### **UNITED STATES** SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

### FORM 6-K

**REPORT OF FOREIGN ISSUER** PURSUANT TO RULE 13a-16 OR 15d-16 **OF THE SECURITIES EXCHANGE ACT OF 1934** 

For the month of August 2023

(Commission File No. 001-40241)

## LAVA Therapeutics N.V. (Translation of registrant's name into English)

Yalelaan 62 3584 CM Utrecht, The Netherlands (Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F. Form 20-F ⊠ Form 40-F □

EXHIBIT LIST

Exhibit	Description
99.01	Corporate Presentation as of August 15, 2023

#### SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

LAVA Therapeutics, N.V.

(Registrant)

Date: August 15, 2023

By: /s/ Fred Powell

Fred Powell

**Chief Financial Officer** 





Gamma-delta T cell engagers for the development of next-generation cancer therapeutics

Corporate Presentation August 2023

#### Legal Disclosure: Forward-looking Statements

This presentation contains statements that constitute forward-looking statements. Many of the forward-looking statements contained in this presentation can be identified by the use of forward-looking words such as "anticipate," "believe," "could," "expect," "should," "plan," "intend," "estimate" and "potential," and similar terms and phrases. Forward-looking statements appear in a number of places in this presentation and include, but are not limited to, statements regarding our intent, belief or current expectations. Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management. Such statements are subject to risks and uncertainties, and actual results may differ materially from those expressed or implied in the forward-looking statements due to various important factors. These risk and uncertainties include, among other things, the potential use of our product candidates to treat various tumor targets; the timing and results of our research and development programs, preclinical studies and clinical trials, including the availability of data therefrom, expectations regarding enrollment in clinical trials, the timing of our clinical trial for LAVA-1207, and the submission of INDs or CTAs for our other product candidates; the expected safety profile of LAVA's product candidates; our ability to develop and obtain regulatory approval for and commercialize any of our product candidates; the ability of low-dose interleukin-2 to increase the number of Vy9V82 T cells available for engagement by LAVA's product candidates: the ability of LAVA's collaborators to support or advance collaborations or our product candidates; any payments to us under our license agreement with Seagen or our agreements with our collaborators and our cash runway; our ability to leverage our initial programs to develop additional product candidates using our Gammabody® platform; and the risk that positive results in a preclinical study or clinical trial may not be replicated in subsequent trials or success in early stage clinical trials may not be predictive of results in later stage clinical trials. In addition, there may be adverse effects on our business condition and results from general economic and market conditions and overall fluctuations in the United States and international equity markets, including deteriorating market conditions due to investor concerns regarding inflation and hostilities between Russia and Ukraine, and recent and potential future disruptions in access to bank deposits or lending commitments due to bank failures. For a discussion of other risks and uncertainties, and other important factors, any of which could cause our actual results to differ from those contained in the forward-looking statements, see the "Risk Factors" section, as well as discussions of potential risks, uncertainties and other important factors, in the filings we make with the Securities and Exchange Commission from time to time.

Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. Although we believe that we have a reasonable basis for each forward-looking statement contained in this presentation, the events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements.

Any forward-looking statements represent the Company's views only as of the date of this presentation and do not represent its views as of any subsequent date. The Company explicitly disclaims any obligation to update any forward-looking statements. By attending this presentation, you acknowledge and agree that you are cautioned not to place undue reliance on any forward-looking statements, and that you will conduct your own analysis and be solely responsible for forming your own view of the potential future performance of the Company.



## Pioneering Next-Generation Cancer Therapeutics

	<ul> <li>Leverage the unique quality of Vγ9Vδ2 T cells to selectively kill tumor cells</li> <li>Gammabody<sup>®</sup> combines potent tumor cell killing with no activation of suppressive regulatory T cells, low</li> </ul>
	potential for on-target/off-tumor toxicity and cytokine release syndrome
Cli	nical stage company
• 1	LAVA-1207 (PSMA) Phase 1/2a trial for mCRPC enrolling. Most recent data released at ASCO GU Feb 2023
-	<ul> <li>Favorable safety profile to date, preliminary signs of anti-tumor activity were observed</li> </ul>
• 1	LAVA-051 (CD1d) Phase 1a no longer recruiting and will be discontinued after no patients remain on treatment
	<ul> <li>Trial showed favorable safety profile and initial anti-tumor activity in patients with relapsed and refractory chronic lymphocytic leukemia and multiple myeloma</li> </ul>
Ro	bust pipeline
• 5	Seagen: licensed SGN-EGFRd2 (LAVA-1223) IND cleared
• .	Janssen: licensed undisclosed Gammabody <sup>®</sup> candidate; Onboarded June 2023
• 1	LAVA-1266 (CD123) IND/CTA enabling activities ongoing, expected to be ready 1H 2024
• 1	Multiple preclinical programs
So	lid financials
	\$112.4M (Q2 2023) in cash, cash equivalents and investments; cash runway into 2026

