24 February 2020
EMADOC-628903358-1680

Public summary of opinion on orphan designation

Naltrexone for the treatment of fibromyalgia

On 7 November 2019, the Committee for Orphan Medicinal Products (COMP) adopted a negative opinion on the orphan designation application for naltrexone for the treatment of fibromyalgia. A negative decision C(2019)8451 was issued by the European Commission on 16 December 2019.

The sponsor applied for orphan designation on the basis of the seriousness of the disease and insufficient returns on investment, as well as an assumption of potential benefit over currently available methods of treatment. The COMP confirmed that fibromyalgia is a seriously debilitating condition due to widespread pain that can be associated with depression and anxiety. The Committee also confirmed that there are no satisfactory methods of treatment authorised in the EU and that the medicine could provide benefits to patients with fibromyalgia.

The negative opinion was based on the following reasons:

- The sponsor did not demonstrate that marketing the medicine in the EU is unlikely to generate sufficient return to justify the necessary investment. The sponsor did not adequately justify their view that orphan designation would reduce the costs of development, thereby providing sufficient return on investment.

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:

Contact details of the current sponsor for this orphan designation can be found on the EMA website.

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.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union