OncoNano Receives Authorization to Proceed from FDA for IND Application and Fast Track Designation for ONM-100, Intraoperative Imaging Agent to Detect Tumors and Metastatic Lymph Nodes That Often Go Undetected During Surgery

SOUTHLAKE, TX. – January 4, 2019 – OncoNano Medicine, Inc. today announced that the U.S. Food and Drug Administration (FDA) has accepted its Investigational New Drug (IND) application for ONM-100, an intravenously administered imaging agent to detect tumors and metastatic lymph nodes in solid cancers during surgery. In addition, OncoNano received Fast Track designation from the FDA for ONM-100.

ONM-100 is the first product from a platform based upon the OncoNano’s library of unique micelles that respond to pH variability. Specifically, ONM-100 is delivered to the tumor and subsequently fluoresces in the acidic tumor microenvironment, which will allow surgeons to visualize the tumor during surgery using existing infrared-based surgical cameras. The OncoNano micelle platform is also being used to develop therapeutics, cancer nanovaccines and immune therapies. OncoNano is currently concluding the Phase 1 clinical trial for ONM-100 in the Netherlands.

“These two positive responses from the FDA reflect the progress that we have made on ONM-100,” said Kathy Rath, Vice President, Regulatory Affairs at OncoNano Medicine. “The Fast Track designation will allow us to have an ongoing, open dialogue with the FDA with the goal to make this important technology available to surgeons and their patients at the earliest possible time.”

“We are excited for the opportunity to work closely with the FDA while developing this critical solution to the problems surgeons face every day,” said Yalia Jayalakshmi, Vice President, Clinical Development at OncoNano Medicine. “With these responses and the emerging clinical data demonstrating the potential of the product in multiple types of solid tumors, including breast, head and neck, esophageal and colorectal cancers, we are well positioned to advance ONM-100 into a Phase 2 clinical study in 2019.”

More information on the FDA’s Fast Track designation can be found here.

About OncoNano Medicine
OncoNano Medicine is developing a new class of pH-activated compounds that digitalize and exploit the variability of pH in disease. pH variability is a proven, simple and effective identifier of diseased tissue providing a foundation for the development of a broad range of highly targeted therapeutics and imaging agents. OncoNano is the first company to advance product
candidates using pH as a biomarker for cancer immunotherapy, therapeutic use and intra-operative imaging based on its pH-sensitive micelle technology.

www.onconanomed.com

Contacts
MacDougall Biomedical Communications
Lauren Arnold, 781-235-3060
larnold@macbiocom.com