OncoNano Medicine Announces Positive Preclinical Data for ONM-501 at AACR 2022 Annual Meeting

- ONM-501 is a dual-activating polyvalent STING agonist for immuno-oncology applications formulated with OMNI™, the company's core immune activating polymer technology -

SOUTHLAKE, Texas – April 13, 2022 – OncoNano Medicine, Inc. today announced positive results from a preclinical study of ONM-501, a novel dual-activating polyvalent STING (**ST**imulator of **IN**terferon **G**enes) agonist for immuno-oncology applications. The data, presented at the American Association for Cancer Research (AACR) Annual Meeting 2022, demonstrate the efficacy and tolerability of ONM-501 in animal models for multiple tumor types. ONM-501 is formulated with the core OncoNano OMNI™ polymer technology consisting of STING-activating pH-sensitive micelles loaded with an endogenous agonist.

"We are thrilled by the continued positive preclinical results for ONM-501. STING has consistently been a challenging pathway to target, so we are encouraged by the constellation of our impressive preclinical data showing anti-tumor efficacy and an adaptive response differentiated from cyclic dinucleotide (CDN) STING agonists," said Ruolan Han, Ph.D., Vice President of Nonclinical & Translational Medicine for OncoNano Medicine. "In preclinical studies to date, ONM-501 has demonstrated the ability to produce a burst and sustained activation of the STING signaling pathway that leads to a robust adaptive immune response with low systemic drug exposure and toxicity. We look forward to continuing our IND-enabling activities as we advance ONM-501 toward our first in human trial in early 2023."

ONM-501 was evaluated for anti-tumor efficacy and tolerability in multiple animal oncology models. The findings from multiple preclinical studies evidence the following about ONM-501:

- STING activation was observed by measuring *IFNB1* and *CXCL10* mRNA in PBMCs from different species
- Anti-tumor efficacy both as a monotherapy and in combination with anti-PD1 in both immune "hot" and "cold" tumor models
- Anti-tumor effect mediated by host STING and dependent on CD8+ T cells
- Ability to induce an abscopal effect - tumor inhibition was observed in both primary and distal tumors in the same animal
- Ability to induce adaptive immune memory
- Ability to inhibit lung metastasis in an immune "cold" triple negative orthotopic breast cancer 4T1 model

- Unique nanoparticle formulation delivered intratumorally achieves high local drug retention, low systemic exposure and a potential for a reduced risk of toxicity

Presentation Overview

TITLE: ONM-501: A polyvalent STING agonist for oncology immunotherapy
PRESENTER: Qingtai Su, Ph.D., Senior Scientist, OncoNano Medicine

About OncoNano Medicine
OncoNano Medicine is developing a new class of products that utilize principles of molecular cooperativity in their design to exploit pH as a biomarker to diagnose and treat cancer with high specificity. Our product candidates and interventions are designed to help patients across the continuum of cancer care and include solid tumor therapeutics, agents for real-time image-guided surgery and a platform of immune-oncology therapeutics that activate and guide the body's immune system to target cancer.

OncoNano's lead development candidate is pegsitacianine, a novel fluorescent nanoprobe, that is currently under study in Phase 2 clinical trials as a real-time surgical imaging agent for use in multiple cancer surgeries. ONM-501, OncoNano's second development program, is a next generation STING (**ST**imulator of **IN**terferon **G**enes) agonist that is advancing towards a first in human trial in the first half of 2023. Pegsitacianine and ONM-501 have been supported by grants received from the Cancer Prevention Research Institute of Texas. Learn more at www.OncoNano.com.

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