



NEWS RELEASE

# Satellos Announces Acceptance of Regulatory Filing to Commence a Phase 1 Clinical Trial with SAT-3247

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Dosing of first participant in 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, today announced acceptance of a clinical research proposal to a Human Research Ethics Committee (HREC) in Australia seeking regulatory authorization under their Therapeutic Goods Administration's (TGA's) Clinical Trial Notification (CTN) scheme to conduct a first-in-human Phase 1 clinical trial of SAT-3247.

"Receiving clearance to commence clinical development of SAT-3247 represents a watershed moment for Satellos as we advance the first small molecule drug of its kind with the potential to restore the innate muscle regeneration and repair process that we discovered is dysfunctional in people living with Duchenne," said Frank Gleeson, CEO and Co-founder of Satellos. "We are excited to be advancing SAT-3247 into first-in-human studies and begin this next important chapter for Satellos in developing an oral pill which we believe has the potential to be disease modifying."

The Phase 1 clinical trial will comprise two components. In the first component of the study, 72 healthy volunteers will be enrolled in a blinded, randomized, placebo-controlled, staggered, parallel design to assess the safety and pharmacokinetic properties of SAT-3247. Participants will be randomized across 5 single-ascending dose (SAD) cohorts, 4 multiple-ascending dose (MAD) cohorts and one food effect (FE) dose cohort. In the second component of the study, 10 adult volunteers with genetically confirmed DMD will be enrolled in a 28-day, open-label dose cohort to compare safety and pharmacokinetic properties with the healthy volunteer data and explore



pharmacodynamic markers.

## About SAT-3247

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 of Duchenne) 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 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](http://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](http://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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