



Solid Biosciences Presents New SGT-001 IGNITE DMD Study Results at World Muscle Society 2022 Congress Demonstrating Improvements in Ambulatory Function

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- Stride velocity 95th centile (SV95C) data demonstrate improvements at one-year post-dosing compared with declines observed in control and natural history patients -

- SV95C is an objective, real-world assessment of ambulatory function measured by the ActiMyo wearable device, qualified as a secondary endpoint for Duchenne patients five years of age and older by the European Medicines Agency -

CHARLESTOWN, Mass., Oct. 13, 2022 (GLOBE NEWSWIRE) -- Solid Biosciences, a life sciences company focused on advancing meaningful therapies for Duchenne muscular dystrophy (Duchenne), today reported additional positive one-year data from the IGNITE DMD Phase I/II clinical trial of its microdystrophin gene therapy, SGT-001, for the functional endpoint of stride velocity 95th centile (SV95C).

SV95C is an objective assessment of peak ambulatory performance accepted as a qualified secondary endpoint for Duchenne patients five years of age and older by the European Medicines Agency (EMA). This assessment represents the fastest spontaneous strides in a patient's daily life, captured in a real-world setting using the ActiMyo wearable device developed by SYSNAV. In the IGNITE DMD clinical trial, patients receiving SGT-001 improved from baseline in SV95C at one year, whereas a control patient included in the study and natural history data both demonstrated declines over the same period. IGNITE DMD patients demonstrated average improvements in SV95C of 8.8%-9.5% compared to baseline, 23.9%-24.6% compared to natural history and 26.0%-26.7% compared to the control patient. These results are being presented in a virtual poster at the 27th International Hybrid Annual Congress of the World Muscle Society (WMS), taking place in Halifax, Nova Scotia, Canada from October 11-15.

"Standard clinical assessments used to evaluate ambulatory function in Duchenne can be prone to bias and variability that can make interpretation of longitudinal changes difficult, especially in open label trials," said Laurent Servais, Professor of Paediatric Neuromuscular Diseases at the University of Oxford and lead author on the poster. "The SV95C endpoint is based on real-world data captured through a device that patients wear as they move through their daily lives. As a result, we believe SV95C is a meaningful, sensitive endpoint to use in the evaluation of therapeutic efficacy in clinical trials for Duchenne."

The company also presented 2-year data for Patients 4-6 from IGNITE DMD in a flash presentation and poster during the "DMD - Trials & Treatments" session of the meeting. The data was initially presented at the 2022 Muscular Dystrophy Association Clinical & Scientific Conference in [March](#).

"Data presented at WMS collectively demonstrate that our differentiated microdystrophin construct provides durable benefit to patients with Duchenne across multiple endpoints that are meaningful to clinicians, patients and their families," said Roxana Donisa Dreghici, MD, Senior Vice President and Head of Clinical Development at Solid. "We are especially excited by the SV95C results as, to our knowledge, this is the first time that data from this real-world assessment are being reported for a Duchenne gene therapy trial, and we believe it represents a meaningful, continuous measure of patients' motor function during daily activities. We intend to include SV95C as an endpoint in the clinical evaluation of SGT-003, our next-generation Duchenne gene therapy, which is expected to commence in late-2023."

About Solid Biosciences Inc.

Solid Biosciences is a life sciences company focused on advancing transformative treatments to improve the lives of patients living with Duchenne. Disease-focused and founded by a family directly impacted by Duchenne, our mandate is simple yet comprehensive – work to address the disease at its core by correcting the underlying mutation that causes Duchenne with our gene therapy candidate SGT-003. 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 the Company's plans to present data from IGNITE DMD, the implication of interim clinical data, the safety or potential treatment benefits of SGT-001 or SGT-003 in patients with Duchenne, the Company's regulatory plans and discussions, the Company's SGT-003 program, including the Company's expectation for filing an IND, timelines, 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 its SGT-003 program on the timelines expected or at all; obtain and maintain necessary approvals from the FDA and other regulatory authorities; obtain and maintain the necessary approvals from investigational review boards at clinical trial sites and independent data safety monitoring board; replicate in clinical trials positive results found in preclinical studies and early-stage clinical trials of its product candidates; whether the interim data referenced in this release will be predicative of the final results of the trial or will demonstrate a safe or effective treatment benefit of SGT-001 or SGT-003; whether the methodologies, assumptions and applications the Company utilizes to assess particular safety or efficacy parameters will yield meaningful statistical results; advance the development of its product candidates under the timelines it anticipates in current and future clinical trials; successfully transition, optimize and scale its manufacturing process; obtain, maintain or protect intellectual property rights related to its product candidates; compete successfully with other companies that are seeking to develop Duchenne 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 product 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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