

Stem cell trial for blindness approved in U.S.

By Maggie Fox, REUTERS

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WASHINGTON - Advanced Cell Technology said Monday it had won U.S. Food and Drug Administration approval to try out human embryonic stem cells for treating macular degeneration, a common cause of vision loss.

It is the second FDA approved trial for ACT's stem cell product and the third for the controversial and powerful stem cells.

ACT said it would start recruiting patients with dry age-related macular degeneration using retinal pigment epithelial, or RPE cells, which ACT makes from human embryonic stem cells.

"Dry AMD is the leading cause of blindness in individuals over the age of 55," Dr. Robert Lanza, ACT's chief scientific officer, said in a statement.

"As the population ages, the incidence of AMD is expected to double over the next 20 years," he added.

In October, Geron Corp enrolled the first patient in the first ever approved study of human embryonic stem cells, to treat people whose spinal cords have been crushed.

In November, ACT won FDA approval for the second human trial of human embryonic stem cells to treat people with a progressive form of blindness called Stargardt's macular dystrophy.

AMD, a slowly progressing disease, blurs vision at first but later causes a big black hole in the field of vision.

Wet AMD can be treated with laser surgery, photodynamic therapy and injections of Roche's drug Lucentis into the eye. Taking a specific combination of vitamins and zinc can reduce the risk of dry AMD and perhaps slow its progression.

There are no good treatments for advanced cases of dry AMD, which causes an estimated 85 percent of cases of macular degeneration, according to the U.S. National Eye Institute.

ACT estimates dry AMD that is serious enough to treat affects 10 million to 15 million Americans and sees a potential global market of \$25 billion or more.

The approval "marks a major step forward, not just within the stem-cell sector, but, potentially for modern healthcare techniques," Gary Rabin, interim chairman and CEO of ACT, said in a statement.

Stem cells are the body's master cells, the source of all other cells. Embryonic stem cells, taken from days-old human embryos, are especially pliable.

Opponents object to their use because to get the cells, someone has to take apart a human embryo.

Last year, the Obama administration overturned the strictest of the limitations on using federal funds for the research, but last summer, two researchers challenged the policy.

A U.S. appeals court has ruled that funding could continue while the government appeals, but grants from the National Institutes of Health have been frozen and unfrozen as various courts have weighed in and the court battles are continuing.