

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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**FORM 6-K**

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**Report of Foreign Private Issuer  
Pursuant to Rule 13a-16 or 15d-16 of  
the Securities Exchange Act of 1934**

For the month of January, 2019

Commission File Number: 001-36619

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**Affimed N.V.**

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**Im Neuenheimer Feld 582,  
69120 Heidelberg,  
Germany**  
(Address of principal executive offices)

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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

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

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**AFFIMED N.V.**

Beginning on January 7, 2019, representatives from Affimed N.V. ("Affimed") will be in San Francisco attending various conferences and meetings with investors and corporations.

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**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, in Heidelberg, Germany, January 7, 2019.

AFFIMED N.V.

By: /s/ Adi Hoess

Name: Adi Hoess

Title: Chief Executive Officer

By: /s/ Florian Fischer

Name: Florian Fischer

Title: Chief Financial Officer

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**EXHIBIT INDEX**

Exhibit	Description of Exhibit
99.1	Affirmed N.V. January 2019 Corporate Presentation

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# Actualizing the Untapped Potential of the Innate Immune System

Affimed's Approach to Advancing Immuno-oncology  
January 2019



This presentation and the accompanying oral commentary contain “forward-looking” statements that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this presentation and the accompanying oral commentary, including statements regarding our future financial condition, business strategy and plans and objectives of management for future operations, are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “believe,” “will,” “may,” “estimate,” “continue,” “anticipate,” “intend,” “should,” “plan,” “might,” “approximately,” “expect,” “predict,” “could,” “potentially” or the 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<sup>®</sup> 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, 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, expectations regarding 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 trends that may affect the industry or us and the risks uncertainties and other factors described under the heading “Risk Factors” in Affimed’s filings with the Securities and Exchange Commission.

Forward-looking statements involve known and unknown risks, uncertainties, assumptions and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Forward-looking statements represent our management’s beliefs and assumptions only as of the date of this presentation. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons why actual results could differ materially from those anticipated in the forward-looking statements, even if new information becomes available in the future.

## PRODUCTS

- Versatile innate cell engagers targeting hematologic and solid tumors
- Only company with clinically validated innate cell engagers

## PARTNERSHIPS

- Collaborations based on proprietary CD16A engager capabilities and innate immunity expertise
- Genentech, Merck (MSD), Nektar Therapeutics, MD Anderson Cancer Center, Columbia University, Leukemia & Lymphoma Society

Giving patients back their innate ability to fight cancer

## PLATFORM

- Fit-for-Purpose ROCK® platform generates customizable innate cell engagers with proprietary CD16A target

## CORPORATE FACTS

- Nasdaq listed since 2014 (NASDAQ: AFMD)
- 76 employees (62 FTEs) in Heidelberg (HQ), Munich, New York
- *Pro forma* cash, equivalents, financial assets\* of ~\$139M (September 2018); cash runway into 2021

FTE, full-time employees; HQ, headquarters; IP, intellectual property

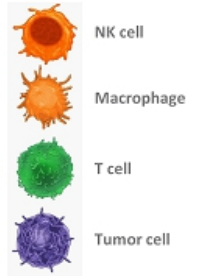
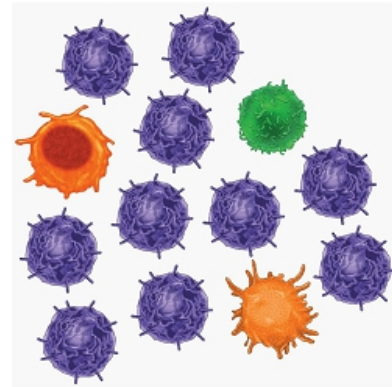
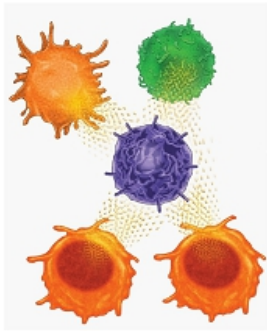
\*Pro forma" includes upfront and contractually committed payments received in October 2018 under Genentech collaboration. "Financial assets" comprises short-term deposits.

# Immunotherapies Need to Overcome Tumor Immune Evasion

## Immunosurveillance



## Tumor growth



Elimination

Evasion



# Affimed Brings a New Approach to Counter Tumor Immune Evasion Through the Innate Immune System

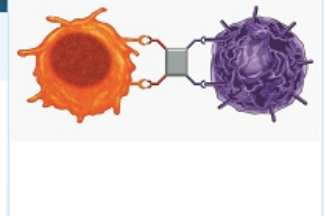


## Current Treatments

- Advanced I-O agents demonstrate it is possible to activate the immune system to trigger tumor killing
- Despite these advances, a cure remains elusive and more options are needed to truly help patients

