



NEWS RELEASE

Summit Therapeutics Signs Agreement to Sell Phase III Asset Ridinilazole to Biossil, Inc.

2026-07-14

MIAMI--(BUSINESS WIRE)-- Summit Therapeutics Inc. (NASDAQ: SMMT) today announced it has signed an agreement with Toronto-based Biossil, Inc. for the sale of ridinilazole, an investigational Phase III precision antibiotic owned by Summit. Biossil is an artificial intelligence (AI)-native biopharma company focused on advancing late-stage programs in life-threatening indications with urgent unmet medical needs.

Previously, ridinilazole was evaluated in Summit's Phase III Ri-CoDiFy study for the treatment of patients suffering from C. difficile infection (C. diff. infection or CDI), an area of high unmet need. The study showed that ridinilazole resulted in a higher observed Sustained Clinical Response (SCR) rate than vancomycin but did not meet the study's primary endpoint for superiority within the established time boundaries. SCR is defined as Clinical Response of the treated episode of CDI and no recurrence of the infection through 30 days after the end of treatment. These results were **announced** by Summit in December 2021 and subsequently published in the journal Clinical Infectious Diseases.¹ Ri-CoDiFy, as well as earlier-stage clinical studies of ridinilazole, demonstrated its ability to spare the gut microbiome compared to vancomycin, the standard of care in C. difficile infection, which is believed to impact recurrence of the disease. The gut microbiome and its homeostasis have been linked to overall quality of human health across several recent studies.

"Ridinilazole has long represented a scientifically differentiated approach to addressing Clostridioides difficile infection, a serious disease that continues to place a substantial burden on patients, caregivers, and healthcare

systems,” said Robert W. Duggan, Chairman and Co-Chief Executive Officer of Summit. “We believe Biossil’s AI-native development capabilities and focus on urgent unmet medical needs make them well positioned to advance this program, while allowing Summit to continue prioritizing our core oncology strategy and the development of ivonescimab. Summit is pleased that Biossil is planning to continue clinical development of ridinilazole to unlock its potential. The exploratory data in previous clinical trials, which require further study, demonstrated numerical differences favoring ridinilazole versus vancomycin, including microbiome preservation, lower recurrence rates, reduced toxin production, dosing convenience, and tolerance.”

Under the terms of the agreement, Summit will receive \$500,000 upfront and up to \$104.5 million in regulatory and commercial milestones, plus tiered royalties on net sales.

“Introduction of novel, microbiome-sparing antibiotics has lagged the growing global need,” said Alexander Mosa, MD, PhD, CSO and Chair of Biossil. “Recurrent *C. difficile* infection, selection of antibiotic-resistant genes, and gut dysbiosis are common, burdensome, and in need of new approaches. We thank Summit for entrusting us with continued development of ridinilazole, and we will advance this program with urgency and focus.”

The use of ridinilazole is not approved and its safety and efficacy have not been evaluated by regulatory authorities, including the United States Food and Drug Administration (FDA).

About *C. Difficile* Infection

Clostridioides difficile, or *C. difficile*, infection (CDI) is a bacterial infection of the colon that produces toxins causing inflammation of the colon, severe watery diarrhea, painful abdominal cramping, nausea, fever, and dehydration. CDI can also result in more serious disease complications, including bowel perforation, sepsis, and death. CDI is a contagious infectious disease that represents a serious healthcare issue in hospitals, long-term care facilities, and the wider community. According to the Peggy Lillis Foundation, *C. difficile* causes nearly 500,000 infections in the United States each year and contributes to more than 29,000 deaths annually.² The foundation also describes *C. difficile* as the most common healthcare-associated infection.² CDC surveillance data show that CDI continues to affect both healthcare and community settings, with 2024 Emerging Infections Program sites reporting an incidence of 124.4 cases per 100,000 people and most cases associated with recent antibiotic exposure.³ Recent peer-reviewed analyses further underscore CDI’s ongoing economic burden, including substantial excess healthcare costs among commercially insured adults⁴ and high per-patient annual direct medical costs associated with recurrent CDI.⁵

About Biossil, Inc.

