

Atara Biotherapeutics (ATRA) Collaborator MSK receives breakthrough designation for EBV targeted T cells

Key Takeaway

We believe breakthrough designation for the EBV-CTL program in post-transplant lymphoproliferative diseases is important for several reasons: 1) clarification of the regulatory path in this indication could lead to expanded development in other EBV-associated diseases that ATRA/MSK may decide to pursue; 2) agreement on manufacturing with the FDA would apply potentially to all optioned MSK T-cell programs; and 3) could provide an accelerated path to approval.

Breakthrough therapy designation for the treatment of Rituxan refractory EBV associated lymphoproliferative disease (LPD) following a bone marrow transplant. Data from patients in two trials using ATRA's optioned cytotoxic T lymphocytes activated against EBV (EBV-CTL) was previously published in the journal Blood. Data in 19 patients with a EBV-LPD following a bone marrow transplant, demonstrated that 68% achieved a CR. More importantly in 10 of these patients that had previously failed Rituxan (that typically have a 33-56 day median survival), 70% achieved a CR and survival in these 7 patients ranged from 127 days to 10 years.

FDA Type B meeting will clarify regulatory path going forward. We expect management to obtain more details on the requirements for approval after this meeting (not scheduled yet). Importantly, agreement with the FDA on manufacturing would apply to all these T cell programs. Updated data from these studies are expected to be presented at a medical conference in 2015. We expect ATRA to exercise their option on the MSK programs after obtaining regulatory guidance but possibly even prior to their meetings with the agencies.

CMV-CTL data continue to impress with high response rates in patients with refractory CMV viremia and disease. Updated data with additional cycles of therapy in antiviral resistant CMV viremia and CMV disease patients demonstrated conversion to complete responses of some patients with stable disease and partial responses. In antiviral resistant CMV viremia patients (N=25 evaluable), ORR was 64% (9 CRs and 7 PRs) and in antiviral resistant CMV disease patients (N=9 evaluable), ORR was 67% (5 CRs and 1 PR)

BUY

Price target \$35.00

Price \$19.56

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Company Description

Atara Biotherapeutics, Inc. is a clinical stage biopharmaceutical company focused on developing novel therapeutics for serious unmet medical needs, with an initial focus on muscle wasting conditions and oncology. Its product candidates are biologics targeting myostatin and activin, members of the transforming growth factor-beta, protein superfamily, which play roles in the growth and maintenance of muscle and many other body tissues. The company's product candidate includes PINTA 745, STM 434 and ATA 842. Atara Biotherapeutics was founded by Isaac E. Ciechanover on August 22, 2012 and is headquartered in Brisbane, CA.

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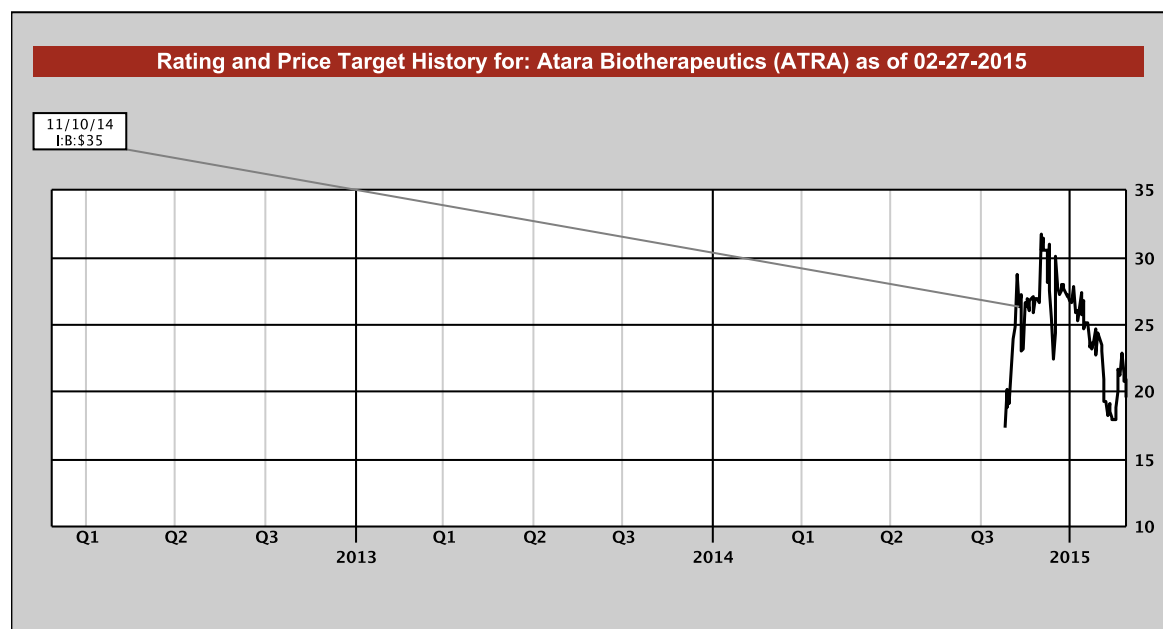
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