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[redacted]

Novartis Pharma AG
Lichtstrasse 35
CH-4056 Basel
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[redacted]

To : CHMP Chairman
Dr Harald Enzmann
European Medicines Agency
7 Westferry Circus
Canary Wharf
London E14 4HB

Cc : Dr. Jan Mueller-Berghaus (Rapporteur), Dr. Outi Mäki-Ikola (Co-Rapporteur), [redacted]

04 December 2018

Re: Withdrawal of canakinumab 150 mg solution for injection in a pre-filled pen and 150 mg solution for injection in a pre-filled syringe for the prevention of major cardiovascular events - Procedure No. EMA/H/C/004754/0000

Dear Dr Enzmann,

Novartis would like to inform you of the decision to withdraw the application for Marketing Authorisation of canakinumab 150 mg solution for injection in pre-filled syringe and 150 mg solution for injection in pre-filled pen, which was intended to be used for the prevention of major cardiovascular events in adults with a prior myocardial infarction (MI) and hsCRP $\geq$ 2 mg/L.

This decision was taken because the Applicant cannot address the major objections, raised by the CHMP in the Day 180 List of Outstanding Issues to support a positive benefit/risk assessment in the proposed cardiovascular indication in patients with a prior MI within the timeframe of the Centralised Procedure.

We would like to thank the Rapporteur, Co-Rapporteur, EMA, PRAC and CHMP members for the time and effort dedicated in their review and the guidance provided during the procedure.

Novartis reserves the right to make further submissions at a future date in this or other therapeutic indications.

Novartis agrees for this letter to be published on the European Medicine Agency website.

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Yours sincerely,

Novartis Pharma AG on behalf of Novartis Europharm Ltd.

[redacted]

Global Program Regulatory Director
Regulatory Affairs
Novartis Pharma AG
On behalf of Novartis Europharm Ltd.

Global Therapeutic Area Leader
Regulatory Affairs
Novartis Pharma AG
On behalf of Novartis Europharm Ltd.

Related and previously submitted sequences:

The eCTD summary table provides information on previously submitted sequences and indicates a relationship, where applicable, to the current sequence.

Sequence	Submission	Related sequence
0000	Initial MAA	N/A
0001	Responses to VSI	0000
0002	Responses to VSI	0001
0003	Request for a revision of the adopted timetable	0000
0004	Responses to Day 120 list of questions	0000
0005	Responses to VSI – Change of applicant	0004
0006	Withdrawal notification	0000