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Xencor (XNCR - OUTPERFORM): XNCR Presents Preclinical Update on Bispecific Programs and XmAb13677/MOR208 Clinical Data at ASH

Price: $10.96 **12-Month Price Target: $18**

- **XNCR presented preclinical results for three of their bispecific programs, CD3 x CD123, CD3 x CD20 and CD3 x CD38 at the American Society for Hematology meeting.** Bispecific antibodies have higher cytotoxic potential than monoclonals, as they bind to both T-cells and tumor cells to stimulate T-cell mediated killing. In contrast to other bispecifics, XNCR's bispecific antibodies possess engineered Fc domains, allowing augmented antibody functions such as extended half-life.

- **Poster 2136 described the bispecific antibody XmAb14045 that targets CD123 (IL-3R). XmAb14045 stimulated killing by human T cells of CD123+ cell lines, but had no cytotoxic activity against a CD123- cell line.** The prolonged serum half-life of XmAb14045 of 6.2 days was also demonstrated in mice, in marked contrast to non-Fc domain-containing bispecific formats. CD123 is highly expressed on acute myeloid leukemia stem cells and blasts, representing a promising target of antibody therapies for AML.

- **In vivo efficacy of XmAb14045 was demonstrated in three cynomolgus monkeys treated with a single dose of XmAb14045 at 0.01, 0.1 or 1 mg/kg.** Strikingly, XmAb14045 induced a rapid depletion of circulating CD123+ cells (>99%) within 1 hr. Circulating CD4+ and CD8 T cells were activated rapidly and activation was sustained for 48 hours. In addition, bone marrow CD123+ cells were depleted by over 95% at all doses and did not recover for 8 days after treatment.

- **Poster 4727 reported the development and preclinical data of two novel bispecific antibodies, XmAb13243 and XmAb13551, targeting CD38, which is highly expressed on malignant plasma cells and is therefore a potential therapy for multiple myeloma patients.**

- **Both XmAb13243 and XmAb13551 demonstrated long half-lives and strong activity in immunodeficient SCID mice engrafted with PMBCs.** Human IgG2, IgM and IgE, produced by engrafted B cells that differentiate into CD38+ plasma cells, were reduced to levels below detection by day 14 (>50-fold for IgG2, >1000-fold for IgM and > 80-fold for IgE). By comparison, daratumumab, a monoclonal CD38 antibody currently in clinical development for MM, reduced levels of IgG2, IgM and IgE by 2-fold, 6-fold and 3-fold, respectively. Furthermore, both bispecific antibodies suppressed human anti-tetanus antibody titers in the SCID mice to baseline (>100-fold) in an induced immune response model, whereas daratumumab suppressed titers by only 2-fold. In addition, XmAb13243 and XmAb13551 rapidly depleted CD38+ cells by > 95% in cynomolgus monkeys with a single dose.

- **Poster 3111 described development and preclinical data of two novel bispecific antibodies, XmAb13676 and XmAb13677, which target CD20, a well-established target of antibody therapeutics of B-cell leukemias and lymphomas.** Both antibodies had extended half-lives of ~ 6.6 days and demonstrated affinities for CD20 of 420 pM (XmAb13676) and 16 pM (XmAb13677).

- **Efficacy was demonstrated in three cynomolgus monkeys at three doses, with both XmAb13676 and XmAb13677 depleting >97% of circulating CD40+ B-cells within 4 hours.** Strikingly, at the highest doses, B cells remained at baseline for the duration of the study (29 days). CD40+ B-cells were also depleted by over 90% at all doses in lymph nodes and bone marrow, with B cell populations at the higher dose levels not recovering by 29 days. Circulating CD4+ and CD8+ T cell activation was observed immediately after treatment, and sustained for over 48 hours after dosing, and returned to baseline from 2 to 7 days after treatment.

- **We view the strong cell-killing ability and persistence seen in each of these three programs as highly encouraging.** Bispecifics appear to hold several key clinical, manufacturing and regulatory advantages over the adoptive T-cell therapy (ACT) approach in the treatment of hematological malignancies, and we believe investors are undervaluing the potential of bispecifics to be competitive with engineered T-cells. We expect at least one bispecific program to move into the clinic in 2015, likely XmAb14045.