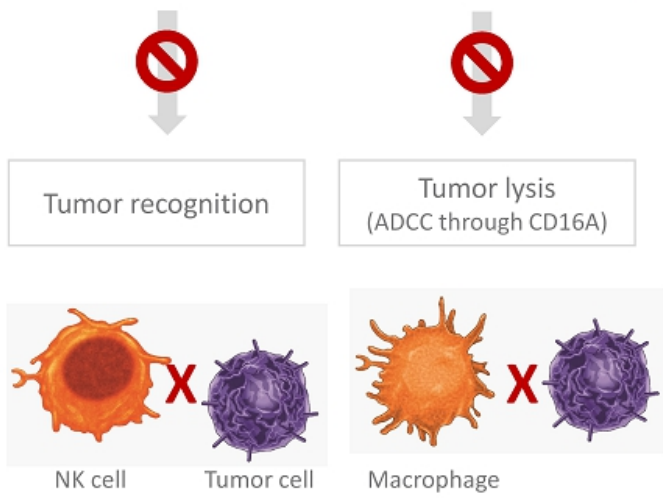
## Affimed

- Affimed is committed to improving patient outcomes through the power of the **innate immune system**
- **Affimed's ROCK®** platform creates medicines that enable the body's immune cells to recognize and kill tumor cells



# Affimed's Innate Cell Engagers Can Give Patients Back their Innate Ability to Fight Cancer

## Cancer Patient's Innate Immune System



Affimed's unique approach activates innate cells through proprietary CD16A targeting

### Innate Cell Engagers

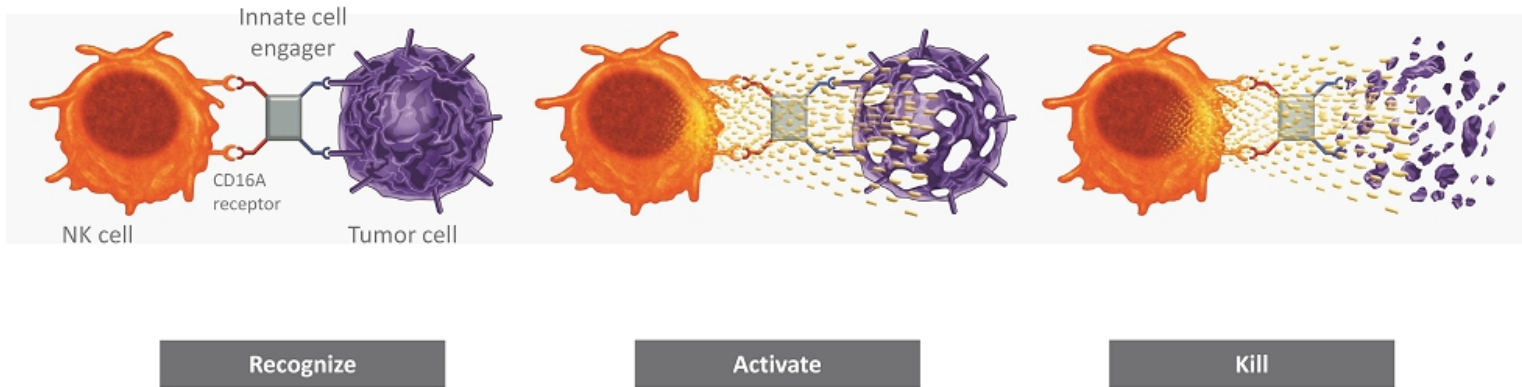
- Increase binding of CD16A
- Increase NK cell activation
- Increase cytotoxicity (ADCC)

# CD16A Engagers Bridge Together Innate Immune and Tumor Cells Through Proprietary ROCK<sup>®</sup>-based Antibodies

Bridging of innate and tumor cells

Stimulation of tumor lysis through ADCC

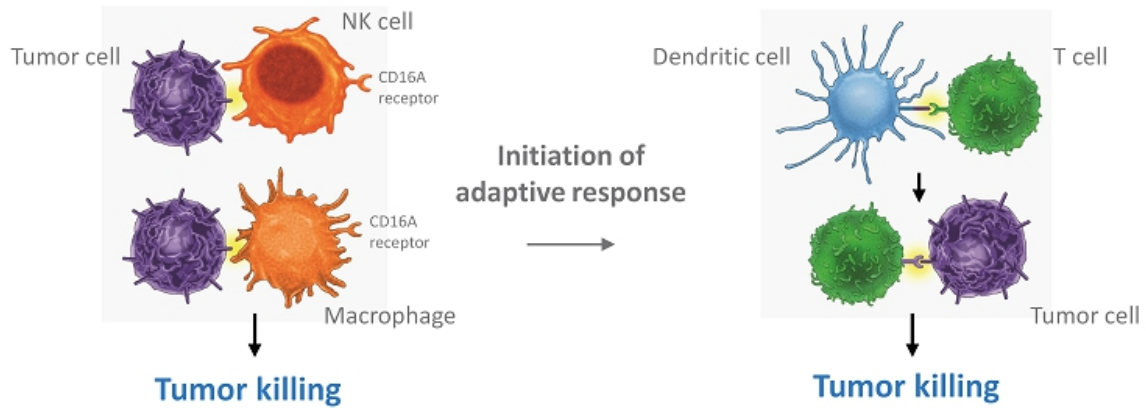
Restoration of cytotoxicity in tumor cell killing



# Innate Immunity Plays an Important Role in Tumor Recognition and Killing, as well as Initiating an Adaptive Response

Innate Immunity, First Line of Defense

Adaptive Immunity, Second Line of Defense



Activation of the innate and adaptive immune system is the optimal integrated I-O approach

