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MacroGenics (MGNX - OUTPERFORM): Preclinical Data of MGD007 Demonstrate Anti-Tumor Activity in the Colorectal Cancer Setting

Price: \$25.37

12-Month Price Target: \$70

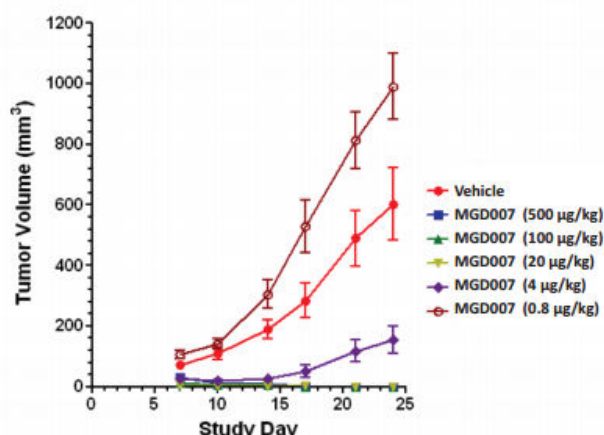
- **Dual affinity re-targeting proteins (DARTs) are a new class of protein therapeutics designed to simultaneously bind effector cells (eg. T-cells) and target cells (eg. cancer cells) to elicit the killing of the target cells.** As the originator and sole company producing DARTs, MGNX has produced over 100 DART molecules and has partnerships with Servier, Gilead, Boehringer, and Pfizer for up to 19 DART programs. To date, preclinical data from the two lead DART candidates, MGD006 (CD3xCD123) and MGD007 (CD3xgpA33), have shown similar preclinical efficacy that serve as proof of concept and support for entering clinical trials. Data from both molecules show binding of the DART to CD3 T-cells and target cells (acute myeloid leukemia for MGD006 or colorectal cancer cells for MGD007) resulting in the mediation of T-cell activation, T-cell proliferation, and tumor cell lysis. Both molecules have *in vivo* data showing mice models treated with these candidates having regression of the tumor. MGD006 and MGD007 are anticipated to enter clinical trials in Q2:14 and H2:14, respectively. Two other preclinical candidates are expected to enter the clinic in 2015. The preclinical data from these two lead DARTs provide support for the mechanism of action and potential efficacy of the novel class of DART molecules.
- **At AACR, MGNX presented preclinical data for MGD007, a bi-specific dual affinity re-targeting protein (DART) molecule, showing anti-tumor activity against colorectal cancer *in vitro* and in mice.** MGD007 targets T-cells through CD3 and gpA33 expressing cancer cells (greater than 95% of colorectal cancer, including cancer stem cells) through the glycoprotein A33 antigen. MGD007 doses of as low as 4 µg/kg were shown to elicit activity in colorectal cancer mouse models (Figure 1 and 2) suggesting potentially unprecedented potency compared to other biologics that are administered at mg/kg doses (eg. Herceptin (4 mg/kg), Kadcyla (3.6 mg/kg), rituximab (~9 mg/kg) and Adcetris (1.8 mg/kg)). MGNX also presented data that showed good tolerability of MGD007 by cynomolgus monkeys of up to 200 µg/kg qiw and a good pharmacokinetic profile with a mean half-life and a mean residence time of 6.8 days and 7.8 days for a 100 µg/kg dose (Figure 3). MGD007 specifically removes gpA33 expressing tumor cells and not tumor cells that do not express gpA33 (Figure 4), further demonstrating MGD007's specificity and mechanism of action. *In vitro* data show MGD007 elicits cytotoxic T-lymphocyte activity that requires the engagement of gpA33 containing tumor cells (Figure 5). MGD007's mechanism of action is associated with the upregulation of granzyme B and perforin in T cells and T cell activation and expansion (Figure 6). In addition to supporting an IND submission for the colorectal cancer setting, this preclinical proof of concept suggests that gpA33 may be a good target for other gpA33 expressing tumors including gastrointestinal, pancreatic, and gastroesophageal cancers.
- **MGNX expects to initiate a Phase I study of MGD007 in H2:14 in the colorectal cancer setting. Under the Servier agreement, MGNX will receive a \$5M milestone payment from Servier upon IND acceptance of MGD007.** Additionally, the Phase 2 and 3 clinical trial costs will be shared between Servier and MGNX. MGNX retains the commercial rights in North America, Japan, Korea, and India, while Servier has the rights for all remaining territories. MGNX will receive low double digit to mid-teen royalties of MGD007 sales from Servier.
- **MGNX plans to initiate a global Phase III clinical trial of margetuximab in combination with irinotecan or paclitaxel in the HER2+ (IHC 3+ or IHC2+ with HER2 gene amplification by FISH) refractory gastroesophageal cancer setting in H2:14.** The primary outcome will be overall survival, and enrollment is expected to take approximately 3 years.
- **The enrollment of the first 21 patients of the Phase IIa study of margetuximab in the relapsed or refractory low HER2 expressing metastatic breast cancer setting (IHC 2+, HER2 gene not amplified by FISH) is estimated to complete by YE:14.** If two or more responses are observed, the study will be expanded to a total of 41 patients. MGNX considers five or more partial or complete responses out of the 41 patients to have adequate activity for additional clinical development.
- **The first three dose expansion cohorts of the Phase I study of MGA271 (Fc-optimized B7-H3 antibody) in the B7-H3 positive (IHC 2/3+) tumor setting is expected to complete by YE:14, and additional expansion cohorts of MGA271 as monotherapy and combination therapy in other tumors are anticipated to begin in 2014.**
- **We reiterate our OUTPERFORM rating and \$70 price target.** Our \$70 price target is derived from the sum of multiples of sales and royalties from the company's proprietary and partnered products, each discounted back to YE:14.

