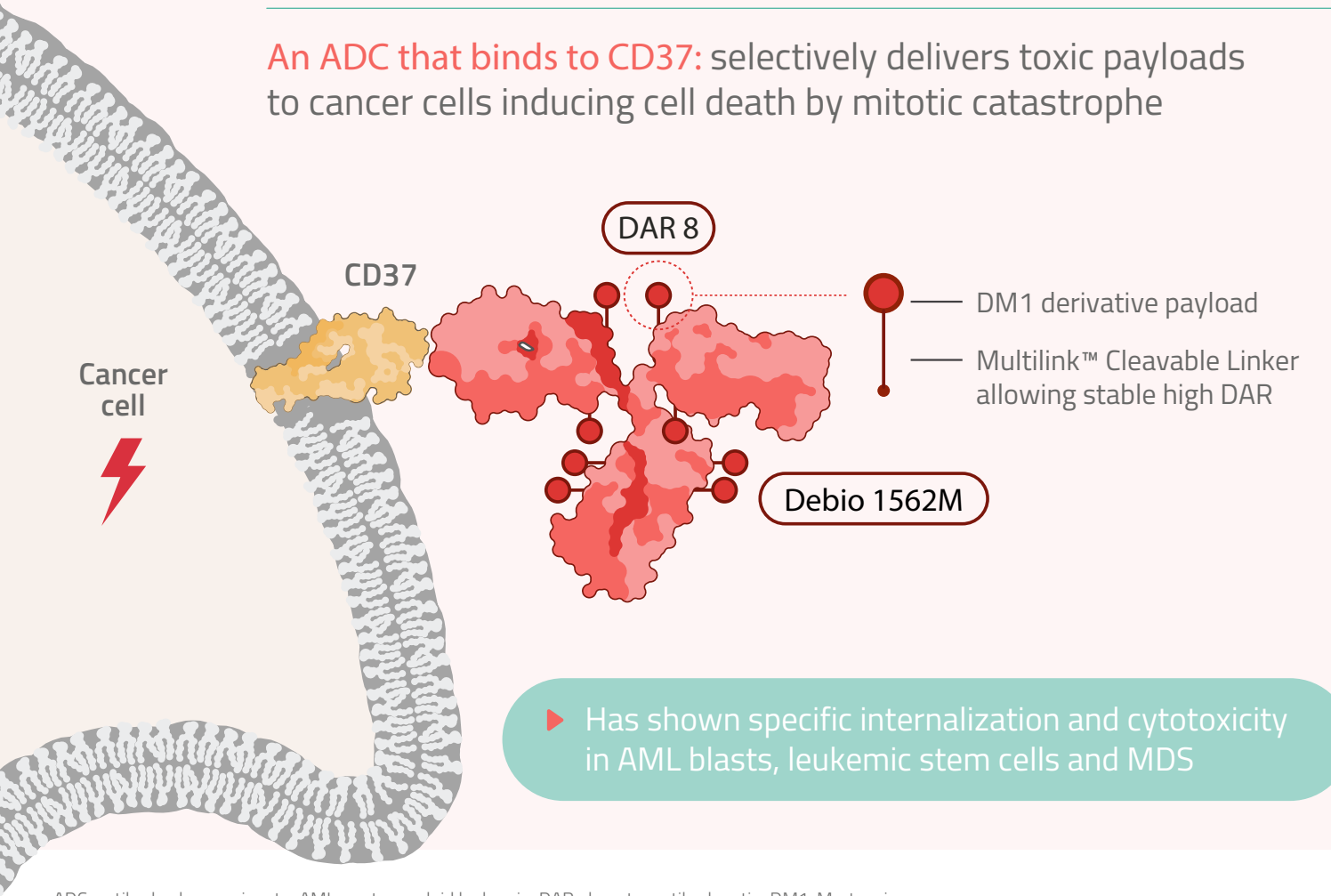
Debiopharm
WE DEVELOP FOR PATIENTS

Debio 1562M-101 Clinical Trial

A FIH STUDY TO ASSESS THE SAFETY, TOLERABILITY, AND ANTILEUKEMIC ACTIVITY OF DEBIO 1562M IN PARTICIPANTS WITH ACUTE MYELOID LEUKEMIA (AML)

An ADC that binds to CD37: selectively delivers toxic payloads to cancer cells inducing cell death by mitotic catastrophe



- Has shown specific internalization and cytotoxicity in AML blasts, leukemic stem cells and MDS

ADC: antibody-drug conjugate; AML: acute myeloid leukemia; DAR: drug-to-antibody ratio; DM1: Mertansine.

Phase 1

DOSE ESCALATION
R/R AML/HR-MDS

Endpoints
Primary: Safety, DLT, MTD
Secondary: Efficacy, PK

DOSE OPTIMIZATION
R/R AML

Endpoints
Primary: Safety, RP2D
Secondary: Efficacy, PK

Phase 2

R/R AML

Endpoints
Primary: Complete response
Secondary: Safety, efficacy, PK

Clinical Trial

First in Class CD37 targeting ADC (NCT06969430)[1]

A Phase 1/2, first-in-human, multicenter, open-label, single-arm trial

Key eligibility criteria

Age ≥ 18 years

ECOG PS ≤ 2

Adequate renal and hepatic function

ADC: antibody-drug conjugate; AML: acute myeloid leukemia; DLT: dose-limiting toxicities; ECOG PS: Eastern Cooperative Oncology Group performance status; MTD: maximum tolerated dose; PK: pharmacokinetics; RP2D: recommended phase II dose; R/R: relapsed or refractory.

1: Debiopharm International SA. A Study to Assess the Safety, Tolerability, and Antileukemic Activity of Debio 1562M in Participants With Acute Myeloid Leukemia (AML) [Internet]. clinicaltrials.gov; 2025 May [cited 2025 Jun 3]. Report No.: NCT06969430. Available from: https://clinicaltrials.gov/study/NCT06969430