NOVARTIS [redacted] [redacted]

CHMP Chairman: Tomas Salmonson
European Medicines Agency
30 Churchill Place
Canary Wharf
London E14 5EU
United Kingdom

cc:
[redacted]
All CHMP members

8 November 2016

EMEA/H/C/001131/II/45/G – Type II variation – New indication in relapsed Chronic Lymphocytic Leukemia (CLL) – Withdrawal of combination with bendamustine
Arzerra (Ofatumumab) 100 mg and 1000 mg, concentrate for solution for infusion

Dear Dr Salmonson,

I would like to inform you that, in line with the response to the Request for Supplementary Information from CHMP, Novartis Europharm Ltd has taken the decision to withdraw the application for the combination ofatumumab and bendamustine regarding the proposed new indication in relapsed CLL.

This withdrawal is based on the objection raised by the CHMP regarding the study design and patient population from the corresponding study.

The benefit-risk profile of the combination ofatumumab and bendamustine and the use of this combination in previously untreated CLL patients are not impacted by this withdrawal.
In addition, the proposed combination of ofatumumab and fludarabine plus cyclophosphamide in patients with relapsed CLL is unaffected by the present withdrawal.

This withdrawal does not impact ongoing clinical trials with ofatumumab or any future plan for the development of the product.

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

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

NOVARTIS

Yours sincerely

[redacted]