## Gammabody<sup>®</sup> Pipeline: Potential in Hematological and Solid Tumor Indications

Candidate	Target	Indication(s)	Discovery	Preclinical	Phase 1	Phase 2	Anticipated Milestones & Recent Updates
LAVA-1207	PSMA	mCRPC					<ul> <li>Most recent data released: ASCO GU 1Q 2023</li> <li>Next data release expected within 12 months</li> </ul>
LAVA-051	CD1d	MM CLL AML					<ul> <li>Enrollment has been discontinued</li> <li>Complete Phase 1 clinical trial data to be presented when final patients end treatment</li> </ul>
SGN-EGFRd2 (LAVA-1223)	EGFR	Solid Tumors			<b>OSeager</b>	r	<ul> <li>Licensed to Seagen 3Q 2022</li> <li>IND cleared</li> <li>Phase 1 Study in Advanced Solid Tumors expected to begin 2023</li> </ul>
Janssen Collaboration		undisclosed		Ja	nssen		Lead candidate selected by Janssen 2Q 2023
LAVA-1266	CD123	Hematologic Malignancies					<ul> <li>IND/CTA enabling activities ongoing, expected to be ready 1H 2024</li> </ul>
LAVA-1278	CD40	Hematologic Malignancies					
AML: acute myeloi PSMA: prostate-spe EGFR: epidermal gr	phocytic leuke id leukemia cific membrar owth factor re	mia ne antigen	atologic malignanc	cy 💹 Discontir	nued <mark>S</mark> olid	Tumor	Undisclosed
©LAVA Therapeutics 202	3						4

### Team Led by Experienced Leaders in the Biotech and Pharma Field



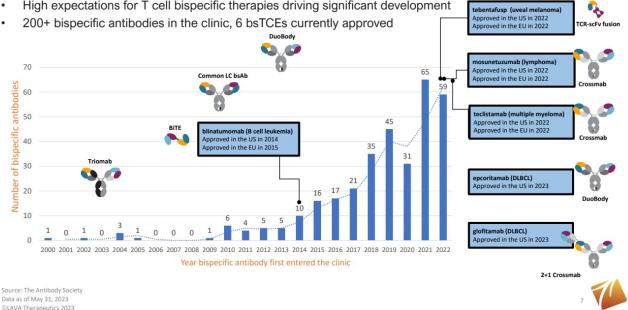
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LAVA's Proprietary Gammabody® Platform Bispecific Gamma-Delta T Cell Engagers



### **Enthusiasm for Bispecific T Cell Engagers**

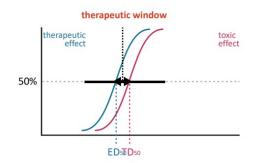
- High expectations for T cell bispecific therapies driving significant development •
- 200+ bispecific antibodies in the clinic, 6 bsTCEs currently approved

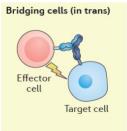


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## Enthusiasm for Bispecific T Cell Engagers

- High expectations for targeted T cell therapies in cancer, but often:
  - Narrow therapeutic window:
  - Cytokine Release Syndrome
  - On-target/off-tumor-related toxicities
  - Activates immunosuppressive T cells
  - Sporadic efficacy in solid tumors

