UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of
The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported)

December 3, 2025

CAPRICOR THERAPEUTICS, INC.

(Exact name of Registrant as Specified in its Charter)

Delaware	**001-34058**	**88-0363465**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

10865 Road to the Cure, Suite 150, San Diego, California	**92121**
(Address of principal executive offices)	**(Zip Code)**

(858) 727-1755
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	**Trading Symbol(s)**	**Name of Each Exchange on Which Registered**
Common Stock, par value $0.001 per share	CAPR	The Nasdaq Capital Market

Item 7.01 Regulation FD Disclosure.

On December 3, 2025, Capricor Therapeutics, Inc., a Delaware corporation (the "Company"), provided an update on the Company's recently announced top-line results from the HOPE-3 trial, in the form of a slide presentation during its conference call. The slide presentation is located on the "Investors" section of the Company's website at www.capricor.com. A copy of the slide presentation is also attached hereto as Exhibit 99.1 and is incorporated by reference into this Item 7.01 of this Current Report on Form 8-K.

The information under Item 7.01 of this Current Report on Form 8-K and Exhibit 99.1 attached hereto is being furnished and shall not be deemed to be filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be incorporated by reference into any of the Company's filings under the Exchange Act, unless expressly set forth as being incorporated by reference into such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1	Capricor Therapeutics, Inc. Slide Presentation dated December 3, 2025.
104	Cover Page Interactive Data File (formatted as inline XBRL).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, hereunto duly authorized.

CAPRICOR THERAPEUTICS, INC.

Date: December 3, 2025

By: /s/ Linda Marbán, Ph.D.
Linda Marbán, Ph.D.
Chief Executive Officer

Exhibit 99.1


Capricor Therapeutics™
HOPE-3 Phase 3 Study
Topline Data Call
Capricor Therapeutics, Inc.
Nasdaq: CAPR
December 3, 2025

Forward Looking Statements

Statements in this presentation regarding the efficacy, safety, and intended utilization of Capricor's product candidates; the initiation, conduct, size, timing and results of clinical trials; the pace of enrollment of clinical trials; plans regarding regulatory filings, future research and clinical trials; regulatory developments involving products, including future interactions with regulatory authorities and the ability to obtain regulatory approvals or otherwise bring products to market; manufacturing capabilities; dates for regulatory meetings; the potential that required regulatory inspections may be delayed or not be successful which would delay or prevent product approval; the ability to achieve product milestones and to receive milestone payments from commercial partners; and any other statements about Capricor's management team's future expectations, beliefs, goals, plans or prospects constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Any statements that are not statements of historical fact (including statements containing the words "believes," "plans," "could," "anticipates," "expects," "estimates," "should," "target," "will," "would" and similar expressions) should also be considered to be forward-looking statements. There are a number of important factors that could cause actual results or events to differ materially from those indicated by such forward-looking statements. More information about these and other risks that may impact Capricor's business is set forth in Capricor's Annual Report on Form 10-K for the year ended December 31, 2024, as filed with the Securities and Exchange Commission on March 26, 2025, and in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2025, as filed with the Securities and Exchange Commission on November 10, 2025. All forward-looking statements in this presentation are based on information available to Capricor as of the date hereof, and Capricor assumes no obligation to update these forward-looking statements.

Capricor has entered into an agreement for the exclusive commercialization and distribution of Deramiocel for Duchenne muscular dystrophy in the United States and Japan with Nippon Shinyaku Co., Ltd. (U.S. subsidiary: NS Pharma, Inc.), subject to regulatory approval. Deramiocel and the StealthX™ vaccine are investigational candidates and have not been approved for commercial use in any indication.

