[redacted]

Novartis Pharma AG
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CH-4056 Basel
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[redacted]

To:
Product and Application Business Support (PA-BUS)
European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

[redacted]

26 October 2022

Subject: Withdrawal of type II variation: Indication extension application for Ilaris (canakinumab) for Schnitzler's syndrome; Procedure EMEA/H/C/001109/II/0075

Ilaris® (canakinumab) 150 mg powder for solution for injection
Ilaris® (canakinumab) 150 mg/ml solution for injection

Dear Madam / Sir,

We would like to inform you that Novartis has taken the decision to withdraw the type II variation (C.I.6.a.) for the addition of a new therapeutic indication, application procedure EMEA/H/C/001109/II/0075.

The withdrawal of the application is based on the CHMP consideration that the data submitted in support of this type II variation do not permit a benefit-risk assessment to be made for the proposed indication.

This withdrawal of the application does not have any impact on ongoing studies. The use of Ilaris in its approved indications remains unchanged based on the positive benefit-risk balance for the registered indications.

We reserve the right to make further submissions in the future to this or other therapeutic indications.

Novartis would like to sincerely thank the Rapporteurs/Co-Rapporteurs, EMA, PRAC and the CHMP members for the time dedicated to review this application and guidance provided during the procedure.

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

Yours sincerely,

[redacted]
On behalf of Novartis Europharm Limited