EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 May 2023
Media and Public Relations

Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 10 – 12 May

New safety information for healthcare professionals

Gavreto: measures to minimise increased risk for tuberculosis

This DHPC aims to inform healthcare professionals of the increased risk of tuberculosis and measures to minimise this risk, which was identified following a post-marketing review.

In the EU, Gavreto (pralsetinib) is indicated as monotherapy for the treatment of adult patients with rearranged during transfection (RET) fusion-positive advanced non-small cell lung cancer (NSCLC) not previously treated with a RET inhibitor.

Tuberculosis, mostly extrapulmonary, has been reported in patients receiving this medicine. An investigation of global safety data for Gavreto identified nine cases of tuberculosis in patients, of which the majority (7/9) occurred in tuberculosis-endemic regions.

Before starting treatment, patients should be evaluated for active and inactive (latent) tuberculosis, as per local recommendations. In patients with active or latent tuberculosis, standard antimycobacterial therapy should be initiated before treatment with Gavreto is started.

Voxzogo: introduction of a new type of syringe

This DHPC informs healthcare professionals about the introduction of a new type of syringe for Voxzogo (vosoritide), a medicine that is used to treat achondroplasia, a rare disease that affects growth of almost all bones in the body.

From June 2023, the packs will contain new solvent needles and new administration syringes due to supply chain reasons. Since the new syringe uses a different graduation marking, in international insulin units (IU), healthcare professionals should ensure that caregivers and patients are informed about correct dose administration. The product information has been amended to reflect the alternative needle and syringe use. There are no changes to the Voxzogo dose.

The DHPCs for Gavreto and Voxzogo will be forwarded to EMA's human medicines committee (CHMP). When adopted, the DHPCs will be disseminated to healthcare professionals by the marketing authorisation holders, according to an agreed communication plan, and published on the 'Direct healthcare professional communications' page and in national registers in European Union (EU) Member States.