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- Risks to achievement of our price target include clinical failures and product advancement and development success rates for MGNX's licensees below that for which we have modelled.

Figure 1: MGD007 Mediates Anti-tumor Activity

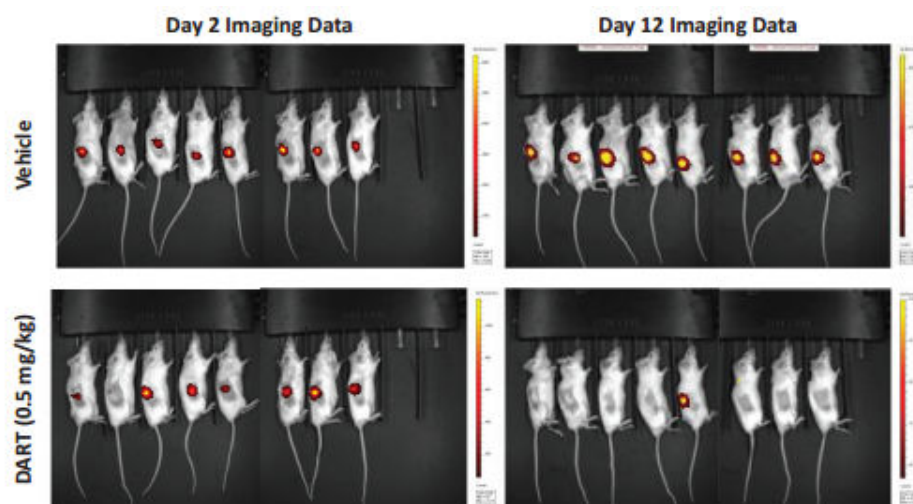
Winn Model: Colo205 Target Cells / Activated T-cells (E:T ratio 1:1)



Female NOD/SCID mice (n = 8/group) were implanted SC with Colo205 tumor cells + human T cells (1:1 ratio) on Day 0 followed by treatment with vehicle control or 0.8 to 500 µg/kg MGD007 on Days 0-3 for a total of 4 doses administered IV. MGD007 at dose levels of 4 µg/kg or greater significantly inhibited Colo205 colorectal tumor growth.