# Fit-for-Purpose ROCK<sup>®</sup> Platform Allows Innate Cell Engagers to be Designed for Specific Indications



ROCK<sup>®</sup> Platform is Affimed's proprietary technology to generate in-house innate cell engagers

## Versatile Platform

Tailor tetravalent, bispecific innate cell engagers with high avidity and affinity, and variable PK profiles

*Generate novel IP to broaden leadership in innate immunity*

## Strong Engineering

Proven record in building potent and stable molecules in a short time

*Elegant predictability for powerful medicines*

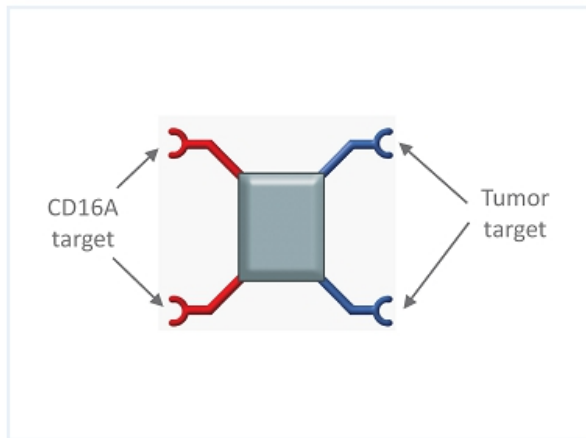
## Proprietary Target

Specific CD16A-targeting addresses major hurdles required for potent activation

*The right approach to unlock innate immunity*

# CD16A-Targeted Cell Engagers Are Highly Effective in Activating Innate Cell Cytotoxicity

Innate cell engagers, bispecific antibodies created by the ROCK<sup>®</sup> platform, feature:



\*Based on AFM13 clinical studies.

## Genentech Invested in Affimed's CD16A Engager Capabilities and Expertise in Innate Immunity



**Genentech**

*A Member of the Roche Group*

**\$96M**

Upfront, near term funding

**\$5B**

Potential milestones, royalties

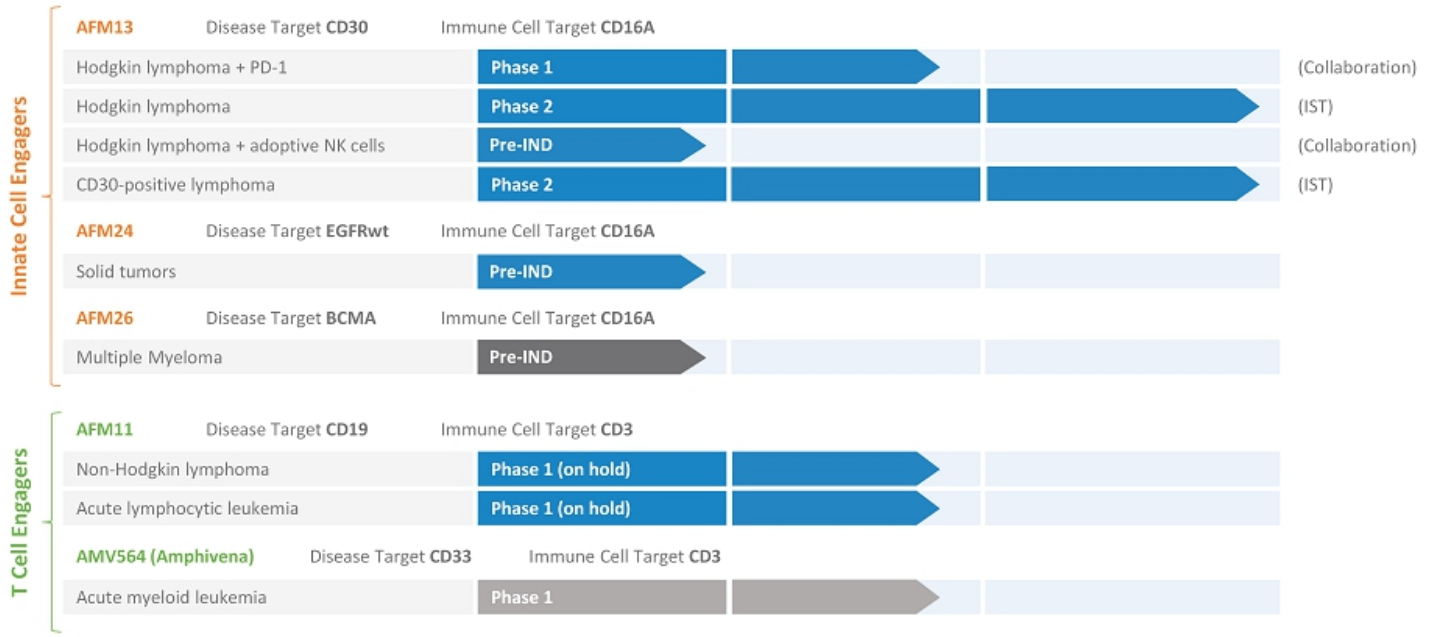
Strategic partnership driven by our **clinical stage CD16A-targeted** innate cell engagers

