

# ASH23 – Galapagos KOL Event

Investor Relations  
10 December 2023

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**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, statements regarding our strategy and plans, including 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 the timing and likelihood of business development projects and external innovation, statements regarding our strategic transformation, statements regarding our regulatory outlook, statements regarding our R&D plans, strategy and outlook, including progress on our immunology or oncology portfolio, and CAR-T-portfolio, and any potential changes in such strategy, statements regarding our pipeline and complementary technology platforms facilitating future growth, statements regarding our expectations on commercial sales of our product candidates (if approved), our product candidates, and any of our future approved products, statements relating to the development of our commercial organization, and statements and expectations regarding the rollout of our products or product 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, 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 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 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 audience 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.

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, be retained, copied or transmitted.

# Galapagos speakers

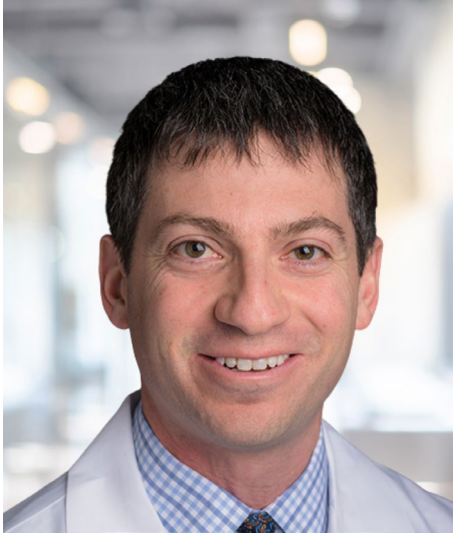


Dr. Paul Stoffels\*,  
CEO



Jeevan Shetty, MD,  
Head Clinical Development  
Oncology

# Key opinion leaders



Prof. M. Davids

Dana Farber Cancer Institute



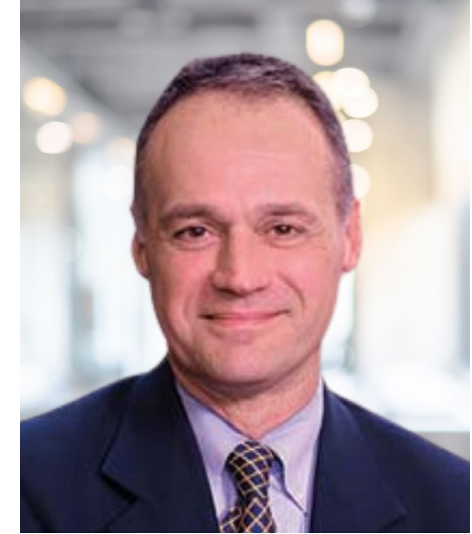
Prof. P. Ghia

University of Milan, Italy



Prof. S. Anguille

University of Antwerp, Belgium



Prof. M. Bishop

University of Chicago



# Agenda

## 1 Welcome and introduction

## 2 GLPG5201 in CLL & RT

EUPLAGIA-1 Results

Roundtable with Prof. Davids & Prof. Ghia

## 3 GLPG5101 in NHL

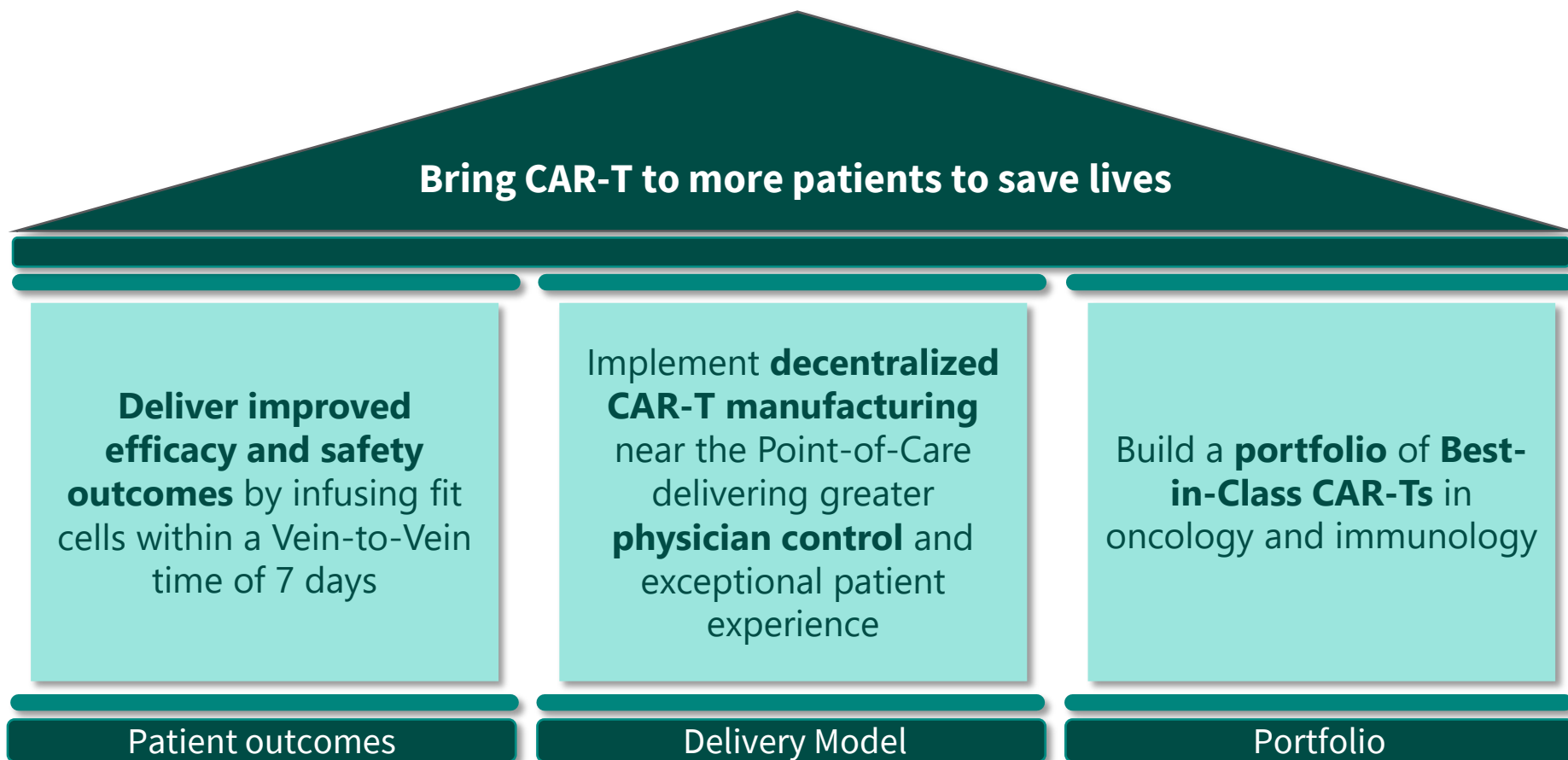
ATALANTA-1 Results

Roundtable with Prof. Anguille & Prof. Bishop

## 4 Concluding remarks

## 5 Q&A

# Our aspiration in cell therapy

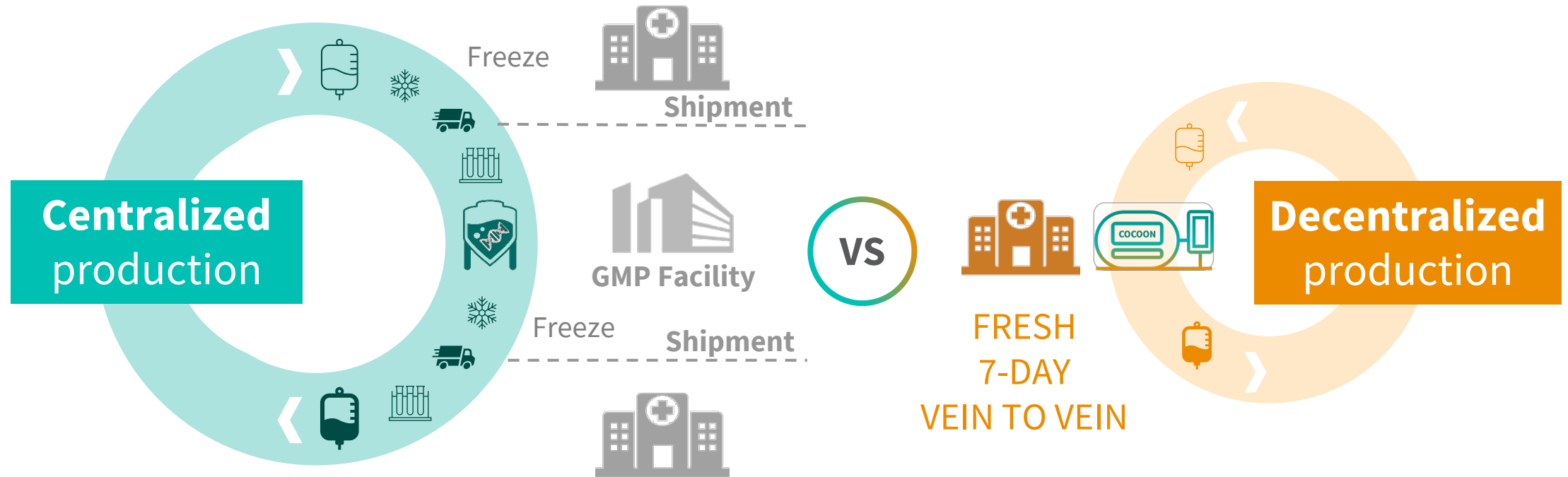


