NEWS RELEASE

Satellos Announces FDA Clearance of IND Application for Forazapadin in Facioscapulohumeral Muscular Dystrophy (FSHD) and a Partnership with FSHD Canada Foundation Providing Non-Dilutive Financing to Support Clinical Development

2026-09-24

- FDA clearance expands development of forazapadin into a second degenerative muscle disease with significant unmet medical need
- FSHD Canada Foundation to provide up to US$5 million in non-dilutive financing toward the clinical development of forazapadin in FSHD
- Phase 2 study in FSHD expected to begin in Q4 2026

TORONTO, Sept. 24, 2026 (GLOBE NEWSWIRE) -- Satellos Bioscience Inc. (NASDAQ: MSLE, TSX: MSCL), a clinical-stage drug development company developing potentially life-improving medicines to treat degenerative muscle diseases, today announced that the U.S. Food and Drug Administration (FDA) has cleared its Investigational New Drug (IND) application for forazapadin for the treatment of facioscapulohumeral muscular dystrophy (FSHD). The company plans to initiate a Phase 2 clinical study in FSHD in the fourth quarter of 2026. Satellos also announced that the FSHD Canada Foundation has agreed to provide up to US$5 million in non-dilutive financing toward the clinical development of forazapadin in FSHD.

“We believe the biology targeted by forazapadin has the potential to address significant unmet needs in degenerative muscle diseases, and our expansion into FSHD reflects the broad potential of our muscle regeneration approach,” said Frank Gleeson, co-founder and chief executive officer of Satellos. “Progress in

medicine happens when researchers, clinicians, industry partners and advocacy organizations come together around a common goal, and we are grateful to the FSHD Canada Foundation for its partnership and confidence in our work. This support is expected to enable us to advance forazapadin into clinical development in FSHD and extend our muscle regeneration strategy to a second patient community."

"People living with FSHD, like me, are eager to find treatments that can stop our muscles from getting weaker. But we would also like to get some of those muscles back," said Neil Camarta, co-founder of the FSHD Canada Foundation. "That is what makes this announcement so meaningful. Seeing forazapadin advance into clinical trials to evaluate the potential for muscle regeneration in FSHD is an important step for our community. While we know there is still a long road ahead, it is encouraging to see innovative approaches like this moving into the clinic. FSHD Canada appreciates the support we received from our friends at Solve FSHD, the FSHD Society and FSHD Global in helping make this possible. Time is muscle!"

The collaboration between Satellos and the FSHD Canada Foundation provides non-dilutive capital to advance forazapadin's clinical development in FSHD. Under the agreement, the Foundation has agreed to contribute up to US$5 million in milestone payments over the next five quarters in exchange for a capped revenue-sharing interest in future FSHD-related proceeds. The funds are expected to support the IND-cleared Phase 2 randomized, double-blind, placebo-controlled proof-of-concept clinical study designed to evaluate the safety, tolerability, pharmacokinetics and potential efficacy of orally administered forazapadin at 60 mg and 120 mg doses in adults aged 18 and older living with FSHD, which we expect to initiate in the fourth quarter of 2026.

Wildon Farwell, M.D, chief medical officer of Satellos added, "We are excited to receive FDA clearance of our IND application for forazapadin in a second disease indication, one for which there are currently no approved therapies. FSHD is a genetic disease in which muscle regeneration appears to be compromised. We look forward to working with the FSHD community to evaluate the potential of forazapadin to impact muscle regeneration and benefit people living with FSHD. In particular, we are delighted that the clearance included 60 mg and 120 mg dose levels of forazapadin, enabling evaluation of two doses of our small molecule drug candidate."

FSHD is one of the most common forms of muscular dystrophy, affecting an estimated 800,000 individuals worldwide. It is caused by abnormal activation of the DUX4 gene, which damages muscle and contributes to progressive muscle weakness. Symptoms often begin in the muscles of the face, shoulders and upper arms before progressing to other parts of the body. The severity and rate of progression vary from person to person, and there are currently no approved disease-modifying therapies.

The clearance of this IND represents the second clinical indication for which forazapadin is being developed. Forazapadin is currently being evaluated for Duchenne muscular dystrophy (DMD), where preliminary data from an ongoing Phase 2 clinical trial in adults living with DMD showed a favorable safety profile, reduced muscle fat

fraction as measured by MRI, and increased total effort observed after six months of treatment at 60 mg. The company believes these findings may be consistent with muscle regeneration.

