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Withdrawal of application for the marketing authorisation of Artobend (autologous human chondrocytes *in vitro* expanded)

TETEC Tissue Engineering Technologies AG withdrew its application for a marketing authorisation of Artobend (an advanced therapy medicinal product) for the treatment of cartilage defects of the knee joint.

The company withdrew the application on 18 November 2020.

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

Artobend was developed to repair defects in the cartilage of the knee in patients who are experiencing symptoms such as pain and problems moving the knee. It was intended for use in adults and children whose leg bones are no longer growing (growth-plate closure), when the affected area was no greater than 10 cm^2.

Artobend contains human chondrocytes, cells found in healthy cartilage, that have been prepared from the patient's own cartilage tissue.

How does Artobend work?

Cartilage in the knee can be damaged because of an accident, such as a fall or a sports injury, or due to osteochondritis dissecans, a condition often caused by a lack of blood supply to the joint, causing the bone and cartilage to die and break loose.

Artobend is made from the patient's own cartilage cells collected from a small sample of healthy tissue from the patient's knee. The cells are grown in a laboratory on a structure (scaffold) made of a protein called collagen. This is then implanted into the affected knee, where it is expected to produce new tissue, thereby repairing the defect in the knee.

What did the company present to support its application?

The company presented the interim results of one main study comparing Artobend with microfracture surgery (a type of surgery used to treat defects in cartilage) in 263 adults between 18 and 65 years of age or children aged 14 to 17 years with growth-plate closure in the knee. The main measure of

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effectiveness was the change in IKDC score 24 months after treatment. The IKDC score is based on patients' rating of their knee symptoms, function, and impact on daily living and sports activities.

How far into the evaluation was the application when it was withdrawn?

The application was withdrawn while the European Medicines Agency was still evaluating the initial information from the company.

What did the Agency recommend at that time?

As the Agency was still evaluating the initial information from the company, it had not yet made any recommendations.

What were the reasons given by the company for withdrawing the application?

In its letter notifying the Agency of the withdrawal of the application, the company stated that it withdrew its application because it could not yet provide additional data that the Agency required.

Does this withdrawal affect patients in clinical trials?

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

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