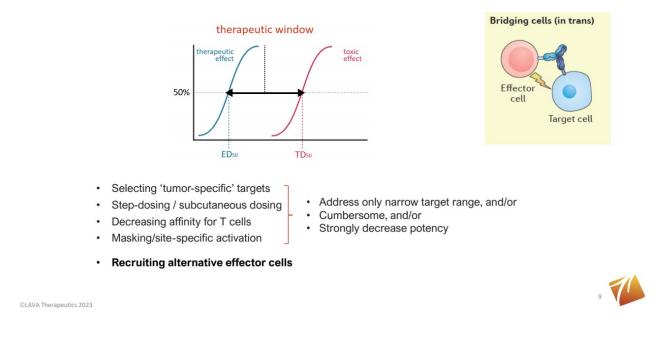






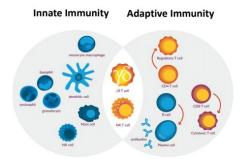
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## Strategies for Widening the Therapeutic Window



### **Bispecific** γδ T cell-engagers aim to harness innate & adaptive immunity

- Largest γδ-T cell subset in blood: (~90-95% of total γδ-T cells)
- · Natural ability to recognize and kill tumor cells
- Presence of  $\gamma\delta$  T cells associated with improved outcomes in cancer patients
- Recognize tumors through phosphoantigen-BTN2A1/3A1 complex
- · Consistent pro-inflammatory cytotoxic effector T cell population

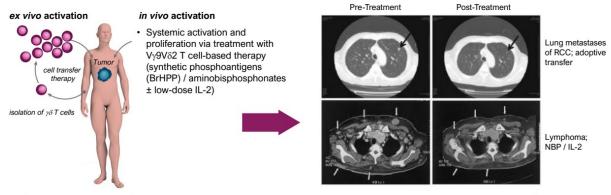


Adapted from Dranoff G., Nature Rev. Cancer 2004; 4: 11-22



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#### Systemic Activation of $V\gamma 9V\delta 2$ T Cells Showed Promise



- · Clinical trials with in/ex vivo activation protocols showed promising objective responses and safety
- No signs of high grade cytokine release syndrome (CRS) as a result of  $V\gamma 9V\delta 2$  T cell activation

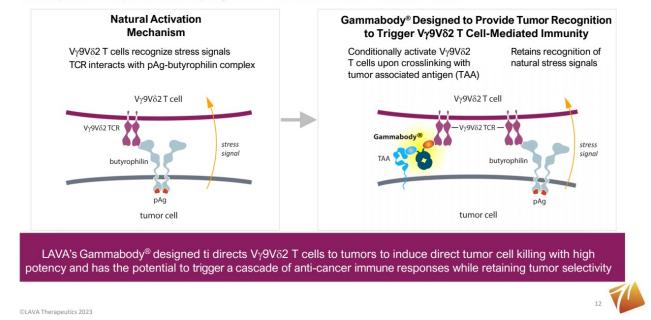
Early attempts with Vγ9Vδ2 T cell-based therapy showed promise, but efficacy may have been limited by systemic, non-tumor specific activation of Vγ9Vδ2 T cells and exhaustion

Kobayashi H et al., Cancer Immunol Immunother 2011; 60: 1075-1084 Wilhelm M et al., Blood 2003; 102: 200-206

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## Off-the-Shelf Gammabody® Platform: Designed to Enhance Innate Tumor Recognition by Directing V $\gamma$ 9V $\delta$ 2 T Cells to the Cancer Cells



## Cascade of Anti-Cancer Responses – Potential Translation to Favorable Therapeutic Window

#### Efficacy:

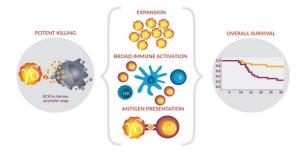
- Potent killing of cancer cells (EC<sub>50</sub>s in the low picomolar range)
- No co-activation of immune-suppressive Tregs which dampen antitumor efficacy of cytotoxic T cells
- Orchestrate innate and adaptive immune responses, potentially resulting in potent and durable responses
- Activity against hematologic malignancies and solid tumors, including immunologically "cold" tumors
- Potential for expansion of Vγ9Vδ2 T cells can result in an increased number of anti-tumor Vγ9Vδ2 T cells in the tumor

#### Safety:

- · Conditional activation with high accuracy
- Greatly reduced potential for cytokine release syndrome (CRS); No evidence of CRS in NHP studies