Also at ASH, XNCR's partner MorphoSys AG (MOR.DE, not covered) presented final results and the follow-up of a Phase I/IIa study of XmAb5574/MOR208 in patients with relapsed or refractory (r/r) chronic lymphocyctic leukemia (CLL) or small lymphocytic lymphoma (SLL), as well as an interim data analysis of a Phase IIa open label study of MOR208 in r/r non-Hodgkin lymphomas (NHL). XNCR receives certain developmental, regulatory and sales milestone payments from MorphoSys AG and would also receive undisclosed royalties in the high single-digit to low-teen percent range upon commercialization of MOR208.

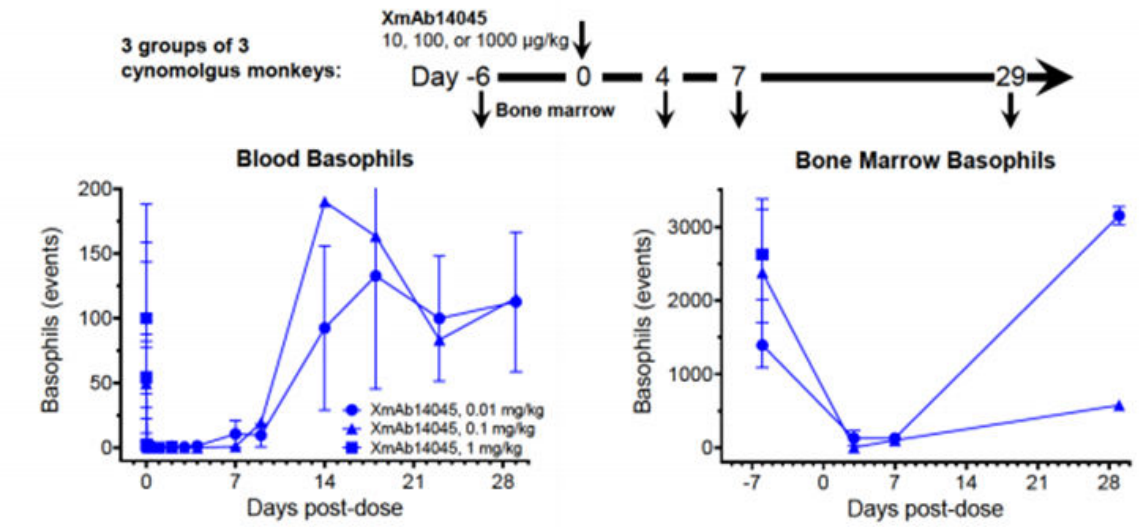
In the CLL/SLL study at the recommended dose, 12 patients (75%) had a partial response by physical exam criteria (IWCLL1996) and 6 patients (37.5%) had a partial response using additional CT criteria (IWCLL2008). In addition, progression-free survival (PFS) of up to 60 weeks for patients in the extended treatment arm was observed. For the r/r NHL study, M0R208 demonstrated encouraging preliminary single-agent efficacy with overall response rates (ORRs) of 26% for DLBCL, 23% for FL and 36% for iNHL and response duration reached 13.8 months.

MOR208 was generally well tolerated, with no maximum-tolerated dose identified in the CLL/SLL study. The most common adverse events were infusion reactions, increased aspartate transaminase (AST), increased alanine aminotransferase (ALT), neutropenia, thrombocytopenia, fever, chills, and peripheral neuropathy.

Reiterate OUTPERFORM and $18 price target. Our $18 price target is derived from the sum of multiples on sales and royalties from XNCR's proprietary and partnered products, each discounted back.