ABOUT FORAZAPADIN

Forazapadin is a proprietary, oral, small molecule drug candidate being developed by Satellos as a novel approach to regenerating skeletal muscle lost in degenerative muscle diseases or injury conditions. Forazapadin targets AAK1, a key protein identified by Satellos as believed to be capable of helping restore the body's natural muscle repair and regeneration biology, a fundamental process that is disrupted in DMD, FSHD and other degenerative conditions. By inhibiting AAK1, forazapadin treatment aims to re-establish a biochemical signal believed to be involved in supporting muscle regeneration. Satellos is advancing forazapadin as a potential treatment for DMD that is independent of dystrophin and applicable regardless of exon mutation status as either a stand-alone or adjunctive therapy, with ongoing Phase 2 clinical studies including BASECAMP, a global, randomized, placebo-controlled study in pediatric participants, and TRAILHEAD, an open-label study in adult participants. A Phase 2 clinical study to evaluate the safety, efficacy and tolerability of forazapadin in adults with FSHD is expected to begin in the fourth quarter of 2026.

The company previously referred to the program as SAT-3247 and expects to transition to broader use of the program's International Nonproprietary Name, forazapadin, in future scientific, regulatory and corporate communications.

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 forazapadin, an orally administered small molecule AAK1 inhibitor designed to address deficits in muscle repair and regeneration. Forazapadin is being evaluated as a potential disease-modifying treatment for Duchenne muscular dystrophy (DMD) in two Phase 2 clinical trials, BASECAMP in pediatric participants with DMD and TRAILHEAD in adults living with DMD. The FDA also cleared an Investigational New Drug (IND) application for the clinical evaluation of forazapadin for the treatment of facioscapulohumeral muscular dystrophy (FSHD). The company has identified additional muscle diseases and injury conditions where restoring muscle repair and regeneration may have therapeutic benefit and plans to pursue these opportunities in future clinical development. For more information, visit **www.satellos.com** and connect with Satellos on **X**, **LinkedIn**, **Facebook** and **Instagram**.

ABOUT THE FSHD CANADA FOUNDATION

The FSHD Canada Foundation is a Calgary-based charitable organization dedicated to finding a cure for facioscapulohumeral muscular dystrophy (FSHD), one of the most prevalent forms of muscular dystrophy affecting adults and children. Founded by Neil Camarta and Craig Kelley, the Foundation funds and partners on research,

natural-history studies, biomarker development, and clinical programs aimed at advancing treatments for the FSHD community in Canada and worldwide. For more information, visit fshd.ca.

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 evaluation of forazapadin as a disease-modifying treatment to Duchenne muscular dystrophy (DMD); the possibility of pursuing regulatory approval for forazapadin, the potential for forazapadin to represent a disease-modifying approach to the therapeutic treatment of people living with facioscapulohumeral muscular dystrophy (FSHD); forazapadin's proposed mechanism of action, including statements regarding the role of AAK1 in muscle repair and regeneration; the interpretation of preliminary clinical data, including the belief that observed results may be consistent with muscle regeneration; forazapadin's potential applicability as a treatment for DMD regardless of exon mutation status, whether as a stand-alone or adjunctive therapy; the enrollment in, advancement, design and timing of results of forazapadin through clinical trials, including the BASECAMP, TRAILHEAD and planned Phase 2 FSHD clinical trials and the anticipated design parameters thereof; the potential of forazapadin to address significant unmet needs across multiple degenerative muscle diseases and Satellos' plans to pursue additional muscle diseases and injury conditions in future clinical development; forazapadin's prospective impact on FSHD patients or patients with other degenerative muscle disease or muscle injury; the anticipated timing for evaluation in FSHD and the launch of a related Phase 2 clinical trial; contributions by FSHD Canada Foundation to advance forazapadin's clinical development in FSHD, including the timing and amounts thereof, and Satellos' anticipated use of such financing proceeds; Satellos' technologies and drug development plans; and Satellos' expectation for broader use of the program's International Nonproprietary Name, forazapadin, in future scientific, regulatory and corporate communications. 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. These statements are based on assumptions and subject to risks and uncertainties. In making forward-looking statements, the Company has relied on various assumptions, including but not limited to: the validity of the company's scientific hypotheses regarding AAK1 inhibition and muscle regeneration; the receipt of anticipated milestone payments under the FSHD Canada Foundation agreement; its ability to obtain future funding on favorable terms, if at all; obtaining positive results in its clinical trials; its ability to obtain necessary regulatory approvals; its ability to arrange for the manufacturing of its product

candidates and technologies; and general business, market and economic conditions. 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), the research and development of therapeutics, the results of preclinical and clinical trials, the possibility that preliminary clinical data may not be replicated in later studies or that the company's interpretation of such data may prove incorrect, 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 and uncertainties described in more detail in the “Risk Factors” section of Satellos' Annual Information Form dated March 27, 2026, and amended and restated short form base shelf prospectus dated August 11, 2026 (each of which is located on Satellos' SEDAR+ profile) and incorporated by reference in Satellos’ Form F-10 filed with the Securities and Exchange Commission on August 11, 2026, and in Satellos' public filings on EDGAR (sec.gov) and SEDAR+ (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.

CONTACTS
Investors: Caitlin Lowie, Vice President, Investor Relations & Communications, **ir@satellos.com**
Media: Emily Williams, Senior Director, Communications, **media@satellos.com**

Source: Satellos Bioscience Inc.