Athersys stem cell therapy wins scientists' plaudits

Mass Device

By Mary Vanac *[1]*

Doctors and researchers at the Athersys Inc. (NSDQ:ATHX) investor meeting in New York City expressed hope that the company's stem cell therapy — MultiStem — could raise the ceiling on care for heart attack, stroke and some cancer patients, among others.

Biopharmaceutical company Athersys invited nearly a dozen stem cell experts — including Ruth McKernan [2], head of Pfizer Regenerative Medicine, with which Athersys is working on a therapy for inflammatory bowel disease — to its annual investor day May 15.

Of course, the experts had good things to say about MultiStem, the off-the-shelf stem cell product on which Athersys is doing clinical trials as a treatment for heart attack, stroke and bone marrow transplant patients.

"We and a growing number of others believe that MultiStem represents a significant advance in the field of regenerative medicine," chairman and CEO Gil Van Bokkelen said [3]. That's because "it's a drug-like stem cell therapy that can be manufactured on an industrial scale, it can be administered like Type O blood, it exhibits a consistent safety profile and it can provide multiple therapeutic benefits," Van Bokkelen said.

One of the differences between MultiStem and competing therapies is the Athersys cells are scalable.

"Unlike traditional bone marrow or hematopoietic stem cell transplants that require a single donor for each patient, we have the ability to produce up to millions of doses of material from a single donor," Van Bokkelen said. "This enables us to manufacture a clinical-grade product in a reproducible and consistent manner."

In the body, MultiStem can promote multiple factors that protect tissue, promote tissue healing and repair and reduce inflammation in several ways. Athersys, which is conducting a Phase I trial of MultiStem to treat heart attack patients, is finding evidence that its stem cells also could treat peripheral vascular disease.

"MultiStem provides us with tremendous breadth, in terms of development opportunities," Van Bokkelen said. "Through our broad research and network of collaborations with leading research labs and clinical experts, we're generating a deep knowledge about the biology of MultiStem and its therapeutic potential across a range of disease areas. This allows us to explore future development

opportunities in areas of significant clinical need."

Those collaborations also have enabled Athersys to spread development costs among many institutions and to run a lean headquarters in Cleveland.

As a company, Athersys has spent a lot of time building an intellectual property portfolio [4] to protect and extend its research and manufacturing capabilities.

"That's a valuable asset that allows us to drive these platforms forward ... in a way that allows us to protect the interests of our shareholders," Van Bokkelen said.

Experts at the Athersys investor day painted a bigger picture of MultiStem's potential — and the potential of other stem cell therapies — to raise the ceiling above current clinical practices and results.

"We've hit the ceiling" in treating heart attack patients, Dr. Warren Sherman, an interventional cardiologist and director of stem cell research and regenerative medicine at the Center for Interventional Vascular Therapy at Columbia University Medical Center in New York, told meeting participants. "There's not much more we can do once the patients come to the emergency room."

But what if we can undo the damage that's been done?

"Repair mechanisms are our best hope for attempting to reverse what has gone on," Sherman said. "There is a profound unmet need" among patients for regenerative therapies.

Athersys and its experts released some new information about the company's trials of MultiStem for neurological damage:

- Preclinical information recently published in the *Journal of Experimental Stroke & Translational Medicine* shows that MultiStem helps patients several days after stroke. Current standard-of-care requires patients to be treated within four hours of a stroke.
- New preclinical data demonstrated MultiStem works by significantly reducing both inflammation and death of neurons in the brain following a stroke.
- New data and preclinical research show MultiStem preserves the blood-brain barrier after traumatic brain injury and results in expression of anti-inflammatory proteins.
- New preclinical research shows MultiStem can inhibit and reverse the "dieback" of neural cells following spinal cord injury.

"I began working with MultiStem several years ago because I was excited by the possibility of an off-the-shelf, non-immunogenic, intravenous stem cell therapy that could potentially ameliorate the effects of spinal cord injury," Dr. Jerry Silver, neuroscience professor at Case Western Reserve University and adjunct professor of neurosurgery at the Cleveland Clinic, in an Athersys press release [5] about the

investor day.

"My research experience with these cells is that they are, indeed, fascinating. I have seen remarkable effects with MultiStem in preventing axonal dieback and promoting axonal sprouting — the most impressive impact of any potential therapy in my 30 years of research," Silver said. "More studies are needed to determine the full functional benefits, but the results we've seen so far are extremely promising."

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