Solid Biosciences Doses First Participant in Phase 3 IMPACT DUCHENNE Clinical Trial Evaluating SGT-003 in Duchenne Muscular Dystrophy

May 7, 2026

- Initiation of Phase 3 IMPACT DUCHENNE placebo-controlled, randomized, double-blind trial as part of Solid's integrated, multi-trial development program designed to support registration and global regulatory authorizations for SGT-003 -

- Solid received a positive opinion from the European Medicines Agency (EMA) on its Pediatric Investigation Plan (PIP) for SGT-003, establishing alignment on a pediatric clinical development framework in Europe -

- 46 participants have been dosed with SGT-003 in the Phase 1/2 INSPIRE DUCHENNE clinical trial using a steroid-only prophylactic immunomodulation regimen; SGT-003 has been generally well tolerated as of a May 4, 2026, cutoff date -

CHARLESTOWN, Mass., May 07, 2026 (GLOBE NEWSWIRE) -- Solid Biosciences Inc. (Nasdaq: SLDB) (the "Company" or "Solid"), a life sciences company developing precision genetic medicines for neuromuscular and cardiac diseases, today announced that the first participant has been dosed in IMPACT DUCHENNE, the Company's multi-country, placebo-controlled, randomized, double-blind, Phase 3 clinical trial investigating SGT-003 for the treatment of Duchenne muscular dystrophy (Duchenne).

IMPACT DUCHENNE and the ongoing Phase 1/2 INSPIRE DUCHENNE clinical trials are components of an integrated, multi-trial clinical development program designed to evaluate the safety and efficacy of a single intravenous dose of SGT-003 in individuals living with Duchenne. Since the initiation of the INSPIRE DUCHENNE trial in June 2024, SGT-003 has been administered to 46 participants, with approximately 30 participants dosed as of year-end 2025. As of a May 4, 2026, safety cutoff, SGT-003, which is administered using a steroid-only prophylactic immunomodulation regimen, has been generally well tolerated with no observed cases of drug induced liver injury, myocarditis, thrombotic microangiopathy or atypical hemolytic uremic syndrome.

The initiation of the Phase 3 IMPACT DUCHENNE trial reflects Solid's deliberate approach to generating well-controlled clinical data in a randomized and blinded setting to support potential accelerated approval and inform further regulatory interactions. The Company continues to engage with the US Food and Drug Administration (FDA) and is committed to ongoing collaboration with the Agency to address the unmet need in Duchenne.

"Dosing the first participant in our Phase 3 trial marks a critical moment for Solid Biosciences and for the Duchenne community," said Gabriel Brooks, M.D., Chief Medical Officer of Solid Biosciences. "With the initiation of a randomized, placebo-controlled clinical trial, we are reinforcing our conviction in SGT-003 and our long-standing commitment to generating well-controlled, high-quality data. Families living with Duchenne continue to face difficult treatment decisions in a setting of significant unmet medical need. Solid remains focused on helping inform the Duchenne community of potential additional treatment options through the responsible and rigorous clinical evaluation of SGT-003."

The first participant was dosed in Australia at The Children's Hospital at Westmead.

Global Regulatory Updates
In the US, Solid previously announced the outcome of a Type C meeting with the FDA during which alignment was reached on the overall IMPACT DUCHENNE trial design, including the pre-specified primary endpoint of change from baseline at 18 months in time to rise from supine (TTR) velocity. The Phase 3 trial is designed to play a key role in supporting various US and ex-US regulatory pathways. Additionally, SGT-003 has received FDA Fast Track, Rare Pediatric and Orphan Drug designations.

Solid has also made significant progress in advancing the regulatory strategy for SGT-003 across the globe. The Company has received a positive opinion from the EMA's Paediatric Committee on its Pediatric Investigation Plan (PIP), providing alignment on the proposed pediatric development framework for SGT-003 in Europe. Approval of a PIP is required for a future marketing authorization application. The finalization of the PIP, together with receipt of Orphan drug designation from the European Commission, reflect Solid's progress in advancing SGT-003 in Europe.

In addition, Solid was one of only three recipients of the newly relaunched Innovation Passport under the UK's Innovative Licensing and Access Pathway (ILAP), which focuses more selectively on transformative products that address unmet clinical needs. Solid has had multiple engagements under this designation with the goal of mapping an accelerated time to market as well as expedited patient access.

About Duchenne
Duchenne is a genetic muscle-wasting disease predominantly affecting boys, with symptoms usually appearing between three and five years of age. Duchenne is a progressive, irreversible, and ultimately fatal disease that affects approximately one in every 5,000 live male births and has an estimated prevalence of 10,000 to 15,000 cases in the United States alone, representing significant unmet need.

