

Monopar and NorthStar Join Forces to Develop Radio-Immuno-Therapeutics (RITs) Targeting Severe COVID-19

CHICAGO and BELOIT, Wis., June 16, 2020 (GLOBE NEWSWIRE) -- Monopar Therapeutics Inc. (Nasdaq: MNPR) (Chicago, IL) and NorthStar Medical Radioisotopes, LLC (Beloit, WI) announced today a 50/50 collaboration to develop potential Radio-Immuno-Therapeutics (RITs) to treat severe COVID-19 (patients with SARS-CoV-2 infection). Monopar is a clinical-stage biopharmaceutical company and NorthStar is a commercial producer and supplier of medical radioisotopes. This collaboration combines NorthStar's expertise in the innovative production, supply, and distribution of important medical radioisotopes with Monopar's expertise in therapeutic drug development and its pre-IND stage humanized urokinase plasminogen activator receptor (uPAR) targeted monoclonal antibody known as MNPR-101, along with a proprietary portfolio of related monoclonal antibodies that target uPAR or its ligand uPA.

The uPA system (comprised of the serine protease enzyme uPA and its receptor uPAR) has been demonstrated to be selectively expressed on aberrantly activated immune cells. In response to coronavirus infection, these rogue immune cells produce pro-inflammatory cytokines that can cause runaway inflammation throughout the body, commonly referred to as a cytokine storm. It is this systemic hyper-inflammatory state that is thought to be largely responsible for the severe lung injury and further multiple organ damage that contributes to poor outcomes and death in patients with severe COVID-19.

In this collaboration, Monopar and NorthStar plan to couple MNPR-101 to a therapeutic radioisotope supplied by NorthStar in order to create a highly selective agent that has the potential to kill aberrantly activated cytokine-producing immune cells. By eradicating these cells with a targeted RIT, the goal is to spare healthy cells while quickly reducing the cytokine storm and its harmful systemic effects.

"This collaboration is a powerful combination of unique scientific and technical expertise to help combat severe COVID-19," said Chandler Robinson, MD, CEO of Monopar Therapeutics. "The companies will be conducting a development program to determine if Monopar's uPA/uPAR monoclonal antibodies can be transformed into RITs that are effective as treatments against severe COVID-19, as well as other corona viruses."

"We are pleased to work together with Monopar in the battle against COVID-19," said Stephen Merrick, CEO of NorthStar Medical Radioisotopes. "Our hope is that, by joining forces, we can develop a targeted radiopharmaceutical treatment that has the ability to prevent patients with severe COVID-19 from being placed on ventilators and from dying."

"To help mitigate the cytokine storm and reduce deaths associated with COVID-19, our goal is to develop an RIT that selectively eliminates the rogue aberrantly activated immune cells that produce these cytokines," said Andrew Mazar, PhD, Chief Scientific Officer of Monopar.

“uPAR is selectively expressed on these rogue immune cells but not on healthy cells. An antibody carrying a therapeutic radioisotope could gain entry into these cells through uPAR and deliver its cytotoxic payload to kill these cells while sparing normal tissue.”

“NorthStar will apply its expertise to identify and supply the optimal therapeutic radioisotope to couple with Monopar’s uPAR monoclonal antibodies,” said James T. Harvey, PhD, Senior Vice President and Chief Science Officer of NorthStar. “We will deploy the most appropriate development approaches and production technology to ensure that both development and, if successful, commercial-scale volumes of this radioisotope can be supplied in order to meet potential demand.”

This targeted therapeutic approach to treating severe COVID-19 is supported by a recently published study (Rovina et al. 2020) demonstrating that soluble urokinase plasminogen activator receptor (suPAR), which is shed by aberrantly activated immune cells that make uPAR, is an early predictor of severe respiratory failure in COVID-19 and its presence increases as patients develop severe COVID-19.

About Monopar Therapeutics Inc. (Monopar)

Monopar Therapeutics is a clinical-stage biopharmaceutical company focused on developing proprietary therapeutics designed to extend life or improve the quality of life for cancer patients. Monopar's pipeline consists of Validive® for the prevention of chemoradiotherapy-induced severe oral mucositis in oropharyngeal cancer patients; camsirubicin for the treatment of advanced soft tissue sarcoma; and a late-stage preclinical antibody MNPR-101. For more information, visit: <https://www.monopartx.com>.

About NorthStar Medical Radioisotopes, LLC (NorthStar)

NorthStar Medical Radioisotopes is a global innovator in the production and distribution of radioisotopes used for medical imaging and therapeutic purposes. NorthStar is a company committed to providing the United States with reliable and environmentally friendly radioisotope supply solutions to meet the needs of patients and to advance clinical research. The Company’s first product is the RadioGenix® System (technetium Tc 99m generator), an innovative and flexible platform technology initially approved by the U.S. Food and Drug Administration in February 2018. For more information, visit: <https://www.northstarm.com>.

Forward-Looking Statements

Statements contained in this press release regarding matters that are not historical facts are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. The words “may,” “will,” “could,” “would,” “should,” “expect,” “plan,” “anticipate,” “intend,” “believe,” “estimate,” “predict,” “project,” “potential,” “continue,” “target” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Examples of these forward-looking statements include statements concerning the collaboration’s ability to develop a targeted radiopharmaceutical treatment that has the ability to prevent patients with severe COVID-19 from being placed on ventilators and from dying. The forward-looking statements involve risks and uncertainties including, but not limited to, the lack of any clinical activities to date with respect to MNPR-101 and that pre-clinical development activities to date have been focused on the treatment of cancers, the requirement for additional capital to complete preclinical and clinical development, and if successful, commercialization, not being able to couple MNPR-101 to a therapeutic radioisotope, the conjugate not being able to kill

aberrantly activated cytokine-producing immune cells, the conjugate not being able to use uPAR to gain entry into these cells and release this cytotoxic payload to kill these cells while sparing normal tissue, not being able to ensure volumes of this radioisotope can be manufactured and scaled up to meet potential demand, uncertainties about levels of demand if and when a treatment is available for commercialization and the significant general risks and uncertainties surrounding the research, development, regulatory approval and commercialization of therapeutics. Actual results may differ materially from those expressed or implied by such forward-looking statements. Risks are described more fully in Monopar's filings with the Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made. Monopar and NorthStar undertake no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made. Any forward-looking statements contained in this press release represent Monopar's and NorthStar's views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date.

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