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# Capricor Therapeutics Announces Late-Breaking HOPE-3 Data at the 2026 MDA Conference Demonstrating Significant Functional Benefits of Deramiocecel for Duchenne Muscular Dystrophy

- *Reduced progression of myocardial fibrosis measured by LGE on cardiac MRI ( $p=0.022$ )*
- *Significant improvement in LVEF versus placebo in patients with baseline cardiomyopathy ( $p=0.017$ )*
- *Global Statistical Test (GST) composite endpoint showed significant overall treatment benefit*
- *Duchenne Video Assessment (DVA) showed approximately 83% slowing of disease progression ( $p=0.018$ ), consistent with mid-level (elbow) PUL v2.0 results*
- *Deramiocecel BLA currently under FDA review with a PDUFA target action date of August 22, 2026*

SAN DIEGO, March 12, 2026 (GLOBE NEWSWIRE) -- [Capricor Therapeutics](#) (NASDAQ: CAPR), a biotechnology company developing transformative cell and exosome-based therapeutics for the treatment of rare diseases, today announced additional analyses and new functional outcomes data from the Phase 3 HOPE-3 clinical trial of Deramiocecel in Duchenne muscular dystrophy (DMD), which were presented yesterday at the 2026 Muscular Dystrophy Association (MDA) Clinical & Scientific Conference in Orlando, Florida.

## MDA Presentation Highlights:

- Cardiac MRI analyses demonstrated Deramiocecel's impact on cardiac structure in patients with DMD. Evaluation of late gadolinium enhancement (LGE), a marker of myocardial fibrosis, showed a significant reduction in fibrotic segments in patients treated with Deramiocecel versus placebo, corresponding to a three-segment treatment difference at 12 months ( $p=0.022$ ). The presence of LGE reflects replacement of viable myocardium with fibrotic tissue and is associated with progressive cardiac dysfunction and heart failure risk in DMD cardiomyopathy.
- In patients with baseline cardiomyopathy, Deramiocecel demonstrated an even greater treatment effect on cardiac function. In this subgroup, treatment resulted in a 3.3 percentage-point improvement in LVEF versus placebo, corresponding to greater than 100% attenuation of expected cardiac decline ( $p=0.017$ ).
- A Global Statistical Test (GST), a patient-level composite including Performance of Upper Limb (PUL v2.0), left ventricular ejection fraction (LVEF), and Patient Global Impression of Severity (PGI-S), demonstrated a statistically significant overall

treatment benefit favoring Deramiocelel ( $p=0.017$ ). This composite integrates multiple clinically meaningful domains of disease, reflecting how patients feel and function.

- Additional functional outcomes evaluating hand-to-mouth activity, an important measure of patient independence, were also presented. Data from the Duchenne Video Assessment (DVA), a measure of activities of daily living in individuals with Duchenne, showed that the “eat 10 bites” task resulted in approximately 83% slowing of disease progression compared with placebo ( $p=0.018$ ). These findings align with results from the mid-level (elbow) PUL v2.0 assessment ( $p=0.008$ ), providing concordant evidence across both validated clinical and real-world functional measures.

“These newly released data provide additional clinically meaningful evidence supporting the potential impact of Deramiocelel on the daily lives and long-term outcomes of patients living with Duchenne,” said Linda Marbán, Ph.D., Chief Executive Officer of Capricor. “We are particularly encouraged by the Duchenne Video Assessment, which captures real-world functional tasks that matter most to patients and families, including everyday activities such as eating independently. The alignment between these real-world functional measures and the preservation of arm and hand function observed in HOPE-3 further reinforces the clinical relevance of Deramiocelel’s benefit. With our Biologics License Application currently under FDA review and a PDUFA target action date of August 22, 2026, we remain focused on working with the FDA toward potential approval and bringing this therapy to patients as quickly as possible.”

Additional information about the 2026 Muscular Dystrophy Association Clinical & Scientific Conference is available at <https://www.mda.org/science/conference>.

The Company’s MDA presentation is available in the [Investors](#) section of Capricor’s website.

The full HOPE-3 study results have been submitted for publication in a peer-reviewed scientific journal.

### ***About Duchenne Muscular Dystrophy***

Duchenne Muscular Dystrophy (DMD) is a severe, X-linked genetic disorder characterized by progressive muscle degeneration affecting the skeletal, respiratory, and cardiac muscles. It is caused by the absence of functional dystrophin, a key structural protein in muscle cells. DMD affects approximately 15,000 individuals in the United States and primarily impacts boys. Over time, deterioration of the heart muscle leads to cardiomyopathy and heart failure, which is the leading cause of death in DMD. There is no cure, and treatment options remain limited.

### ***About Deramiocelel***

Deramiocelel (CAP-1002) consists of allogeneic cardiosphere-derived cells (CDCs), a rare population of cardiac cells that have been shown in preclinical and clinical studies to exert potent immunomodulatory and anti-fibrotic actions in the preservation of cardiac and skeletal muscle function in muscular dystrophies such as DMD. CDCs act by secreting extracellular vesicles known as exosomes, which target macrophages and alter their expression profile to adopt a healing rather than pro-inflammatory phenotype. CDCs have been investigated in more than 250 peer-reviewed scientific publications and administered to over 250 human subjects across multiple clinical trials.

Deramiocel has received Orphan Drug Designation for the treatment of DMD from both the U.S. FDA and the European Medicines Agency (EMA). In addition, it has been granted Regenerative Medicine Advanced Therapy (RMAT) designation in the U.S., Advanced Therapy Medicinal Product (ATMP) designation in Europe, and Rare Pediatric Disease Designation from the FDA, which may qualify Capricor for a Priority Review Voucher upon approval.

### ***About Capricor Therapeutics***

Capricor Therapeutics (NASDAQ: CAPR) is a biotechnology company dedicated to advancing transformative cell and exosome-based therapeutics to redefine the treatment landscape for rare diseases. At the forefront of our innovation is our lead product candidate, Deramiocel, an allogeneic cardiac-derived cell therapy that is currently in late-stage development for the treatment of Duchenne muscular dystrophy (DMD). Extensive preclinical and clinical data have demonstrated Deramiocel's potent immunomodulatory and anti-fibrotic effects in helping to preserve cardiac and skeletal muscle function in DMD. Capricor is also leveraging the power of its exosome technology, using its proprietary StealthX™ platform in preclinical development focused on vaccinology and the targeted delivery of oligonucleotides, proteins, and small-molecule therapeutics, with the potential to treat and prevent a wide range of diseases. At Capricor, we are committed to pushing the boundaries of possibility and forging a path toward transformative treatments for those in need. For more information, visit [capricor.com](https://www.capricor.com), and follow Capricor on [Facebook](#), [Instagram](#) and [X](#).

### ***Cautionary Note Regarding Forward-Looking Statements***

Statements in this press release 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 press release 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 Deramiocele for DMD in the United States and Japan with Nippon Shinyaku Co., Ltd. (U.S. subsidiary: NS Pharma, Inc.), subject to regulatory approval. Deramiocele and the StealthX™ vaccine are investigational candidates and have not been approved for commercial use in any indication.

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