About SGT-003
SGT-003 is an investigational gene therapy containing a novel microdystrophin construct and a proprietary, next-generation capsid, POLARIS-101™ (formerly known as AAV-SLB101), which was rationally designed to target integrin receptors, and has shown enhanced cardiac and skeletal muscle transduction with decreased liver targeting in data from the Phase 1/2 INSPIRE DUCHENNE clinical trial and in nonclinical studies. SGT-003's microdystrophin construct uniquely includes the R16/17 domains, which localize nNOS to the muscle. Nonclinical studies have shown that nNOS can improve blood flow to the muscle thereby reducing muscle breakdown from ischemia and muscle fatigue. Together, these design features suggest that SGT-003 could be a potential best-in-class investigational gene therapy for the treatment of Duchenne.

About the SGT-003 Development Program
The SGT-003 clinical development program consists of two multinational clinical trials – the Phase 1/2 INSPIRE DUCHENNE trial and the Phase 3 IMPACT DUCHENNE trial – which together were designed to generate a comprehensive data package to support potential global regulatory authorizations.

INSPIRE DUCHENNE is a first-in-human, open-label, single-dose, multicenter Phase 1/2 clinical trial evaluating the safety, tolerability and efficacy of a single dose of SGT-003 in pediatric participants with a genetically confirmed Duchenne diagnosis. The trial is being conducted at clinical sites in the United States, Canada, the United Kingdom and Italy.

IMPACT DUCHENNE is a Phase 3 placebo-controlled, randomized, double-blind clinical trial evaluating the efficacy of a single dose of SGT-003 in ambulatory participants with a genetically confirmed Duchenne diagnosis. Clinical trial sites are currently active in Australia and Canada and additional clinical site activations in the UK and US are expected in the second half of 2026, with sites in the EU anticipated to follow, subject to regulatory clearances.

About Solid Biosciences
Solid Biosciences is a precision genetic medicine company focused on advancing a portfolio of gene therapy candidates targeting rare neuromuscular and cardiac diseases, including SGT-003 for Duchenne muscular dystrophy (Duchenne), SGT-212 for Friedreich's ataxia (FA), SGT-501 for catecholaminergic polymorphic ventricular tachycardia (CPVT), SGT-601 for TNNT2-mediated dilated cardiomyopathy and additional fatal, genetic cardiac diseases. The Company is also focused on developing innovative libraries of genetic regulators and other enabling technologies with promising potential to significantly impact gene therapy delivery cross-industry. Solid is advancing its diverse pipeline and delivery platform in the pursuit of uniting experts in science, technology, disease management, and care. Patient-focused and founded by those directly impacted by Duchenne, Solid's mission is to improve the daily lives of patients living with devastating rare diseases. For more information, please visit www.solidbio.com.

Cautionary Note Regarding Forward-Looking Statements
This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding future expectations, plans and prospects for the company; the ability to successfully achieve and execute on the company's goals; anticipated benefits of SGT-003; strategies and expectations for the company's SGT-003 program; expectations for planned enrollment, planned regulatory interactions and the potential approval pathways for SGT-003; and other statements containing the words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "would," "working" and similar expressions. Any forward-looking statements are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in, or implied by, such forward-looking statements. These risks and uncertainties include, but are not limited to, risks associated with the company's ability to advance SGT-003, SGT-212, SGT-501, SGT-601 and other preclinical programs, capsid libraries and other enabling technologies on the timelines expected or at all; obtain and maintain necessary approvals from the FDA and other regulatory authorities; replicate in clinical trials positive results found in preclinical studies and early-stage clinical trials of the company's product candidates; manufacture sufficient quantities of our drug product in a timely manner and maintain adequate supply to support our clinical development and potential commercialization; obtain, maintain or protect intellectual property rights related to its product candidates; replicate preliminary or interim data from clinicals trials in the final data of such trials; compete successfully with other companies that are seeking to develop Duchenne, FA, CPVT and other neuromuscular and cardiac treatments and gene therapies; manage expenses; and raise the substantial additional capital needed, on the timeline necessary, to continue development of SGT-003, SGT-212, SGT-501, SGT-601 and other candidates; achieve its other business objectives and continue as a going concern. For a discussion of other risks and uncertainties, and other important factors, any of which could cause the company's actual results to differ from those contained in the forward-looking statements, see the "Risk Factors" section, as well as discussions of potential risks, uncertainties and other important factors, in the company's most recent filings with the Securities and Exchange Commission. In addition, the forward-looking statements included in this press release represent the company's views as of the date hereof and should not be relied upon as representing the company's views as of any date subsequent to the date hereof. The company anticipates that subsequent events and developments will cause the company's views to change. However, while the company may elect to update these forward-looking statements at some point in the future, the company specifically disclaims any obligation to do so.

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