# CAR-T therapy at Point-of-Care



# Galapagos' CAR-T Manufacturing Platform

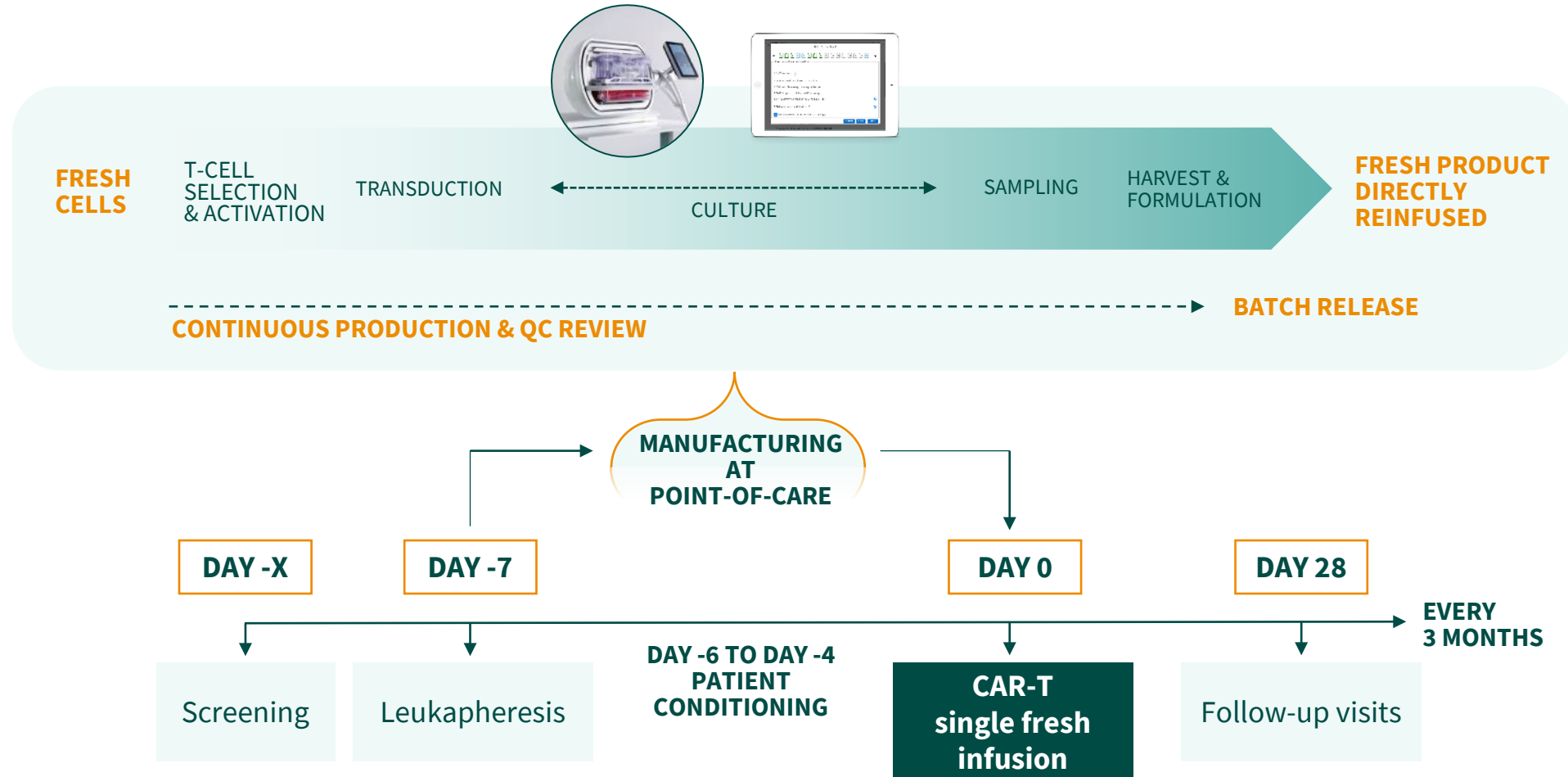
*Our decentralized Point-of-Care model*



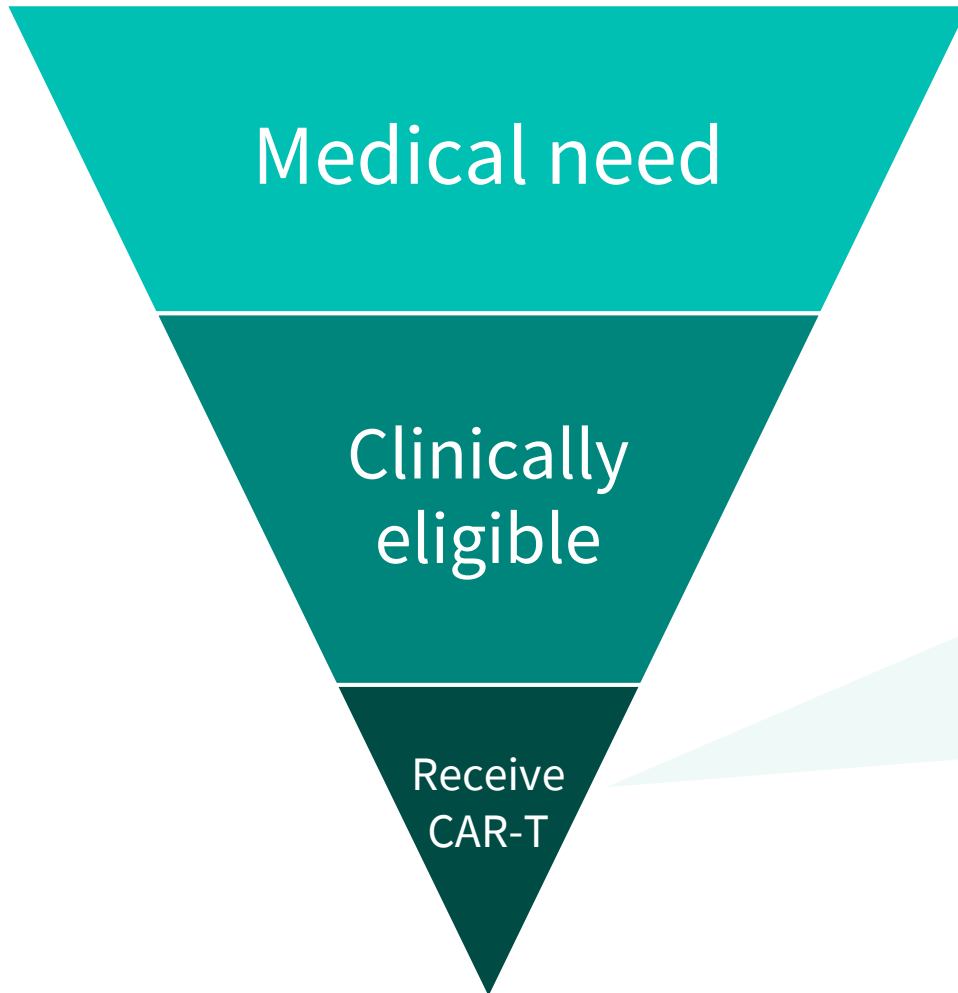


# 7-day vein-to-vein, fresh-to-fresh

*Potential for rapid, automated and scalable CAR-T treatment*



# Leverage CAR-T Point-of-Care solution



**Patients with high unmet medical needs** could benefit from Point-of-Care CAR-T therapies:

- Fast-progressing cancers
- Poor prognosis/short(er) life expectancy

**~ 70%\* of eligible patients do NOT receive CAR-T** due to:

- Limited capacity
- Complex logistics
- Restricted access

# 3 Point-of-Care CAR-T programs in the clinic

*Diversifying and accelerating our pipeline in hematological malignancies*

PROGRAM	CLASS		PHASE 1	PHASE 2	PHASE 3	APPROVED
GLPG5101	CD19 CAR-T		rrNHL	ATALANTA-1		
GLPG5201	CD19 CAR-T		rrCLL & RT	EUPLAGIA-1		
GLPG5301	BCMA CAR-T	rrMM	PAPILIO-1			
	Next-gen CAR-T					

# Important progress in our oncology TA in 2023

*Delivering on CAR-T programs with Point-of-Care manufacturing*

**Strong Phase 1 data in  
CLL (incl. RT) & NHL**

With '5201 and '5101

**Tech transfer to  
1<sup>st</sup> US site initiated**

With Boston-based Landmark Bio



**Initiating MM study with '5301**

3<sup>rd</sup> clinical study

**Increasing Point-of-Care  
footprint**

Signing on additional sites

**Strengthening capabilities**

Key hires across TAs

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# Incidence of CLL and Richter transformation

*Double refractory population growing over time*



## CLL

~20,000 new patients in US and  
~20,000 in E5 p.a.\*<sup>1,2,3</sup>



## r/r CLL

~2,100 new patients in US and  
~1,800 in E5 p.a.\*<sup>4</sup>



## 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.\*<sup>5,6</sup>

## Overall CLL incidence

US



E5

	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

rr, relapsed/refractory; CLL, chronic lymphocytic leukemia; CLL, chronic lymphocytic leukemia; DLBCL, diffuse large B-cell lymphoma; E5, EU5 and UK; RT, Richter transformation; in K, in thousands; in M, in million.