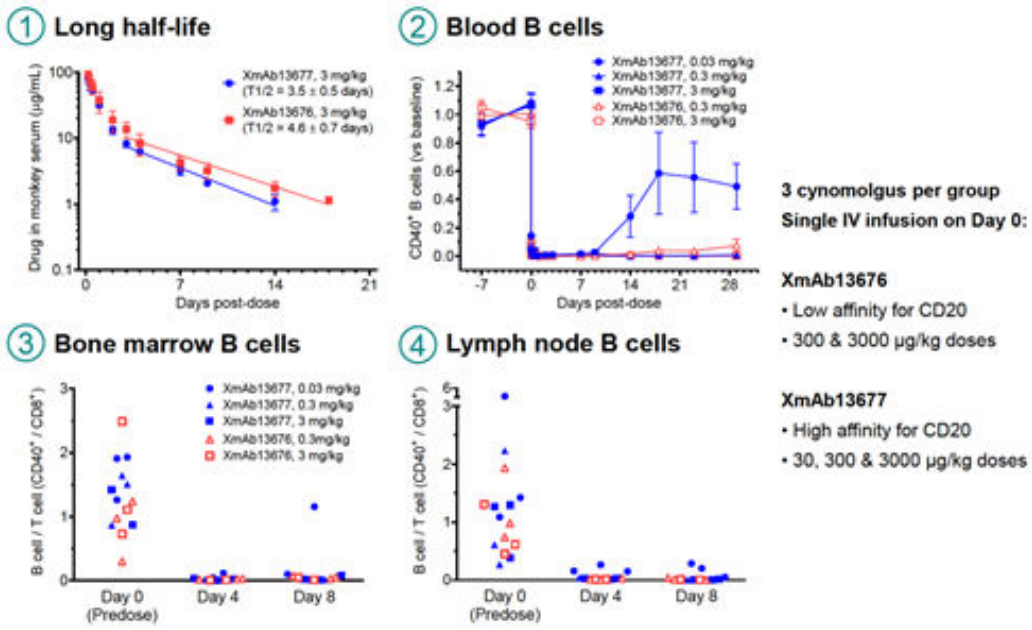
Risks to the attainment of our price target include 1) failure to reach sales expectations for XmAb7195, XmAb5574, XmAb5871 and 2) failure in the clinic of either XmAb7195, XmAb5574, XmAb5871.

Figure 1: Single Dose of XmAb14045 Depletes CD123+ Cells in Monkeys



Source: Company data

Figure 2: XmAb13677 and XmAb 13676 Bispecifics Deplete B cells in Blood and Lymphoid Organs in Monkeys



Source: Company data

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Company	Disclosure
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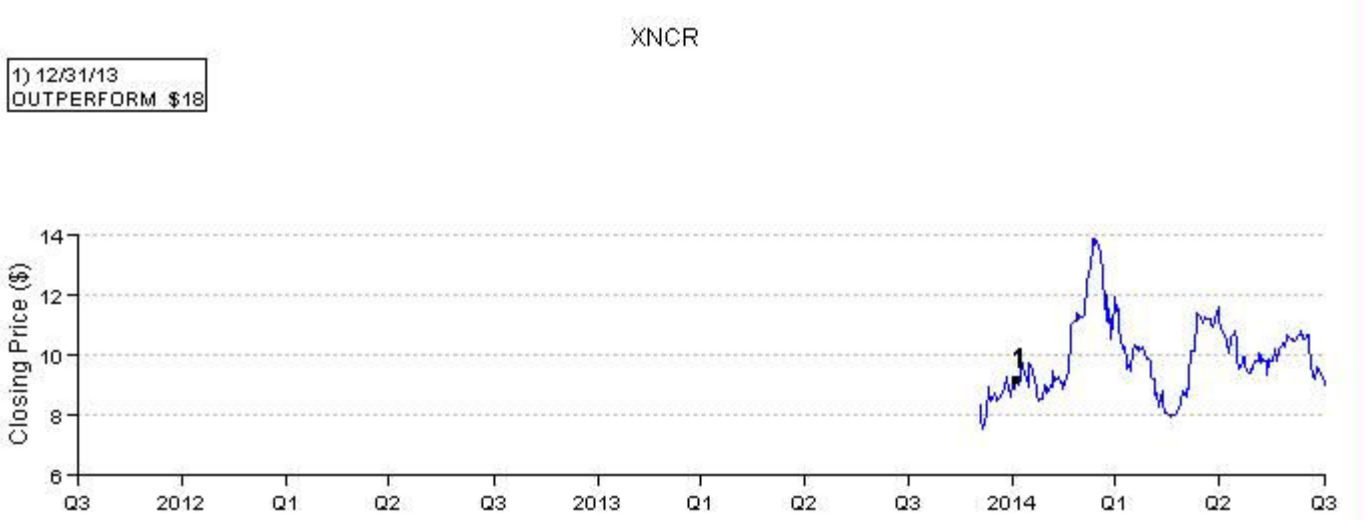

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