Solid Biosciences Awarded Innovation Passport Designation Under the New UK Innovative Licensing and Access Pathway for SGT-003, an Investigational Gene Therapy for Duchenne Muscular Dystrophy

November 6, 2025

- Innovation Passport award facilitates accelerated time to market and helps expedite patient access to transformative new medicines -

- New Innovative Licensing and Access Pathway (ILAP) designation provides unique, end-to-end regulatory access pathway for Solid to work directly with the UK's National Health System (NHS), the UK Medicines and Healthcare products Regulatory Agency (MHRA) and health technology assessment (HTA) bodies: the National Institute for Health and Care Excellence (NICE), the Scottish Medicines Consortium (SMC), and the All Wales Therapeutics and Toxicology Centre (AWTTC) -

- Innovation Passport supports the potential for SGT-003 to become the first-to-market gene therapy in the UK for Duchenne muscular dystrophy -

CHARLESTOWN, Mass., Nov. 06, 2025 (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 SGT-003, the Company's investigational gene therapy for Duchenne muscular dystrophy (Duchenne), has been granted an Innovation Passport under the new ILAP. The Innovation Passport is the entry point for the ILAP, which aims to accelerate time to market and facilitate patient access to new medicines in the UK. The Innovation Passport activates the MHRA and the ILAP partner agencies to develop a product-specific roadmap for regulatory and development milestones.

SGT-003 is one of the first three investigational medicinal products joining the new ILAP, which focuses more selectively on transformative products that address unmet clinical needs.

Jessie Hanrahan, Ph.D., Chief Regulatory & Preclinical Operations Officer of Solid Biosciences, said, "Receiving the Innovation Passport designation is further recognition of SGT-003's potential to transform the treatment paradigm for those living with Duchenne. We are thrilled to have received this designation, which provides early and enhanced interactions with regulators and access to development tools designed to enable accelerated regulatory timelines. We are committed to delivering on SGT-003's promise globally and we look forward to collaborating closely with the UK MHRA and other ILAP partners to bring this potential new therapy to patients as quickly as possible."

Emily Reuben, Co-founder and CEO of Duchenne UK, said, "Having been a member of the Patient Reference Group that helped to shape the original Innovation Passport Designation, it's fantastic to see an investigational medicinal product for Duchenne now benefiting from it. Duchenne UK works closely with regulators, industry and partners globally to try to break down barriers at every stage of the drug development process and to accelerate access to potentially transformative treatments for people living with Duchenne. We hope the new ILAP will deliver on its aim of streamlining and speeding up the development and access for SGT-003, and ultimately, if the data support it, deliver access to a promising new treatment for patients in the National Health Service (NHS). We look forward to working with Solid Biosciences and regulators here in the UK as SGT-003 is developed further."

SGT-003 is currently being evaluated in the ongoing Phase 1/2 INSPIRE DUCHENNE clinical trial, which is enrolling participants at 15 active clinical trial sites across the US, UK, Italy and Canada. Additionally, Solid has activated the first clinical trial site and is screening participants for IMPACT DUCHENNE, an ex-US, Phase 3, randomized, double-blind, placebo-controlled clinical trial of SGT-003.

About ILAP
The ILAP was first launched in 2021 to accelerate development of and access to promising medicines. The relaunched ILAP is the only end-to-end access pathway in the world where early multi-stakeholder engagement is established at an early stage of clinical development. The new pathway features enhanced input and interactions with the MHRA and the ILAP partners, including the All Wales Therapeutics and Toxicology Centre (AWTTC), the National Institute for Health and Care Excellence (NICE) the Scottish Medicines Consortium (SMC) and the NHS. Other benefits of the ILAP include access to a range of services that support clinical development (including clinical trial delivery), market access, and health system adoption, reducing the end-to-end timeline for product R&D and facilitating rapid access to the UK market. More information about the ILAP can be found here.

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 nonclinical studies. SGT-003's microdystrophin construct uniquely includes the R16/17 domain, which localizes 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 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 pediatric

participants with a genetically confirmed Duchenne diagnosis with a documented dystrophin gene mutation. IMPACT DUCHENNE is a multinational trial designed to enroll participants outside of the United States with the aim of supporting potential ex-U.S. 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 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.

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 programs, ; expectations for additional site activations, planned enrollment, planned regulatory interactions and the potential approval pathways for SGT-003; timing of planned clinical trials of SGT-003; t the sufficiency of the Company's cash, cash equivalents, and available-for-sale securities to fund its operations; 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 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; replicate preliminary or interim data from early-stage 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 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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