- Clinical efficacy
- Tolerable safety profile
- Synergy with other I-O agents

*“This collaboration is based on Affimed’s innate immune cell drug discovery and development expertise and our team’s deep understanding of cancer immunology”*

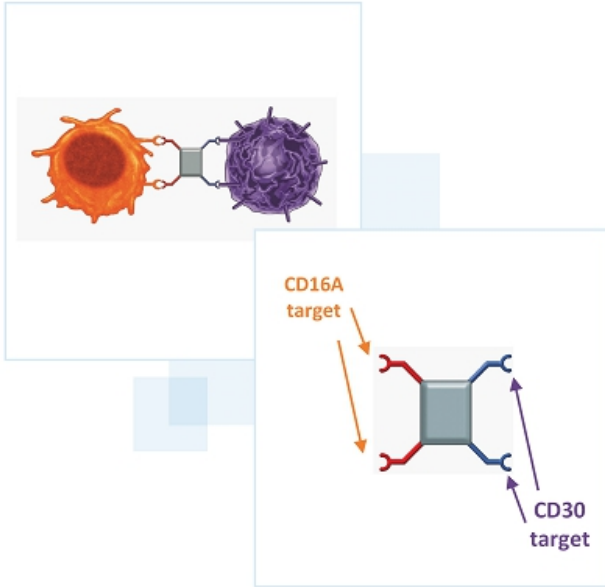
James Sabry, M.D., Ph.D.,  
Global Head of Partnering, Roche

# Differentiated and Versatile Innate Cell Engagers to Target Hematological and Solid Tumors



■ Affimed Programs   
 ■ Partnered Programs   
 ■ Licensed Programs





# Innate Cell Engagers in Hematologic Tumors

Treatment with AFM13

# In Clinical Studies, AFM13 Has Shown Promising Efficacy in Patients With CD30 Positive Lymphoma

## CD30-Positive Lymphoma (PTCL, CTCL)

### Treatment:

- AFM13 monotherapy

### Total of 9 patients treated to date:

- Investigator-sponsored\*, translational study to evaluate immunological effects and preliminary efficacy of AFM13 in R/R CD30+ lymphoma with cutaneous presentation

### Preliminary efficacy data\*\*:

- 9 patients treated in 3 dose cohorts
- 44% ORR including 1 CR and 3 PRs
- Biomarker data: possible correlation between response and tumor NK cell infiltration pre-therapy

## R/R Hodgkin Lymphoma

### Treatment:

- AFM13 in combination with Merck's Keytruda® (pembrolizumab)

### Total of 30 patients treated to date:

- MTD not reached in Part 1; highest dose employed in Part 2/Extension

### Efficacy data#:

- 24 patients evaluable in highest dose cohort
- 88% ORR, 42%/46% CR rate (local/central read)
- Durable responses: 77% estimated 6-month PFS rate
- Deepening of responses over time in multiple patients
- Patients previously transplant ineligible transitioned to transplant after achieving an objective response

\*Principal Investigator: Ahmed Sawas, MD, Columbia University Medical Center, New York, NY.

\*\*A Sawas et al., ASH 2018 Abstract 2908.

#NL Bartlett et al., ASH 2018 Abstract 1620.

CR, complete response; MTD, maximum-tolerated dose;  
ORR, objective response rate;  
PR, partial response; R/R, relapsed/refractory.

### PTCL

- **Lack of standard of care** in R/R – very high unmet need
- Establish new standard of care treating the **vast majority** of R/R patients

*“It’s a group of patients where there is no standard [of care]...the majority of patients recur after chemo and even after transplant.”*

PTCL KOL

### CTCL

- Potential for **small trial** and **accelerated** timelines for Mycosis Fungoides
- Position as the **preferred therapy** for R/R for CD30+ patients

*“Patients will progress through brentuximab vedotin - they are still CD30 positive...And we do not have many other things to offer them.”*

