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Outcome of assessment on use of Mounjaro in treatment of heart failure with preserved ejection fraction in adults with obesity

The European Medicines Agency has finalised its assessment of an application to extend the use of Mounjaro to include treatment of symptomatic long-term (chronic) heart failure with preserved ejection fraction (HFpEF) in adults with obesity.

HFpEF is a condition where the heart becomes too stiff and cannot relax and fill properly between heartbeats. As a result, the heart does not pump out as much blood as the body needs. This results in symptoms including difficulty breathing, tiredness, and swelling, usually affecting the ankles and feet.

Although EMA did not recommend that a separate indication should be granted for the treatment of HFpEF, it agreed to include relevant data from the study submitted with the application in the medicine's product information. This ensures that healthcare professionals have access to up-to-date data on the effects of Mounjaro in adults with chronic HFpEF and obesity.

What is Mounjaro and what is it used for?

Mounjaro is a medicine used together with diet and physical activity to treat adults, adolescents and children aged 10 years and above who have type 2 diabetes which is not satisfactorily controlled. It can be used on its own in patients who cannot take metformin (another diabetes medicine) or as an 'add-on' to other diabetes medicines.

Mounjaro is also used together with diet and physical activity to help people to lose weight and keep their weight under control. It is used in people who have obesity (BMI of 30 kg/m^2 or more) or who are overweight (BMI between 27 and 30 kg/m^2) and have weight-related health problems such as diabetes, abnormally high levels of fat in the blood, high blood pressure or obstructive sleep apnoea (frequent interruption of breathing during sleep). BMI (body mass index) is a measure of your weight in relation to your height.

Mounjaro has been authorised in the EU since September 2022.

It contains the active substance tirzepatide and is available as a solution for injection in prefilled pens and vials.

Further information on Mounjaro's current uses can be found on the Agency's website: ema.europa.eu/en/medicines/human/EPAR/mounjaro.

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What change had the company applied for?

The company applied to extend the use of Mounjaro to treat symptomatic chronic HFpEF in adults with obesity.

How does Mounjaro work?

The active substance in Mounjaro, tirzepatide, acts in the same way as glucagon-like peptide-1 (GLP-1) and glucose-dependent insulinotropic polypeptide (GIP). These hormones are produced in the gut and bind to specific receptors (targets) in the body, such as, among others, the pancreas and the brain. This increases the amount of insulin that the pancreas releases in response to food and helps lower blood glucose levels in people with type 2 diabetes. Targeting these receptors also reduces appetite and helps people manage their weight.

Obesity is an established risk factor for heart failure. In HFpEF, Mounjaro is expected to work in the same way as it does in its existing indications. Losing excess body weight can improve the symptoms of chronic HFpEF in adults with obesity.

What did the company present to support its application?

The company submitted data from a main study involving 731 adults with obesity and chronic HFpEF, who were given either Mounjaro or placebo (a dummy treatment). The main measures of effectiveness were the changes in the severity of heart failure symptoms and their impact on everyday life (evaluated using a questionnaire called KCCQ-CSS after 52 weeks of treatment), as well as the number of cases of death due to problems with the heart and blood circulation or episodes of worsening heart failure. These included hospitalisations for heart failure, urgent visits for heart failure and intensification of diuretic treatment (a medicine that increases urine production and reduces the build-up of water in the body).

What were EMA's conclusions?

Based on the results of the main study, EMA acknowledged that, although Mounjaro did not reduce the number of deaths due to problems with the heart and blood circulation in adults with obesity and HFpEF, it significantly reduced the number of hospitalisations due to heart failure and also improved patients' quality of life. However, the Agency considered that uncertainty remains as to whether these results are a weight-loss-independent effect of Mounjaro and that the use of Mounjaro in this group of people is already covered by the approved indication for weight management. Therefore, a separate indication for the treatment of adults with chronic HFpEF and obesity is not needed.

Although EMA did not recommend that a separate indication should be granted, the prescribing information will be updated to include relevant data, so that healthcare professionals have access to up-to-date data on the effects of Mounjaro in adults with obesity and chronic HFpEF.

Does this outcome affect patients in clinical trials/ compassionate use programmes?

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

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