractory non-Hodgkin lymphoma

^{* 12} days post infusion

^{** &}gt; 6 months after infusion while patient was in ongoing CR

Encouraging efficacy in r/rNHL

ATALANTA-1 preliminary results in heavily pretreated population

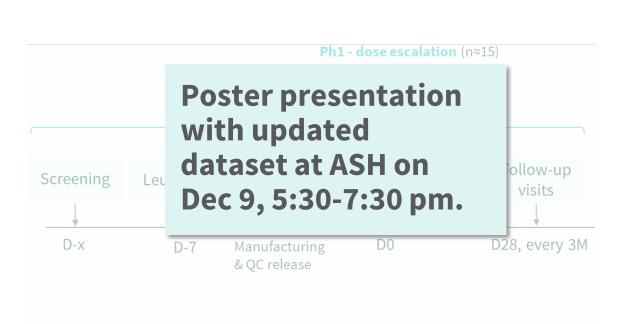
Best objective response



11 of 13 patients responded (ORR 85%)
5 of 6 on DL2 reached a complete response (CRR 83%)
9 of 13 reached a complete response (CRR 69%)

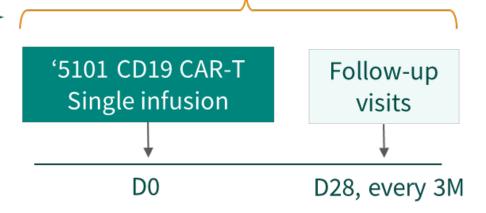


ATALANTA-1 next steps



Ph2 - dose expansion (n≈30 per indication)

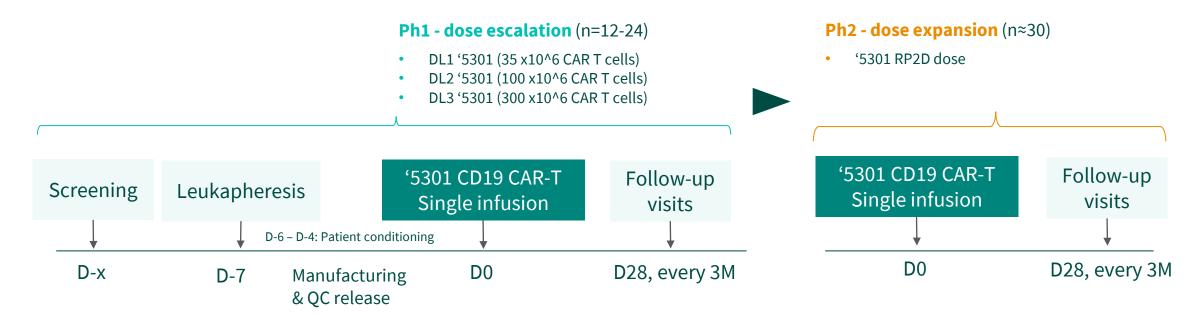
'5101 RP2D dose



- Expand in indications with benefit from short vein-to-vein time
- Implement DL3
- Complete tech transfer to 1st US site Landmark Bio (Boston, MA)

PAPILIO-1 BCMA CAR-T Ph1/2a in r/rMM

GLPG5301 in relapsed/refractory Multiple Myeloma



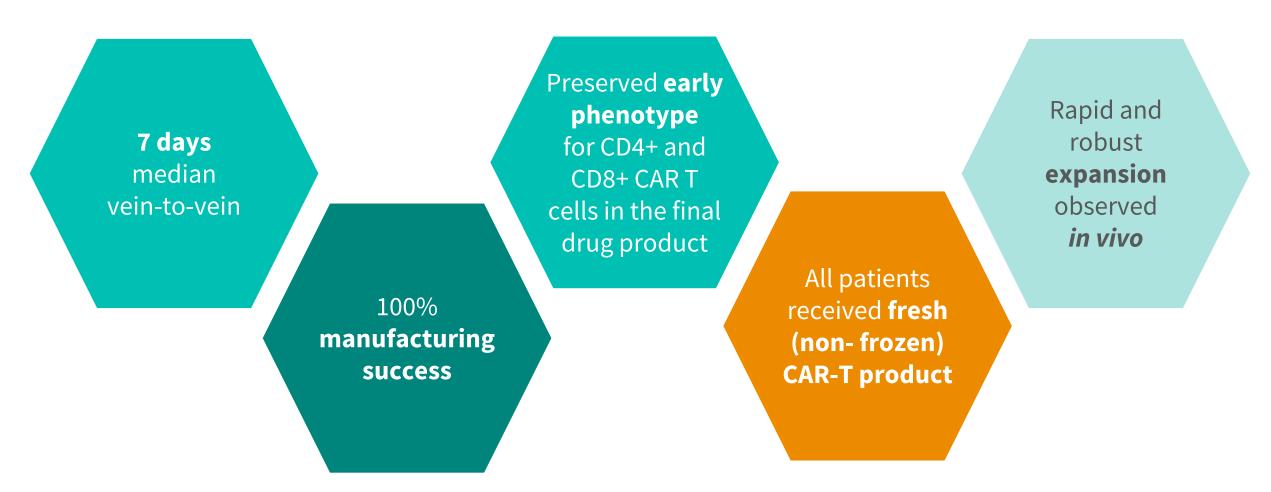
Study population

- r/r Multiple Myeloma or Plasma cell leukemia
- ≥ 2 prior lines of therapy (at least IMiD, PI and anti-CD38)
- No prior BCMA-targeted therapy allowed

First patient expected to be dosed in Q4 2023



Innovative platform for future of CAR-T therapy



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5 Q&A

All

Outlook 2023

Focused on business development opportunities

Data read-outs



- '5101 CD19 CAR-T Ph1 NHL ✓
- '5201 CD19 CAR-T Ph1 CLL ✓
- '5101 CD19 CAR-T Ph1 NHL at ASH
- '5201 CD19 CAR-T Ph1 CLL at ASH

Regulatory progress



- BCMA CTA in MM approval ✓
- CD19 IND preparation in oncology
- '5101 CD19 CTA in rSLE submitted ✓

Trial initiations



- Filgotinib Ph3 AxSpa ✓
- '3667 (TYK2i) Ph2 DM ✓
- '3667 (TYK2i) Ph2 SLE ✓
- '5101 CD19 CAR-T NHL expansion cohorts ✓
- '5301 BCMA CAR-T Ph1/2 MM

KOL event



ASH, Dec 10 2023 (San Diego)

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Strong fundamentals to build a global innovative biotech



Accelerate early-stage pipeline

build on renewed discovery portfolio



Broaden latestage pipeline

combine internal & external innovation



Execute on oncology strategy

advance trials & expand pointof-care network



Intended
Jyseleca
divestment

free up significant resources



Strengthen capabilities

build team of top experts



Disciplined cash use

prioritize to maximize value creation

Delivering on Faster, Forward strategy to unlock value



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4 Outlook & conclusion

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5 Q&A

All

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