CTCL KOL

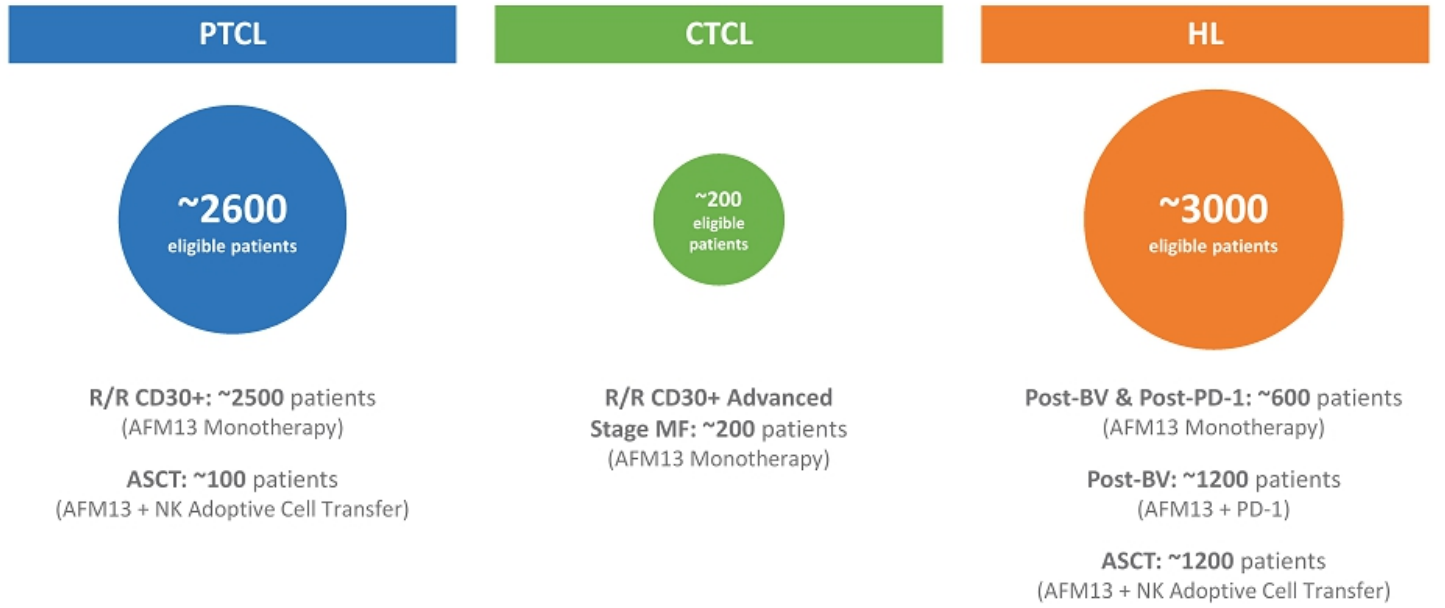
### HL

- **Emerging vacuum** of effective options in R/R as current therapies move to earlier lines
- Expand into **multiple settings** with **mono and combo** approaches

*“As brentuximab vedotin and the PD-1’s move up, there are vacuums that have been created that we need novel therapies to fill.”*

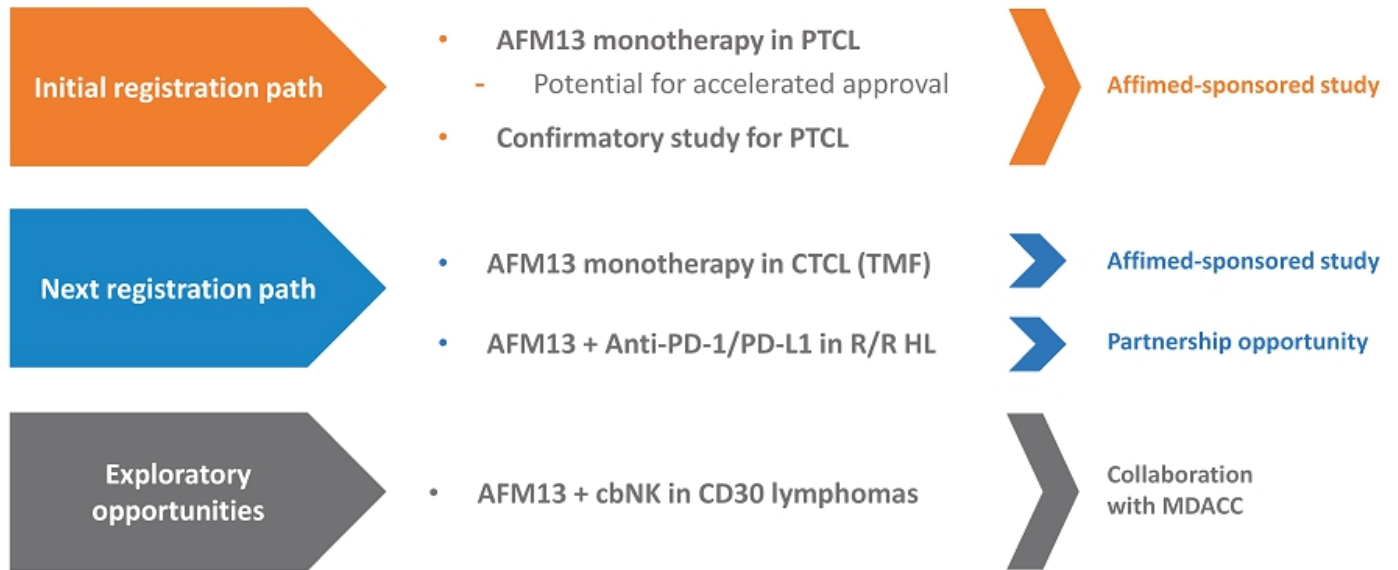
HL KOL

# AFM13 US Opportunity: Commercial Potential to Treat ~6000 Patients



Source: Affimed market research.