Attendees

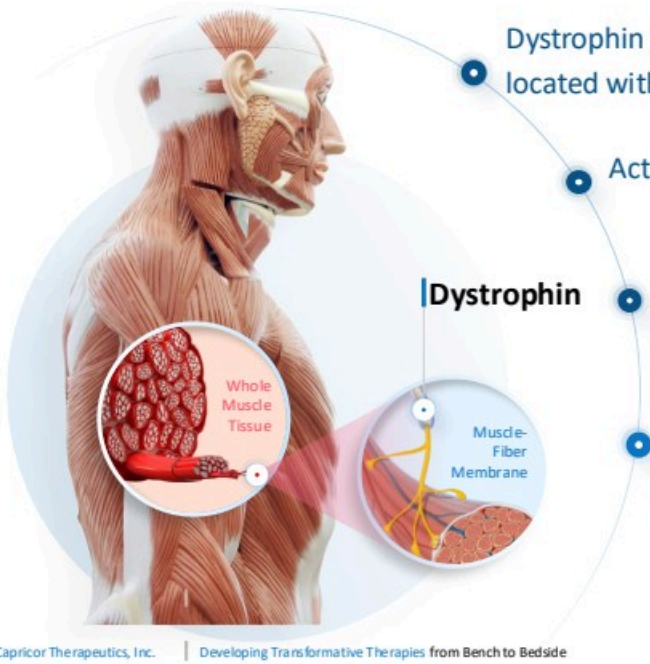
Linda Marbán, Ph.D. Chief Executive Officer, Capricor Therapeutics
AJ Bergmann, M.B.A. Chief Financial Officer, Capricor Therapeutics
Michael Binks, M.D. Chief Medical Officer, Capricor Therapeutics
Mark Awadalla Chief Development Officer, Capricor Therapeutics
Kati Maharry, Ph.D., Senior Director of Biostatistics, Capricor Therapeutics
Nathan Hogan, Ph.D., Director of Biostatistics, Capricor Therapeutics
Craig McDonald, M.D. Professor and Chair of the Department of Physical Medicine and Rehabilitation and Director of the Neuromuscular Disease Clinics at the University of California, Davis. He is the national PI of the Capricor HOPE-3 Trial.
Jonathan Soslow, M.D., MSCI Professor of Pediatrics and Director of Clinical Research, Pediatric Cardiology; Co-Director, Duchenne Multispecialty Clinic; Director of Pediatric Cardiac Magnetic Resonance, Vanderbilt University Medical Center

Agenda

Introduction
Deramiocel Program Overview
HOPE-3 Phase 3 Trial Overview
HOPE-3 Patient Demographics
HOPE-3 Safety Profile Overview
HOPE-3 Efficacy Overview
Conclusions and Next Steps
Q&A

DMD: A Devastating Rare Disease

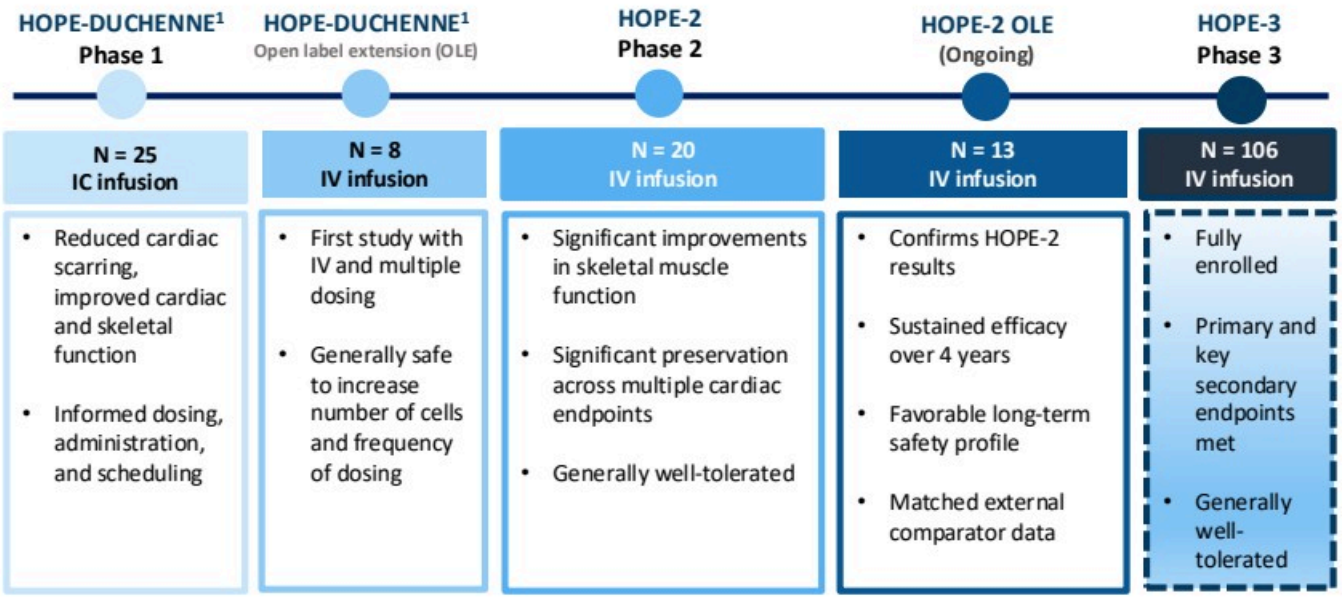
High Unmet Needs Across the Entire Disease Trajectory



