ProNAi Initiates Phase I Cancer Clinical Study of PNT2258

KALAMAZOO, MI, September 20, 2010 -- ProNAi Therapeutics, Inc., a privately held biopharmaceutical company, announced today dosing of its first patient in an open-label, single-arm, Phase I dose-escalation study of PNT2258 in patients with advanced solid tumors for which no standard therapy exists. Patients will receive PNT2258 as an intravenous infusion once daily for 5 consecutive days (Days 1-5) of every 21-day cycle (3 weeks). The first-in-human clinical trial of PNT2258 has the primary objective to assess the safety and tolerability. The study will also examine the pharmacokinetics of PNT2258 and explore biomarkers with the goal of identifying doses for subsequent efficacy studies in cancer patients.

ProNAi’s approach capitalizes on a proprietary and differentiated oligonucleotide platform designed to target nuclear DNA. PNT2258 is the Company’s first drug candidate, a 24-base single-stranded oligonucleotide (PNT100), designed to modulate the Bcl-2 oncogene, encapsulated within a proprietary delivery technology called SMARTICLES®. This novel encapsulation of an oligonucleotide was chosen to prolong circulation times and protect PNT100 from premature degradation. SMARTICLES® were originally discovered and developed by Novosom AG, Halle, Germany, and further enabled by joint efforts with ProNAi. Dr. Wendi Rodriguez, Vice President of Product Development at ProNAi, who led the collaboration of this novel liposome formulation, stated “We are pleased to move PNT2258 into the clinic and to be able to gain insights into the safety and promise of this novel delivery technology”. SMARTICLES intellectual property assets were recently acquired by Marina Biotech, Inc. (NASDAQ: MRNA).

Cancer continues to be second leading cause of death and is a serious unmet medical need. In 2010, it is estimated that 1.5 million men and women will be diagnosed and 0.57 million deaths will occur in the United States according to National Cancer Institute Surveillance Epidemiology and End Results. “We are excited to have developed one of the few systemic oligonucleotide therapies that have entered into this phase of human trials. Our work will be strengthened as we identify partners to assist in the further development of our novel platform.” said Donald R. Parfet, Chairman of the Board of ProNAi and Managing Partner at Apjohn Ventures.

The trial is being conducted at South Texas Accelerated Research Therapeutics (START) with a team led by Dr. Anthony W. Tolcher, Clinical Director of Research at START. “Our team at START is an enthusiastic collaborator with ProNAi as they develop this novel class of oligonucleotides for the treatment of cancer. PNT2258 represents a unique approach to potentially silence gene expression and we are very pleased to be part of its first-in-human testing for safety and tolerability in patients with advanced cancer,” said Dr. Tolcher.
About PNT2258

PNT2258 is a proprietary, intravenously administered anti-cancer agent against Bcl-2, which is a known oncogene that is over-expressed in non-Hodgkin’s Lymphoma and many other cancers, and is comprised of an oligonucleotide encapsulated in a liposome known as SMARTICLES®. PNT2258 therapy will be evaluated used either alone or in combination with other approved cancer therapeutics. ProNAi believes that based on the activity seen in preclinical models, PNT2258 may be promising for the treatment of patients with many solid and hematological cancers such as non Hodgkin’s lymphoma, breast, prostate, lung, ovarian and melanoma.

About SMARTICLES®

SMARTICLES® were discovered by Novosom AG and its utility for DNAi® were developed and enabled by the joint efforts of ProNAi and Novosom scientists. Marina Biotech, Inc. acquired the SMARTICLES® delivery technology in July 2010. The transaction further expands Marina Biotech’s RNA delivery platform IP estate, which now includes DiLA² delivery platform, tkRNAi (bacterial delivery platform), peptide nanoparticle delivery platform, and the SMARTICLES® liposomal delivery platform.

About ProNAi Therapeutics, Inc.