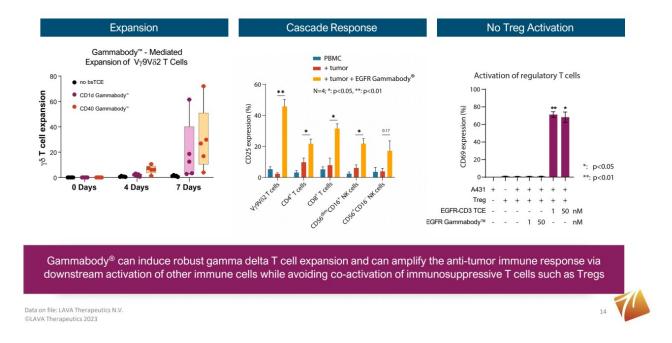
Adapted from Dranoff G, Nature Rev Cancer 2004; 4: 11-22 Kabelitz D et al., Cell Mol Immunol 2020; 17: 925–939

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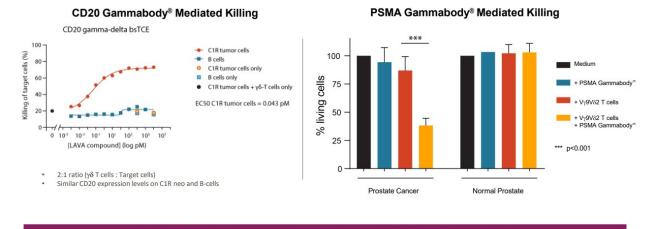




### **Expansion & Cascade Response Without Treg Activation in Preclinical Models**



## Gammabody<sup>®</sup> Can Selectively Kill Cancer Cells While Sparing Healthy Cells in Hematologic Malignancy and Solid Tumor models



Preferential killing of cancer versus healthy cells demonstrated *in vitro* and *ex vivo*; May prevent on-target/off-tumor mediated toxicity and allow for targeting of widely expressed tumor associated antigens

Data on file: LAVA Therapeutics N.V. ©LAVA Therapeutics 2023

## LAVA-1207

Gammabody<sup>®</sup> Designed to Activate  $V_{\gamma}9V_{\delta}2$  T Cells by Targeting PSMA for the Treatment of mCRPC



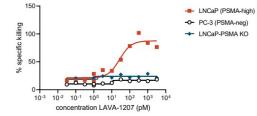
#### LAVA-1207: PSMA-targeting Gammabody® for Prostate Cancer

#### Format

- · Contains a Fc domain for extended plasma half-life; silenced to avoid off-target T cell activation
- · Small size (compared to regular IgG antibodies) to facilitate tumor penetration

#### **Mechanism of Action**

- Specifically directs  $V\gamma 9V\delta 2$  T cells to PSMA-expressing tumor cells – PSMA is a well-validated tumor target
- · Mediates potent killing of PSMA-positive tumor cells
- · Preclinical data support mechanism of action, anti-cancer activity & selectivity



#### Status

• Phase 1/2a trial in mCRPC; patient recruitment ongoing (NCT05369000)

Data on file: LAVA Therapeutics N.V ©LAVA Therapeutics 2023





### **Prostate Cancer Epidemiology**

#### **Prostate Cancer**

- Most frequently diagnosed cancer in males (estimated 288,300 in the United States in 2023)
- Second leading cause of cancer deaths in males (estimated 34,700 in the United States in 2022)
- ~50,000 prevalent cases mCRPC
- 5-year survival mCRPC ~30%
- Est. CRPC market value ~\$11 billion in 2023

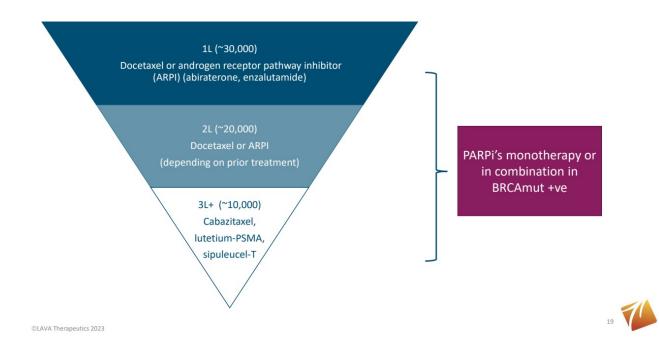
#### **PSMA**

- Overexpressed in >90% prostate cancers; low expression normal tissues
- Increased expression mCRPC vs CSPC
- · Higher levels negatively correlated with survival outcomes
- · Clinically validated Pluvicto (lutetium-177-PSMA-617 radioligand) FDA approved March 2022

