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SINTX ANNOUNCES SUCCESSFUL FDA 510(k) PRE-SUBMISSION MEETING FOR SILICON NITRIDE-PEEK COMPOSITE SPINE IMPLANTS

SALT LAKE CITY, Sept. 08, 2022 (GLOBE NEWSWIRE) -- SINTX Technologies, Inc. (www.sintx.com) (NASDAQ: SINT) ("SINTX" or the "Company"), an original equipment manufacturer (OEM) of advanced ceramic materials for medical and technical applications, announced today it has held a successful 510(k) pre-submission meeting with the United States Food and Drug Administration (FDA) concerning the potential development and commercialization of silicon nitride-PEEK (FleX-SN PEEK) spine implants.

In the meeting, FDA officials provided supportive feedback related to the company's underlying regulatory assumptions and strategies. SINTX intends to utilize the FDA's guidance to move forward with 510(k) filing and initiate commercialization efforts to introduce spine implants made of its novel FleX-SN PEEK composite material. FleX-SN PEEK is among a new line of biomedical innovations created by the Company and is not restricted to any exclusive commercial partner.

"We are pleased to have made such great progress towards the commercialization of FleX-SN PEEK spine implants," stated Dr. Sonny Bal, President and CEO, SINTX Technologies. "With the guidance from the FDA in hand, we can now confidently move forward with our 510(k) submission and discussions with commercial partners. It is very reassuring that FDA has agreed with our approach towards regulatory clearance, and further agreed that a clinical trial is not required with this material."

To create FleX-SN PEEK, SINTX partnered with Solvay (www.solvay.com), a global leader in materials, chemicals, and solutions, to enhance their Zeniva PEEK biomaterial which already features a favorable material modulus and an established clinical track record. The resultant FleX-SN PEEK product is expected to facilitate faster bone healing, improve radiographic imaging, avoid metal ion release in the body, and have broad-spectrum resistance to infection. This makes the composite material attractive for many surgical applications such as spinal implant surgery. Individually, both silicon nitride and PEEK are already FDA-cleared for human implantation with many years of clinical success.

SINTX submitted a Master Access File (MAF) for FleX-SN PEEK to the FDA in early 2021. This file can be referenced under license by SINTX customers using the material for new medical implant designs and products. SINTX continues to collaborate with many partners around the world in the development and testing of novel embodiments and applications of silicon nitride and other advanced ceramic materials. The recent acquisition of Technology Assessment & Transfer (TA&T) expanded the Company's product portfolio into other

ceramic biomaterials such as zirconia and alumina for both medical and industrial applications.

For more information, please visit https://sintx.com/.

About SINTX Technologies, Inc.

SINTX Technologies is an advanced ceramics company that develops and commercializes materials, components, and technologies for medical and technical applications. SINTX is a global leader in the research, development, and manufacturing of silicon nitride, and its products have been implanted in humans since 2008. Over the past two years, SINTX has utilized strategic acquisitions and alliances to enter into new markets. The Company has manufacturing facilities in Utah and Maryland.

Forward-Looking Statements for SINTX Technologies, Inc.

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 (PSLRA) that are subject to a number of risks and uncertainties. Risks and uncertainties that may cause such differences include, among other things: preparation of the 510(k) may take longer than currently expected and may not support clearance by the FDA; products containing FleX-SN PEEK composite material may not be accepted by the market; FleX-SN PEEK products may not facilitate faster bone healing, improve radiographic imaging, avoid metal ion release in the body, nor have broad-spectrum resistance to infection, which would significantly limit commercial success. the FDA may not clear any products for commercialization; the industry may not accept the new products or may turn to products they deem more effective or less expensive; patients may not realize the expected benefits of our products; volatility in the price of SINTX's common stock; the uncertainties inherent in new product development, including the cost and time required to commercialize such product(s); market acceptance of our products once commercialized; SINTX's ability to raise additional funding and other competitive developments. Readers are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the date on which they are made and reflect management's current estimates, projections, expectations, and beliefs. There can be no assurance that any of the anticipated results will occur on a timely basis or at all due to certain risks and uncertainties, a discussion of which can be found in SINTX's Risk Factors disclosure in its Annual Report on Form 10-K, filed with the Securities and Exchange Commission (SEC) on March 25, 2022, and in SINTX's other filings with the SEC. SINTX disclaims any obligation to update any forward-looking statements. SINTX undertakes no obligation to publicly revise or update the forward-looking statements to reflect events or circumstances that arise after the date of this report.

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