17 September 2021
EMA/512898/2021
EMEA/H/C/005189/0000

Refusal of the marketing authorisation for Raylumis (tanezumab)

The European Medicines Agency has recommended the refusal of the marketing authorisation for Raylumis, a medicine intended for the treatment of pain associated with osteoarthritis.

The Agency issued its opinion on 16 September 2021. The company that applied for authorisation, Pfizer Europe MA EEIG, may ask for re-examination of the opinion within 15 days of receiving the opinion.

What is Raylumis and what was it intended to be used for?

Raylumis was developed as a medicine to treat moderate to severe chronic pain of the hip or knee in adults with osteoarthritis. Raylumis was intended for patients whose disease cannot be controlled well enough with non-steroidal anti-inflammatory drugs (NSAIDs) or opioids (a painkiller related to morphine) or patients who cannot take these medicines.

Raylumis contains the active substance tanezumab and was to be available as a solution for injection under the skin.

How does Raylumis work?

The active substance in Raylumis, tanezumab, is a monoclonal antibody (a type of protein) that has been designed to recognise and attach to a protein called nerve growth factor (NGF). NGF is involved in the control of pain and is elevated in joints of osteoarthritis patients. Tanezumab is intended to block NGF from attaching to specific receptors (targets) on nerve cells that control pain and is expected to relieve pain associated with osteoarthritis.

What did the company present to support its application?

The company presented the results from three main studies involving 3,021 patients with moderate to severe chronic pain in knees or hips and moderate to severe problems with the normal functioning of the joints, due to their osteoarthritis. The studies compared the effects of Raylumis on pain and physical function with that of placebo (a dummy treatment) or, in one study, NSAIDs.

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

What were the main reasons for refusing the marketing authorisation?

Although Raylumis showed better pain relief and improved physical functioning in patients with osteoarthritis affecting the hip or knee compared with placebo, the difference was small. In addition, there was no improvement in pain relief and physical functioning when compared with NSAIDs. In terms of safety, patients on Raylumis were at an increased risk of side effects, such as rapid progressive osteoarthritis and joint replacement, compared with patients receiving placebo or NSAIDs. Therefore, the Agency's opinion was that the benefits of Raylumis in patients with an insufficient response to NSAIDs or opioids were unclear and did not outweigh its risks and recommended refusing marketing authorisation.

Does this refusal affect patients in clinical trials?

The company informed the Agency that there are no consequences for patients in clinical trials with Raylumis.

If you are in a clinical trial and need more information about your treatment, speak with your clinical trial doctor.