Cancer.Net<sup>®</sup> FMI (Future Market Insights) ©LAVA Therapeutics 2023



## mCRPC – Existing Treatment Options



## PSMA-Selected Targeted Agents Landscape

Drug	Study	Patient Population	N	Clinical Results	Common Adverse Events	Current Status			
<sup>177</sup> Lu-PSMA vs BSOC	VISION	mCRPC post 1+ ARPI and 1+ taxane	551 vs 280	ORR: 30 vs 2% PSA50: 46 vs 7 % Median OS: 15.3 vs 11.3 mo Median rPFS: 8.7 vs 3.4 mo	Fatigue (43%), dry mouth (39%), nausea (35%), anemia (32%), decreased appetite(21%)	Approved			
<sup>177</sup> LU-PNT2002	SPLASH	Prior ARPI. No prior chemo	27	PSA50: 42%	Dry mouth (25.9%), nausea (18.5%), fatigue (18.5%), hematuria and anemia (11.1%)	Phase 3 Fast-track designation			
Anti-PSMA bispecifics									
AMG160 Anti-PSMAxCD3	Phase 1	mCRPC post-ARPI9s) and taxane(s)	35	PSA50: 34.3% ORR: 13.3%	CRS (84%)	Discontinued Replaced by AMG340			
JNJ-63898081 Anti-PSMAxCD3	Phase 1	CRPC, 1+ prior therapies	39	PSA50: 2/39 (5.1%)	Pyrexia (69.2%), CRS (66.7%), chills (46.2%), fatigue (41.0%)	Discontinued			
HPN-424 Anti-PSMA xCD3xalbumin	Phase 1/2a	mCRPC >2 prior systemic therapies	80	PSA50: 3/80 (3.8%) Treatment >24 weeks: 24%	CRS (63%) Grade 3+ AEs: AST increase (18%), ALT incr. (11%), anemia (11%)	Discontinued			
REGN5678 + cemiplimab Anti-PSMAxCD28	Phase 1/2	CRPC, two prior lines including an ARPI	35	ORR: 3/8 evaluable PSA50: 4/35 (11.4%)	CRS 6/35 (17.1%) irAEs <u>&gt;g</u> rade 3: 4/35 (11.4%)	Continuing dose escalation			

### LAVA-1207 – Phase1/2a Study Design

- Dose escalation in patients with mCRPC (EudraCT 2021-001789-39; NCT05369000)
- Primary objectives: investigate safety and tolerability of LAVA-1207
- · Secondary objectives: evaluate PK, PD, immunogenicity and preliminary signs of antitumor activity
- · LAVA-1207 administered via IV infusion every 2 weeks
- Investigating combination with low dose IL-2



## LAVA-1207 – Patient Baseline Characteristics

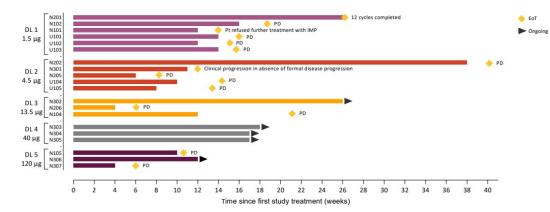
Patient Baseline Characteristics						
Age, median (range)	68 (51-76)					
Years since diagnosis, median (range)	9 (3-21)					
Prior systemic therapies, median (range)	4 (3-10)					
Location of metastases						
Bone	19					
Lymph node	14					
Lung	2					
Liver	5					
Other visceral	2					
Type of progression						
PSA	17					
Bone	12					
Nodal	12					
Visceral	10					

N=20

Data cut-off date: 8 Dec 2022



### LAVA-1207 - Time on Treatment

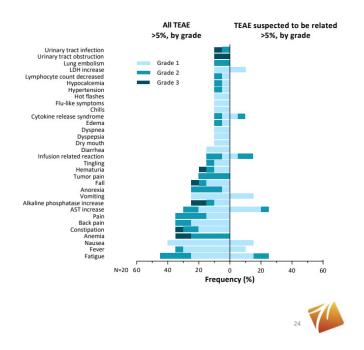


- · Patients were treated with LAVA-1207 with treatment duration ranging from 4 to 38 weeks
- Subsequent to ASCO GU 2023 presentation, LAVA has completed recruitment for dose levels 6 (± IL-2) and 7 monotherapy
- Data cut-off date: 8 Dec 2022

