Solid Biosciences Announces Positive Feedback from Type C Meeting with FDA for SGT-003 Gene Therapy for Duchenne Muscular Dystrophy

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- IMPACT DUCHENNE: Company aligned with FDA on Phase 3 randomized, double-blind, placebo-controlled trial design -

- IMPACT DUCHENNE: Company anticipates first participant dosing in Q1 2026 -

- Company plans for additional meetings with the FDA in 1H 2026 to align on a potential accelerated approval pathway for SGT-003 -

- INSPIRE DUCHENNE: SGT-003 continues to be generally well tolerated with 36 participants dosed as of February 9, 2026, in Phase 1/2 trial -

CHARLESTOWN, Mass., Feb. 09, 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 a positive regulatory update from its recent Type C meeting with the U.S. Food and Drug Administration (FDA) that supports the continued advancement of SGT-003 as a potential treatment for Duchenne muscular dystrophy.

Solid reached alignment with the FDA on the overall study design for the Company's randomized, double-blind, placebo-controlled Phase 3 clinical trial, IMPACT DUCHENNE. The FDA agreed that the trial design was reasonable including: the patient population of ambulant participants 7 to <12 years of age, the primary endpoint of change from baseline in Time to Rise (TTR) velocity from supine position evaluated at 18 months and other key secondary endpoints.

"As outlined at the start of 2026, we have structured our U.S. regulatory strategy around engaging with the FDA regarding a potential accelerated approval pathway for SGT-003, and the successful alignment on the design of our Phase 3 IMPACT DUCHENNE trial marks a critical first step in that plan," said Bo Cumbo, President & CEO of Solid Biosciences. "The IMPACT DUCHENNE trial is currently planned to be conducted at sites in Australia, Canada, the EU and the UK. Due to strong key opinion leader (KOL) and patient demand, we are also evaluating the potential to open sites in the US.

"36 participants have been dosed in the ongoing Phase 1/2 INSPIRE DUCHENNE trial and SGT-003 continues to be generally well tolerated as of a February 9, 2026, cutoff. With dosing of the first participant in the Phase 3 IMPACT DUCHENNE trial expected later this quarter, this regulatory clarity adds further momentum to SGT-003 as we progress toward our second meeting with the FDA where we plan to discuss the confirmatory evidence necessary to support a potential accelerated approval pathway. Our dedication to the Duchenne community remains unwavering: they deserve therapeutic options, and we are committed to collaborating with the FDA to help make that a reality," Mr. Cumbo concluded.

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 3,500 to 5,000 live male births and has an estimated prevalence of 5,000 to 15,000 cases in the United States alone.

About SGT-003
SGT-003 is an investigational gene therapy containing a differentiated microdystrophin construct and a proprietary, next-generation capsid, 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 binding domain, which localizes nNOS to the muscle membrane. 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 INSPIRE DUCHENNE
INSPIRE DUCHENNE is a first-in-human, open-label, single-dose, multicenter Phase 1/2 clinical trial to evaluate the safety, tolerability and efficacy of SGT-003 in pediatric participants with a genetically confirmed Duchenne diagnosis with a documented dystrophin gene mutation. INSPIRE DUCHENNE is a multinational trial designed to enroll participants in the United States, Canada, the United Kingdom and Italy.

About IMPACT DUCHENNE
IMPACT DUCHENNE is a Phase 3 randomized, double-blind, placebo-controlled trial to evaluate the efficacy of a single dose of SGT-003 in ambulatory participants aged 7 to less than 12 with a genetically confirmed Duchenne diagnosis. IMPACT DUCHENNE is a multinational trial intended to support potential regulatory authorizations.

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 neuromuscular and 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, priorities and key clinical and preclinical milestones; strategies and expectations for the company's SGT-003 and other clinical and pre-clinical

programs; expectations for site activations, planned enrollment, planned data announcements, 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 and other clinical and 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; obtain, maintain or protect intellectual property rights related to its product candidates; enroll patients in ongoing trials; activate clinical trial sites; 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 and its 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.

Solid Biosciences Investor Contact:
Nicole Anderson
Director, Investor Relations and Corporate Communications
Solid Biosciences Inc.
investors@solidbio.com

Media Contact:
Glenn Silver
FINN Partners
glenn.silver@finnpartners.com

Source: Solid Biosciences Inc.