\*refers to 2023; 1. CancerMPact, Cerner Envisa, accessed Nov 1st 2023; 2. Key Statistics for Chronic Lymphocytic Leukemia | American Cancer Society; 3. Eichhorst B et al Annals of Oncology 2021; 4. High-risk defined as 3L. Derived from CancerMPact, Treatment Architecture, Cerner Envisa 2023; 5. IMARC report, 2023; 2-15% of incidence per Lightning Health literature review, Aug-23; 6. Sigmund AM et al. 2022; Thompson PhA et al. 2022.

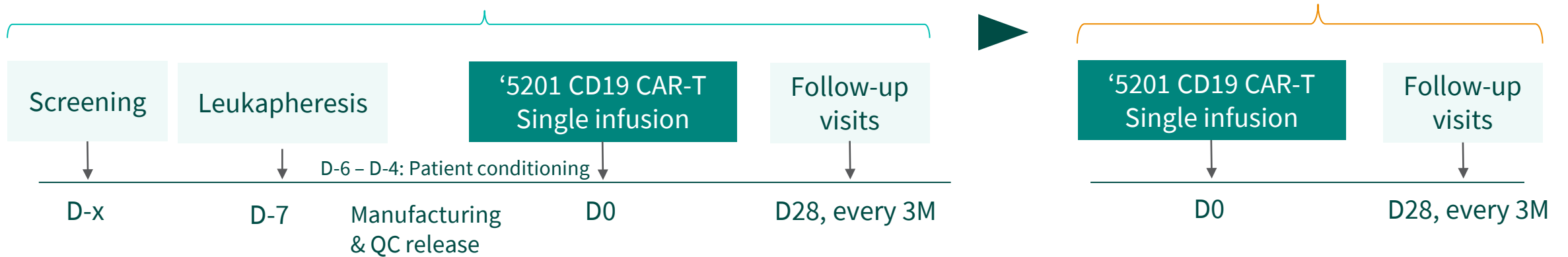
# EUPLAGIA-1 CD19 CAR-T Ph1/2a in r/rCLL & RT

## Ph1 - dose escalation (n≈15)

- DL1 '5201 (35 x10<sup>6</sup> CAR T cells)
- DL2 '5201 (100 x10<sup>6</sup> CAR T cells)
- DL3 '5201 (300 x10<sup>6</sup> CAR T cells)

## Ph2 - dose expansion (n≈30)

- '5201 RP2D dose



### Patient population

## Key eligibility criteria

- Patients with RT eligible regardless of prior therapy
- CD19+ relapsed/refractory CLL or SLL after ≥ 2 prior lines of therapy including BTKi, BCL2i, PI3Ki
- Age ≥ 18 years
- ECOG PS 0 and 1
- Incl. transplant ineligible
- No prior CD19-targeted therapy allowed

# EUPLAGIA-1 patient baseline characteristics

## Heavily pretreated population of CLL & RT patients

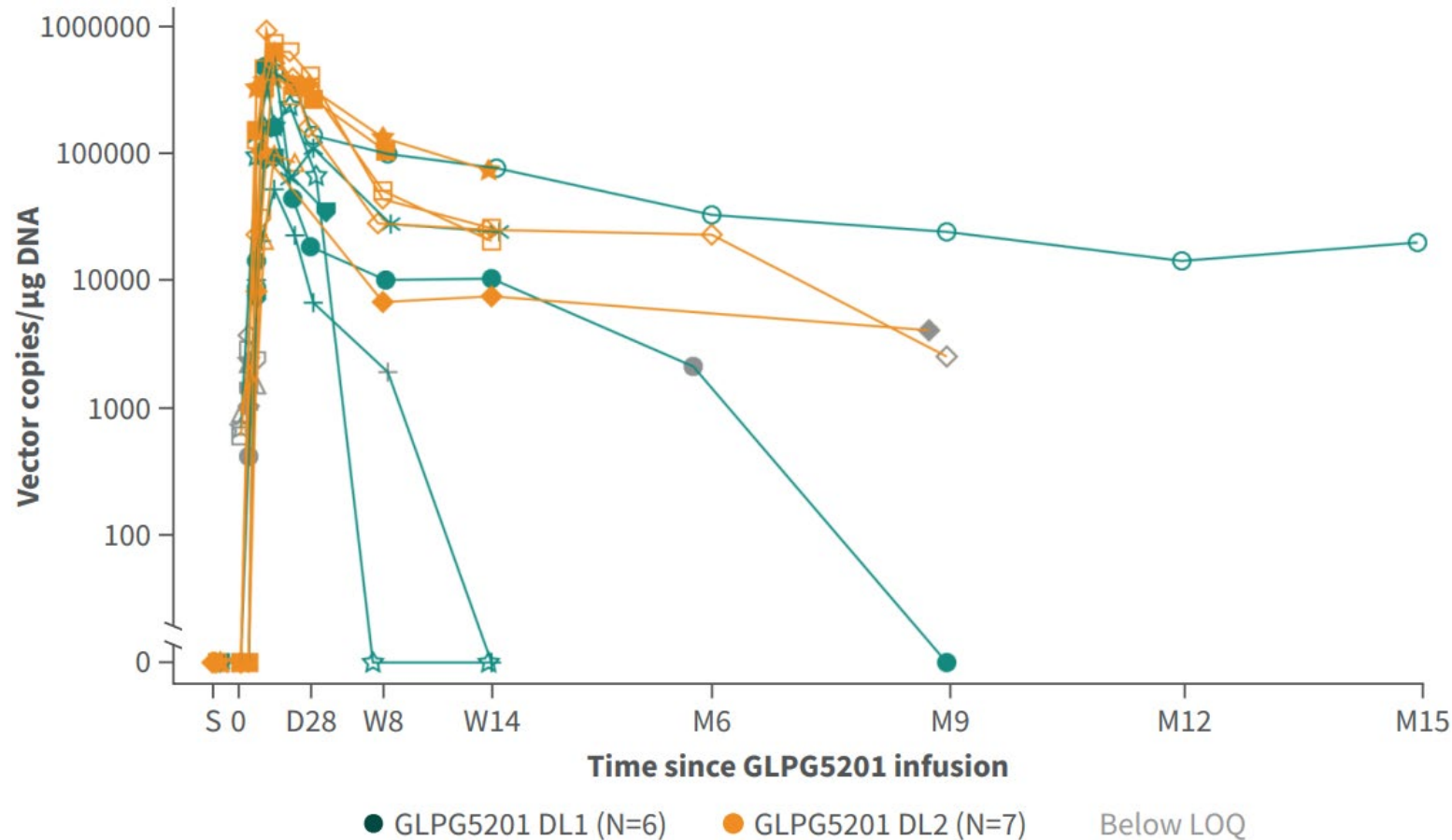
All patients (N=15)	
Age, median (range), years	66 (50-74)
Male, n (%)	10 (67)
Disease subtype, n (%)	
CLL	6 (40)
RT	9 (60)
No. of prior therapy lines, median (range)	
Prior BTKi, n (%)	13 (87)
Prior venetoclax, n (%)	12 (80)
Prior BTKi and venetoclax, n (%)	11 (73)
Prior allo-HSCT, n (%)	1 (7)
High-risk features*, n (%)	
17p deletion	3/13 (23)
TP53 mutated	6/13 (46)
Complex karyotype**	3/6 (50)
IGHV unmutated***	13/13 (100)

Data to be presented at ASH 2023 (Tovar N, et al.) ASH poster #2112, 9 Dec 2023 5:30-7:30 PM. Cut-off date: 26 April 2023.

