EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

Anika Therapeutics S.r.l. withdraws its marketing authorisation application for Hyalograft C autograft

The European Medicines Agency has been formally notified by Anika Therapeutics S.r.l. of its decision to withdraw its application for centralised marketing authorisation for the medicine Hyalograft C autograft (cultured autologous chondrocytes on hyaluronan based scaffold), 4 million cells seeded on scaffold, for implantation. It was intended to be used for the surgical repair of symptomatic cartilage defects of the femoral condyle (medial, lateral) or trochlea, caused by acute or repetitive trauma in adults.

The application for the marketing authorisation for Hyalograft C autograft was submitted to the Agency on 28 February 2012. Hyalograft C autograft is an advanced therapy medicinal product (ATMP). At the time of the withdrawal, the medicine was under review by the Agency's Committee for Advanced Therapies (CAT) and the Committee for Medicinal Products for Human Use (CHMP).In its official letter, dated 14 January 2013, the company stated that it is withdrawing its application since, as part of the preliminary CAT / CHMP evaluation, major objections were identified, which the applicant was not able to address within the agreed timeframe.

Hyalograft C autograft has been used in a number of European Union (EU) countries since before the introduction of the EU regulation on advanced therapies in 2009. This regulation made it compulsory for advanced therapies already available in the EU to undergo evaluation by the Agency in order to obtain an EU-wide marketing authorisation.

Following the withdrawal, Hyalograft C autograft will no longer be available. Health care professionals will need to consider other treatment options for patients with femoral cartilage defects. Patients who have any questions should speak to their doctor.More information about Hyalograft C autograft and the state of the scientific assessment at the time of withdrawal is available in a question-and-answer document.

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Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. Withdrawal of an application does not prejudice the possibility of a company making a new application at a later stage.
3. Advanced-therapy medicinal products are medicines for human use that are based on gene therapy, somatic-cell therapy or tissue engineering. They offer ground-breaking new opportunities for the treatment of disease and injury. More information can be found at: http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000294.jsp&mid=WC0b01ac05800241e0
4. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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