ADIENNE
PHARMA & BIOTECH

Dr. Tomas Salmonson
CHMP Chairman
European Medicines Agency
30 Churchill Place
Canary Wharf
London E14 4HB
United Kingdom

Caponago (Italy), 4th July 2016

Subject: Withdrawal of BEGEDINA®, begelomab, 0.9 mg/ml, concentrate for solution for infusion initial Marketing Authorization Application - EMEA/H/C/004144

Dear Dr. Salmonson,

I would like to inform you that, at this point of time, ADIENNE S.r.I.S.U. has taken the decision to withdraw the application for Marketing Authorisation of BEGEDINA® (INN begelomab), 0.9 mg/ml, concentrate for solution for infusion, which was intended to be used for:
"the treatment of steroid-resistant acute Graft-versus-Host Disease (GvHD) in adult patients who underwent allogeneic haematopoietic progenitor cell transplantation (HPCT)".

This withdrawal is based on the following reasons:
in order to allow early access for patients to begelomab as a new treatment for the steroid-resistant acute Graft-versus-Host Disease, the application was filed as conditional marketing authorization based on data of two preliminary phase I/II and phase II clinical studies.
ADIENNE acknowledges the need to submit additional data from the currently ongoing confirmatory phase II/III study for marketing authorization approval.
ADIENNE reserves the right to make further submissions at a future date in this or other therapeutic indication(s).
We agree for this letter to be published on the EMA website.

Please, do not hesitate to contact us if you have questions concerning the content of this letter.

Yours sincerely,

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[redacted]

General Manager