BTKi, bruton tyrosine kinase inhibitors; CLL, chronic lymphocytic leukemia; HSCT, hematopoietic stem cell transplantation; RT, Richter Transformation; IGHV, immunoglobulin heavy chain variable region. \*Information on 17p deletion and TP53 mutation were reported for 13 patients \*\*karotyping was reported for 6 patients. Complex karyotype was defined as 3 or more aberrations \*\*\*IGHV mutation status reported for 13 patients

# Cellular expansion and persistence of GLPG5201

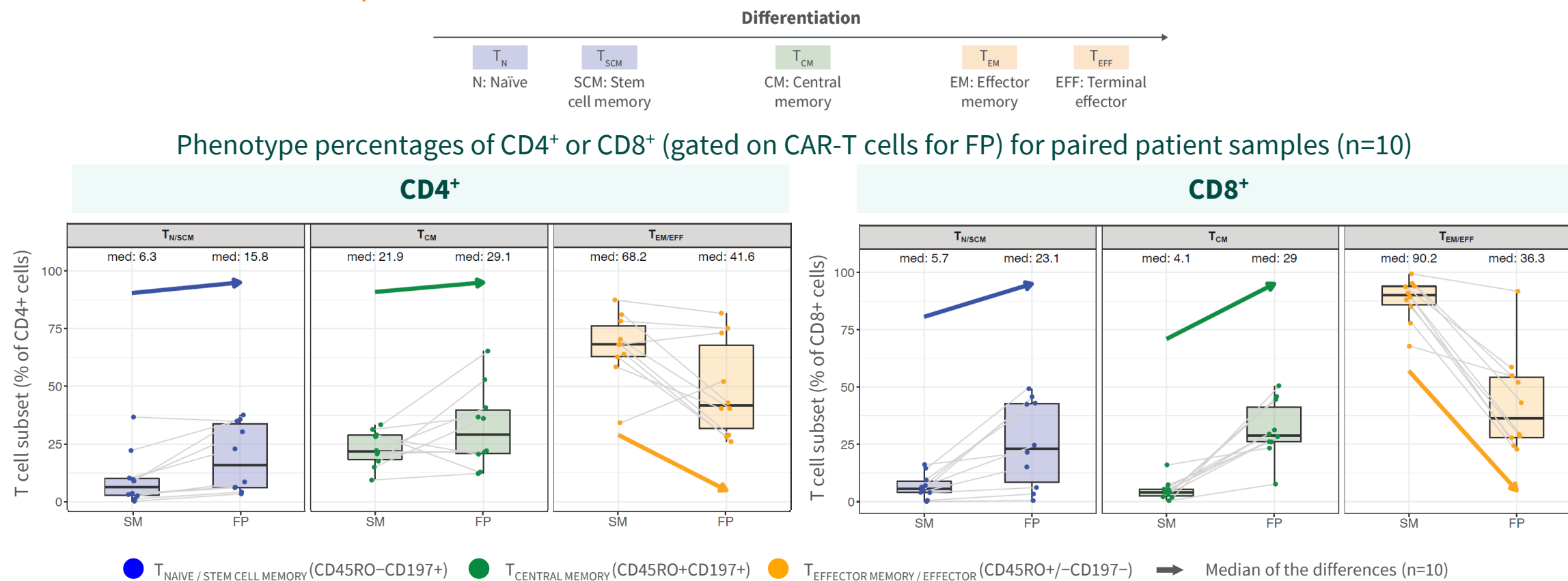
*Robust CAR T-cell expansion observed in all patients*



- GLPG5201 detected in peripheral blood **up to 15 months** post-infusion
- Median time to peak expansion of **14 days**

# GLPG5201 product characteristics

*GLPG5201 enriches frequency of early phenotype (i.e.  $T_{N/SCM}$  and  $T_{CM}$ )  $CD4^+$  and  $CD8^+$  CAR-T cells in final drug product compared to T cells in starting material, in tandem with decrease in  $T_{EM/EFF}$  CAR-T cells*





# Good safety profile with '5201

*EUPLAGIA-1 preliminary Phase 1 results in heavily pretreated patient population*

	All patients N=15
<b>CRS, n (%)</b>	<b>7 (47)</b>
Grade 1/2	7
Grade $\geq 3$	0
<b>ICANS, n (%)</b>	
Any grade	0

● '5201 is well-tolerated

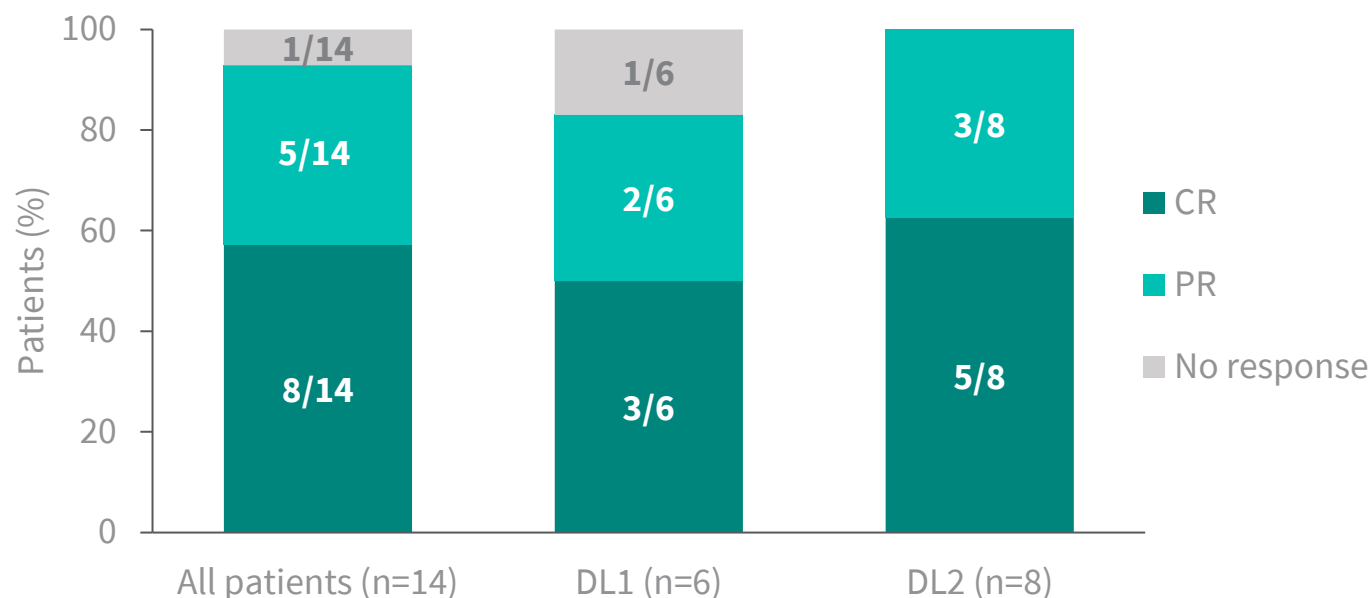
● No CRS  $\geq$  Grade 3

● No ICANS reported

# High clinical activity observed in rrCLL & RT

## *EUPLAGIA-1 preliminary Phase 1 results in heavily pretreated population*

### Best objective response\*



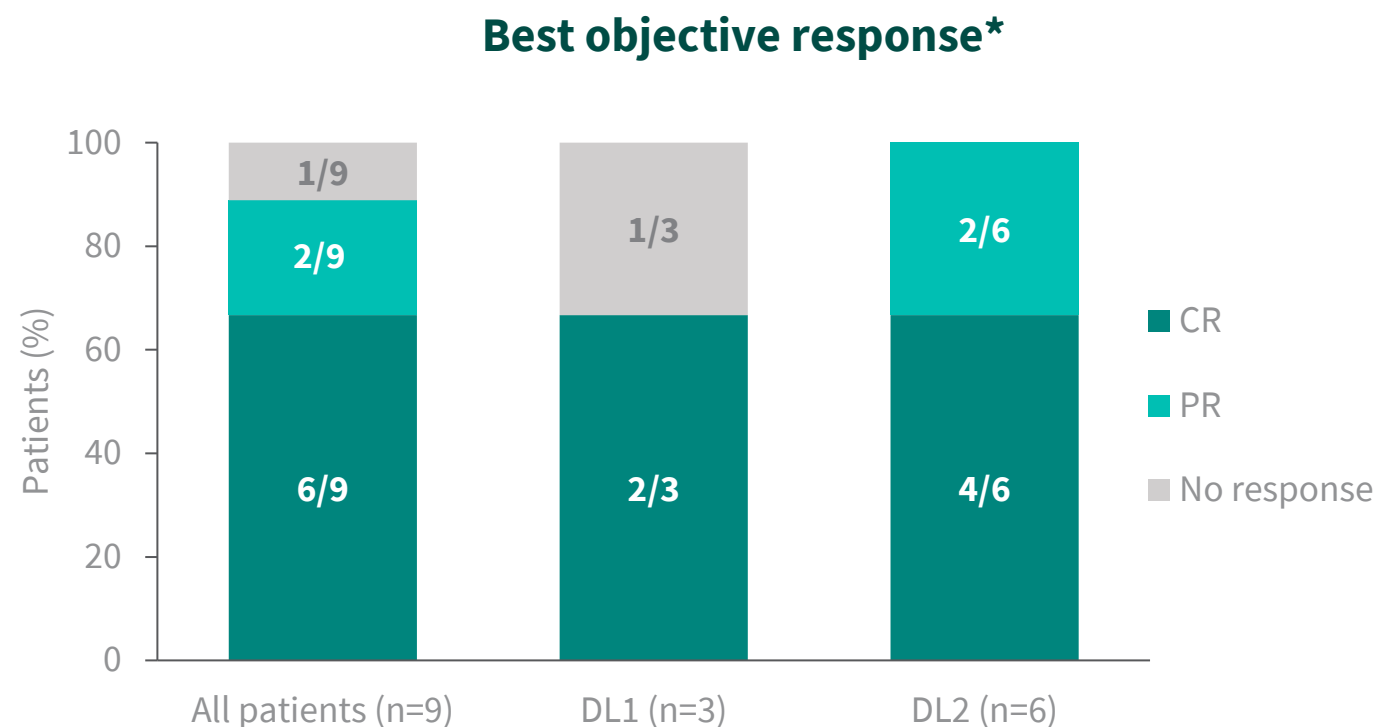
- 13/14 patients responded (**ORR 93%**)
- 8/8 patients on **DL2** responded (**ORR 100%**)
- 8/14 patients reached a complete response (**CRR 57%**)
- 5/8 on **DL2** reached a complete response (**CRR 63%**)

Data presented at ASH 2023 (Tovar N, et al.) ASH poster #2112, 9 Dec 2023 5:30-7:30 PM. Cut-off date: 6 September 2023.