# Multiple Clinical Development Opportunities With AFM13



# AFM13, a First-in-Class Innate Cell Engager, Delivers Clinically Meaningful Efficacy as Monotherapy or Combination Therapy in CD30+ Tumors



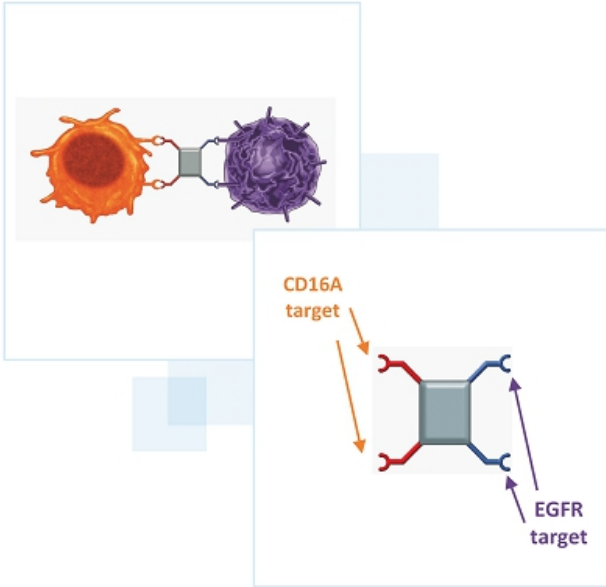
## Achievements

- Lead agent demonstrated clinical proof of concept for ROCK® innate cell engagers
- Efficacy with monotherapy and combination therapy (TCL, HL)
- Tolerable safety profile



## Opportunities and Next Steps

- Initiating pivotal clinical trial as monotherapy in TCL (potential for accelerated approval), H1 2019
- Initiation of IST with MDACC for AFM13 + adoptive NK cells in CD30+ lymphomas, H1 2019
- Groundwork for further CD16A engagers (AFM24, AFM26\*, early pipeline)



# Innate Cell Engagers in Solid Tumors

Treatment with AFM24

## AFM24 is a Novel Approach to Treat Many Types of Solid Tumors that Overexpress EGFR



### EGFR Expressing Tumors & Current EGFR Targeting Therapies

- EGFR is overexpressed in several tumors (CRC, NSCLC, HNSCC, GBM, TNBC)
  - EGFR-mediated signaling is frequently affected by mutations in various tumors leading to increased tumor growth
- Current therapies rely on EGFR signal inhibition and may be limited by:
  - Associated toxicities
  - Acquired resistance
  - Limited antitumor immune response

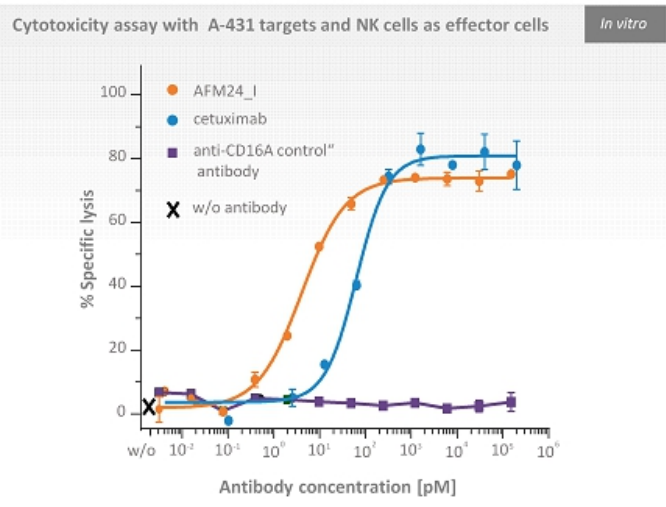
### Affimed's Solution to EGFR Tumors is AFM24 (CD16A/EGFR)

- Innate cell engager bridging NK cells and macrophages to EGFR expressing tumors
  - An influx of TILs and NK cells is associated with a beneficial prognosis in EGFR tumors
- New mode of action addressing safety of SOC and resistant patient population
- IND filing planned by mid-2019

