



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## Report for the Application Evaluation Decision

Phase I/II ex vivo gene therapy clinical  
trial for RDEB using autologous skin  
equivalent grafts genetically corrected  
with a COL7A1-encoding SIN retroviral  
vector

2024-518368-10-00

**Decision****MSC:**

France

**Decision:**

Authorised

**Decision date:**

29/01/2025

**Tacit decision:**

No

**Application Part:****Conditions:****Reason:****Justification:****Disagreement with Part I****Submission date:**