- Dystrophin is a structural protein located within the muscle fiber membrane
- Acts both as a cushion and glue
- Without dystrophin, muscles (**cardiac and skeletal**) are unable to function properly, suffer progressive damage and eventually die
- Much of the muscle injury that occurs in dystrophin-deficiency is attributable to **secondary damage caused by inflammation**

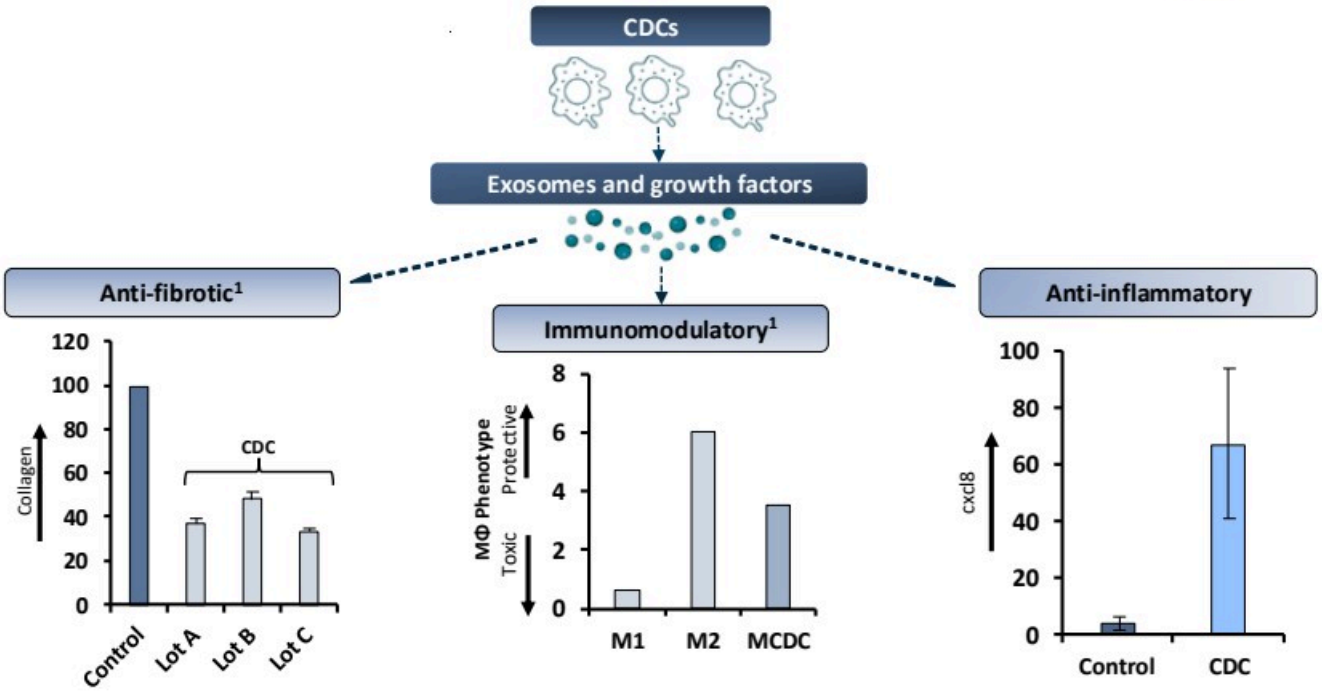
Deramiocel's Clinical Development

10 Years of Development in DMD



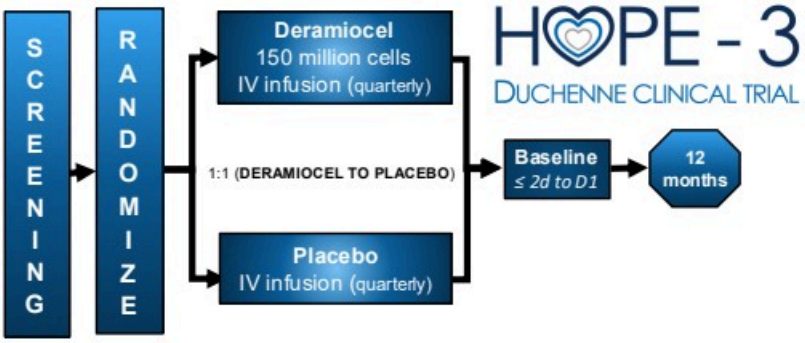
[1]Study funded with the support from the California Institute for Regenerative Medicine (CIRM)

Deramiocel's Multi-Modal Mechanism



[1]de Couto et al., 2015

HOPE-3 Pivotal Phase 3 Trial

