

SUMMARY OF INTERNAL MEETING
[For Internal Purposes Only]

Submission: BLA 125781/0

Office: OTP

Product: delandistrogene moxeparvovec-rokl

Applicant: Sarepta Therapeutics, Inc.

Meeting Date/Time: Tuesday, May 16, 2023, from 3pm-4pm ET

FDA Participants

Maureen DeMar

Rachel Duddy

Narayan Nair

Andrew Harmon

Atul Bhattaram

Brendan Day

Dennis Cato

Emmanuel Adu-Gyamfi

Brian Stultz

Wei Liang

John Scott

Carolyn Yong

Theresa Chen

Denise Gavin

Cong Wang

Iwen Wu

Meghna Alimchandani

Anna Kwilas

Lilia Bi

Vishnu Sharma

Christopher Saeui

Lori Tull

Andrew Byrnes

Kimberly Schultz

Elizabeth Hart

Heather Lombardi

Leila Hann

Natasha Thorne

Andrey Sarafanov

Shiowjen Lee

Lisa Stockbridge

Tyree Newman

Abby Shearin

Anurag Sharma

Carolyn Laurencot

Xiaofei Wang

Ramani Sista
Mike Singer
Mara Miller
Triet Tran
Boguang Zhen
Sukyoung Sohn
Larissa Lapteva
Nadia Whitt
Allen Wensky
Celia Witten
Hao Zhu
Kimberly Schultz
Tony Lorenzo
Rosa Sherafat-Kazemzadeh
Christine Harman
Lei Xu
Olivia Ma
Varsha Garnepudi
Carolyn Renshaw
Peter Marks
Zhenzhen Xu
Tao Pan
Anita Richardson
Iwen Wu
Benjamin Cyge
Iwen Wu
Kimberly Schultz
Boguang Zhen
Andrey Sarafanov
Sandhya Sanduja
Christopher Jason
Meghna Alimchandani
Boguang Zhen

Summary:

The purpose of this internal meeting was to discuss the outcome of the Advisory Committee (AC) meeting held on Friday, May 12, 2023, and to plan the next steps for this BLA with Center Director, Peter Marks. Clinical, Clinical Pharmacology and Biostatistics all expressed the reasons that their position remained unchanged and that they believe the application should move forward as a Complete Response based on the data provided. Dr. Peter Marks wanted to review the team's position and justification before commenting on a path forward. Dr. Marks requested the review team to review the comments in the public docket including the videos and the caregiver perspective study that was done by Canary Advisors before making a final conclusion.

END