First Stem Cell Therapy Recommended for Approval in EU

The European Medicines Agency (EMA) recommended Holoclar (Chiesi Farmaceutici), the first advanced therapy medicinal product containing stem cells, for approval in the EU, according to a news release.

Holoclar is a treatment for moderate to severe limbal stem cell deficiency due to physical or chemical burns to the eye(s) in adults. It is a living tissue equivalent intended to be transplanted in the affected eye(s) after removal of the altered corneal epithelium. Holoclar is made from a biopsy taken from a small undamaged area (minimum of 1 to 2 mm) of the patient’s cornea and grown in a laboratory using cell culture.

The recommendation for approval, made by the Committee for Medicinal Products for Human Use (CHMP), was based on an assessment carried out by the EMA’s Committee for Advanced Therapies. The CHMP opinion will be sent to the European Commission for the adoption of a decision on an EU-wide marketing authorization. Once granted, decisions about price and reimbursement will occur at the level of each EU member state.

OCULENTIS RESPONDS TO CLAIMS RELATED TO SAFETY OF THE LENTIS MPLUS X IOL

Oculentis released a statement in response to recent articles published in The Observer and other news outlets concerning the safety of the Lentis Mplus X IOL. The company maintained in a news release that the statements made against its product, mostly reports that it has caused serious loss of vision, are “either entirely untrue or seriously misleading.”

The safety concerns reported in the media focus mostly on procedures performed at the UK-based refractive surgery chain Optical Express. According to Oculentis, The Observer has, over the years, printed several critical articles about Optical Express. “Unfortunately, in addition to the general refractive laser business, our product has now also been drawn into this dispute,” the Oculentis statement reads.

According to a response from Optical Express, quoted in The Observer article, although one patient in question had “an issue with higher-order aberrations” including halos and poor night vision after implantation of the Mplus X, the end result was “a very good ocular outcome.” The chain also commented that “in almost every case these symptoms subside,” and that they are not lens specific. It also maintains that only 0.5% of all multifocal IOLs, including the Mplus and Mplus X, implanted in its practices require removal.

In Oculentis’ statement, the company also responded to what it called “several factual inaccuracies” contained in The Observer articles. The company stated that it was aware of a total of four reports having been made to the Medicines and Healthcare products Regulatory Agency (MHRA). The first report, from Moorfields Eye Hospital in London, has been closed by the MHRA, and the three others, made in December 2014, “lacked detail” but are reportedly being investigated by the company. Oculentis has not received an incident report from any other authority in the EU, the news release said.

Additionally, Oculentis stated that no regulator, independent scientific body, or expert has ever suggested that Mplus X lenses are “faulty.” The company maintained that the lenses comply with all relevant safety and regulatory standards and acknowledged that, as with any surgery, complications arise in a minority of patients. “Oculentis sincerely regrets if the two individuals referred to [in The Observer article] have not achieved the improvements which they expected as a result of the surgery they have undergone, but the anecdotes of two individuals cannot in any way justify an assertion that the lens itself which they have been prescribed is faulty,” the news release states.

Oculentis questioned whether some of the claims made against the Mplus X were a result of competition in the business and industry, rather than rooted in factual evidence.

According to the company, several comments from CEO Ben Wanders were taken out of context by the media. Oculentis said that the countries mentioned by Mr. Wanders as examples of varying patient and surgeon preference were not in reference to cultural issues. Further, “suboptimal outcomes may be traced back to a multitude of reasons and cannot be automatically classified as a mistake by the surgeon, as suggested by the journalist.”

Oculentis confirmed that it has not withdrawn the product from any market worldwide.

Refractive Surgery Alliance Asks CDC to Retract Keratitis Report

The Refractive Surgery Alliance (RSA) has requested that the Centers for Disease Control and Prevention (CDC) retract its November 2014 report on keratitis, maintaining that it overstates the risk of contact lenses, according to a news release.

The CDC report was based on an analysis of US billing data. The RSA stated that it is concerned the report has created a false impression that the cost for reimbursed medical care extending from contact lens misuse approaches US$180 million and involves 1 million clinical visits per year.