ProNAi Therapeutics, Inc. is a venture backed biopharmaceutical company founded in 2004 pioneering a new class of targeted drugs based on utilizing single strands of DNA oligonucleotides to target genomes responsible for complex, proliferative diseases such as cancer. The Company’s lead drug candidate, PNT2258, has demonstrated safety and in vivo efficacy in a variety of preclinical tumor xenograft models. ProNAi is positioned to develop additional cancer therapies from its pre-clinical leads targeting other oncogenes including c-myc, k-ras, and her-2. The company has successfully raised over $15 million from Apjohn Ventures, Sigvion Capital, the Michigan Economic Development Corporation on behalf of the State of Michigan, Biosciences Research and Commercialization Center (BRCC), Amherst Fund and private investors.

Forward-Looking Statements made in this news release may be forward-looking statements within the meaning of Federal Securities laws that are subject to certain risks and uncertainties and involve factors that may cause actual results to differ materially from those projected or suggested. Factors that could cause actual results to differ materially from those in forward-looking statements include, but are not limited to: (i) the ability of ProNAi to obtain additional funding; (ii) the ability of ProNAi Therapeutics to attract and/or maintain manufacturing, research, development and commercialization partners; (iii) the ability of ProNAi and/or a partner to successfully complete product research and development, including preclinical and clinical studies and commercialization; (iv) the ability of the ProNAi Therapeutics and/or a partner to obtain required governmental approvals; and (v) the ability of ProNAi Therapeutics and/or a partner to develop and commercialize products that can compete favorably with those of competitors.
About South Texas Accelerated Research Therapeutics (START)

South Texas Accelerated Research Therapeutics (START) is located in San Antonio, at the START Center for Cancer Care. The mission of START is to accelerate the development of new anticancer drugs with the purpose of improving quality of life and survival for patients with cancer. START consists of a team of highly trained physicians and staff with extensive experience in Phase I clinical trials research. In 2008, START expanded globally with the launch of START Madrid representing the first step in our goal to keep the development of anticancer agents operating 24 hours a day. Because of the work of scientists like those at START, real progress is being made against cancer. Through the hard work of these physicians and the continuing advances in technology START is able to improve the tools to understand, detect, and diagnose cancer. Today, people with cancer are living longer than ever before with a better quality of life.

About Marina Biotech, Inc.

Marina Biotech is a biotechnology company focused on the development and commercialization of therapeutic products based on RNA interference (RNAi). The Marina Biotech pipeline currently includes a clinical program in Familial Adenomatous Polyposis (a precancerous syndrome) and two preclinical programs -- in hepatocellular carcinoma and bladder cancer. Marina Biotech's goal is to improve human health through the development of RNAi-based compounds and drug delivery technologies that together provide superior therapeutic options for patients. Additional information about Marina Biotech is available at http://www.marinabio.com.

Forward-Looking Statements made in this news release may be forward-looking statements within the meaning of Federal Securities laws that are subject to certain risks and uncertainties and involve factors that may cause actual results to differ materially from those projected or suggested. Factors that could cause actual results to differ materially from those in forward-looking statements include, but are not limited to: (i) the ability of Marina Biotech to obtain additional funding; (ii) the ability of Marina Biotech to attract and/or maintain manufacturing, research, development and commercialization partners; (iii) the ability of Marina Biotech and/or a partner to successfully complete product research and development, including preclinical and clinical studies and commercialization; (iv) the ability of the Marina Biotech and/or a partner to obtain required governmental approvals; and (v) the ability of Marina Biotech and/or a partner to develop and commercialize products that can compete favorably with those of competitors. Additional factors that could cause actual results to differ materially from those projected or suggested in any forward-looking statements are contained in Marina Biotech’s most recent periodic reports on Form 10-K and Form 10-Q that are filed with the Securities and Exchange Commission. Marina Biotech assumes no obligation to update and supplement forward-looking statements because of subsequent events.
ProNAi Contact:

Charles L. Bisgaier, Ph.D.  Robert Forgey, MBA  
President & CEO  COO  
cbisgaier@pronai.com  rforgey@pronai.com  

Tel: 269-815-8098  
E-mail: info@pronai.com  
Website: http://www.pronai.com