\*Combined response, iwCLL for CLL patients without RT and Lugano classification for patients with RT. DL1: 35E6 CAR-positive viable T cells, DL2: 100E6 CAR-positive viable T cells. CR, complete remission; CRR, CR rate; DL, dose level; ORR, objective response rate; RT, Richter Transformation; PR, partial response; rrCLL, relapsed/refractory chronic lymphocytic leukemia. 1 CLL patient not yet efficacy-evaluable (D28 not reached).

# High clinical activity observed in RT subset

## *EUPLAGIA-1 preliminary Phase 1 results in RT patients*



8 of 9 patients with RT responded (**ORR 89%**)

All 6 RT patients on **DL2** responded (**ORR 100%**)

6 of 9 RT patients reached a complete response (**CRR 67%**)

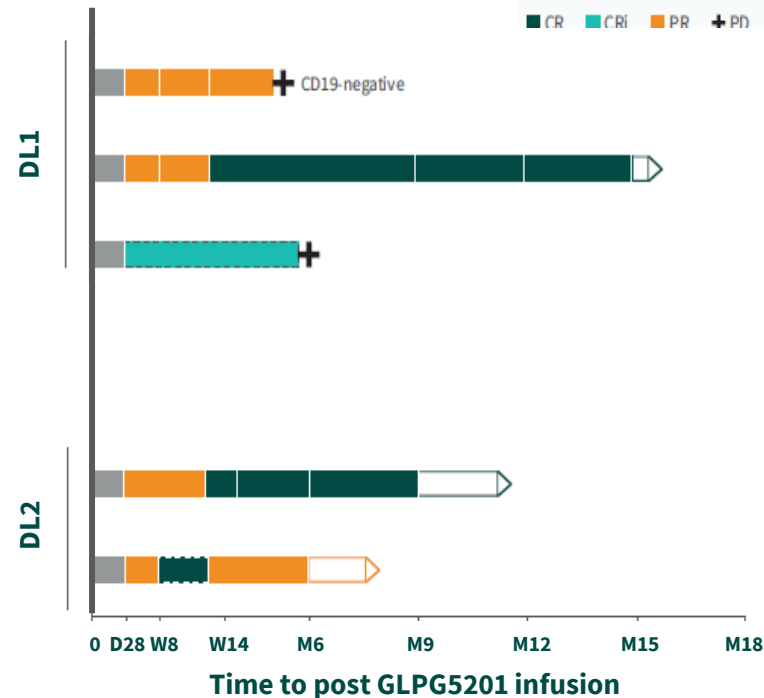
# Initial durability of response in CLL & RT

## *EUPLAGIA-1 preliminary Phase 1 results in heavily pretreated population*

- 14 patients were efficacy-evaluable (D28 reached)
- **13/14 efficacy-evaluable patients responded**
- **10/13 (77%) responding patients had ongoing responses**
- Median DoR not reached
- Median on study follow-up 6 months (range 1-15)
- **3 patients progressed** after initial response

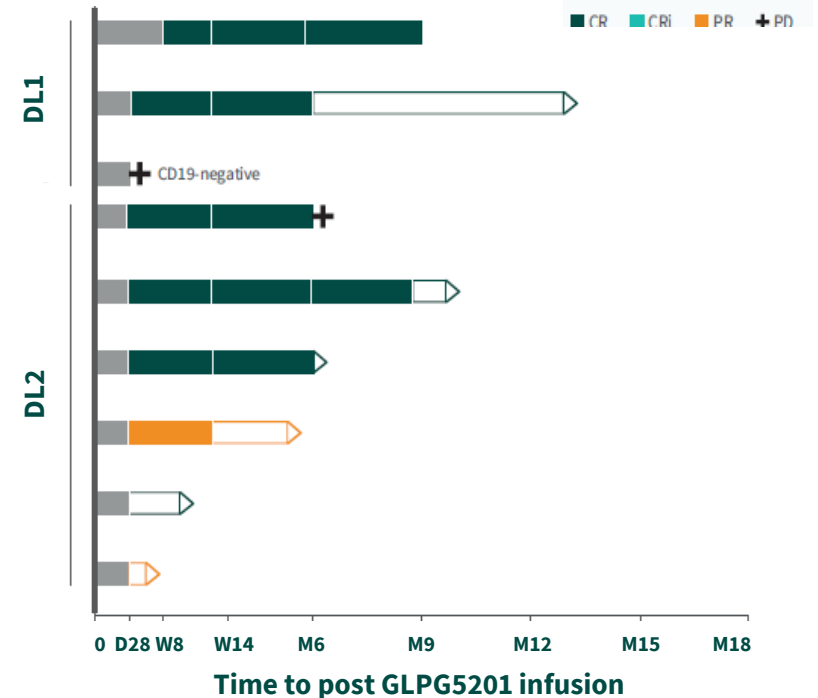
### CLL patients

iwCLL response as per investigator assessment



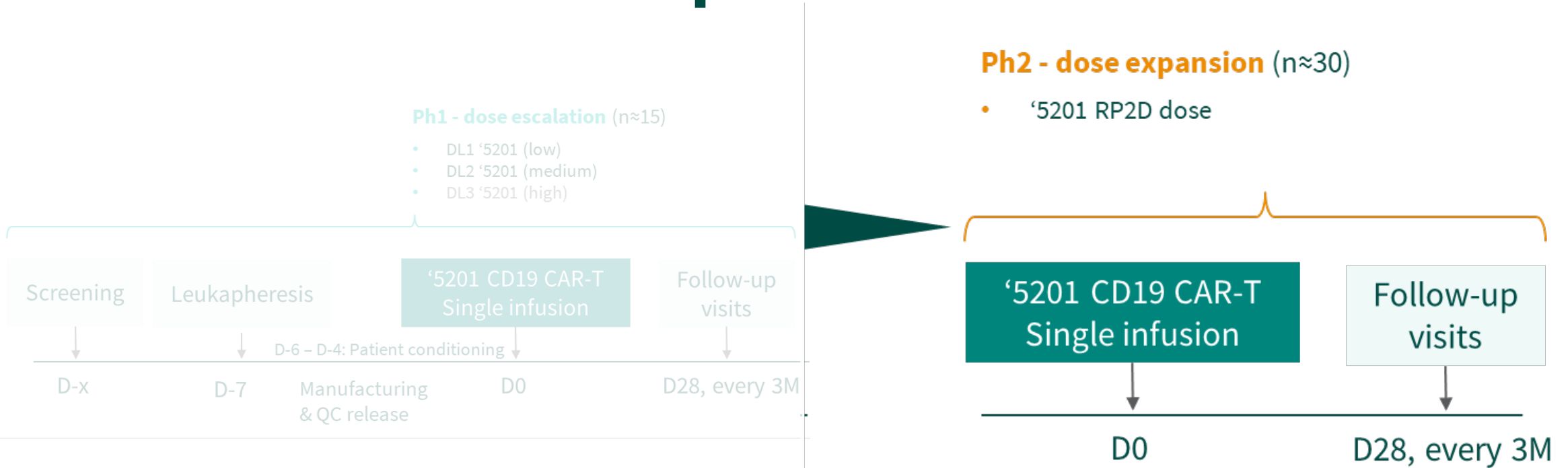
### RT patients

Lugano response as per investigator assessment



Data to be presented at ASH 2023 (Tovar N, et al.) ASH poster #2112, 9 Dec 2023 5:30-7:30 PM. Cut-off date: 6 September 2023.  
iwCLL 2018 criteria for patients with CLL and Lugano classification for patients with RT, as per investigator assessment. Dashed edges indicate a CR or CRi assessed by physical exam as per investigator assessment, not confirmed by imaging. An outlined white bar with leading arrowhead indicates ongoing response beyond last timepoint measured. DoR, duration of response; CLL, chronic lymphocytic leukemia; CR, complete response; CRi, CR with incomplete marrow recovery; iwCLL, International Workshop on CLL; PD, progressive disease; PR, partial response; RT, Richter transformation.

