ACT Receives Approval for First Human Embryonic Stem Cell Trial in Europe

Moorfields Eye Hospital in London is Site for Phase 1/2 Trial to Treat Stargardt’s Macular Dystrophy

MARLBOROUGH, Mass.-- Advanced Cell Technology, Inc. (“ACT”); (OTCBB: ACTC), a leader in the field of regenerative medicine, announced today that it has received clearance from the U.K. Medicines and Healthcare products Regulatory Agency (MHRA) to begin treating patients as part of a Phase 1/2 clinical trial for Stargardt’s Macular Dystrophy (SMD) using retinal pigment epithelium (RPE) derived from human embryonic stem cells (hESCs). ACT received similar approval from the Gene Therapy Advisory Committee (GTAC), which has responsibility for the ethical oversight of proposals to conduct clinical trials involving gene or stem cell therapies in the U.K. The European Medicines Agency (EMA) previously granted Orphan Drug designation for the company's RPE cell product for use in treating SMD.

“This is another important milestone for ACT and for the field of regenerative medicine,” said Gary Rabin, chairman and CEO of ACT. “We are pleased that the Moorfields Eye Hospital in London has agreed to participate as a site for this study as we continue to assess the capabilities of hESC-derived RPE cells to repair the retina and reduce the impact of these devastating eye diseases. We recently announced the dosing of the first patients in our Phase 1/2 clinical trials for Stargardt’s macular dystrophy and dry age-related macular degeneration (dry AMD) with hESC-derived RPE cells in the U.S., and both patients successfully underwent the outpatient transplantation surgeries. Clearance from the MHRA to begin an SMD trial in the U.K. is the first step in our European clinical trial program. Europe not only represents the world’s second-largest pharmaceutical market, but it is also home to some of the best eye hospitals and surgeons in the world. Building international relationships around our clinical programs, such as with Professor James Bainbridge at Moorfields Eye Hospital is very important to our strategy of developing new regenerative medicine therapies.”

Stargardt's Macular Dystrophy affects an estimated 80,000 to 100,000 patients in the U.S. and Europe, and causes progressive vision loss, usually starting in people between the ages of 10 to 20. Eventually, blindness results from photoreceptor loss associated with degeneration in the pigmented layer of the retina, the retinal pigment epithelium. The first patient to be treated in the U.S. with stem cell-derived RPE cells was a young woman who
was already legally blind as a consequence of this disease. This newly-approved clinical trial in Europe will be a prospective, open-label study designed to determine the safety and tolerability of RPE cells derived from hESCs following sub-retinal transplantation to patients with advanced SMD, and it is similar in design to the FDA-cleared U.S. trial initiated in July.

“This is the first time an embryonic stem cell trial has ever been approved anywhere else in the world,” said Robert Lanza, M.D., ACT's chief scientific officer. “Stargardt’s disease is currently untreatable, and is one of the leading causes of juvenile blindness in the world. Collectively, degenerative eye diseases afflict over 25 million people in the U.S. and Europe alone. These diseases have a devastating impact on patients and their families, which has been a strong motivating factor for developing this new treatment. In Stargardt’s disease, the loss of RPE cells in the patient's macula causes a loss of photoreceptors – the cones and rods with which we see – leading to blindness. We believe that transplanting new, healthy RPE cells may provide an effective treatment for SMD and perhaps other macular degenerative diseases such as dry AMD. We are excited to start these trials in Europe, and look forward to analyzing the data we continue to collect in our ongoing trials to determine the engraftment and function of the transplanted RPE cells.”

The trial will be led by Professor James Bainbridge, consultant surgeon at Moorfields Eye Hospital, and Chair of Retinal Studies at University College London.

"Stargardt's disease is a form of macular degeneration that causes disabling loss of sight in young people and is currently untreatable," said Professor Bainbridge. “There is real potential that people with blinding disorders of the retina including Stargardt's disease and age-related macular degeneration might benefit in the future from transplantation of retinal cells. The ability to generate retinal cells from stem cells in the laboratory has been a significant advance and the opportunity to help translate such technology into new treatments for patients is hugely exciting. Testing the safety of retinal cell transplantation in this clinical trial will be an important step towards achieving this aim.”

About Macular Degeneration and SMD

Degenerative diseases of the retina are among the most common causes of untreated blindness in the world. As many as 30 million people in the U.S. and Europe suffer from macular degeneration, which represents a $25-30 billion worldwide market that has yet to be effectively addressed.

About Advanced Cell Technology, Inc.

Advanced Cell Technology, Inc. is a biotechnology company applying cellular technology in the field of regenerative medicine. For more information, visit http://www.advancedcell.com.

Forward-Looking Statements
Statements in this news release regarding future financial and operating results, future growth in research and development programs, potential applications of our technology, opportunities for the company and any other statements about the future expectations, beliefs, goals, plans, or prospects expressed by management constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Any statements that are not statements of historical fact (including statements containing the words “will,” “believes,” “plans,” “anticipates,” “expects,” “estimates,” and similar expressions) should also be considered to be forward-looking statements. There are a number of important factors that could cause actual results or events to differ materially from those indicated by such forward-looking statements, including: limited operating history, need for future capital, risks inherent in the development and commercialization of potential products, protection of our intellectual property, and economic conditions generally. Additional information on potential factors that could affect our results and other risks and uncertainties are detailed from time to time in the company’s periodic reports, including the report on Form 10-K for the year ended December 31, 2010. Forward-looking statements are based on the beliefs, opinions, and expectations of the company’s management at the time they are made, and the company does not assume any obligation to update its forward-looking statements if those beliefs, opinions, expectations, or other circumstances should change. Forward-looking statements are based on the beliefs, opinions, and expectations of the company’s management at the time they are made, and the company does not assume any obligation to update its forward-looking statements if those beliefs, opinions, expectations, or other circumstances should change. There can be no assurance that the Company’s clinical trials will be successful.

Investors:
CEOcast, Inc.
James Young, 212-732-4300
or

Press:
ACT Corporate Communications
Bill Douglass, 646-450-3615
or
Russo Partners
Martina Schwarzkopf, Ph.D., 212-845-4292

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