

'Mother' Nature Could Turn Key In Pluristem's Fledgling CLI Bid

By **Randy Osborne**
Editor

SAN FRANCISCO – By using maternal cells from placenta, Pluristem Therapeutics Inc.'s stromal stem-cell therapy work dodges ethical issues that have long plagued the field, but whether the method might turn into the come-from-behind mother of all such therapies in angiogenesis will not be known for a while.

"When I had the idea four and a half years ago to use the maternal part of the placenta, the understanding was that it was dead tissue after nine months," said Zami Aberman, president and CEO of the Haifa, Israel-based firm, in town to attend the J.P. Morgan Healthcare Conference. "They told me there is no evidence but it's common knowledge. I questioned the common knowledge."

Last week, the company said interim results from Phase I trials with its PLX-PAD candidate in critical limb ischemia, which often afflicts diabetics and can lead to amputation, found the drug to be safe and maybe efficacious, with three of nine patients showing a trend toward improvement (as measured by Rutherford's Category) after the finish of their three-month follow-up period.

"The maternal side of the placenta is the only place in nature that two systems are working together, the mother and the baby, and they're not attacking each other," Aberman said, so Pluristem may have discovered the "magic cells" that can be given without triggering an immune response. Cells in the mother "are the ones that should undergo some kind of immunomodulation in order not to attack the baby," he said. "The baby, on the other hand, has naïve cells, so it will not attack the mother."

So far, so good. As William R. Prather, Pluristem's vice president of corporate development explained, "We're just farmers. We harvest the cells from the placenta, we grow them [in a bioreactor that uses a three-dimensional process], we inject them and stand back and get out of the

way." The approach means Pluristem's researchers need not worry about which formula of factors will stimulate angiogenesis, since the cells deployed will provide a plentiful variety.

High on Pluristem's list as the next indication in which to try the approach is diabetic polyneuropathy. "The treatment [for that disorder] is probably not different from what we're doing now in CLI," Prather said. "We think the feds will allow the safety trials" in CLI to suffice in the diabetic polyneuropathy effort, so that the company could go into Phase II trials next year for both and possibly win approval in 2014.

"Our health care system, certainly big pharma, is not quite ready for personalized medicine," Prather said, so Pluristem is going for an "off the shelf, one-size-fits-all product" that will appeal to a

partner. One dose will be chosen from the five being tested. The Phase II trial will enroll between 60 and 100 patients, and the Phase III study will sign up 300.

Pluristem officials figured they'd wait until after Phase II to begin seriously hunting for a collaborator, though a pact could happen anytime. "God bless Athersys," Prather said, referring to the preclinical-stage stem-cell deal struck by New York-based Pfizer Inc. with Athersys Inc., of Cleveland, valued potentially as high as \$111 million. The deal is centered on inflammatory bowel disease, and Athersys is developing Multistem – adult stem cells derived from bone marrow – for several conditions, including bone marrow transplant support, ischemic stroke and acute myocardial infarction. (See *BioWorld Today*, Dec. 22, 2009.)

Other candidates for limb ischemia are farther along than Pluristem's PLX-PAD, Aberman conceded, but the race

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–William R. Prather, vice president of corporate development, Pluristem Therapeutics Inc.

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WORD ON THE STREET

- “Cost pressure is a reality of the 21st century so why should we even complain?”
–*Erich Hunziker, CFO of Roche AG, during the J.P. Morgan conference*
- “We will emerge a stronger company as a result of this.”
–*Henri Termeer, CEO of Genzyme Corp., trying to reassure the J.P. Morgan audience after a dismal year of manufacturing and product setbacks*
- “The financing environment is always adequate for companies who are continuing to make progress and hit milestones.”
–*Tim Rodell, CEO of Globelimmune Inc., echoing a sentiment voiced by several private biotechs to recently close venture rounds despite a tough fundraising environment*

WEEK IN WASHINGTON

- The FDA reported the approval of 19 new chemical entities and seven new biologics in 2009, compared to 21 NCEs and four biologics approved in 2008.
- The Endocrinologic and Metabolic Drugs Advisory Committee backed approval of **Actelion Pharmaceuticals Ltd.**'s Zavesca (miglustat) in Niemann-Pick Type C disease.

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for an effective therapy is far from won. Also last week, San Diego-based Vical Inc. said licensee AnGes MG Inc., of Osaka, Japan, reached an agreement with the FDA on the design of a 560-patient Phase III trial of Collategene, a potential treatment for patients with peripheral arterial disease, though AnGes is unlikely to start the study until the treatment gets approval in Japan, where it's under review. Collategene exploits Vical's DNA technology to deliver a gene encoding hepatocyte growth factor. Other late-stage drugs in development for lower limb ischemia are both

licensees of Vical. (See *BioWorld Today*, Jan. 13, 2010.)

Pluristem marches on. Half the patients who have undergone coronary bypass surgery cannot complete cardiac rehab because they can't walk, due to arterial disease in their legs, which “gives you some idea about the breadth of the market,” Prather said, estimating the size at \$4 billion to \$6 billion, understandably a tempting target for multiple players.

Though Aberman's firm did not present at the J.P. Morgan event “where everyone is,” Prather said, the firm told its story at the Biotech Showcase, held here for two days concurrent with the larger meeting. ■

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