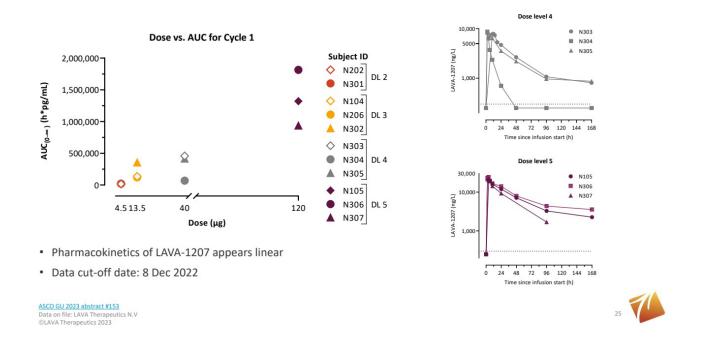


#### LAVA-1207 – Initial Phase 1 Data - Safety

- Favorable safety profile to date, with no occurrence of high-grade (>2) cytokine release syndrome or dose-limiting toxicities
- Most observed AEs not suspected to be related and no DLT
- Treatment emergent AEs (TEAEs) that were suspected to be related were grade 1 or 2
- No increase in severity or frequency of TEAEs with increasing doses and no patient discontinued treatment due to AE
- One grade 4 AE occurred (spinal cord compression, DL 5), which was non-related
- Data cut-off date: 8 Dec 2022

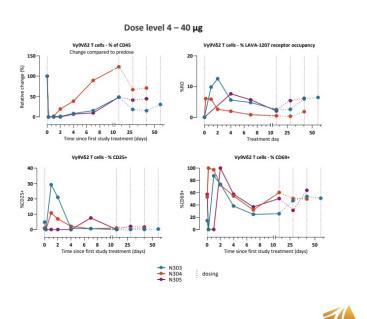


### LAVA-1207 – Pharmacokinetics



#### LAVA-1207 – Pharmacodynamics

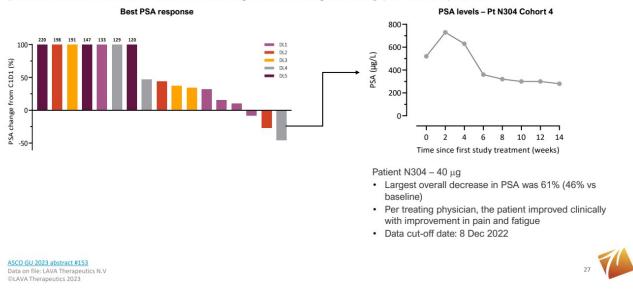
- Pharmacodynamics reflect changes expected as per MoA
  - Pronounced drop in Vγ9Vδ2-T cell frequency 2 hr after dosing, suggesting Vγ9Vδ2-T cell re-distribution, with subsequent recovery
  - Vγ9Vδ2-T cell activation markers (CD25 and CD69) upregulated following dosing
  - Receptor occupancy detectable up to day 14 after Eol, with peak levels ranging from 6.1% to 12.6%
- Data cut-off date: 8 Dec 2022



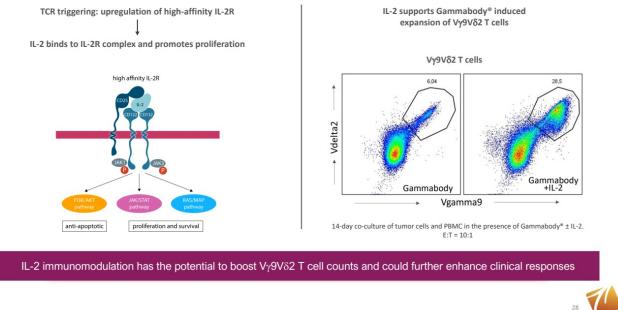
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### LAVA-1207

Preliminary signs of anti-tumor activity were observed, with iRECIST stable disease (iSD) in 8 out of 14 evaluable patients at week 8 and PSA levels stabilizing or decreasing in heavily pre-treated patients