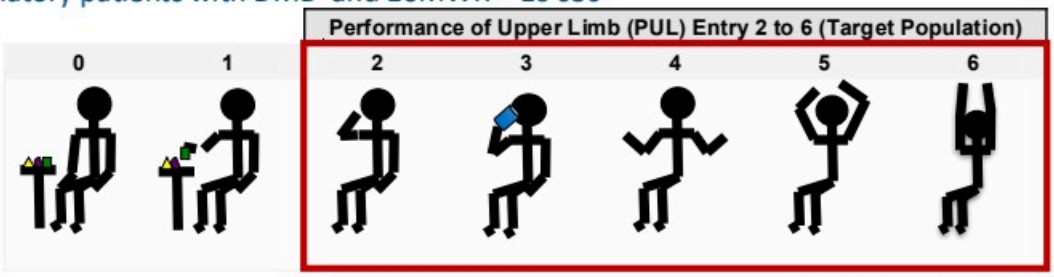


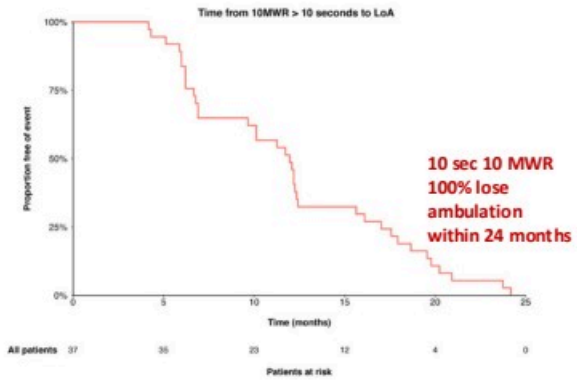
Design & Endpoints

- Randomized: n=106 patients
- 1:1, double-blind, placebo-controlled
- **Primary endpoint**: PUL v2.0
- **Key secondary endpoint**: LVEF
- **Other secondary endpoints**: mid-level PUL v.2.0, GST, LGE, etc.

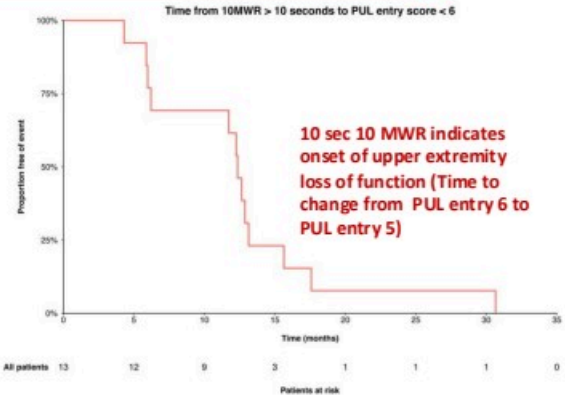
Approaching Loss of Ambulation

Late-ambulatory patients with DMD and 10MWR > 10 sec





10 sec 10 MWR 100% lose ambulation within 24 months



10 sec 10 MWR indicates onset of upper extremity loss of function (Time to change from PUL entry 6 to PUL entry 5)

McDonald CM, Signorovitch J, Mercuri E, et al. PLoS One. 2024 Jun 3;19(6):e0304099.

