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EMA/277400/2013
Patient Health Protection

Scientific recommendation on classification of advanced therapy medicinal products

Article 17 – Regulation (EC) No 1394/2007

Disclaimer: This document is a summary for public release of a scientific recommendation on classification of advanced therapy medicinal products. The original text adopted by the Committee for Advanced Therapies (CAT) has been redacted to delete commercially confidential information.

The present scientific recommendation refers exclusively to the case as presented to the European Medicines Agency (EMA) without prejudice to future evaluations by the Agency.

This scientific recommendation is not binding and is without prejudice to any decision taken by Member State competent authorities on matters falling within their own remits.

Short descriptor (or name when available) of the proposed active substance

Allogeneic bone marrow derived mesenchymal cells (MSCs) expanded ex vivo in synthetic media

Brief description of the proposed finished product

MSCs suspended in an injection saline solution in an injection bag

Proposed indication

Acute Graft-versus-Host Disease grades III and IV resistant to first line treatment

EMA/CAT comment

Consideration of Article 1(2) of Directive 2001/83/EC (definition of medicinal product – see Annex A)

- Allogeneic MSCs consist of Allogeneic bone marrow derived mesenchymal cells (MSCs) which can be considered a 'substance' in the meaning of the pharmaceutical legislation (in accordance with article 1(3) of Directive 2001/83/EC), administered in humans with Graft-versus-Host Disease

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- The product is presented as having properties for treating disease in human being.
- According to Article 1(2), the restoration, correction or modification of the physiological function is to be mediated by the substances that exert a "pharmacological, immunological or metabolic action". As allogeneic bone marrow derived mesenchymal cells (MSCs) consist of mesenchymal cells, it can be agreed that the product acts via pharmacological, metabolic or immunological means.

Fulfilment of Article 2(1) of Regulation (EC) No 1394/2007 (definition of advanced therapy medicinal product – see Annex A)

- The product contains living cells.
- The Allogeneic bone marrow derived mesenchymal cells (MSCs) have been subject to substantial manipulation (such as isolation and expansion in culture) that alters the biological characteristics, physiological function or structural properties relevant to the intended clinical use.
- The underlying mechanism of action for this effect is not completely elucidated. The applicant states that the mesenchymal cells may induce resolution of the disease or regression of Graft-versus-Host Disease via several mechanisms acting in concert, including suppression of activated T-cell, inhibition of inflammatory cytokines secretion, reducing the inflammatory reaction. Therefore, it can be agreed that Allogeneic bone marrow derived mesenchymal cells (MSCs) have immunomodulatory and immunosuppressive activities that can be used in the treatment of Graft-versus-host-Disease.

Based on the above considerations, it is considered that the Allogeneic bone marrow derived mesenchymal cells (MSCs) falls within the definition of somatic cell therapy medicinal product as provided in Article 2(1)(a) of Regulation (EC) No 1394/2007.

EMA/CAT conclusion

On the basis that:

- The product consists of substantially manipulated living cells so that biological characteristics, physiological function or structural properties relevant to the intended clinical use have been altered.

- The product is presented as having properties for treating a disease in human being

- The product is presented as acting via immunological means.

the EMA/CAT considers that the product falls within the definition of a somatic cell therapy medicinal product as provided in Article 2(1)(a) of Regulation (EC) No 1394/2007.