### Addition of IL-2 supports Gammabody® induced Vy9V\delta2 T cell proliferation



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#### **Summary of Initial Phase 1 Data**

- LAVA-1207 reached a dose of 120 μg (starting dose 1.5 μg) without the occurrence of high-grade (>2) CRS or DLTs in therapy refractory mCRPC patients
  - Frequency and severity of AEs do not appear to be dose-dependent
  - Most observed AEs were not suspected to be related
- Preliminary signs of clinical activity observed with disease stabilization and PSA reduction during dose escalation
- · Pharmacodynamics reflect changes as expected per MoA
- · Dose escalation continues in both Europe and the United States
- · IL-2 immunomodulation will be explored in additional parallel cohorts
- · Expect to release data within 12 months





## LAVA-051

Targets CD1d to Activate  $V\gamma 9V\delta 2$  T Cells and iNKT Cells for the Potential Treatment of CLL, MM & AML



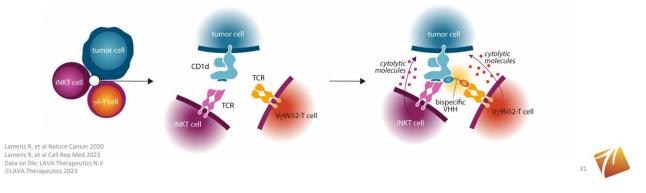
## LAVA-051: First-in-Class Gammabody® Targeting CD1d

#### Format

- · Humanized bispecific single domain antibody (bsVHH) of 27kDa
  - Short plasma half-life, prolonged functional half-life through high affinity TCR binding

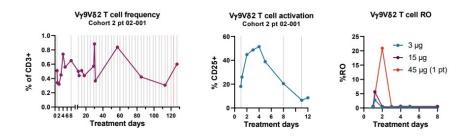
#### **Mechanism of Action**

- Engages  $V\gamma 9V\delta 2$  T cells to mediate potent killing of CD1d-expressing tumor cells
  - CD1d is expressed on tumor cells in CLL, MM and AML
  - Activates iNKT cells to mediate the killing of CD1d-expressing tumor cells as a secondary mechanism of action
  - Preclinical data support mechanism of action, anti-cancer activity, effector cell expansion and tumor selectivity



#### LAVA-051 – Phase 1 Data Confirms MoA in Patients with MM and CLL

- · Favorable safety profile in doses up to 200µg
  - No CRS and no ICANS (ASTCT) and no clinically relevant increase in the CRS-related cytokine IL-6



- · Pharmacodynamic parameters reflect changes expected for the LAVA-051 mechanism of action
  - Vγ9Vδ2 T cell activation markers (CD25 and CD69) upregulated following dosing
  - Maximum  $V\gamma 9V\delta 2$  T cell receptor occupancy (RO) increased with escalating dose
  - iNKT cell activation was assessable, and observed, in one patient
- Data cut-off date: 11 Nov 2022

ASCO 2022 abstract 2577; ASH 2022 abstract #2014 Data on file: LAVA Therapeutics N.V ©LAVA Therapeutics 2023

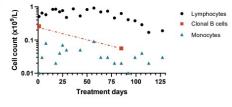


### LAVA-051 – Potential Signs of Activity

#### CLL

- Patient with R/R CLL (15 μg)
- Temporary enlargement and tenderness of several involved lymph nodes accompanied by grade 2 fever during Cycle 1
- Resembled a tumor-flare reaction, as reported in CLL with lenalidomide
- Patient assessed as having stable disease
- · Percent of clonal B cells in peripheral blood decreased
- · Numbers of CD1d expressing monocytes remained similar





#### EHA 2002 abstract #1463 R/R = Relapsed/Refractory Permission for photo obtained Data on file: LAVA Therapeutics N.V ©LAVA Therapeutics 2023

#### MM

- High-risk MM patient (45 μg)
- 4 prior lines of therapy within 6 years from diagnosis
- · Refractory to last 3 lines of treatment
- 23% reduction in M-protein

