



Sanara MedTech Inc. and InfuSystem Holdings, Inc. Announce Exclusive United States Distribution Agreement with, and Minority Investment in, ChemoMouthpiece, LLC

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FORT WORTH, TX / GlobeNewswire / September 11, 2024 / Sanara MedTech Inc. Based in Fort Worth, Texas, Sanara MedTech Inc. ("Sanara," the "Company," "we," "our" or "us") (NASDAQ: SMTI), a medical technology company focused on improving clinical outcomes and reducing healthcare expenditures in the surgical, chronic wound and skincare markets, and InfuSystem, Inc. ("InfuSystem"), the operational subsidiary of Sanara's joint venture partner InfuSystem Holdings, Inc., announced today the execution of an exclusive United States distribution agreement with, and minority investment in, ChemoMouthpiece, LLC ("ChemoMouthpiece").

Ron Nixon, Sanara's CEO, stated, "Oral mucositis is a debilitating condition impacting hundreds of thousands of oncology patients annually. ChemoMouthpiece has developed a clinically validated product with FDA 510(k) clearance that can bring relief to affected patients. The American Medical Association has recently issued the CPT code (effective July 2024) to be applied for potential reimbursement by physicians and payers for the use of an oral cavity device for a cryotherapy procedure in conjunction with chemotherapy. The product aligns well with Sanara's skincare strategy, which includes the licensed collagen peptides from Tufts University that focus on radiation dermatitis. We look forward to providing the Chemo Mouthpiece® oral cryotherapy device to oncology patients undergoing chemotherapy."

Transaction Overview

- ChemoMouthpiece owns and manufactures a 510(k) cleared device that uses cryotherapy to reduce the incidence and severity of oral mucositis in patients undergoing stomatotoxic chemotherapy treatments.
- SI Healthcare Technologies, LLC (f/k/a SI Wound Care, LLC) ("SI Technologies"), a 50/50 joint venture between Sanara and InfuSystem, will be the exclusive distributor of ChemoMouthpiece's kits in the United States.
- SI Technologies plans to market and distribute the product through InfuSystem to approximately 3,000 cancer centers through InfuSystem's existing sales team.
- SI Technologies will purchase the product kits from ChemoMouthpiece at a fixed price and pay a royalty on net revenues for the use of the product intellectual property.
- Sanara invested \$5 million for a 6.6% ownership position in ChemoMouthpiece.
- SI Technologies will have a purchase option that expires on January 31, 2029 to purchase the U.S. business of ChemoMouthpiece, including all U.S. intellectual property related to the product.
- Sanara has drawn \$15.5 million on its term loan with CRG Servicing, LLC and will fund this investment as part of that draw.

Oral Mucositis

Oral mucositis causes painful mouth ulcers, which are a common complication of chemotherapy and radiation. In the U.S., there are an estimated 500,000 – 1,000,000 patients who have oral mucositis annually and the estimated market size exceeds \$600 million. SI Technologies believes this product will show material cost reductions for oncology treatment centers, improve patient quality of life and allow for continued treatment of cancer therapy for patients. ChemoMouthpiece is planning to publish studies in the future reinforcing the efficacy of their product.

Richard Dilorio, InfuSystem's CEO, stated, "Sanara and InfuSystem entered into our partnership in order to bring together our combined technical, operational and commercial strengths to deliver proprietary efficacious products to patients. We believe this exclusive agreement, which builds on our partnership, will allow us to do that by offering the Chemo Mouthpiece® oral cryotherapy device and bringing potential relief to thousands of cancer patients suffering from oral mucositis."

David Yoskowitz, ChemoMouthpiece's President and CEO stated, "We are pleased to have selected SI Technologies as our exclusive distribution partner in the United States. We believe that InfuSystem's experienced team of seasoned oncology professionals currently calling on approximately 3,000 U.S. cancer centers will accelerate the uptake of the Chemo Mouthpiece, bringing a much-needed option for patients that would otherwise suffer from the debilitating effects of oral mucositis." David added, "We understand that the executive team of SI Technologies has a long history of launching products into the oncology space, and coupled with Sanara's ownership position in ChemoMouthpiece, we are confident that they will execute the successful launch of the Chemo Mouthpiece® oral cryotherapy device."

Pickwick Capital Partners, LLC, served as the exclusive advisor to ChemoMouthpiece on this transaction.