Source: MacroGenics

Figure 2: Xenograft Imaging Following Treatment with gpA33 x CD3 DART

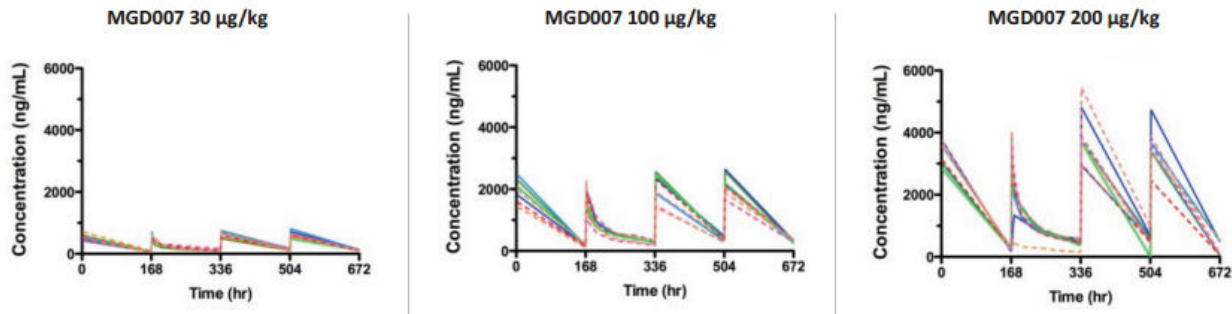


Caliper imaging of NSG mice co-implanted SC with Colo205 luciferase-labeled cells and activated T-cells (E:T = 1:1). gpA33 x CD3 DART (precursor to MGD007) or vehicle were administered IV once daily for 4 days and xenografts were monitored.

Source: MacroGenics

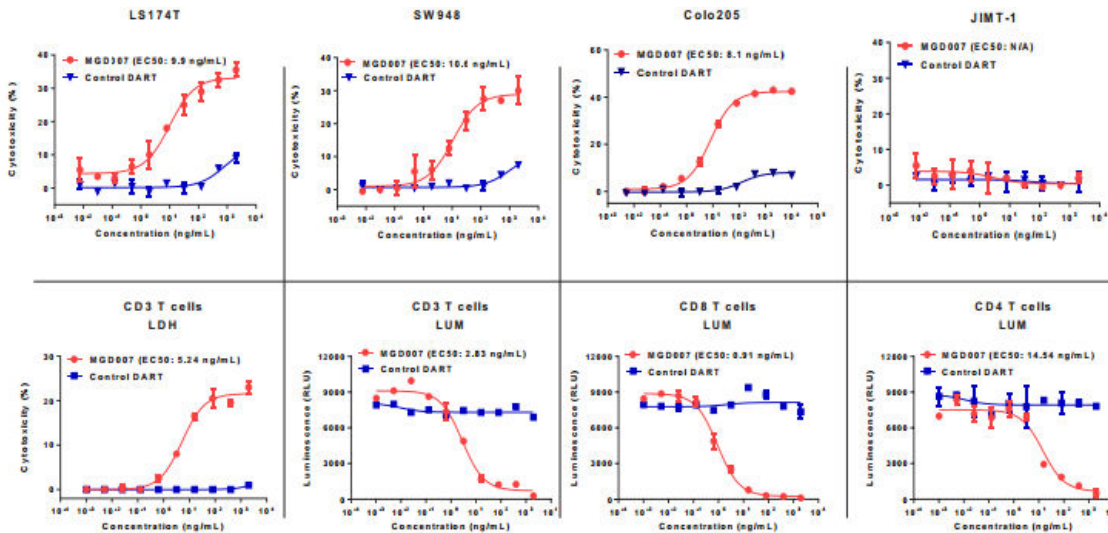
Figure 3: Circulating Serum Concentrations of MGD007 Following Dosing in Cynomolgus Monkeys

Circulating Serum Concentrations of MGD007 Following Dosing in Cynomolgus Monkeys



