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EU recommends stem cell therapy

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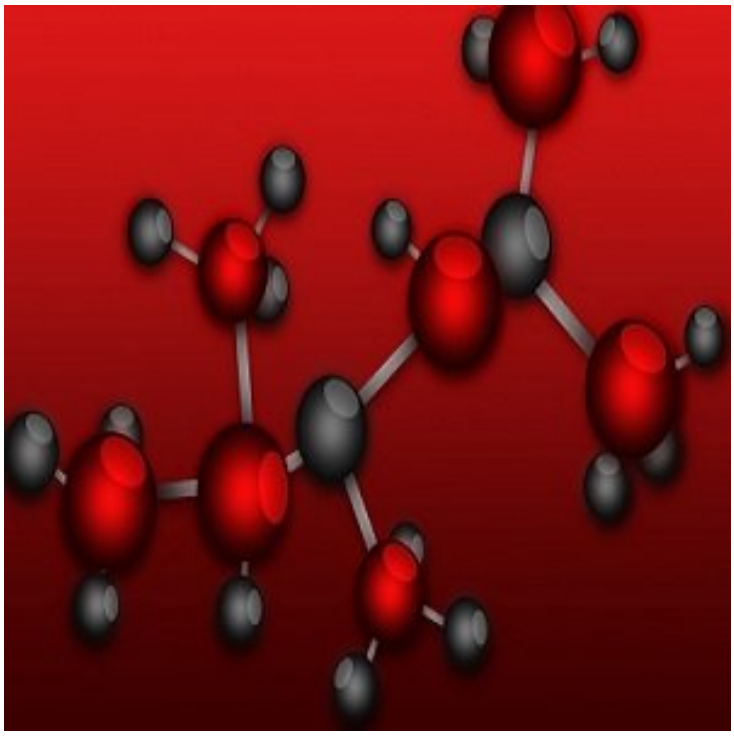

Singapore: European Medicines Agency (EMA) has recommended Holoclar, an advanced therapy medicinal product (ATMP) containing stem cells, for approval in the European Union (EU).

Holoclar is a treatment for moderate to severe limbal stem cell deficiency (LSCD) due to physical or chemical burns to the eye(s) in adults. It is the first medicine recommended for LSCD, a rare eye condition that can result in blindness.

The recommendation was made by the Committee for Medicinal Products for Human Use (CHMP) based on an assessment carried out by the Committee for Advanced Therapies (CAT), the Agency's expert committee for ATMPs.

"This recommendation represents a major step forward in delivering new and innovative medicines to patients," says Enrica Alteri, head, EMA's Human Medicines Evaluation Division. "EMA has used all available support tools to facilitate the development and assessment of Holoclar. It is an advanced therapy medicinal product that has been designated as an orphan medicine. This allowed the Agency to provide support including several rounds of free scientific advice to the applicant during Holoclar's development."

Stem cells can act as a repair system for the body. Limbal stem cells are located in the eye at the border between the cornea (clear front part of the eye) and the sclera (white of the eye). These cells are important for regenerating and healing damage to the outer layer of the cornea (corneal epithelium). Physical or chemical burns can cause loss of these stem cells, resulting

in LSCD.

Holoclar is a living tissue equivalent intended to be transplanted in the affected eye(s) after removal of the altered corneal epithelium. It is made from a biopsy taken from a small undamaged area (minimum of 1-2 mm2) of the patient's cornea and grown in the laboratory using cell culture.