People and ideas for innovation in healthcare

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****PRESS RELEASE****

NICE recommends Holoclar▼ (ex vivo expanded autologous human corneal epithelial cells containing stem cells) for the treatment of moderate to severe limbal stem cell deficiency after eye burns

First advanced therapy medicinal product containing stem cells to receive a Marketing Authorisation in Europe[1] recommended for use in eligible NHS patients

Manchester (UK), 23 August 2017 - Chiesi UK today announced that the National Institute for Health and Care Excellence (NICE) has published final guidance recommending Holoclar as an option in adults with moderate to severe limbal stem cell deficiency (LSCD) after eye burns, if it is only used to treat one eye and in those who have already had a conjunctival limbal autograft (or there is not enough tissue for a conjunctival limbal autograft or it is contraindicated). NICE also indicated that Chiesi should provide Holoclar in line with the discount agreed in the patient access scheme.[2]

Holoclar is now also recommended by NICE in adults with moderate to severe LSCD after eye burns for treating both eyes only in the context of research, and when there is not enough tissue for a conjunctival limbal autograft.

Chiesi's UK Managing Director Tom Delahoyde said, "Chiesi is extremely pleased that patients with LSCD can now have access to this innovative and breakthrough medicine on the NHS in England and Wales, reducing the need for external donors and damage to the donor eye. Today's recommendation is a culmination of many years of research and development and we are delighted that NICE has recommended that eligible patients have access to this personalised and regenerative medicine for a rare and seriously debilitating orphan condition."

Holoclar uses a patient's own stem cells to regenerate and repair damaged eye tissue and is the first advanced therapy medicinal product containing stem cells as the active substance to receive a Marketing Authorisation in Europe (granted in February 2015).[1] Holoclar is licensed for the treatment of adults with moderate-to-severe LSCD (defined by the presence of superficial corneal neovascularisation in at least two corneal quadrants, with central corneal involvement, and severely impaired visual acuity), unilateral or bilateral, due to physical or chemical ocular burns. Holoclar also won the prestigious UK Prix Galien Orphan Product award for innovation and research in 2016.

LSCD is a rare and seriously debilitating condition affecting one or both eyes; left untreated it results in chronic pain, burning, photophobia, inflammation, corneal neovascularisation, stromal scarring and the reduction or complete loss of vision.[3,4] Chemical and physical ocular burn injuries are thought to be the most common cause of LSCD.[5] Those likely to benefit from treatment with Holoclar include workers injured in industrial accidents (e.g. alkali/acid splash injuries) and military personnel injured in action (e.g. due to explosive devices). It is estimated that the maximum UK prevalent population eligible for treatment with Holoclar is 121 patients.[6]

Once NICE recommends a treatment 'as an option' in final guidance, the NHS must make sure it is available within three months (unless otherwise specified) of its date of publication.

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About LCSD
LCSD is a rare and seriously debilitating condition affecting one or both eyes that left untreated results in chronic pain, burning, photophobia (eye discomfort in bright light), inflammation, corneal neovascularisation (new blood vessels growing across the front of the eye), stromal scarring and the reduction or complete loss of vision.[3,4] In this condition, affected patients lack cells called limbal stem cells, which are found at the edge of the cornea (the transparent layer in front of the eye) and which normally continuously renew and repair the cornea.

Chemical and physical ocular burn injuries are thought to be the most common cause of LSCD.[5] The reported incidence of new cases of severe chemical corneal injury in the UK is 0.02 in 100,000 people per year, i.e. 13 new cases per year.[7,8]

The management of LSCD depends on the extent of the damage and symptomatology and aims at achieving symptom relief, improvement in visual acuity and ocular stabilisation.[1]

About Holoclar
Holoclar is licensed for the treatment of adult patients with moderate-to-severe limbal stem cell deficiency (defined by the presence of superficial corneal neovascularisation in at least two corneal quadrants, with central corneal involvement, and severely impaired visual acuity), unilateral or bilateral, due to physical or chemical ocular burns. A minimum of 1 - 2 mm^2 of undamaged limbus is required for biopsy.[9]

For full details of adverse reactions and contraindications, see the summary of product characteristics at https://ec.europa.eu/health/documents/community-register/2015/20150217130830/anx_130830_en.pdf

Adverse events should be reported▼. This medicinal product is subject to additional monitoring to allow the quick identification of new safety information. It is therefore important to report any suspected adverse events related to this medicinal product. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard.

About Chiesi Group
Based in Parma, Italy, Chiesi Farmaceutici is an international research-focused Healthcare Group, with over 80 years of experience in the pharmaceutical industry, present in 26 countries. Chiesi researches, develops and markets innovative drugs in the respiratory therapeutics, specialist medicine and rare disease areas. Its R&D organisation is headquartered in Parma (Italy), and integrated with 6 other key R&D groups in France, the USA, the UK, Sweden and Denmark to advance Chiesi's pre-clinical, clinical and registration programmes. Chiesi employs nearly 5,000 people. For more information please visit www.chiesi.com

About Holostem Terapie Avanzate
Holostem Terapie Avanzate is the first biotechnological company entirely devoted to development and manufacture of Advanced Therapies Medicinal Products (ATMPs) based on cultures of epithelial stem cells both for cell and gene therapy.

Holostem is a university spin-off founded in 2008 through the profitable union among the scientific know-how of internationally renowned researchers such as Michele De Luca and Graziella Pellegrini, the innovative spirit of the University of Modena and Reggio Emilia and the industrial know-how of Chiesi Group.

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Holostem is located into the Centre for Regenerative Medicine "Stefano Ferrari" of the University of Modena and Reggio Emilia and is aimed to promote epithelial stem cell-based regenerative medicine for patients with no alternative therapeutic solutions.

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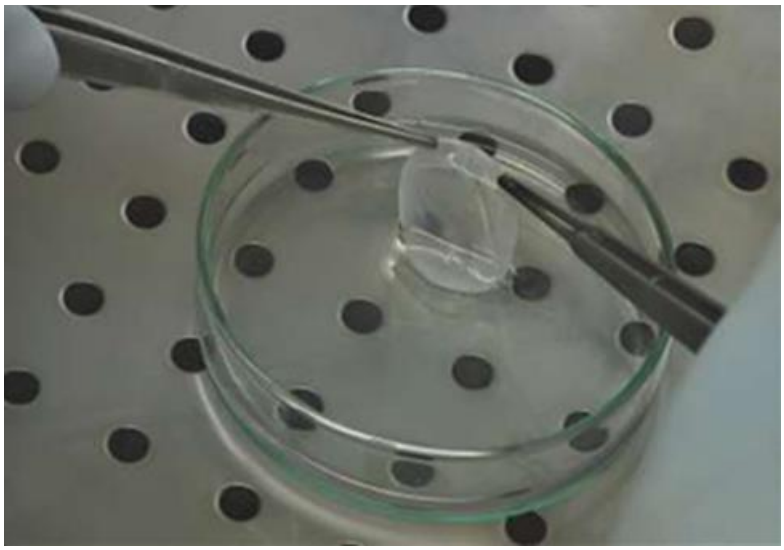

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