Source: MacroGenics

Figure 4: MGD007-Mediated CTL Activity Against gpA33-Target Cells

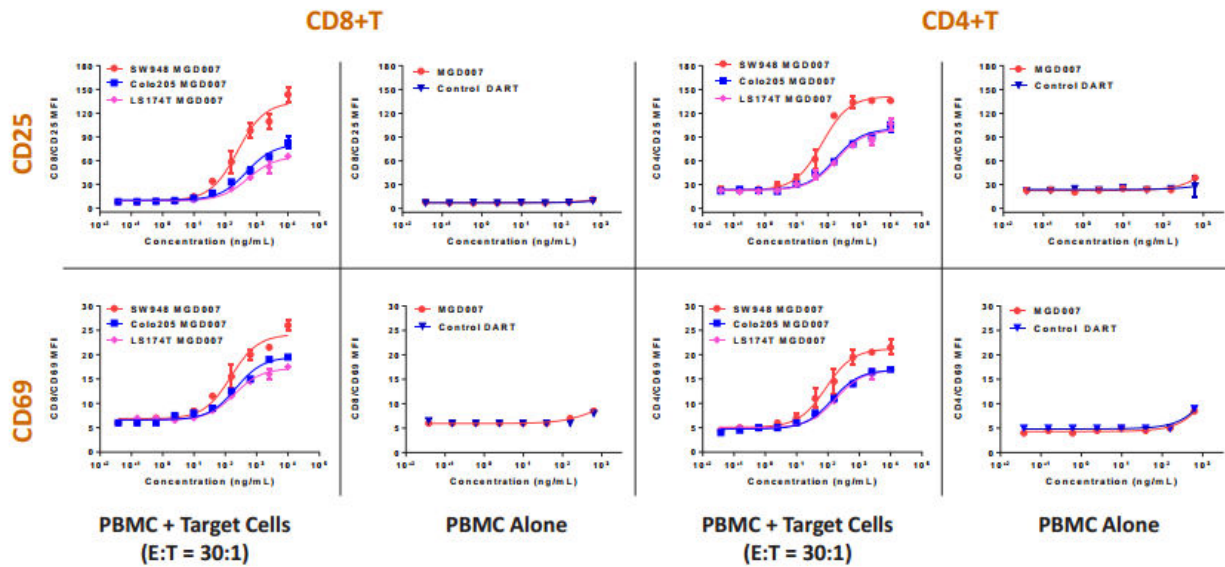


Top Row: MGD007 mediated specific redirected T-cell killing of gpA33-expressing target tumor cells (SW948, LS174T, and Colo205) by using human PBMCs as effectors (LDH-release assay; E:T cell ratio = 30:1; EC_{50} ~8-11 ng/mL). In contrast, no killing was observed against a breast cancer cell line lacking gpA33 expression (JIMT-1).

Bottom Row: MGD007 mediated cytotoxic T-lymphocyte (CTL) activity against luciferase-transduced Colo205 cells by using purified human T-cells (CD3, CD8, or CD4) from the same donor at E:T cell ratio of 10:1 by LDH-release assay or LUM assay as indicated.

Source: MacroGenics

Figure 5: MGD007-Mediated T-cell Activation is Dependent on gpA33 Target Cell Engagement



MGD007 mediated T-cell activation as measured by upregulation of CD25 and CD69 by CD8 and CD4 cells in the presence of gpA33-expressing target cells. No activation was observed with a control DART or by incubating MGD007 with PBMCs alone.

Source: MacroGenics

Figure 6: MGD007-Mediated Cytolytic Activity of T Cells is Associated with Upregulation of Granzyme B / Perforin and T-cell Expansion