Biossil is an AI-native drug development company advancing a pipeline of late-stage, first-in-class candidates for

heterogeneous and life-threatening diseases. With teams in Toronto and Boston, and partnerships with leading academic medical centers and research hospitals, Biossil integrates proprietary AI with deep clinical and translational expertise to advance promising clinical-stage assets.

About Summit Therapeutics Inc.

Summit Therapeutics Inc. is a biopharmaceutical oncology company focused on the discovery, development, and commercialization of patient-, physician-, caregiver- and societal-friendly medicinal therapies intended to improve quality of life, increase potential duration of life, and resolve serious unmet medical needs.

Summit was founded in 2003 and the company's shares are listed on the Nasdaq Global Market (symbol "SMMT"). Summit is headquartered in Miami, Florida, with additional offices in Palo Alto, California, Princeton, New Jersey, Dublin, Ireland, and Oxford, UK.

For more information, please visit <https://www.smmmtx.com> and follow Summit on X @SMMT_TX.

References

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3. Centers for Disease Control and Prevention. *Clostridioides difficile* Infection Surveillance: Emerging Infections Program Healthcare-Associated Infections–Community Interface Report, 2024. Atlanta, GA: U.S. Department of Health and Human Services, CDC; 2026.
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Summit Forward-Looking Statements

Any statements in this press release about the Company's future expectations, plans and prospects, including but not limited to, statements about the clinical and preclinical development of the Company's product candidates,

entry into and actions related to the Company's partnership with Akeso Inc. and other collaborations, the intended use of the net proceeds from the private placements, the Company's anticipated spending and cash runway, the therapeutic potential of the Company's product candidates, the potential commercialization of the Company's product candidates, the timing of initiation, completion and availability of data from clinical trials, the potential submission of applications for marketing approvals, the expected timing of BLA submissions or FDA decisions, potential acquisitions, statements about the previously disclosed At-The-Market equity offering program ("ATM Program"), the expected proceeds and uses thereof, the Company's estimates regarding stock-based compensation, and other statements containing the words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "would," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including the Company's ability to sell shares of our common stock under the ATM Program, the conditions affecting the capital markets, general economic, industry, or political conditions, including the effects of geopolitical developments, domestic and foreign trade policies, and monetary policies, the results of our evaluation of the underlying data in connection with the development and commercialization activities for ivonescimab, the outcome of discussions with regulatory authorities, including the Food and Drug Administration, the uncertainties inherent in the initiation of future clinical trials, availability and timing of data from ongoing and future clinical trials, the results of such trials, and their success, global public health crises, that may affect timing and status of our clinical trials and operations, whether preliminary results from a clinical trial will be predictive of the final results of that trial or whether results of early clinical trials or preclinical studies will be indicative of the results of later clinical trials, whether business development opportunities to expand the Company's pipeline of drug candidates, including without limitation, through potential acquisitions of, and/or collaborations with, other entities occur, expectations for regulatory approvals, laws and regulations affecting government contracts and funding awards, availability of funding sufficient for the Company's foreseeable and unforeseeable operating expenses and capital expenditure requirements and other factors discussed in the "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of filings that the Company makes with the Securities and Exchange Commission. Summit defines a "positive study" as a clinical study with one or more prespecified primary endpoints in which one of those endpoints achieves a statistically significant benefit according to the protocol or statistical analysis plan. Any change to our ongoing trials could cause delays, affect our future expenses, and add uncertainty to our commercialization efforts, as well as to affect the likelihood of the successful completion of clinical development of ivonescimab. Accordingly, readers should not place undue reliance on forward-looking statements or information. In addition, any forward-looking statements included in this press release represent the Company's views only as of the date of this release and should not be relied upon as representing the Company's views as of any subsequent date. The Company specifically disclaims any obligation to update any forward-looking statements included in this press release.

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Source: Summit Therapeutics