Proveca

Proveca Pharma Ltd.
[redacted]

Date: 06 09 2024

[redacted]
European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Subject: Withdrawal of EMEA/H/C/003883/II/0029

Dear [redacted]

I would like to inform you that, at this point of time, Proveca Pharma Limited has taken the decision to withdraw the application to modify the approved therapeutic indication to include a new indication/population for Sialanar.

This withdrawal is based on the CHMP consideration that indicates that the Committee will not be able to conclude that the benefits outweigh the risks on the basis of the data provided.

The withdrawal does not have any impact on any ongoing trials and compassionate use programmes.

Proveca remains committed to the development of Sialanar and reserves the right to make further submissions at a future date in this or other therapeutic indication(s).

Proveca would like to sincerely thank the (Co)Rapporteurs, EMA, PRAC and the CHMP members for the time dedicated to reviewing this application and the support provided during the procedure.

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

Yours sincerely,

[redacted]
Proveca Pharma Limited