



## HARNESSING THE UNTAPPED POTENTIAL OF THE INNATE IMMUNE SYSTEM FOR ONCOLOGY

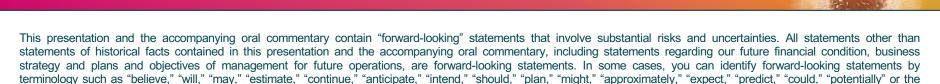
Q3 2023 Financial Results & Operational Progress

NASDAQ: AFMD

November 14, 2023

### Forward-Looking Statements / Cautionary Note

negative of these terms or other similar expressions.



Forward-looking statements appear in a number of places throughout this presentation and the accompanying oral commentary and include statements regarding our intentions, beliefs, projections, outlook, analyses and current expectations concerning, among other things, the value of our ROCK® platform, the safety and efficacy of our product candidates, our ongoing and planned preclinical development and clinical trials, our collaborations and development of our products in combination with other therapies (as well as the fact that the current clinical data of AFM13 in combination with NK cell therapy is based on AFM13 precomplexed with allogeneic cord blood-derived NK cells from The University of Texas MD Anderson Cancer Center, as opposed to Artiva's AB-101), the timing of and our ability to make regulatory filings and obtain and maintain regulatory approvals for our product candidates, our intellectual property position, our collaboration activities, our ability to develop commercial functions, clinical trial data, our results of operations, cash needs, financial condition, liquidity, prospects, future transactions, growth and strategies, the industry in which we operate, the macroeconomic trends that may affect the industry or us, such as the instability in the banking sector experienced in the first quarter of 2023, impacts of the COVID-19 pandemic, political events, war, terrorism, business interruptions and other geopolitical events and uncertainties, such as the Russia-Ukraine conflict and the risks, uncertainties and other factors described under the heading "Risk Factors" in Affirmed's filings with the Securities and Exchange Commission (the SEC).

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## Today's Speakers





Adi Hoess, MD, PhD
Chief Executive Officer

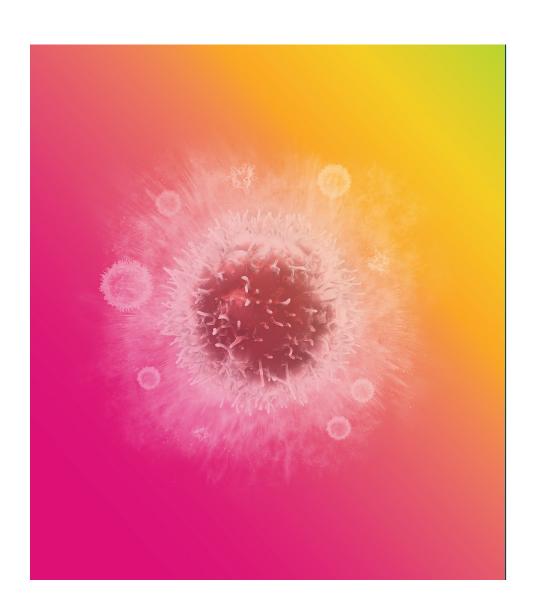


Andreas Harstrick, MD
Chief Medical Officer



Angus Smith
Chief Financial Officer





## **Adi Hoess**

Chief Executive Officer



### **Continued Progress on 2023 Goals & Priorities**



- Sites open and recruiting; initial safety and efficacy data from LuminICE-203 expected in H1 2024
- Received FDA fast-track designation
- Encouraging feedback from the FDA on Type C meeting
- AFM24: Streamlined development path
  - Focus on combination with atezolizumab; data presentation planned in December 2023
  - · Assessing combination with an off-the-shelf NK cell product
- AFM28: Phase 1 monotherapy is generating safety and efficacy data
  - · Cleared third dose cohort without dose-limiting toxicities; enrolling patients in fourth dose cohort
  - Further progress updates planned in H1 2024



# A New Class of HL Patients Has Emerged: Those Who Have Progressed Beyond BV and CPIs – the Double Refractory Patient



### DOUBLE-REFRACTORY / RELAPSED HODGKIN LYMPHOMA: TACKLING RELAPSE AFTER BV AND CPI



"The approval of BV and CPIs has revolutionized the management of R/R HL. In recent years, these agents have rapidly moved to earlier lines of therapy.

