

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: Friday, May 19, 2023, from 9:30am-10:30am ET

FDA Participants

Maureen DeMar

Nadia Whitt

Brendan Day

Anthony Lorenzo

Andrey Sarafanov

Denise Gavin

Carolyn Laurencot

Leila Hann

Carolyn Yong

Atul Bhattaram

Andrew Harmon

Lei Xu

Theresa Chen

Wei Liang

Emmanuel Adu-Gyamfi

Xiaofei Wang

Shiowjen Lee

Tyree Newman

Olivia Ma

Ramani Sista

John Scott

Abigail Shearin

Rosa Sherafat

Sukyoung Sohn

Iwen Wu

Cong Wang

Heather Lombardi

Varsha Garnepudi

Lilia Bi

Anurag Sharma

Christine Harman

Takeesha Taylor-Bell

Carolyn Renshaw

Natasha Thorne

Elizabeth Hart

Benjamin Cyge

Narayan Nair
Meghna Alimchandani
Mike Singer
Mara Miller
Elin Cho
Steven Oh
Melissa Mendoza
Celia Witten
Vishnu Sharma
Hao Zhu
Peter Marks
Dennis Cato
Christopher Jason
Carolyn Laurencot
Narayan Nair
Tyree Newman
Sandhya Sanduja

Summary:

The purpose of this internal meeting was to discuss and reach consensus on an updated timeline for Accelerated Approval of the BLA. The new Action Due Date (ADD) of June 22, 2023 was agreed upon with the following tentative dates:

1. Proposed Labeling first draft to Sarepta: June 2, 2023 (review team to send to leadership May 26th).
2. Proposed PMR/PMC's to Sarepta: June 2, 2023 (office clearance May 26th, PMC/PMR coordinators May 31st)
3. Final Reviews: June 9, 2023
4. Proposed SBRA to leadership: June 16, 2023

Dr. Peter Marks, the RPM and CMC and Clinical leadership will be meeting with the Applicant on Monday, May 22, 2023, at 10:30am to update the Applicant on the new timeline and updated indication for this BLA. The agenda for the meeting will include:

1. Dr. Marks will open the meeting by discussing his assessment.
2. Dr. Marks will discuss the new indication statement which includes only using the data for 4–5-year-olds for further labeling negotiations for the use of micro dystrophin as a surrogate endpoint.
3. Dr. Marks will discuss the new action due date of June 22, 2023.
4. Clinical will discuss adequate powering of different age subgroups in the confirmatory clinical trial.
5. CMC will comment on the manufacturing process and thank them for revalidating the (b) (4) assay.

END