19 April 2013
EMA/COMP/102965/2013
Committee for Orphan Medicinal Products

Public summary of opinion on orphan designation

Zoledronic acid for the treatment of complex regional pain syndrome

On 6 February 2013, the Committee for Orphan Medicinal Products (COMP) adopted a negative opinion on the orphan designation application for zoledronic acid for the treatment of complex regional pain syndrome (CRPS). A negative decision was issued by the European Commission on 17 April 2013.

The sponsor applied for orphan designation on the basis of the seriousness and the rarity of the condition.

The negative opinion was based on the following reason:

- The data submitted by the sponsor were not considered sufficient to demonstrate that the medicine could plausibly be used in the treatment of CRPS. The main data provided in support of the application was obtained from a conference abstract reporting on a non-sponsor generated study that lacked relevant details that would be necessary for an in-depth assessment of the results.

Requests for designation as an orphan medicinal product are made for investigational products. Absence of orphan designation does not preclude the development of this product, including its use in clinical trials. A marketing authorisation can still be obtained if quality, safety and efficacy are demonstrated.

For more information:

Sponsor's contact details:

Axsome Therapeutics Limited
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For contact details of patients' organisations whose activities are targeted at rare diseases see:

- Orphanet, a database containing information on rare diseases which includes a directory of patients' organisations registered in Europe.
- European Organisation for Rare Diseases (EURORDIS), a non-governmental alliance of patient organisations and individuals active in the field of rare diseases.