

Satellos Receives Clearance by U.S. FDA and Global Regulators to Initiate Pediatric Phase 2 Study of SAT-3247 for Duchenne Muscular Dystrophy

- *Placebo-controlled Phase 2 study will evaluate SAT-3247 treatment over three months among ambulatory children with Duchenne*
- *Study endpoints include safety and tolerability, effect on muscle force and function, and impact on muscle quality and regeneration*
- *Enrollment of first study participant anticipated by end of 2025*

TORONTO--(BUSINESS WIRE)--December 9, 2025--Satellos Bioscience Inc. (TSX: MSCL, OTCQB: MSCLF) (“Satellos” or the “Company”), a clinical-stage biotechnology company developing life-improving medicines to treat degenerative muscle diseases, today announced that it has received Investigational New Drug (IND) clearance by the U.S. Food and Drug Administration (FDA), as well as other global regulatory agencies, to conduct SAT-3247-CL-201, a three-month, randomized, double-blind, placebo-controlled, proof-of-concept, Phase 2 study of SAT-3247 in 51 ambulatory children with Duchenne muscular dystrophy (Duchenne or DMD).

“We are delighted to achieve U.S. and global clearance to start our Phase 2 pediatric study of SAT-3247, which we have named BASECAMP. This important milestone positions Satellos to demonstrate the potential for SAT-3247 to safely restore the body’s ability to repair and regenerate muscle in children living with Duchenne, and to alter disease progression,” said Frank Gleeson, co-founder and CEO of Satellos. “With encouraging functional data from our Phase 1b study in adults, we have confidence in the potential for SAT-3247 to make an impact for children with Duchenne, and we are excited to begin enrollment in the trial imminently.”

In addition to the FDA clearance, the United Kingdom’s Medicine and Healthcare products Regulatory Agency (MHRA) granted authorization of the company’s Clinical Trial Application (CTA); Australia’s Human Research Ethics Committee (HREC) accepted the Therapeutic Goods Administration’s (TGA’s) Clinical Trial Notification (CTN) scheme for regulatory authorization; and the Medicines and Medical Devices Agency of Serbia (ALIMS) approved the company’s CTA. The clinical trial application is still under review in the European Union and Canada in accordance with established timelines and procedures.

SAT-3247 is an oral small-molecule therapy designed to restore the body’s ability to regenerate muscle, a process that is impaired in Duchenne. In a Phase 1a/b study in adults, SAT-3247 was safe and well-tolerated with a desirable pharmacokinetic (PK) profile. Part B of the study, composed of adults with Duchenne treated with SAT-3247 over a 28-day period, demonstrated a 118.6% mean improvement in maximum grip strength in the dominant hand and 97.9% mean improvement in the non-dominant hand, representing an approximate doubling of grip strength from ~2 kg to ~4 kg.

BASECAMP is a three-month global, randomized, double-blind, placebo-controlled, proof-of-concept study in 51 ambulatory children with Duchenne. Primary endpoints will evaluate the safety and tolerability of SAT-3247 and its effect on muscle force. Secondary endpoints will evaluate SAT-3247’s impact on muscle quality, function, and regeneration. The first participant is expected to be enrolled into the study by the end of 2025. Satellos expects to report initial interim data from BASECAMP in Q2 2026 and data from the LT-001 study in adults with DMD in Q1 2026.

ABOUT SAT-3247

SAT-3247 is a proprietary, oral, small molecule drug being developed by Satellos as a novel treatment to regenerate skeletal muscle that is lost in Duchenne muscular dystrophy and other degenerative or injury

conditions. Satellos is advancing SAT-3247 as a potential treatment for DMD, independent of dystrophin and regardless of exon mutation status.

ABOUT SATELLOS BIOSCIENCE INC.

Satellos is a clinical-stage drug development company focused on restoring natural muscle repair and regeneration in degenerative muscle diseases. Through its research, Satellos has developed SAT-3247, a first-of-its-kind, orally administered small molecule drug designed to address deficits in muscle repair and regeneration. SAT-3247 targets AAK1, a key protein that Satellos has identified as capable of replacing the signal normally provided by dystrophin in muscle stem cells to effect repair and regeneration. By restoring this missing dystrophin signal in DMD, SAT-3247 enables muscle stem cells to divide properly and more efficiently, promoting natural muscle repair and regeneration. SAT-3247 is currently in clinical development as a potential disease-modifying treatment initially for DMD. Satellos also is leveraging its proprietary discovery platform MyoReGenX™ to identify additional muscle diseases or injury conditions where restoring muscle repair and regeneration may have therapeutic benefit and represent future clinical development opportunities. For more information, visit www.satellos.com.

NOTICE ON FORWARD-LOOKING STATEMENTS

This press release includes forward-looking information or forward-looking statements within the meaning of applicable securities laws regarding Satellos and its business, which may include, but are not limited to, statements regarding the potential for SAT-3247 to represent a disease modifying approach to the therapeutic treatment of people living with Duchenne; anticipated benefits to patients from a small molecule treatment for Duchenne; the expected timing for enrollment in the BASECAMP study; the advancement SAT-3247 through clinical trials; the pharmacodynamic properties and mechanism-of-action of SAT-3247; the potential of our approach in other degenerative muscle diseases; its/their prospective impact on Duchenne patients, patients with other degenerative muscle disease or muscle injury or trauma, and on muscle regeneration generally; and Satellos' technologies and drug development plans. All statements that are, or information which is, not historical facts, including without limitation, statements regarding future estimates, plans, programs, forecasts, projections, objectives, assumptions, expectations or beliefs of future performance, occurrences or developments, are "forward-looking information or statements." Often but not always, forward-looking information or statements can be identified by the use of words such as "shall", "intends", "believe", "plan", "expect", "intend", "estimate", "anticipate", "potential", "prospective", "assert" or any variations (including negative or plural variations) of such words and phrases, or state that certain actions, events or results "may", "might", "can", "could", "would" or "will" be taken, occur, lead to, result in, or, be achieved. Such statements are based on the current expectations and views of future events of the management of the Company. They are based on assumptions and subject to risks and uncertainties. Although management believes that the assumptions underlying these statements are reasonable, they may prove to be incorrect. The forward-looking events and circumstances discussed in this release, may not occur and could differ materially as a result of known and unknown risk factors and uncertainties affecting the Company, including, without limitation, risks relating to the pharmaceutical and bioscience industry (including the risks associated with preclinical and clinical trials and regulatory approvals), and the research and development of therapeutics, the results of preclinical and clinical trials, general market conditions and equity markets, economic factors and management's ability to manage and to operate the business of the Company generally, including inflation and the costs of operating a biopharma business, and those risks listed in the "Risk Factors" section of Satellos' Annual Information Form dated March 26, 2025 (which is located on Satellos' profile at www.sedarplus.ca). Although Satellos has attempted to identify important factors that could cause actual actions, events or results to differ materially from those described in forward-looking statements, there may be other factors that cause actions, events or results to differ from those anticipated, estimated or intended. Accordingly, readers should not place undue reliance on any forward-looking statements or information. No forward-looking statement can be guaranteed. Except as required by applicable securities laws, forward-looking statements speak only as of the date on which they are made and Satellos does not undertake any obligation to publicly update or revise any forward-looking statement, whether resulting from new information, future events, or otherwise.

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