This shift in practice means that double-refractory (i.e., refractory to both BV & CPI) HL is becoming an increasingly common clinical problem."

2021 by The American Society of Hematology DOI 10.1182/hematology.2021000256

Regardless of treatment, a majority of R/R HL patients will need multiple therapies<sup>1,2</sup>

> 50% of patients receiving SCT will progress<sup>3,4</sup>

1. Othman, et. al.; Emerging Therapies in Relapsed and Refractory Hodgkin Lymphoma: What Comes Next After Brentuximab Vedotin and PD-1 Inhibition? Curr Hematol Malig Rep. 2021 Feb;16(1):1-7. doi: 10.1007/s11899-020-00603-3. Epub 2021 Jan 6. PMID: 33409966. | 2. Kuruvilla et. al.; Pembrolizumab versus brentuximab vedotin in relapsed or refractory classical Hodgkin lymphoma (KEYNOTE-204): an interim analysis of a multicentre, randomised, open-label, phase 3 study. Lancet Oncol. 2021 Apr;22(4):512-524. doi: 10.1016/S1470-2045(21)0005-X. Epub 2021 Mar 12. Erratum in: Lancet Oncol. 2021 May;22(5):e184. PMID: 33721562. | 3. Narendranath et.al.; Double-refractory Hodgkin lymphoma: tackling relapse after brentuximab vedotin and checkpoint inhibitors. Hematology Am Soc Hematol Educ | Program 2021; 2021 (1): 247–253. | 4. Sureda et.al. Improving outcomes after autologous transplantation in relapsed/refractory Hodgkin lymphoma: a European expert perspective. BMC Cancer 20, 1088 (2020).



# For Double Refractory Patients, There Are Few Compelling Treatment Options





Treatment options for R/R HL beyond BV & CPIs are limited

Therapies included in NCCN guidelines for R/R HL are characterized by low CR and PFS; furthermore, these agents were studied in R/R patients between 2000-2010, prior to the introduction of BV & CPIs

NCCN guidelines: hodgkins.pdf (nccn.org)

KOL research in R/R HL confirms a high unmet need in post-BV & CPI patients

"Options are very limited, high unmet need exists"

"High unmet need for patients post-BV, CPI and chemo...very limited options, a **wasteland**"



(OLIIZ



Future therapies currently being studied for R/R HL are limited

- Pembro+Lag3 limited data to-date
   ➤ ORR 29% & CR 9%¹
- Current intelligence shows no other novel drugs under clinical investigation for double R/R HL



KOL#1





## **Andreas Harstrick**

**Chief Medical Officer** 



# Recent Interactions with FDA Validated Overall Approach and Confirmed Need for Data to Support Further Guidance





### Insights from FDA Written Response to the Type C request :

- FDA is highly engaged to support the progress and design of the study combining acimtamig and AlloNK® as evidenced by the granted fast track designation and Type C feedback.
- LuminICE-203 study designed based on FDA's recommendations/ guidelines to support accelerated approval, the final alignment on the package to support regulatory approval will depend on the demonstrated magnitude of clinical benefit
- The FDA agrees with AFMD's approach to address the question of the contribution of single components activity by adding a cohort to the study evaluating the treatment with AB-101/IL-2 only.



# AlloNK® Cohort to be Added to LuminICE-203 Study to Demonstrate Contribution of Components



### PHASE 2 TRIAL, R/R HL (SIMON TWO-STAGE DESIGN)



#### **EXPLORATORY ARM IN CD30+ R/R PTCL**

Cohort 5, one of the Stage 1 doses, N = 20





# AFM13-104: Acimtamig (AFM13) + NK Cells Show Outstanding Clinical Results in Late-Stage Patients with 94% ORR and 72% CR Rate

### Patient Case Study: CR of Multiple Disease Sites<sup>1</sup>

### **Patient Population<sup>2</sup>**

R/R HL/ NHL Patients<sup>2</sup> N=42 (37 HL/ 5 NHL)

