WELLS FARGO

Company Update — December 2, 2021

Biotechnology

Affimed NV (AFMD)

AFMD: Virtual NDR Highlights Unique Technology, Pipeline Depth, Breadth and Near-Term Value Drivers

Our Call

We hosted AFMD on a virtual non-deal roadshow yesterday (12/1) with focus on the company's expanding pipeline of innate cell engagers (ICE). Key areas included 1) recent data in advanced CD30+ lymphoma for AFM13 pre-complexed w/ cord blood NK cells and expectations for the 12/9 investor event; 2) Review of AFM24 (EGFR ICE) phase 1 dose escalation data and 3) Expectations at ASH for AFM28 (CD123 ICE) preclinical data.

In our view AFMD leads the development of ICEs and is uniquely placed to develop these as a monotherapy, in combination with a PD-(L)1 inhibitor and potentially most disruptively, with NK cells, using a simple process to pre-complex ICE with *ex-vivo* expanded NK cells. We believe AFMD is undervalued given clinical value drivers for AFM13 phase 2b data in T cell lymphoma, expansion data for AFM13 pre-complexed with NK cells, data from 1 or more of the 6 AFM24 expansion cohorts in solid tumors and phase 1 start for AFM28 in acute myeloid leukemia.

On 12/9 AFMD and MD Anderson (MDA) are to host an investor event to review in greater deal top-line data for AFM13 pre-complexed NK (pcNK) cells, released 11/22. AFMD confirmed that while MDA's Dr Nieto will provide additional detail, MDA and AFMD are working on a high-profile publication for the data; recall MDA's NK-CAR trial was published in the New England Journal of Medicine. AFMD confirmed that patients enrolled were very heavily pretreated and that all had failed, ADCETRIS a PD-(L)1, multiple lines of chemotherapy and in over 50%, an autologous and or allogeneic stem cell transplant — the remainder were largely transplant ineligible due to an inability of induction therapy to drive a deep enough response. At the current time, day 29 response assessment is not available following a second AFM13-pcNK cycle in all patients, and MDA/AFMD expect to present full 2nd cycle and longer follow-up at a major medical meeting 1H22, likely at AACR (4/8-13), ASCO (6/3-7) or EHA (6/9-12). For patients who are transplant naive and who achieve a deep response to AFM13-pcNK, the goal would be to take the patient to transplant, however for those failing one or more transplants, a salvage transplant is not a consideration and as a result of the encouraging data, FDA is reviewing a proposed protocol amendment that will allow patients to receive additional cycles of treatment; AFMD is also considering a day 1,3, 5 AFM13-pcNK split dose strategy. AFMD and MDA intend to expand the high dose cohort from 12 to 40 patients, split 30 Hodgkin and 10 CD30+ve non-Hodgkin lymphoma.

AFMD has reviewed an AFM13-pcNK product profile with physician and payers. Physicians opined that a response rate of >50% would be considered a "game changer", while payers would view reimbursement of AFM13-pcNK as a CAR-T, and understand the need to reimburse for ancillary procedures and treatments associated with CAR-T. Whilst AFMD noted competitor CD30 CAR-T data expected at ASH also appear impressive, AFM13-pcNK is given safely in the outpatient setting as an off the shelf product, versus a CAR-T that is administered in-patient and per the ASH abstract, required a median 6-weeks for product manufacture. Key to achieving outpatient administration in the community setting is the ability to use a cryopreserved product, and at ASH, AFMD will share exploratory data for cryopreserved AFM13-pcNK noting that in parallel the company has collaborations, including NKGen and Artiva, providing access to established GMP manufacture of NK cells and cryopreserved product, providing optionality.

