TETEC
Tissue Engineering Technologies AG

Aktiengesellschaft zur Entwicklung und Herstellung von biologischem Gewebeersatz

[redacted]

[redacted]

Harald Enzmann
CHMP Chair
European Medicines Agency
PO Box 71010
1008 BA Amsterdam
The Netherlands

18. NOVEMBER 2020

WITHDRAWAL OF MARKETING AUTHORISATION APPLICATION
ARTOBEND (IN VITRO EXPANDED HUMAN AUTOLOGOUS ARTICULAR CHONDROCYTES) (H0004598)

Dear Dr. Enzmann,

TETEC Tissue Engineering Technologies AG, [redacted] would like to inform you that at this point we have taken the decision to withdraw our application for Marketing Authorisation for Artobend (in vitro expanded human autologous articular chondrocytes), with immediate effect.

Artobend is an Advanced Therapy Medicinal Product (ATMP) intended for the repair of symptomatic, localised, full-thickness cartilage defects of the knee joint in patients with closed epiphyseal growth plates.

The decision to withdraw the application is based on input received from the rapporteurs by the Committee for Advanced Therapies (CAT), indicating that additional data should be provided which are not yet available.

We would like to sincerely thank the (Co-)Rapporteurs, EMA, CAT and CHMP members for the time dedicated to reviewing our application and the support provided during the process.

This withdrawal does not have any impact on ongoing clinical studies with Artobend. TETEC Tissue Engineering Technologies AG is willing and reserves the right to re-apply for marketing authorisation of Artobend at a future date.

TETEC Tissue Engineering Technologies agrees for this letter to be published on the EMA website.

Sincerely yours,

[redacted]