7 prior lines therapy (median) (1-14)

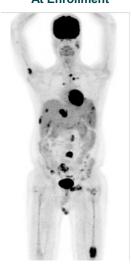
42 prior brentuximab vedotin

**39** prior anti-PD-1

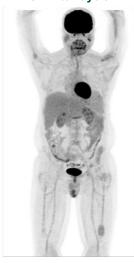
32 prior SCT

**0%** ORR to immediate prior therapy





**CR After Cycle 1** 



### **Unprecedented Results<sup>2</sup>**

36 patients treated at 1x108 per kg dose

**94% ORR** (1x108 per kg dose)

72% CR (26/36)

No CRS, GVHD or ICANS



<sup>1.</sup> Nieto Y, Affimed Virtual Investor Event, December 2021

Nieto Y, ASH 2023 Abstract: Innate Cell Engager (ICE®) AFM13 Combined with Preactivated and Expanded (P+E) Cord Blood (CB)-Derived natural killer (NK) Cells for Patients (Pts) with Refractory CD30-Positive Lymphomas: Final Results.

## AFM24 Combination Development: PD-L1 and Allogeneic NK Cells Combinations



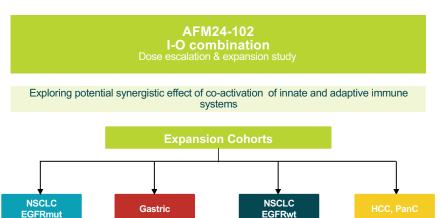
AFM24 clinically activates the innate and adaptive immune systems in heavily pre-treated patients with EGFRmut NSCLC

### Combination with atezolizumab

- 480 mg confirmed as the RP2D
- 4 expansion cohorts recruiting, including NSCLC EGFRmut cohort
- Data expected in December 2023 (excluding EGFRmut NSCLC)
- Data from the EGFR mutant cohort expected in H1 2024

## Combination with <u>allogeneic</u> NK cells under evaluation

- Combo with autologous NK cells established feasibility and safety
- Clinically meaningful stabilization of disease in heavily pre-treated patients with microsatellite stable colorectal cancer





AFM24 + CPI holds the promise to address significant unmet needs in advanced patients with EGFR expressing solid tumors



# AFM28 Designed to Improve Efficacy and Safety in AML to Prevent or Delay R/R Disease



### **Monotherapy**

Establish a dosing regimen and assess safety and preliminary activity

### **Status**

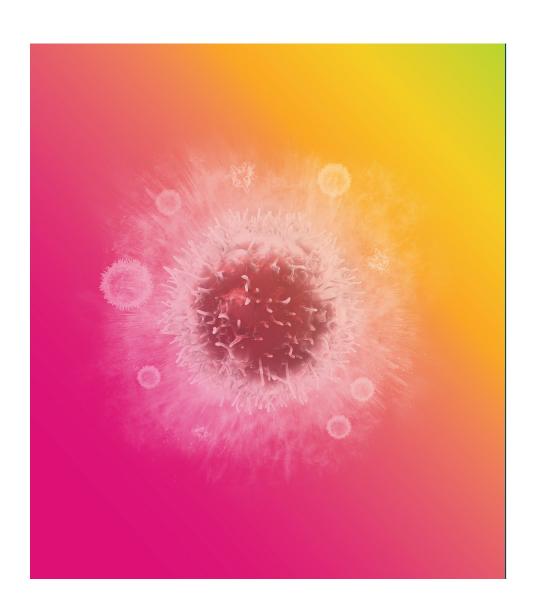
- Cleared 3<sup>rd</sup> dose cohort cleared without dose limiting toxicities
- Completed enrollment in 4th dose cohort

### **NK cell combinations**

### **Status**

• Study initiation planned as soon as feasible





## **Angus Smith**

**Chief Financial Officer** 



## **Selected Balance Sheet and Cash Flow Metrics**

Balance Sheet	As of September 30, 2023 (millions of €)	As of December 31, 2022 (millions of €)
Total Cash, Cash Equivalents and financial assets	97.5	190.3

