

July 8, 2013

Regenerative Cell Therapy: Autologous versus allogeneic is the wrong question? It's pre-clinical, manufacturing, and clinical data that drive safety.

Companies mentioned include:

Athersys, Inc. (ATHX) – \$1.68 – Buy

Baxter (BAX) – \$69.88 – NR

Capricor (private)

Cardio3 Biosciences (private)

Cytomedix (CMXI) – \$0.42 – NR

Cytori Therapeutics (CYTX) – \$2.43 – Buy

Dendreon (DNDN) – \$4.48 – Sell

IntellCellBioScience (SVFC) – \$0.05 – NR

Lonza (LONN.VX) – CHF72.30 – NR

Mesoblast Ltd. (MBLTY) – \$25.14 – Buy

NeoStem, Inc. (NBS) – \$0.57 – NR

Osiris (OSIR) – \$10.40 – NR

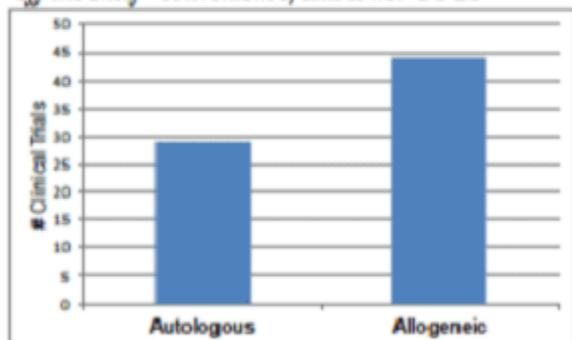
Pfizer (PFE) – \$27.97 – NR

Pluristem (PSTI) – \$2.98 – Hold

Teva Pharmaceuticals (TEVA) – \$38.94 – Buy

*Closing prices (7/05/2013)

More clinical trials are taking place with allogeneic cells, which we believe is due to a good safety profile, "off-the shelf" convenience, and lower COGS



Source: Clinicaltrials.gov and Maxim Group estimates

Jason Kolbert



Source: <http://thegreatharryhoudini.com>

- **“What the eyes see and the ears hear, the mind believes” – Harry Houdini.** In the wake of Pluristem's clinical hold, some investors have been asking if there are implications for other allogeneic companies. NeoStem closed its presentation at the Alliance for Regenerative Medicine (ARM) conference in April 2013, with a slide that autologous cells are safe. Well, that depends? Were the autologous cells manipulated, enriched, exposed to media, or expanded? The NeoStem product is “manipulated.” In this report, we review the safety data for allogeneic cells and claims from autologous companies like NeoStem that allogeneic cells are less safe or not safe. In fact, we believe this is misdirection on the part of autologous companies.
- **Manipulation?** Generally speaking, both autologous and allogeneic cells are manipulated. The definition of manipulation varies from minimally manipulated to manipulated, but it is a misnomer to claim that no manipulation occurs.
- The clinical hold on Pluristem has become fodder for some who want to raise the allo safety question. We spoke with Athersys and Mesoblast (allogeneic cells), and both companies told us that they have had zero immune-related AE's. All of these companies (allogeneic and autologous) are using different cell types, isolation procedures, product composition, and delivery. Both types are manipulated. Athersys has safely delivered doses of more than 1 billion cells systemically with no reported immune reactions. Mesoblast has tested its products in hundreds of patients with no allo-related AEs. The only company on the landscape that we see that is truly minimally manipulated is IntelliCell Bioscience (SVFC).
- **Our conclusion:** We believe both allogeneic and autologous with few exceptions qualify as manipulated products; therefore, the safety of both products must be assessed in pre-clinical, manufacturing, and clinical studies. We believe both allogeneic and autologous products will be approved for various indications. Most importantly, if the outcome is initially binary (it works or it doesn't), then patient convenience and cost of goods are likely to be major market factors. In this case, allogeneic has multiple advantages over the autologous process, which is more expensive and less patient friendly.

Maxim Group LLC 405 Lexington Avenue New York, NY 10174 – www.maximgrp.com

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