Both patients ceased treatment due to COVID-19



### LAVA-051 – Preliminary Conclusions

- Phase 1 trial supports MoA and safety of the Gammabody<sup>®</sup> platform
  - Binding and activation of  $V\gamma9V\delta2$  T cells and associated effects on tumors
- · Trial for relapsed or refractory CLL and MM to be discontinued
  - Trial ended due to challenging enrollment; highly competitive space
  - No safety concerns contributing to decision to discontinue the study
  - No longer recruiting
  - Will be terminated when all patients have completed treatment
  - Complete Phase 1 clinical trial data to be presented when final patients end treatment





## SGN-EGFRd2 (LAVA-1223) – Licensed to Seagen

Gammabody<sup>®</sup> for the treatment of EGFR-expressing solid tumors



#### SGN-EGFRd2 (LAVA-1223) – EGFR-Targeting Gammabody®

#### Format

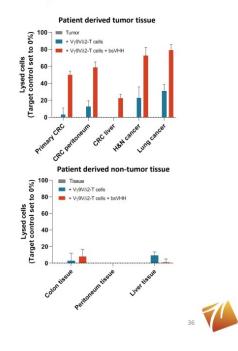
Gammabody<sup>®</sup> containing a silenced Fc domain

#### **Mechanism of Action**

 Induces preferential lysis of EGFR-expressing tumor cells while relatively sparing EGFR-expressing normal cells

#### Status

- IND cleared
- Phase 1 Study in Advanced Solid Tumors expected to begin 2023
- · Exclusive worldwide license agreement with Seagen Inc.
- Seagen to develop and commercialize SGN-EGFRd2 (LAVA-1223); potential for milestones of up to approximately \$650 million and royalties



King L, et al. Cancer Immunol Res 2023, in press Data on file: LAVA Therapeutics N.V ©LAVA Therapeutics 2023 – Licensed to Seagen

## Janssen Collaboration

Lead Candidate in Development Toward Clinic



#### **Janssen Collaboration**

- Lead candidate, aimed at an undisclosed tumor-associated antigen, has been chosen for further development toward clinical studies
  - In May 2020, LAVA entered into a research collaboration and license agreement with Janssen for the discovery and development of a novel bispecific gamma-delta T cell engager for the treatment of cancer
- Janssen is responsible for the future clinical development, manufacture, and commercialization of the candidate at Janssen's sole cost and expense
- Product candidate onboarded June 2023
- LAVA is eligible to receive development, regulatory and commercialization milestone payments and royalties

Data on file: LAVA Therapeutics N.V ©LAVA Therapeutics 2023 – Licensed to Janssen



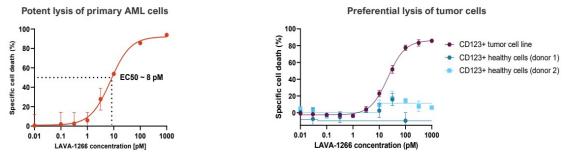
## LAVA-1266

CD123 Targeting Gammabody<sup>®</sup> for the Treatment of Hematologic Malignancies



### LAVA-1266: CD123-Targeting Gammabody®

- In Development for Treating Hematological Malignancies
- · Mechanism of Action
  - Induces preferential lysis of CD123-expressing tumor cells while relatively sparing CD123-expressing normal cells
    - CD123 is overexpressed in a wide range of hematological malignancies



#### Status

- IND/CTA enabling activities ongoing, expected to be ready 1H 2024

Data on file: LAVA Therapeutics N.V ©LAVA Therapeutics 2023



## Anticipated Milestones & Recent Updates



## Gammabody<sup>®</sup> Pipeline: Potential in Hematological and Solid Tumor Indications

Candidate	Target	Indication(s)	Discovery	Preclinical	Phase 1	Phase 2	Anticipated Milestones & Recent Updates
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LAVA-1266	CD123	Hematologic Malignancies					<ul> <li>IND/CTA enabling activities ongoing, expected to be ready 1H 2024</li> </ul>
LAVA-1278	CD40	Hematologic Malignancies					
MM: multiple myel CLL: chronic lymp AML: acute myeloi PSMA: prostate-spec EGFR: epidermal gr mCRPC: metastatic ca	hocytic leuke d leukemia cific membrar owth factor re istration-resis	mia ne antigen	tologic malignand	cy 💹 Discontin	nued <mark>–</mark> Solid	Tumor	Undisclosed



# Gamma-delta T cell engagers for the development of next-generation cancer therapeutics

Corporate Presentation August 2023