About ChemoMouthpiece, LLC

ChemoMouthpiece, LLC is a privately held medical device company that develops and commercializes propriety oral cryotherapy products for cancer patients. The Chemo Mouthpiece® oral cryotherapy device was developed based on the personal experience of inventor, founder and CEO, David Yoskowitz, who when diagnosed with Hodgkin's Lymphoma, experienced oral mucositis firsthand. His treatment options included ice chips to mitigate and minimize the pain. Yet this caused nausea, was difficult to maintain in his mouth, and did not effectively cool the entire oral cavity which led him to search for a better option. The Chemo Mouthpiece® oral cryotherapy device cools down the entire oral cavity, causing vasoconstriction, which in effect slows and reduces the flow of chemotherapy in the oral cavity, thus greatly reducing the risk of developing oral mucositis. The cryotherapy approach has been positively studied for decades and the Chemo Mouthpiece® oral cryotherapy device has significant and improved advantages over conventional cryotherapy interventions. For more information on ChemoMouthpiece, LLC, please visit its website at www.chemomouthpiece.com.

About Sanara MedTech Inc.

Sanara MedTech Inc. is a medical technology company focused on developing and commercializing transformative technologies to improve clinical outcomes and reduce healthcare expenditures in the surgical, chronic wound and skincare markets. The Company markets, distributes and develops surgical, wound and skincare products for use by physicians and clinicians in hospitals, clinics and all post-acute care settings and offers wound care and dermatology virtual consultation services via telemedicine. Sanara's products are primarily sold in the North American advanced wound care and surgical tissue repair markets. Sanara markets and distributes CellerateRX® Surgical Activated Collagen, FORTIFY TRG® Tissue Repair Graft and FORTIFY FLOWABLE® Extracellular Matrix as well as a portfolio of advanced biologic products focusing on ACTIGEN™ Verified Inductive Bone Matrix, ALLOCYTE® Plus Advanced Viable Bone Matrix, BiFORM® Bioactive Moldable Matrix, TEXAGEN® Amniotic Membrane Allograft, and BIASURGE® Advanced Surgical Solution to the surgical market. In addition, the following products are sold in the wound care market: BIAKÖS® Antimicrobial Skin and Wound Cleanser, BIAKÖS® Antimicrobial Wound Gel, and BIAKÖS® Antimicrobial Skin and Wound Irrigation Solution. Sanara's pipeline also contains potentially transformative product candidates for mitigation of opportunistic pathogens and biofilm, wound re-epithelialization and closure, necrotic tissue debridement and cell compatible substrates. The Company believes it has the ability to drive its pipeline from concept to preclinical and clinical development while meeting quality and regulatory requirements. Sanara is constantly seeking long-term strategic partnerships with a focus on products that improve outcomes at a lower overall cost.

About InfuSystem Holdings, Inc.

InfuSystem Holdings, Inc. (NYSE American: INFU), is a leading national health care service provider, facilitating outpatient care for durable medical equipment manufacturers and health care providers. INFU services are provided under a two-platform model. The first platform is Patient Services, providing the last-mile solution for clinic-to-home healthcare where the continuing treatment involves complex durable medical equipment and services. The Patient Services segment is comprised of Oncology, Pain Management and Wound Therapy businesses. The second platform, Device Solutions, supports the Patient Services platform and leverages strong service orientation to win incremental business from its direct payer clients. The Device Solutions segment is comprised of direct payer rentals, pump and consumable sales, and biomedical services and repair. Headquartered in Rochester Hills, Michigan, the Company delivers local, field-based customer support and also operates Centers of Excellence in Michigan, Kansas, California, Massachusetts, Texas and Ontario, Canada.

Information about Forward-Looking Statements

The statements in this press release that do not constitute historical facts are "forward-looking statements," within the meaning of and subject to the safe harbor created by the Private Securities Litigation Reform Act of 1995. These statements may be identified by terms such as "aims," "anticipates," "believes," "contemplates," "continue," "could," "estimates," "expect," "forecast," "guidance," "intend," "may," "plan," "possible," "potential," "predicts," "preliminary," "projects," "seeks," "should," "targets," "will" or "would," or the negatives of these terms, variations of these terms or other similar expressions. These forward-looking statements include, among others, statements regarding the ability to market and distribute the Chemo Mouthpiece device. These items involve risks, contingencies and uncertainties such as the ability to penetrate oncology hospitals and clinics, the extent of product demand, market and customer acceptance, the effect of economic conditions, competition, pricing, uncertainties associated with the development and process for obtaining regulatory approval for new products, the ability to consummate and integrate acquisitions, and other risks, contingencies and uncertainties detailed in the Company's SEC filings, which could cause the Company's actual operating results, performance or business plans or prospects to differ materially from those expressed in, or implied by these statements.

All forward-looking statements speak only as of the date on which they are made, and the Company undertakes no obligation to revise any of these statements to reflect the future circumstances or the occurrence of unanticipated events, except as required by applicable securities laws.

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