EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

Committee for Advanced Therapies gives first certification opinion for advanced therapies medicinal product

New certification procedure designed to help small and medium-sized enterprises developing innovative medicines

The European Medicines Agency's Committee for Advanced Therapies (CAT) adopted the first opinion on the certification of experimental data generated for an advanced therapies medicinal product (ATMP) under development by a small and medium-sized enterprise (SME).

This is the first time the certification system has been used in the European Union. Introduced by the legislation on advanced therapies in December 2008, the procedure foresees that an SME submits to the Agency data on the quality and where available non-clinical data generated with an ATMP from an early stage of development. The CAT carries out a scientific evaluation of these data and may recommend the issuing of a certificate confirming to what extent the data generated so far comply with the review standards that would be applied for the evaluation of a marketing authorisation application.

The certification procedure is intended exclusively for companies meeting the European Commission's SME criteria which develop ATMPs. Its aim is to facilitate the dialogue with the regulatory authorities early in drug development. While certification does not guarantee the approval of a clinical trial for an ATMP in an EU Member State or the granting of a marketing authorisation, the assurance provided by the certification may help SMEs to attract investors and to raise more capital for the development.

The ATMP concerned by the certification is a suspension of mononuclear cells developed for the proposed therapeutic use: acute myocardial infarction and chronic ischaemic heart disease.

Further companies have also signalled their interest in the procedure and the Agency expects the submission of three to four additional applications by September 2010.

Certification applications can be submitted to the European Medicines Agency at any time and more than once during the development of an ATMP. However, because the best time to apply for certification is when the ATMP has reached a level of sufficient development, SMEs are encouraged to contact the Agency's Advanced Therapies secretariat (AdvancedTherapies@ema.europa.eu) to discuss the most appropriate strategy.

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Notes

1. More information about the certification procedure can be found here: http://www.ema.europa.eu/htms/human/advanced_therapies/certification.htm
2. The ATMP concerned by the certificate is a suspension of 5-50 10^7 mononuclear cells in 11 ml X-Vivo-10 medium containing 20 % autologous serum.
3. More information on how to be assigned SME status by the Agency can be found here: http://www.ema.europa.eu/SME/SMEapplication.htm
4. This press release, together with other information on the work of the European Medicines Agency, can be found on the Agency's website: www.ema.europa.eu

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