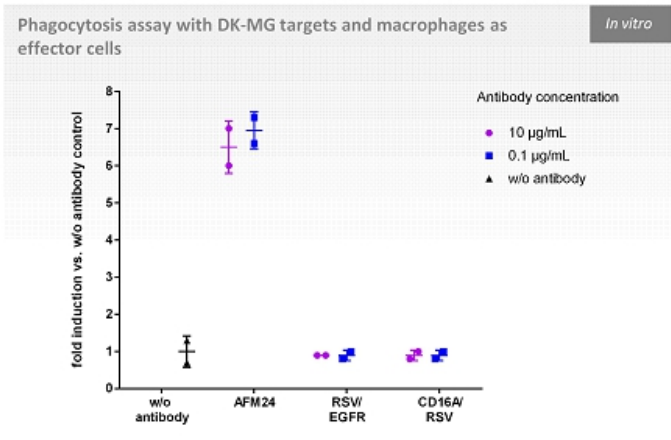


# AFM24's Innate Mechanism Demonstrated Potent Tumor Cell Killing through Activation of NK cells and Macrophages

## AFM24 demonstrated potent killing of target cells through NK cells as effector cells (ADCC)

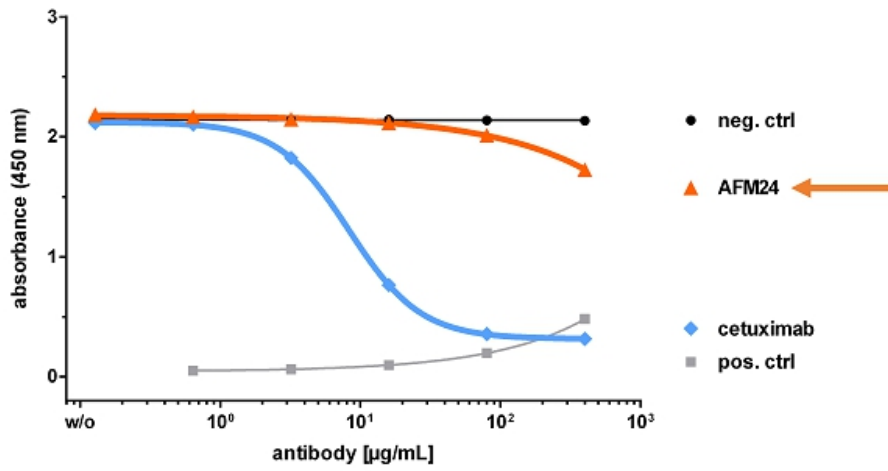


## AFM24 elicited macrophage induced killing of EGFR+ target cells (ADCP)



# AFM24 Reduced Inhibition of EGFR Phosphorylation May Indicate an Improved Safety Profile With Less Skin Toxicity

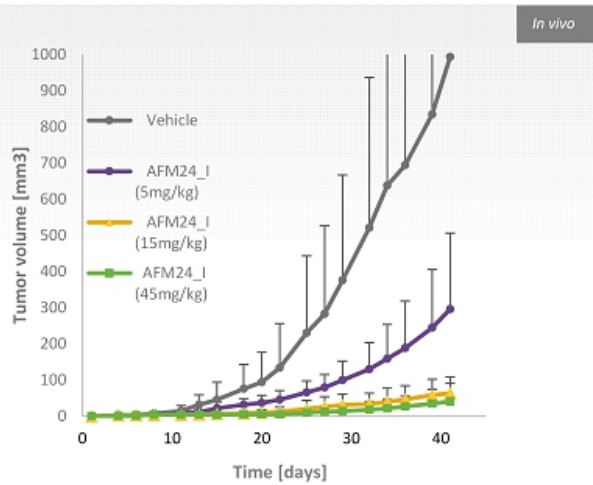
### Inhibition of EGFR Phosphorylation



**AFM24 demonstrated reduced inhibition of EGFR phosphorylation relative to cetuximab**

# AFM24 Demonstrated Potent *in vivo* Tumor Cell Killing and Improved Safety

AFM24 demonstrated dose-dependent tumor growth inhibition in an *in vivo* mouse model

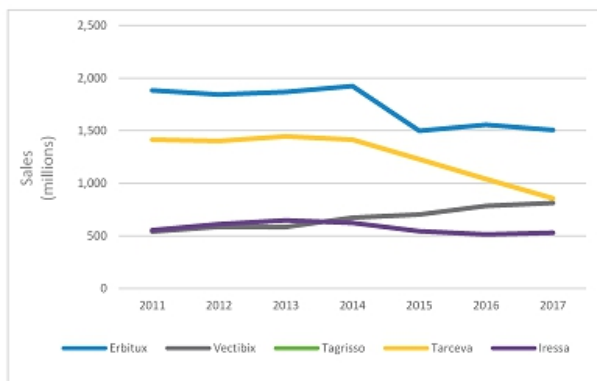


AFM24 showed favorable safety profile in a dose range finding toxicity study in cynomolgus monkeys

- All animals were clinically well throughout the study without notable changes in body temperature, clinical hematology, or clinical chemistries
- Macroscopic and microscopic assessment of tissues showed no findings of toxicities (e.g., skin toxicity)
- AFM24 was markedly more tolerable vs. published results for cetuximab in cynomolgus monkeys
- Furthermore, the half-life of AFM24 was comparable to the half-lives of cetuximab and panitumumab in cynomolgus monkeys

# AFM24 Could Address Clinical Unmet Need Among EGFR-Targeted Therapies

## Current Therapies

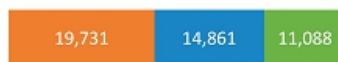


In 2017, sales of EGFR-targeted therapies totaled \$4.7B globally<sup>1</sup>

## AFM24 US Market Opportunity

### Actively Treated Stage IV Patients in 2016, US<sup>2</sup>

#### NSCLC



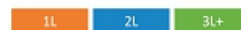
#### Colorectal Cancer



#### TNBC



#### Head and Neck Cancer



1. Source: Company reports  
2. Source: Datamonitor Healthcare survey, 2016

1L, first line; 2L, second line; 3L, third line; CPI, checkpoint inhibitor; EGFR, epidermal growth factor receptor; IL, interleukin; mAbs, monoclonal antibodies; NSCLC, non-small cell lung cancer; SOC, standard of care; TNBC, triple-negative breast cancer; US, United States

