



NEWS RELEASE

Satellos Receives Rare Pediatric Disease Designation from the U.S. FDA for SAT-3247 for the Treatment of Duchenne Muscular Dystrophy

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- SAT-3247 is a proprietary, oral small molecule drug being developed by Satellos as a novel treatment to regenerate skeletal muscle which is lost in Duchenne muscular dystrophy (DMD)
- DMD is a rare genetic disorder characterized by progressive muscle degeneration and weakness
- Satellos has also received Orphan Drug Designation from the FDA for SAT-3247
- Initiation of a Phase 1 clinical trial of SAT-3247 anticipated in Q3 2024

TORONTO--(BUSINESS WIRE)-- **Satellos Bioscience Inc.** ("Satellos" or the "Company") (TSX: MSCL, OTCQB: MSCLF), a public biotech company developing new small molecule therapeutic approaches to improve the treatment of muscle diseases and disorders, announced today that the U.S. Food and Drug Administration (FDA) has granted Rare Pediatric Disease Designation to SAT-3247 for the potential treatment of Duchenne muscular dystrophy ("Duchenne" or "DMD") after receiving Orphan Drug Designation earlier this year. SAT-3247 is a first-in-class oral small molecule therapeutic designed to restore the innate muscle regeneration and repair process, independent of dystrophin and regardless of exon mutation status.

"Obtaining the Rare Pediatric Disease and Orphan Drug Designations for SAT-3247 from the FDA are important milestones for Satellos as we continue to progressively build value in our DMD program," said Frank Gleeson, CEO and Co-founder of Satellos. "The Rare Pediatric Disease Designation for SAT-3247 highlights the continued need for new disease modifying therapeutic options for pediatric patients with Duchenne, a need which we believe SAT-3247



has the potential to address.”

The FDA grants Rare Pediatric Disease Designation for serious and life-threatening diseases that primarily affect children ages 18 years or younger and fewer than 200,000 people in the United States. The Rare Pediatric Disease Priority Review Voucher Program is intended to address the challenges that drug companies face when developing treatments for these unique patient populations. Under this program, a sponsor who receives an approval for a drug or biologic for a “rare pediatric disease” may be eligible for a voucher that can be redeemed to receive priority review of a subsequent marketing application for a different product or sold to another sponsor for priority review of their marketing application.

The FDA grants Orphan Drug Designation to support development of medicines for underserved patient populations, or rare disorders, that affect fewer than 200,000 people in the U.S. Orphan Drug Designation provides certain benefits, including the potential for a seven-year market exclusivity upon regulatory approval, exemption from FDA application fees, tax credits for qualified clinical trials, and a priority review voucher.

About SAT-3247

SAT-3247 is an oral, small molecule drug candidate designed to target the root cause of muscle loss in degenerative diseases, initially in Duchenne. SAT-3247 presents a novel mechanism of action to restore impaired muscle regeneration caused by the absence of functional dystrophin.

About Duchenne Muscular Dystrophy

Duchenne muscular dystrophy is an inherited disease caused by mutations in the dystrophin gene that no longer allow the dystrophin protein to function properly. Consequently, as discovered by Satellos, muscle repair and regeneration are impaired. Satellos designed SAT-3247 to restore the process of muscle repair and regeneration by regulating a dystrophin-independent pathway with the goal of increasing muscle function. SAT-3247 is intended to work as a standalone therapeutic without regard to a patient’s genetic mutation or ambulatory status. Our approach has the potential to complement approaches designed to restore dystrophin production.

About Satellos Bioscience Inc.

Satellos is a publicly traded biotechnology company dedicated to developing life-improving medicines to treat degenerative muscle diseases. Satellos has incorporated breakthrough research in muscle stem cell polarity into a proprietary discovery platform, called MyoReGenX™, to identify degenerative muscle diseases where deficits in this process affect muscle regeneration and are amenable to therapeutic intervention. With this platform, Satellos is building a pipeline of novel therapeutics to correct muscle stem cell polarity and promote the body’s innate muscle repair and regeneration process. The Company’s lead program is an oral, small molecule drug candidate in development as a potential disease-modifying treatment for Duchenne muscular dystrophy. Satellos is headquartered in Toronto, Ontario. 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 value of our DMD program; the advancement of our lead drug candidate into clinical trials; the general benefits of modulating stem cell polarity by administering small molecule drugs; its/their prospective impact on Duchenne patients, patients with other degenerative muscle disease or muscle injury or trauma, and on muscle regeneration generally; the utility of regenerating muscle by modulating polarity; adoption of Satellos' approach by the medical community; 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", "anticipate", "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, 2024 (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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