# EUPLAGIA-1 next steps



- **DL2 selected as recommended Phase 2 dose (RP2D)**
- **Initiate Ph2 expansion cohorts in rrCLL and RT**
- **Initiate tech transfer to 1st US site –Landmark Bio, Boston (MA)**
- **IND submission**



# Key opinion leaders on CLL & RT



Prof. M. Davids

Dana Farber Cancer Institute



Prof. P. Ghia

University of Milan, Italy

# Agenda

## 1 Welcome and introduction

## 2 GLPG5201 in CLL & RT

EUPLAGIA-1 Results

Roundtable with Prof. Davids & Prof. Ghia

## 3 **GLPG5101 in NHL**

ATALANTA-1 Results

Roundtable with Prof. Anguille & Prof. Bishop

## 4 Outlook and conclusion

## 5 Q&A

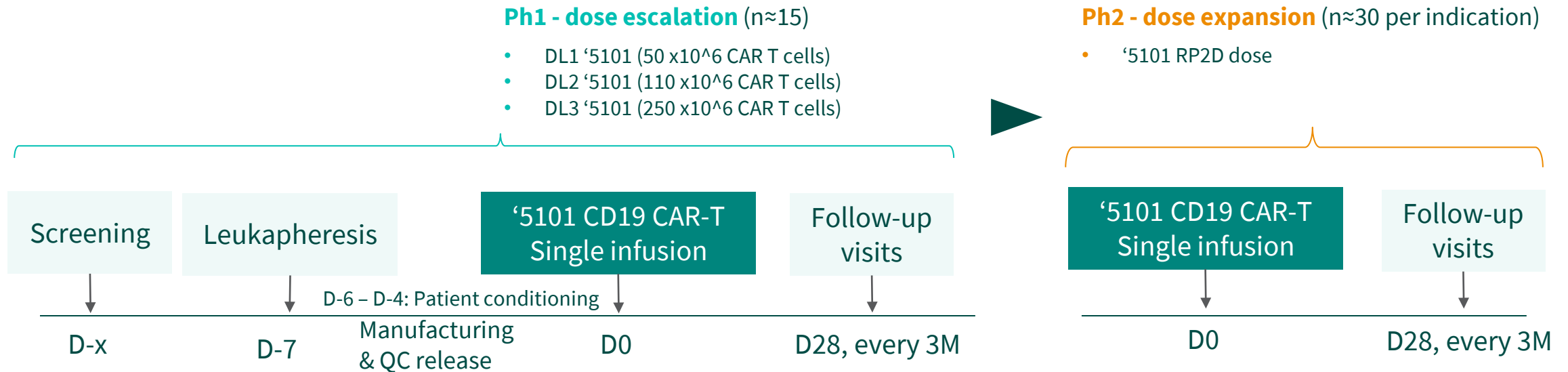
# NHL incidence

	Incidence p.a. (2023)		Potentially CAR-T eligible (2L drug treated)	
	US	E5	US	E5
<b>Non-Hodgkin lymphoma</b>	79,900	70,000	>13,400	>12,000
Diffuse Large B Cell lymphoma <sup>1</sup>	31,800	25,700	8,000	6,700
Follicular Lymphoma <sup>1</sup>	13,800	13,000	4,100	4,000
Marginal Zone Lymphoma <sup>1</sup>	8,800	10,200	NA	NA
Mantle Cell Lymphoma <sup>1</sup>	4,000	3,600	1,300	1,200
Primary CNS Lymphoma <sup>2</sup>	1,400	1,300	NA	NA
Burkitt Lymphoma (sporadic) <sup>3</sup>	1,000	900	NA	NA

(1) CancerMPact, Cerner Envisa 2023; (2) Schaff, LR et al. Blood 2022; (3) Brittney, S et al. StatPearls, NCBI Bookshelf, 2023

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

## '5101 basket trial in DLBCL, MCL, MZL, FL, BL & PCNSL



### Key eligibility criteria

#### Patient population

- r/r DLBCL, MCL, MZL, FL, BL & PCNSL
- ≥ 2 prior lines of therapy, or primary refractory DLBCL or BL
- ≥ 1 prior line of therapy for PCNSL
- Not achieving CR to 2L therapy for BL and PCNSL
- Incl. transplant ineligible
- No prior CD19-targeted therapy allowed

# Baseline characteristics ATALANTA-1

## *Heavily pretreated population of NHL patients*

	Phase 1 (N=14)	Phase 2 (N=9)
<b>Age, median (range), years</b>	<b>65 (50-77)</b>	<b>69 (46-73)</b>
<b>Male, n (%)</b>	<b>11 (79)</b>	<b>4 (44)</b>
<b>Disease subtype, n (%)</b>		
DLBCL	7 (50)	0
FL	3 (21.5)	6 (67)
MCL	3 (21.5)	2 (22)
MZL	1 (7)	1 (11)
<b>IPI/MIPI/FLIPI score; high risk, n (%)</b>	<b>6 (43)</b>	<b>6 (67)</b>
<b>No. of prior therapy lines, median (range)</b>	<b>4 (1-7)</b>	<b>4 (2-11)</b>
<b>ECOG performance status screening, n (%)</b>		
0	6 (43)	4 (44.5)
1	8 (57)	3 (33.5)
2		2 (22)
<b>Prior ASCT, n (%)</b>	<b>6 (43)</b>	<b>3 (33)</b>
<b>Ann Arbor disease stage III-IV, n (%)</b>	<b>13 (93)</b>	<b>6 (67)</b>
<b>Extranodal disease, n (%)</b>	<b>5 (36)</b>	<b>2 (22)</b>

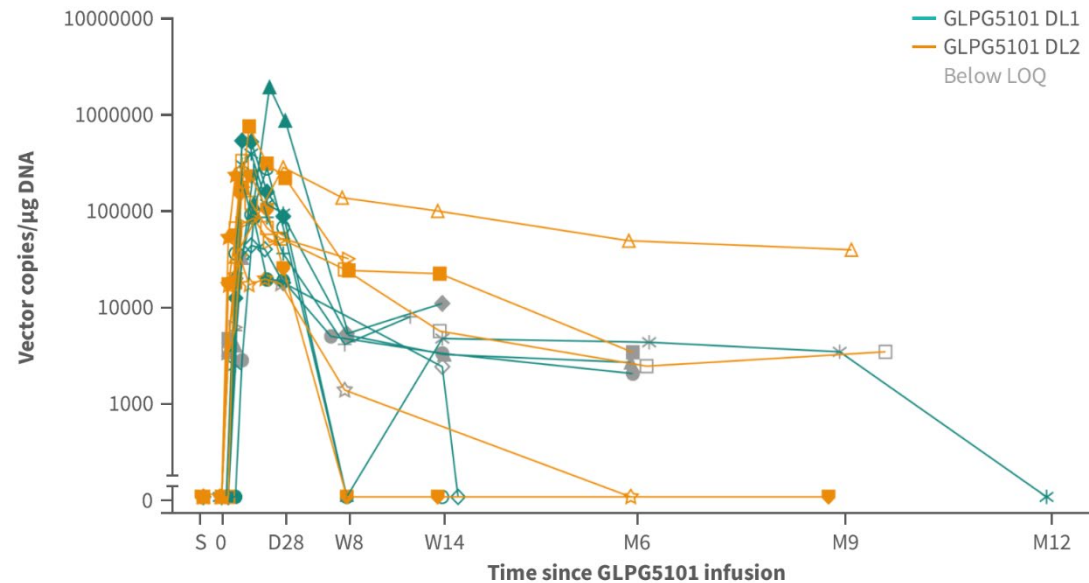


# Cellular expansion and persistence of GLPG5101

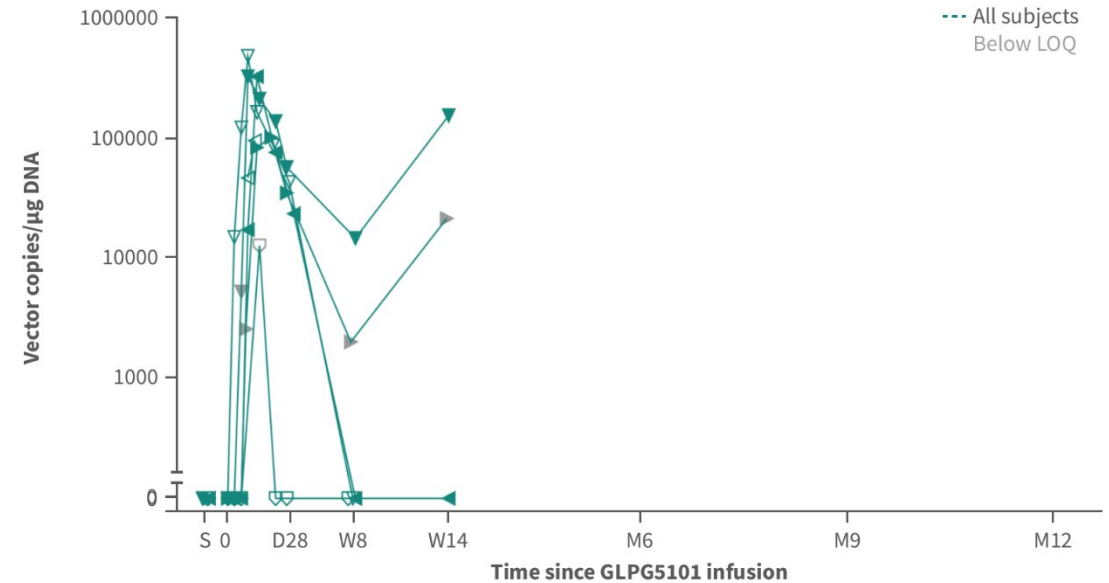
## *Robust CAR T-cell expansion observed across dose levels*

- GLPG5101 detected in peripheral blood up to 9 months post-infusion
- Median time to peak expansion of 14 days

### Phase 1



### Phase 2

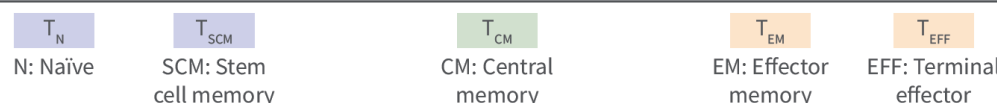


Poster presented at the 2023 ASH Annual Meeting and Exposition; December 09-12, 2023; San Diego, CA.  
Quantification of GLPG5101 in peripheral blood by qPCR. Limit of quantification (LOQ) 1,000 vector copies. Phase 2 target dose is DL2.  
CAR-T, chimeric antigen receptor T cell; DL, dose level; qPCR, quantitative polymerase chain reaction; S, screening.

