14 December 2017
EMA/CHMP/815767/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Alofisel

darvadstrocel

On 14 December 2017, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Alofisel, intended for the treatment of complex perianal fistulas in patients with Crohn's disease. As Alofisel is an advanced therapy medicinal product, the CHMP positive opinion is based on an assessment by the Committee for Advanced Therapies. Alofisel was designated as an orphan medicinal product on 8 October 2009. The applicant for this medicinal product is Tigenix, S.A.U.

Alofisel will be available as a suspension for injection (5 million cells/ml). The active substance of Alofisel is darvadstrocel. Darvadstrocel contains expanded adipose stem cells which, once activated, impair proliferation of lymphocytes and reduce the release of pro-inflammatory cytokines at inflammation sites. This immunoregulatory activity reduces inflammation and may allow the tissues around the fistula tract to heal.

The benefits with Alofisel are its ability to improve the healing process of complex perianal fistulas in patients with Crohn's disease. The most commonly reported side effects include anal abscess and fistula, as well as procedural pain and proctalgia.

The full indication is: "Alofisel is indicated for the treatment of complex perianal fistulas in adult patients with non-active/mildly active luminal Crohn's disease, when fistulas have shown an inadequate response to at least one conventional or biologic therapy. Alofisel should be used after conditioning of fistula, see section 4.2."

It is proposed that Alofisel be administered by specialist physicians experienced in the diagnosis and treatment of conditions for which Alofisel is indicated.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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