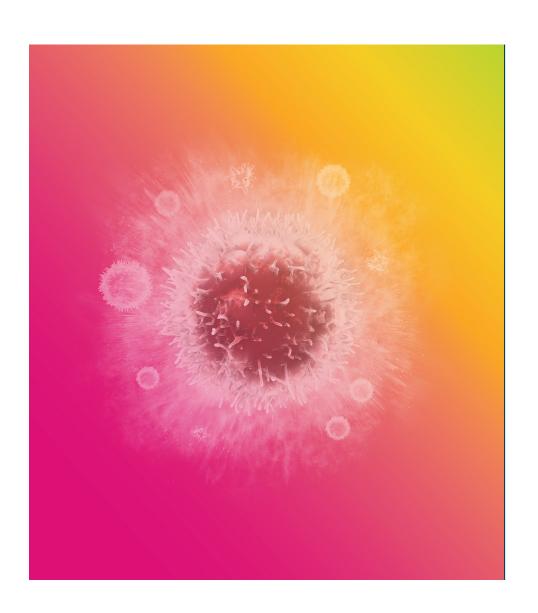
Cash Flow	For the quarter ended September 30, 2023 (millions of €)	For the quarter ended September 30, 2022 (millions of €)
Net cash used in operating activities	(18.2)	(19.0)
Net cash (used)/generated for investing activities	(37.5)	2.2
Cash Flow from financing activities	(1.6)	(0.5)
FX related changes to cash and cash equivalents	0.1	3.0



## **Selected Income Statement Metrics**

	For the quarter ended September 30, 2023 (millions of €)	For the quarter ended September 30, 2022 (millions of €)
Revenue	2.0	14.9
Other Income – net	0.0	0.1
Research and development expense	(21.5)	(26.1)
General and administrative expense	(5.4)	(8.1)
Operating loss	(24.9)	(19.2)
Loss for the period	(24.4)	(16.5)





## **Adi Hoess**

Chief Executive Officer



# Multiple Potential Inflection Points in Q4 2023 and H1 2024 - Cash Runway into 2025



Program	Milestone	Timing
AFM13-104	MDACC update at ASH 2023	Dec 2023
AFM24-102	Data update from three expansion cohorts	Dec 2023
AFM28-101	Progress updates from dose escalation study (safety, dose levels)	H1 2024
AFM24-102	Data update from NSCLC EGFRmut cohort	H1 2024
LuminICE-203	Initial data update	H1 2024

### **Partnered Programs**

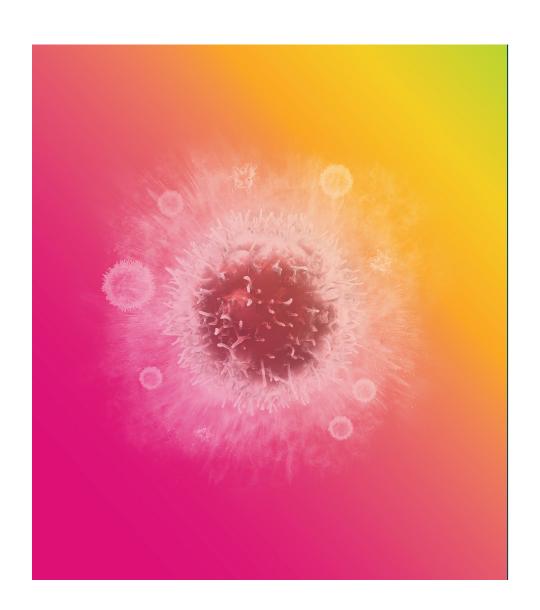
AFM24

AFM28

AFM13

Program	Milestone	Timing
Roivant / Genentech	Multiple ICE® molecules handed over for further development	TBD

Partnered Programs



# Driving the revolution in cancer treatment

Inspired by the immense potential of the innate immune system (NK cells and macrophages), we are dedicated to unlocking profound possibilities through the development of our Innate Cell Engagers (ICE®) and to bringing new hope to those whose lives have been forever changed by the impact of cancer



