Timeline of Lenmeldy FDA Approval

Lenmeldy is a one-time gene therapy that treats the rare and fatal metachromatic leukodystrophy (MLD)

APRIL 2007

Lenmeldy is granted orphan status by the European Medicines Agency (EMA)

APRIL 2010

Interventional clinical trial begins in Milan, Italy

SEPTEMBER 2020

Keira Riley and her family relocated to Italy where Keira began treatment

DECEMBER 2020

Lenmeldy is granted marketing authorisation in the European Union, UK, Iceland, Lichtenstein, and Norway

SEPTEMBER 2021

First patient is treated in the U.S. with Lenmeldy at the University of Minnesota Medical School

MARCH 2024

Lenmeldy receives FDA approval