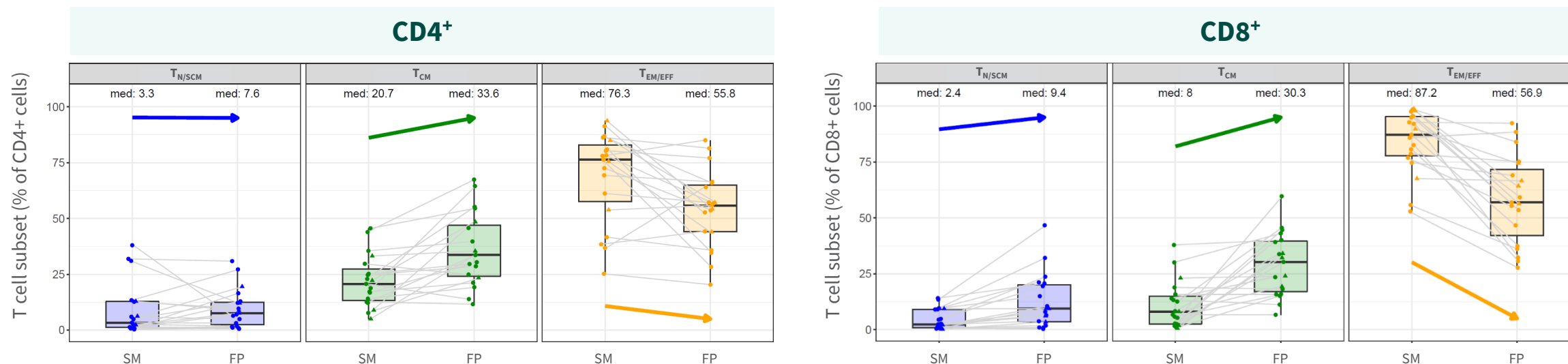
# GLPG5101 product characteristics

*GLPG5101 enriches frequency of early phenotype (i.e.  $T_{N/SCM}$  and  $T_{CM}$ ) CD4+ and CD8+ CAR-T cells in final drug product (FP) compared to T cells in starting material (SM), in tandem with decrease in  $T_{EM/EFF}$  CAR-T cells*

## Differentiation



Phenotype percentages of CD4<sup>+</sup> or CD8<sup>+</sup> (gated on CAR-T cells for FP) for paired patient samples (n=19)



●  $T_{NAIVE/STEM CELL MEMORY}$  (CD45RO-CD197+)    ●  $T_{CENTRAL MEMORY}$  (CD45RO+CD197+)    ●  $T_{EFFECTOR MEMORY/EFFECTOR}$  (CD45RO+/-CD197-)    ➔ Median of the differences (n=19)    ● Phase 1    ▲ Phase 2

# Encouraging safety profile with '5101

## ATLANTA-1 preliminary results in critically ill patient population

	Phase 1 N=14	Phase 2 N=9
<b>CRS, n (%)</b>	<b>7 (50)</b>	<b>3 (33)</b>
Grade 1-2	6	3
Grade 3	1	0
<b>ICANS, n (%)</b>	<b>6 (43)</b>	<b>1 (11)</b>
Grade 1	6	0
Grade 3	0	1
<b>Grade 5 events, n (%)</b>	<b>2 (14)</b>	<b>0</b>

### ● 1 case of Grade 3 CRS

- All other Grade 1-2

### ● 1 case of Grade 3 ICANS

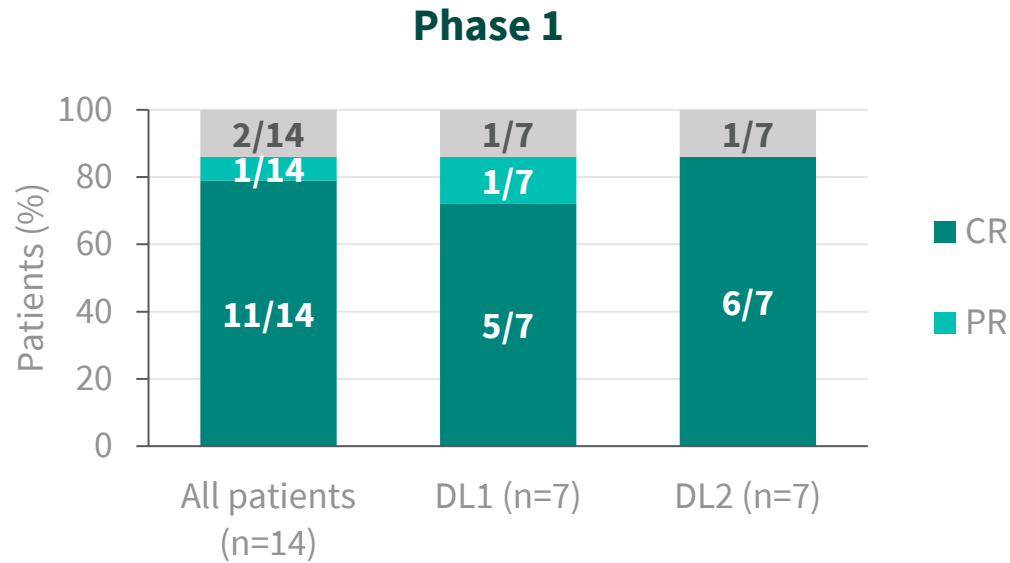
- All other Grade 1

### ● 2 deaths

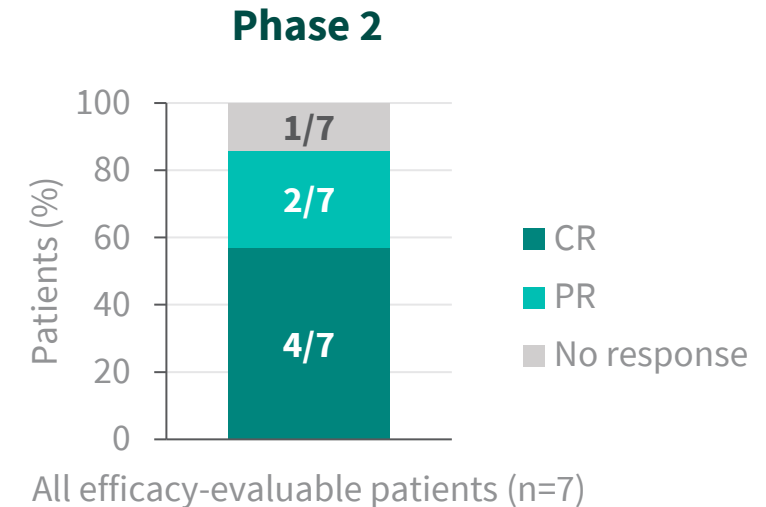
- 1 intra-abdominal hemorrhage\* in patient previously diagnosed with prior thromboembolic disease on LMWH
- 1 urosepsis >6 months post-infusion\*\*

# Encouraging efficacy in r/rNHL

## ATALANTA-1 preliminary results in heavily pretreated population



- 12/14 patients responded (**ORR 86%**)
- 11/14 reached a complete response (**CRR 79%**)
- **CRR of 86% in DL2** (6/7 patients)

