European Medicines Agency
Press office

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PRESS RELEASE
EMEA concludes first accelerated assessment for a medicine for human use

The European Medicines Agency's (EMEA) Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion recommending the granting of a marketing authorisation for the first medicinal product for human use that was evaluated by accelerated assessment.

Accelerated assessment was introduced by the revised EU pharmaceutical legislation in November 2005. The aim of this new regulatory tool is to help speed up access of patients to new medicines of major public-health interest. Companies can request accelerated assessment provided they are able to demonstrate that their product responds to unmet medical needs or constitutes a significant improvement over the available methods of prevention, diagnosis or treatment of a condition. In 2006, the CHMP received 13 requests for accelerated assessment, 4 of which were accepted.

The medicinal product, Soliris (eculizumab), from Alexion Europe SAS, besides being the first medicinal product for which an accelerated assessment procedure was concluded successfully, is also the first product submitted by a company benefiting from specific incentives for small and medium-sized enterprises (SMEs) to receive a positive opinion.

Soliris, a designated orphan medicinal product, is intended to reduce haemolysis (destruction of red blood cells) in patients with paroxysmal nocturnal haemoglobinuria (PNH), a rare blood disorder in which the red blood cells are weak and are thus destroyed more rapidly than normal, causing the urine to turn red or dark during an episode (or paroxysm) of haemolysis. The EMEA review time was 147 days, within the limit of 150 days set by EU legislation for accelerated assessment.

The opinion for Soliris will now be forwarded to the European Commission for adoption of a marketing authorisation decision.

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NOTES

1. A summary of opinion for Soliris with the exact indication is available here.
2. The EMEA guideline on the procedure for accelerated assessment is available here.
3. The CHMP conducts an accelerated assessment in a maximum of 150 days. If it identifies major objections during the assessment, however, the CHMP can revert to the normal timetable for the centralised procedure, which allows a maximum assessment period of 210 days.
4. More information about the EMEA's activities in relation to SMEs is available here.
5. This press release, together with other information about the work of the EMEA, can be found on the EMEA website: http://www.emea.europa.eu

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