ADIENNE
PHARMA & BIOTECH

European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

To the attention of [redacted]

Caponago (Italy), 13th July 2026

Subject: Withdrawal of AZACITIDINE ADIENNE, azacitidine, 25 mg/mL, powder for suspension for injection – EMEA/H/0006695

Dear Dr. [redacted]

I would like to inform you that, at this point of time, ADIENNE S.r.l. has taken the decision to withdraw the application for Marketing Authorisation of **AZACITIDINE ADIENNE, azacitidine, 25 mg/mL, powder for suspension for injection**, which was intended to be used for the treatment of adult patients who are not eligible for haematopoietic stem cell transplantation (HSCT) with:

- Intermediate-2 and high-risk myelodysplastic syndromes (MDS) according to the International Prognostic Scoring System (IPSS);
- chronic myelomonocytic leukaemia (CMML) with 10-29 % marrow blasts without myeloproliferative disorder;
- acute myeloid leukaemia (AML) with 20-30 % blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) classification;
- AML with >30% marrow blasts according to the WHO classification.

This withdrawal is based on the following reasons: additional data needs to be collected in order reply to quality issues identified.

We reserve the right to make further application for this Marketing Authorisation.

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

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