## AFM24, a New Mode of Action to Initiate Innate Immunity in EGFR+ Solid Tumors, such as CRC, NSCLC, and Others



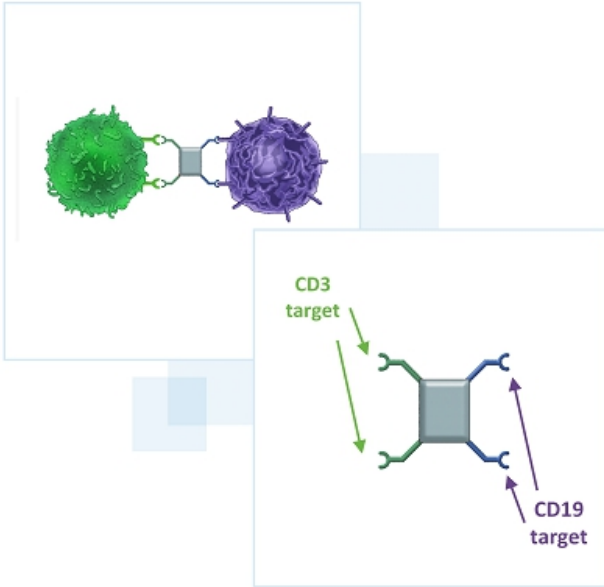
### Achievements

- Demonstrated potent cell killing capabilities in pre-clinical studies
  - Indicates potent efficacy
  - Potential for greater efficacy in tumor types with EGFR mutations/resistance
- Differentiating safety profile in pilot toxicity study



### Opportunities and Next Steps

- New MOA to address patients currently not responding
- Potential for innate/adaptive combinations enhancing efficacy in major solid tumor types
- Planned IND filing by mid-2019, clinical data possible in 2020



# Adaptive Cell Engagers

Treatment with AFM11

# Affimed's T-Cell-targeting Platform Is a Differentiated Approach to Optimize T Cell Engagement



## T Cell Platform

- No non-specific activation of T cells in absence of target cells
- Able to target and lyse tumor cells with low target expression
- Improved PK vs Bi-specific T cell engagers (BiTEs)

*Potential to overcome challenges of other current therapies*

## AFM11 (CD3/CD19)

- Phase 1 dose-escalation trials in R/R ALL and NHL on HOLD after occurrence of SAEs in three patients
- Affimed is assessing all AFM11 data and working with global health authorities to determine next steps

*Unique medicine designed to address limitations of BiTEs and benefit/risk profile of CAR-T*

## Study Update\*

- Phase 1 study of 17 patients with R/R ALL treated with AFM11 in 6 dose cohorts
- Preliminary efficacy data included 3 CRs (2 CRs, 1 CRi), with one patient achieving MRD negativity

*AFM11 efficacy data was recently reported at ASH 2018*

\*G Salogub et al., ASH 2018 Abstract 3969  
ALL, Acute lymphoblastic leukemia; CR, complete response; MRD, minimal residual disease  
NHL, Non-Hodgkin lymphoma; PK, pharmacokinetics; BiTE, bispecific T cell engager

### Highlights

#### ASH2018

- Update on AFM13 Phase 1b combination study with Keytruda® (pembrolizumab) in HL
- Data from AFM13 monotherapy Phase 1b/2a study in R/R CD30-positive lymphoma with cutaneous presentation (CUMC)
- Preclinical data on combination with adoptive NK cells (MDACC), ROCK® engager-based activation of macrophages, and AFM26 (partnered)
- Data from AFM11 Phase 1 dose escalation study in ALL

#### CD16A ENGAGER COLLABORATIONS

- New collaborations with Genentech and Nektar

### Upcoming Anticipated Milestones

#### AFM13

- H1 2019: 12-month data for AFM13 + Keytruda® (pembrolizumab)
- H1 2019: Initiate registration study (monotherapy in TCL)
- H1 2019: Initiate combination study with cbNK cells in CD30+ lymphomas (IST)
- H1 2020: Interim data for monotherapy in TCL

#### AFM24

- Mid-2019: IND filing
- H2 2019: Initiate first-in-human study
- 2020: Clinical data



# Affimed is Actualizing the Next Great Advancement in I-O

Giving patients back their innate ability to fight cancer



## Innate cell engagers

- Fit-for-Purpose ROCK® platform utilizes CD16A
- Effective as monotherapy or combination therapy
- Foundation to offer novel medicines

## Novel therapeutics

- AFM13: Lead agent with registrational path in TCL
- AFM24: Potential to disrupt landscape with a novel MOA
- Uncovering novel combination therapies

## Affimed

- *Only* known company to validate innate cell engagers in the clinic
- Recognized as a leader in innate immunity through Genentech partnership
- Committed to deliver medicines to patients in need

## Experienced Management Team

Proven track record in biotech, pharma, product development, and finance



**Dr. Adi Hoess**  
Chief Executive Officer (CEO)

Extensive background in general management, product commercialization, fundraising and M&A



**Dr. Florian Fischer**  
Chief Financial Officer (CFO)

Strong financial background, lead advisor in a variety of transactions & financings life sciences/healthcare



**Dr. Wolfgang Fischer**  
Chief Operating Officer (COO)

In-depth expertise in R&D with a focus on oncology, immunology and pharmacology



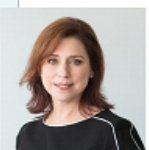
**Dr. Leila Alland**  
Chief Medical Officer (CMO)

Seasoned immuno-oncology expert with broad experience developing oncology products



**Dr. Martin Treder**  
Chief Scientific Officer (CSO)

Broad experience in the field of biotherapeutics R&D in I/O discovery and preclinical development



**Denise Mueller**  
Head Comm Strat/BD

Strong background in commercialization and global marketing including launch of new products

