Sirnaomics Receives FDA Clearance to Initiate Phase 2 Study of STP705 for the Treatment of Non-Melanoma Skin Cancer

GAITHERSBURG, MD, USA, December 20, 2018 /EINPresswire.com/ -- Sirnaomics, Inc., a biopharmaceutical company engaged in the discovery and development of RNAi therapeutics against cancer and fibrotic diseases, announced today that the U.S. Food and Drug Administration (FDA) has agreed to the Company's proposed trial design for a Phase 2 clinical study to evaluate its lead product candidate, STP705, for the treatment of in situ Squamous Cell Carcinoma Nonmelanoma Skin Cancer (NMSC). The Company expects to initiate the study in the first half of 2019.

STP705 is a siRNA (small interfering RNA) therapeutic that utilizes a proprietary polypeptide nanoparticle (PNP)-enhanced delivery system to inhibit expression of TGF-β1 and COX-2, which have been identified as major factors in promoting epithelial cell proliferation and regulating development and progression of NMSC in humans.

"FDA clearance to proceed with the NMSC trial represents an important step forward in demonstrating the broader clinical utility of our siRNA platform," said Sirnaomics' founder and CEO Patrick Y. Lu, PhD. "Building on our technology's potential against fibrotic disease, the drug target selection and tumor targeting delivery capabilities of our platform will help demonstrate the broader therapeutic potential of STP705 as a therapeutic candidate against cancer."

The Phase 2 trial, led by Brian Berman, MD, PhD, Professor Emeritus, Dermatology and Cutaneous Surgery at University of Miami Miller School of Medicine and one of the world's leading experts in NMSC, will evaluate the safety and potential therapeutic effect of STP705 in NMSC patients. "There is a real clinical need for non-invasive, targeted therapy for in situ squamous cell carcinoma," stated Dr. Berman.

"We are very pleased to have someone of Dr. Berman's caliber to lead this anti-cancer study," stated Michael Molyneaux, MD, Sirnaomics' Chief Medical Officer. "Nonmelanoma skin cancer is the most common form of skin cancer and a growing public health problem due to its increasing incidence and associated medical costs. We hope to demonstrate the clinical utility of STP705 as a therapeutic alternative to surgery - the current standard of care for NMSC and which carries the risk of significant adverse effects."

About Nonmelanoma Skin Cancer

NMSC is the most common form of cancer in the United States, affecting an estimated 3.5 million people with medical related costs reaching $650 million annually. The gold standard of treatment for high-risk NMSC is Mohs micrographic surgery (MMS) or radiotherapy. However, with surgery the patients are at a high risk of infection, hematoma and scar development. Nonmelanoma skin cancer (NMSC) is diagnosed more commonly and it is a growing public health problem due to its increasing incidence and medical care costs. NMSC consists of two major subtypes: (i) basal cell carcinoma (BCC) and (ii) squamous cell carcinoma (SCC). BCCs arise from the basal cell layer and constitute the majority of all diagnosed skin cancers (80%). They are able to damage the surrounding tissue, however, they are rarely life threatening or metastatic. SCCs arise from hair follicle stem cells and account for 16% of all skin cancers.

About STP705

STP705 is composed of two siRNA oligonucleotides targeting TGF-β1 and COX-2 mRNA respectively, and formulated in nanoparticles with Histidine-Lysine Co-Polymer (HKP) peptide. Each individual siRNA was demonstrated to inhibit the expression of their target mRNA and combining the two siRNAs produces a synergistic effect that diminishes pro-fibrogenic and pro-inflammatory factors. Molecular analyses of the effects of administering the combination demonstrated that the inhibition of these targets had effects on downstream gene products associated with fibrosis including: α-SMA, Col1A1, and Col3A1. Additional data suggests that reductions in TGF-β1 and COX-2 lead to proapoptotic effects in fibroblasts. TGF-β1 and COX-2 have been well characterized in playing a major role in the progression of tumorigenesis of NMSC. Literature has reported several studies with NMSC patients exhibiting overexpression of TGF-β1 and COX-2 in the lesional tissues. Numerous pre-clinical studies have demonstrated that inhibition of TGF-β1 and COX-2 could potentially have a therapeutic effect in NMSC tumors. As such, an HKP-enhanced delivery of TGF-β1 and COX-2 specific siRNA combination (STP705) is expected to downregulate TGF-β1 and COX-2 expression resulting in the inhibition of tumor growth and provide an alternative non-invasive approach for the treatment of NMSC. The combination therapy, with its multifactorial mode of action on NMSC cells, would: (i) inhibit tissue disruption, cell proliferation and angiogenesis; (ii) maintain cellular integrity of healthy cells; and (iii) promote apoptosis of NMSC cells. STP705 treatment, by inhibiting TGF-β1 and COX-2 expression, would promote BCC and SCC tumor suppression. As such the novel therapeutic STP705 is able to serve as a non-invasive treatment of NMSC.

About Sirnaomics, Inc.

Sirnaomics, Inc., a leading privately held biopharmaceutical company for discovery and development of RNAi therapeutics, is a Delaware corporation headquartered in Gaithersburg, Maryland, USA, with subsidiaries in Suzhou and Guangzhou, China. The company's mission is to develop novel therapeutics to alleviate human suffering and advance patient care in areas of high unmet medical need. The guiding principles of the company are: Innovation, Global Vision with a Patient Centered focus. Members of the senior management team have a great deal of

combined experience in the biopharmaceutical industry, financial, clinical and business management in both the USA and China. The company is supported by funding from institutional investors, corporate partnerships and government grants. Sirnaomics has developed a strong portfolio of intellectual property with an enriched product pipeline. The therapeutic areas of focus include oncology and anti-fibrotic therapeutics. Learn more at www.sirnaomics.com.

CONTACT:

Sirnaomics, Inc.
Michael Molyneaux, MD, MBA
Chief Medical Officer
michaelmolyneaux@sirnaomics.com

ICR Healthcare
Investors:
Stephanie Carrington
Tel: +1 646 277 1282
Email: Stephanie.Carrington@icrinc.com
Media:
James Heins
Tel: +1 203 682 8251
Email: James.Heins@icrinc.com

George Ji
Sirnaomics Inc.
+1 3017401730
email us here