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Rating	Overweight
Ticker	**AFMD**
Price Target/Prior:	**$18.00/NC**
Upside/(Downside) to Target	**166.7%**
Price (12/01/2021)	**$6.75**
52 Week Range	$4.78 - 11.74
Shares Outstanding	119,731,915
Market Cap (MM)	$808
Enterprise Value (MM)	$557
Average Daily Volume	1,435,037
Average Daily Value (MM)	$10
Dividend (NTM)	$0.00
Dividend Yield	0.0%
Net Debt (MM) - last reported	$(251)
ROIC - Current year est.	NM
3 Yr EPS CAGR from current year (unless otherwise noted)	NM

$ EPS	2020A	2021E Curr.	2021E Prior	2022E Curr.	2022E Prior
Q1 (Mar)	(0.12) A	0.01 A	NC	(0.16) E	NC
Q2 (Jun)	(0.17) A	(0.18) A	NC	(0.16) E	NC
Q3 (Sep)	(0.08) A	(0.17) A	NC	(0.25) E	NC
Q4 (Dec)	(0.19) A	(0.22) E	NC	(0.25) E	NC
FY	(0.57) A	(0.55) E	NC	(0.82) E	NC
P/E	NM	NM		NM	

Source: Company Data, Wells Fargo Securities estimates, and Refinitiv.
NA = Not Available, Volatility = Historical trading volatility

Pipeline Review

In 1H22, AFMD expects to complete enrollment of 105 $CD30^{LO/HI}$ relapsed/refractory peripheral T cell lymphoma patients into the registration-directed REDIRECT trial of AFM13. The primary endpoints of the study are overall response rate and duration of response, and AFMD is to provide guidance on data timing once enrollment has been completed.

For EGFR ICE, AFM24, AFMD is encouraged with the emerging safety and efficacy profile (reviewed during 3Q earnings), highlighting ongoing stable disease in 3 subjects in the phase 1 that would have been eligible for the monotherapy expansion cohort. Notably, AFM24 has been well tolerated with no significant organ toxicity. AFMD noted that Grade 3 skin toxicity would be expected in ~1/3rd of patients receiving ERBITUX and with extended dosing hypomagnesia, nail changes and mucosal toxicity is often observed.

At ASH, AFMD is to present the first pre-clinical data for AFM28, a product that targets AML blasts and leukemic stem cells. While the presentation contents remain under embargo, AFMD noted the presentation will highlight some "very interesting" comparisons to other antibody-based agents. Compared to antibodies, ICEs have shown the ability to activate NK cells at target concentrations that are too low for conventional antibodies. Given that AML blasts are sensitive to NK cells, evaluation of AFM123 preloaded NK cells is a high priority for AFMD.

AMF13-104 November 22nd Data Update

On 11/22, AFMD/MDA announced updated AFM13-pcNK data from the AFM13-104 trial with a 10/31 cut off. At the recommended phase 2 dose, AFMD reported a 100% (12/12) investigator-assessed objective response rate (ORR) and 42% (5/12) complete response rate in advanced Hodgkin lymphoma (HL- n=11) or non-Hodgkin lymphoma (n=1) after a single cycle of treatment. AFMD reported no serious adverse events secondary to cell therapy including graft versus host disease.

AFM13-104 is a dose escalation trial evaluating up to 2 cycles of cytokine-preactivated and expanded cbNK AFM13 cells at doses of $1x10^6$ (n=3), $1x10^7$ (n=3) or $1x10^8$ (n=12) cells/kg administered 2 days after fludarabine/cyclophosphamide lymphodepleting chemotherapy and followed by AFM-13 200mg weekly for 3 weeks with disease assessment by FDG-PET at day 28.

MDA has enrolled 18 patients to-date including 16 with relapsed/refractory HL and 2 with NHL, reporting an ORR of 89% (n=16/18) and a complete response rate of 39% (n=7/18). AFM13 pre-complexed cbNK followed by AFM13 was well tolerated with five cases of transient infusion related reactions post AFM13 infusion reported and no serious adverse events of cytokine release syndrome, immune cell-associated neurotoxicity syndrome, or graft-vs-hose disease.