HOPE-3 Demographics

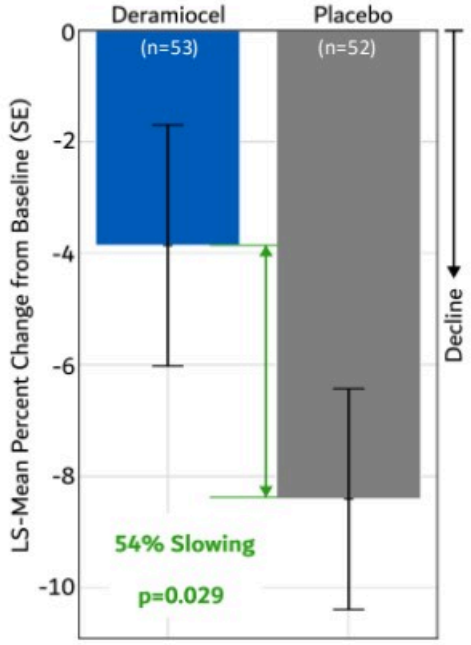
Baseline Demographics	Placebo (n=52)	Deramiocel (n=54)	Overall (n=106)
Age (Years)			
n	52	54	106
Mean (SD)	14.6 (2.95)	15.4 (3.10)	15.0 (3.04)
Median	14	15	15
Min, Max	10, 22	10, 22	10, 22
PUL 2.0 Entry Item Score			
2,3	23 (44.2)	25 (46.3)	48 (45.3)
4,5,6	29 (55.8)	29 (53.7)	58 (54.7)
Diagnosed Cardiomyopathy			
No	13 (25.0)	10 (18.5)	23 (21.7)
Yes	39 (75.0)	44 (81.5)	83 (78.3)
Baseline LVEF%			
n	46	45	91
Mean (SD)	59.303 (6.108)	55.345 (7.743)	57.346 (7.206)
Median	59.309	55.892	57.532
Min, Max	47.395, 73.981	36.537, 71.112	36.537, 73.981
Ambulatory Status			
Non-Ambulatory	44 (84.6)	46 (85.2)	90 (84.9)
Ambulatory	8 (15.4)	8 (14.8)	16 (15.1)

HOPE-3 Safety Profile Results

Overview	Placebo (n=52) n (%)	Deramiocel (n=53) n (%)	Overall (n=105) n (%)
Any TEAEs	43 (82.7)	50 (94.3)	93 (88.6)
TEAEs Related to IP or Administration Procedure	19 (36.5)	44 (83.0)	63 (60.0)
TEAEs Related to IP	16 (30.8)	44 (83.0)	60 (57.1)
TEAEs Related to Administration Procedure	9 (17.3)	23 (43.4)	32 (30.5)
TEAEs by Maximum Severity			
Mild (Grade 1)	18 (34.6)	16 (30.2)	34 (32.4)
Moderate (Grade 2)	22 (42.3)	33 (62)	55 (52.4)
Severe (Grade 3)	2 (3.8)	1 (1.9)	3 (2.9)
Life-Threatening (Grade 4)	1 (1.9)	0	1 (1.0)
Fatal (Grade 5)	0	0	0
Any Serious TEAEs	5 (9.6)	1 (1.9)	6 (5.7)
Serious TEAEs Related to IP or Administration Procedure	1 (1.9)	1 (1.9)	2 (1.9)

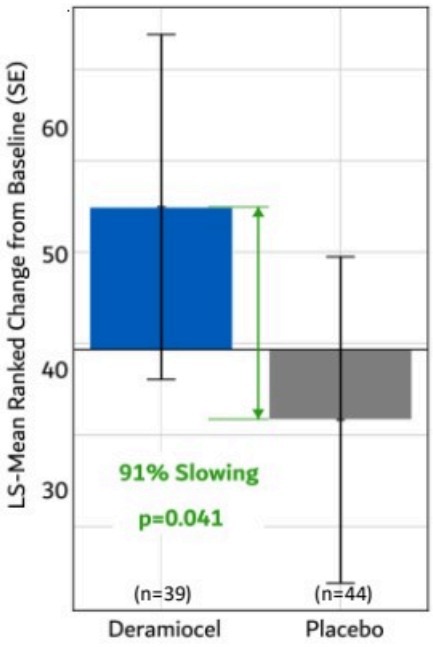
HOPE-3: Primary Endpoint (PUL v2.0)

