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Press Office

Public Statement

Rilonacept Regeneron (Rilonacept)

Withdrawal of the marketing authorisation in the European Union

On 23 October 2009 the European Commission issued a marketing authorisation valid throughout the European Union for the medicinal product Rilonacept Regeneron (Rilonacept). Rilonacept Regeneron was approved for the treatment of cryopyrin-associated periodic syndromes (CAPS).

The marketing authorisation holder (MAH) responsible for Rilonacept Regeneron was Regeneron UK Limited.

The European Commission was notified by letter dated 20 September 2012 of the MAH's decision to voluntarily withdraw the marketing authorisation for Rilonacept Regeneron for commercial reasons. The product had never been placed on the market in any country of the European Community.

On 24 October 2012 the European Commission issued a decision to withdraw the marketing authorisation for Rilonacept Regeneron. Pursuant to this decision the European Public Assessment Report for Rilonacept Regeneron has been updated to reflect the fact that the marketing authorisation is no longer valid.

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