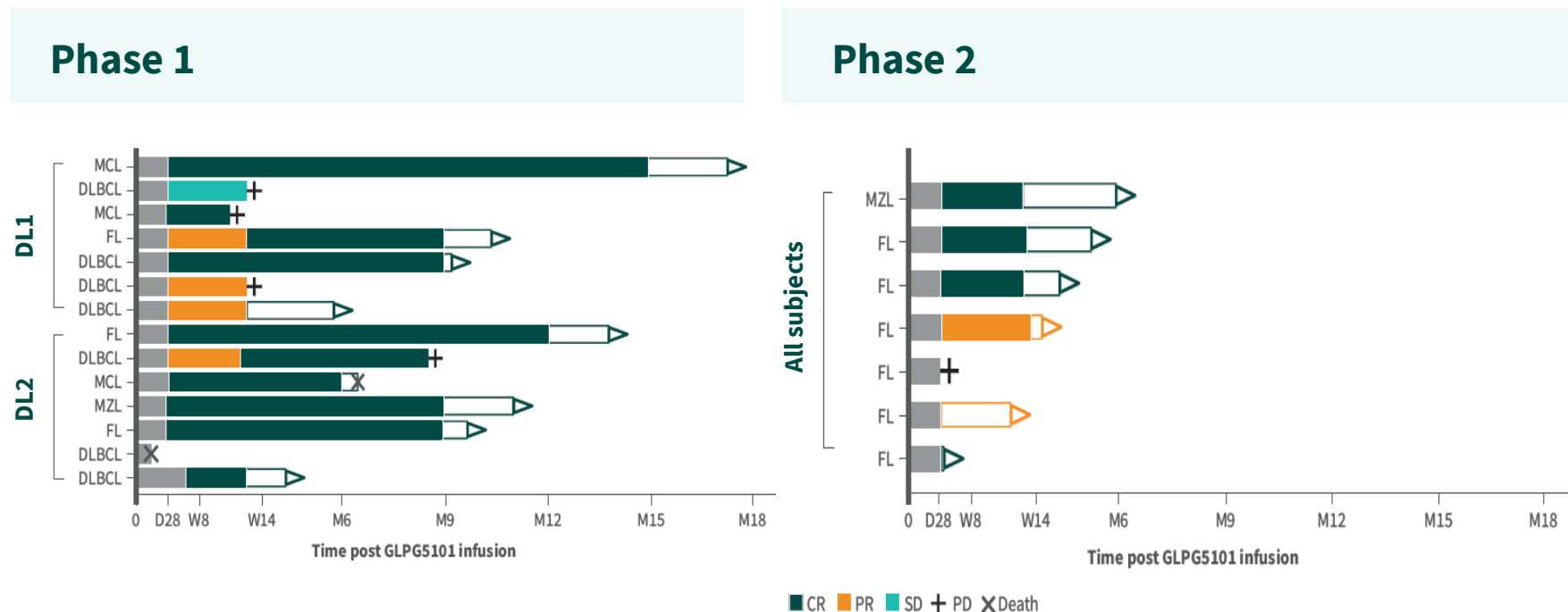


- 7/9 patients were efficacy-evaluable (D28 reached)
- 6/7 patients responded (**ORR 86%**)
- 4/7 reached a complete response (**CRR 57%**)

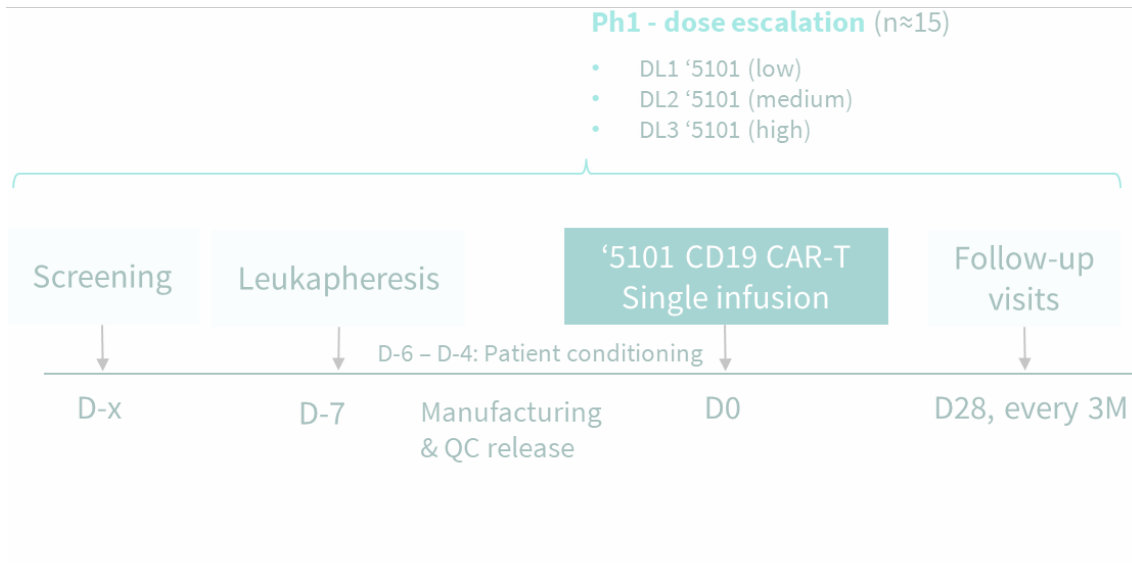
# Initial durability of response in NHL

## ATLANTA-1 preliminary Phase 1 & 2 results in heavily pretreated population

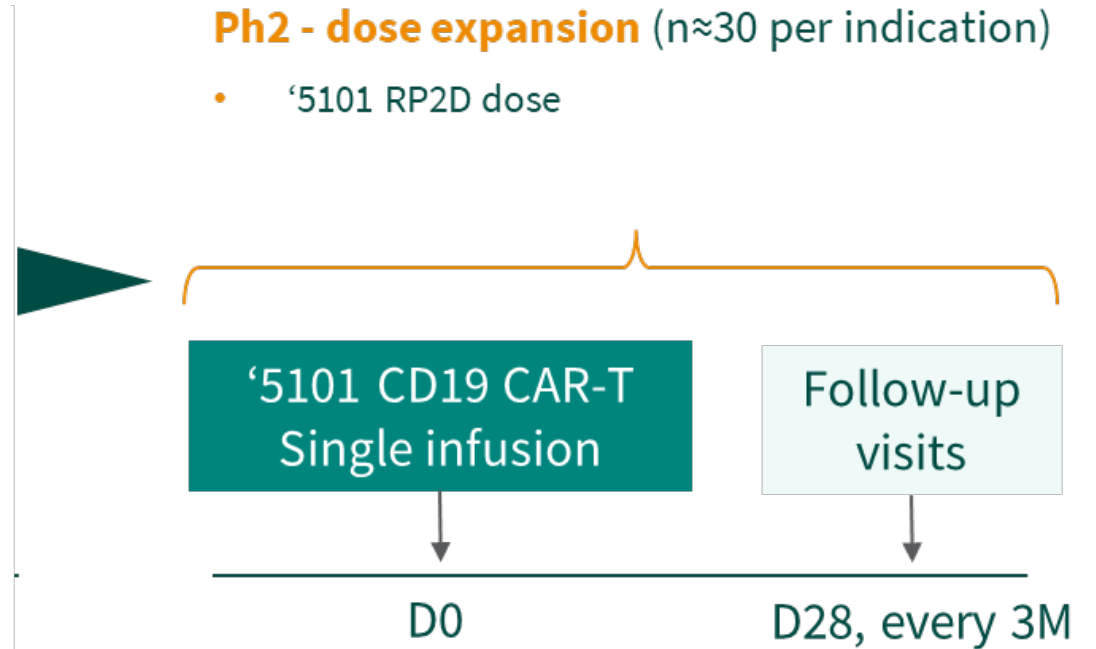
- Median DoR not reached
- Median on study follow-up 8.6 months (range 2.8-15)
- **8/12 responding patients in Ph1 and 6/6 responding patients in Ph2 with ongoing response**
- **In Ph1, 4 patients progressed** after initial response



# ATALANTA-1 next steps



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

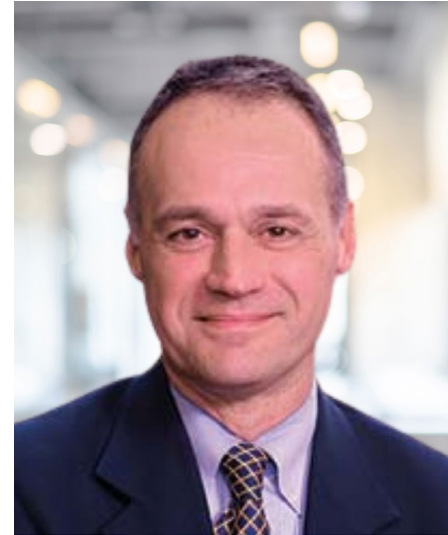


# Key opinion leaders on NHL



Prof. S. Anguille

University of Antwerp, Belgium



Prof. M. Bishop

University of Chicago

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Roundtable with Prof. Anguille & Prof. Bishop

## 4 Concluding remarks

## 5 Q&A



# Innovative decentralized Point-of-Care model offers potential for future of CAR-T therapy

**7 days**  
median  
vein-to-vein

High  
**manufacturing**  
**success rate**

Ability to infuse  
**fresh (non-**  
**frozen) CAR T**  
**product**

Rapid and  
robust  
**expansion**  
observed  
*in vivo*

Preserved **early**  
**phenotype**  
for CD4+ and  
CD8+ CAR T  
cells in final  
drug product

# Agenda

## 1 Welcome and introduction

## 2 GLPG5201 in CLL & RT

EUPLAGIA-1 Results

Roundtable with Prof. Davids & Prof. Ghia

## 3 GLPG5101 in NHL

ATALANTA-1 Results

Roundtable with Prof. Anguille & Prof. Bishop

## 4 Concluding remarks

## 5 Q&A

# #PioneeringForPatients

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