Month 12

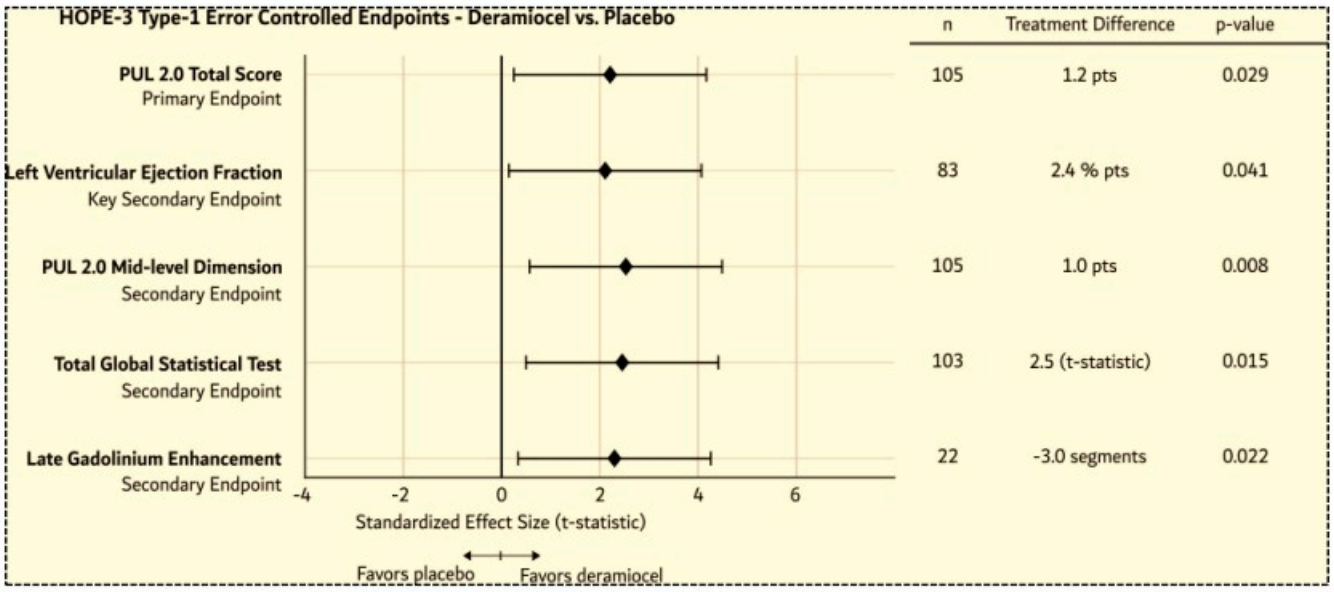


HOPE-3: Key Secondary Endpoint (LVEF)

Month 12



HOPE-3 Topline Efficacy Results

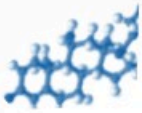


Deramiocel has the Potential to Redefine

the Standard of Care for Duchenne

Deramiocel can be used in combination with existing therapeutics

GENE THERAPIES



EXON SKIPPING THERAPIES

Deramiocel

Potential first-in-class therapy for DMD

CARDIAC AND SKELETAL MUSCLE

CORTICOSTEROIDS

STANDARD CARDIAC MEDICATIONS

Conclusions and Next Steps

- **Pivotal Phase 3 study met the primary endpoint** (PUL v2.0) and the key secondary cardiac endpoint (LVEF), both achieving statistical significance (p=0.03 and p=0.04)
- Statistical significance was achieved in all type 1 error controlled secondary endpoints
- Deramiocel is a potential first-in-class therapy designed to treat DMD skeletal and cardiomyopathy.
- Deramiocel maintained a favorable safety and tolerability profile consistent with prior clinical experience
- **Plan to submit response to the Complete Response Letter incorporating HOPE-3 data, following prior alignment with FDA**

Acknowledgments

All patients and their families who participated in the HOPE studies

- Craig McDonald, M.D. (UC Davis Health), HOPE-3 National PI
- Jonathan Soslow, M.D., MSCI, (Vanderbilt University Medical Center)
- Chet Villa, M.D. (CCMC)
- HOPE-3 investigators
- All Duchenne advocacy organizations

Thank you

Questions