

FGK RS GmbH | Heimeranstrasse 35 | 80339 München | Germany

Prof. Bruno Sepodes
European Medicines Agency (EMA)
Domenico Scarlatilaan 6
1083 HS Amsterdam
The Netherlands

Subject: Withdrawal of Rilonacept FGK Representative Service GmbH
(Rilonacept), 160mg, solution for injection - EMEA/H/C/6537

Dear Prof. Bruno Sepodes,

For the withdrawal of initial marketing authorisation applications

I would like to inform you that, at this point of time, FGK Representative Services GmbH has taken the decision to withdraw the application for Marketing Authorisation of Rilonacept FGK Representative Service GmbH (Rilonacept), 160mg, solution for injection, which was intended to be used in adults and paediatric patients from 12 years for the treatment of idiopathic recurrent pericarditis and reduction in risk of recurrence.

This withdrawal is based on:
business reasons

We reserve the right to make further application for this Marketing Authorisation at a future date in this or other therapeutic indication(s).

We would like to take this opportunity to thank the Rapporteurs/Co-Rapporteurs, Committee for Medicinal Products for Human Use (CHMP), and the European Medicines Agency (EMA) for their time and consideration for this application.

I agree for this letter to be published on the EMA website.

Yours sincerely,

FGK Representative Service GmbH

[Redacted Signature]

12 Feb 2025
Date

FGK Representative Service GmbH
Heimeranstrasse 35
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