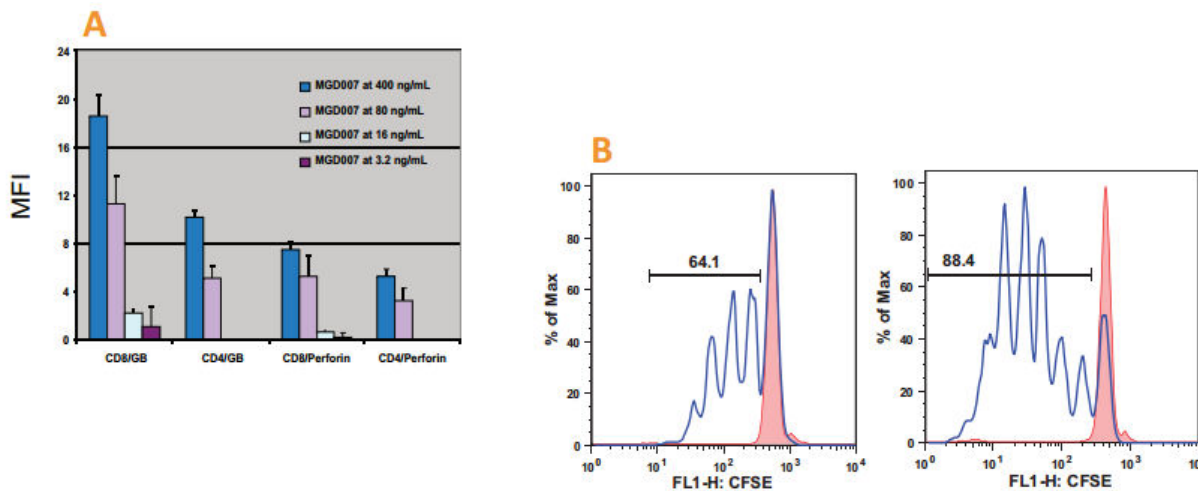


Figure A: Dose-dependent upregulation of granzyme B (GB) and perforin levels in both CD8 and CD4 human T cells was observed in the presence of MGD007 together with Colo205 target cells. Granzyme B and perforin upregulation were greater in CD8+ compared to CD4+ T cells, consistent with the greater level of CTL activity supported by CD8 vs CD4 T cells.

Figure B: MGD007 mediates T-cell expansion in the presence of LS174T target cells following 3 days (left panel) or 4 days (right panel) exposure at E:T cell ratio = 10:1 (MGD007 - blue; Control DART - red). Proliferation of CFSE-labeled T-cells was monitored by levels of CFSE dilution over time by flow cytometry.

Source: MacroGenics

Analyst Certification

I, Gregory R. Wade, Ph.D., David M. Nierengarten, Ph.D., Christopher N. Marai, Ph.D., certify that the views expressed in this report accurately reflect my personal opinion and that I have not and will not, directly or indirectly, receive compensation or other payments in connection with my specific recommendations or views contained in this report.

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Wedbush Equity Research Disclosures as of April 7, 2014

Company	Disclosure
MacroGenics	1,3,4,5,7

Research Disclosure Legend

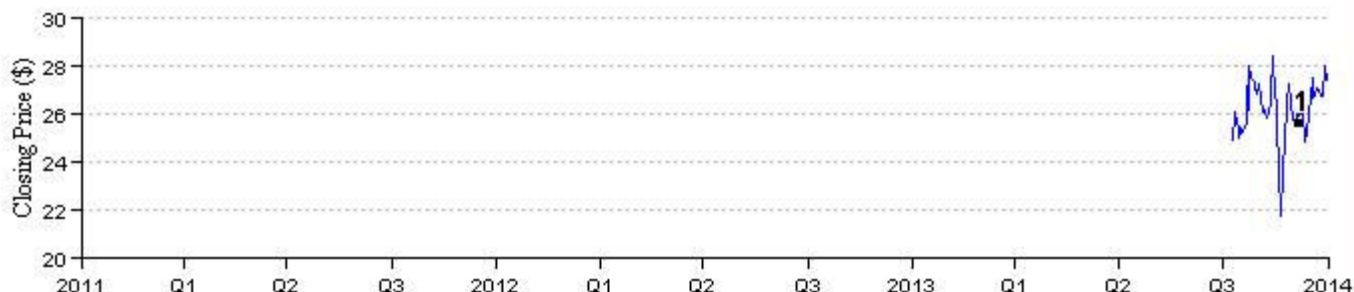
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MGNX

1) 12/03/13
OUTPERFORM \$70



* WS changed its rating system from (Strong Buy/Buy/Hold/Sell) to (Outperform/ Neutral/Underperform) on July 14, 2009.

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