In a letter to the CDC, the RSA listed seven objections to the CDC’s interpretation of the billing data. A key objection was that only 25.2% of the 1 million clinical visits cited list the contact lens billing code as the reason for the visit; the others were for corneal complaints grouped under the general term keratitis.

“Opening the discussion with these comments makes the reader think that the 1 million clinical visits for keratitis in 2010 resulted from contact lens infections,” Guy M. Kezirian, MD, FACS, Founder of the RSA, said in the news release. “This report should be retracted. It has created a false understanding of the risks of contact lenses.”

The RSA stated that it hopes the CDC will respond to its letter and correct the mistaken public perception that its report generated about contact lens risks. The RSA did, however, note that it supports the CDC’s recommendations for common sense precautions that all contact lens users should follow.


Flexivue Approved in Korea

The Presbia Flexivue Microlens (Presbia), a refractive intrastromal lens for the treatment of presbyopia, has received regulatory approval from the Korean Ministry of Food and Drug Safety (MFDS), according to a company news release.

With this approval, the Presbia Flexivue Microlens is now available for commercial use in South Korea, in addition to more than 40 other countries across Europe, Latin America, the Middle East, and Africa. Presbia is currently conducting a clinical trial for FDA approval in the United States.

Nevis Medical will oversee the distribution of the Presbia Flexivue Microlens in South Korea.

Alcon Launches TV Program

Alcon announced the launch of Alcon TV, a communication platform by which the company’s stakeholders can obtain regular information about the company, according to a news release. The program contains business, product, patient

Clickeworthy

1. Shift Workers Sicker and Fatter
Higher rates of illness and obesity were found in shift workers compared with the general population.

2. Poor Sleep Tied to Brain Changes Associated With Dementia
Poor sleep in older adults may be linked to brain changes associated with dementia.

3. More Than Salt, Sugars May Contribute to High Blood Pressure
Compared with dietary sodium, added sugars may contribute more to risk of hypertension and cardiovascular disease.
http://www.medicalnewstoday.com/articles/286795.php

4. Long-Term Cell Phone Use Linked to Brain Cancer Risk
Long-term use of mobile and cordless phones may be associated with an increased risk for glioma.

5. WHO: True Ebola Toll Hidden
As the number of affected patients continues to grow, West Africa still faces major challenges in its Ebola response.
http://www.medpagetoday.com/InfectiousDisease/Ebola/49156
awareness, corporate brand, and corporate social responsibility information.

The first episode focuses on Alcon’s third-quarter results and features Jeff George, Global Head of Alcon. To view the program, visit http://www.alcon.com/news-center/alcontv/.

**Schwind Appoints Fichtner to Head of Sales**

Schwind eye-tech-solutions appointed Michael Fichtner as Head of Sales, the company announced in a news release.

Mr. Fichtner has more than 25 years of experience in the field of semiconductors and solid-state laser systems, including ophthalmic laser systems. Before joining Schwind, he was head of sales for the laser business unit at Jenoptik AG. In his new position, he will be in charge of Schwind’s worldwide sales activities.

**Researchers Find the Human Eye Can Sense Infrared Light**

An international team of researchers discovered that, under certain conditions, the retina can sense infrared light, according to a study in *Proceedings of the National Academy of Sciences*.

The research team, led by scientists at Washington University School of Medicine in St. Louis, initiated its work after members reported seeing occasional flashes of green light when working with an infrared laser. Using retinal cells from mice and humans, the researchers found that when infrared laser light was pulsed rapidly, light-sensing cells in the retina sometimes got a double hit of infrared energy. When that happened, the eye was able to detect light outside the visible spectrum.

“We experimented with laser pulses of different durations that delivered the same total number of photons, and we found that the shorter the pulse, the more likely it was a person could see it,” study author Frans Vinberg, PhD, said in the news release.

According to the researchers, packing a lot of photons into a short pulse of the rapidly pulsing laser light made it possible for two photons to be absorbed at a time by a single photopigment. The combined energy of the two light particles was enough to activate the pigment and allow the eye to see what normally is invisible. The researchers are now studying ways to use this two-photon approach in a new type of ophthalmoscope.

---


*Compiled by Steve Daily, Executive Editor, News; and Callan Navitsky, Senior Editor*