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Media and Public Relations

Press release

New treatment option for rare inflammatory disease

Extension of indication of Kineret for Still's disease in children and adults

The European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has recommended granting an extension of indication to Kineret (anakinra) for the treatment of Still's disease, a rare disease causing inflammation of joints as well as rash and fever, in children and adults.

This new indication in Still's disease includes systemic juvenile idiopathic arthritis (JIA) and adult-onset Still's disease, which are debilitating and difficult-to-treat disorders with few approved treatment options. In children, Still's disease (systemic JIA) is the most severe form of arthritis. Kineret is to be used in infants eight months and older, children, adolescents and adults, with moderate to high disease activity, or when the disease is still active after treatment with non-steroidal anti-inflammatory drugs (NSAIDs) or glucocorticoids.

The availability of this treatment option for infants, children and adolescents was facilitated through discussions between the marketing authorisation holder and EMA's Paediatric Committee (PDCO) on a paediatric investigation plan (PIP). Recognising the potential of the medicine to treat children with Still's disease, it was agreed to address this paediatric need.

Currently, most patients with Still's disease are initially treated with anti-inflammatory drugs, including NSAIDs and glucocorticoids, which can be effective at controlling the disease and its symptoms. However, high doses of steroids are often needed to control inflammation, which can lead to a range of side effects. Other treatment options include monoclonal antibodies that are used in second line of treatment. There is still unmet medical need for authorised efficient treatment for the disease.

Kineret is an immunosuppressive medicine (a medicine that reduces the activity of the immune system). It blocks the activity of a chemical messenger in the body called interleukin 1, which is produced in high levels in patients with rheumatoid arthritis and systemic juvenile idiopathic arthritis, causing inflammation of the joints, joint damage and systemic features like fever, skin rash and inflammation of internal organs.

The CHMP's positive opinion is based on data from clinical trials (two studies were included as part of the PIP) as well as data from scientific literature and meta-analyses of published data. Overall, the evaluation of the medicine is based on 442 patients with Still's disease (245 paediatric and 197 adult). It shows the efficacy of anakinra in both paediatric and adult patients with Still's disease, with the

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 8427 **Facsimile** +44 (0)20 3660 5555
E-mail press@ema.europa.eu **Website** www.ema.europa.eu

majority of patients achieving remission as well as an improvement of the signs and symptoms associated with the condition.

Safety data from the clinical trials and published literature in Still's disease, together with substantial safety data from post-marketing in both Still's disease and other indications, showed that the most common adverse events were reactions at the site of injection, as well as fever, rash and headache.

The opinion adopted by the CHMP is an intermediary step on Kineret's path to patient access in this new indication. The CHMP opinion will now be sent to the European Commission for the adoption of a decision on an EU-wide marketing authorisation. Once a marketing authorisation has been granted, decisions about price and reimbursement will take place at the level of each Member State, taking into account the potential role/use of this medicine in the context of the national health system of that country.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The applicant for Kineret is Swedish Orphan Biovitrum AB.
3. More information on Kineret is available here.
4. More information on paediatric medicines is available here.
5. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

Contact our press officers

Tel. +44 (0)20 3660 8427
E-mail: press@ema.europa.eu
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