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Monopar Therapeutics

Monopar and NorthStar Announce Selection of uPRIT Candidate for Potential Treatment of Severe COVID-19

WILMETTE, Ill. and BELOIT, Wis., Dec. 10, 2020 (GLOBE NEWSWIRE) -- Monopar Therapeutics Inc. (Nasdaq: MNPR) and NorthStar Medical Radioisotopes, LLC, which are jointly developing a urokinase plasminogen activator receptor targeted radio-immuno-therapeutic (uPRIT) for the potential treatment of severe COVID-19, today announced the selection of a uPRIT clinical candidate. Monopar and NorthStar partnered with IsoTherapeutics Group LLC to generate a panel of uPRIT leads, which were then screened by Aragen Bioscience Inc., resulting in the identification of a uPRIT clinical candidate plus several backup candidates.

uPRITs are analogs of MNPR-101, Monopar's proprietary humanized urokinase plasminogen activator receptor (uPAR) targeted antibody, that have been modified to enable attachment of a therapeutic radioisotope. uPRITs bind to uPAR with high affinity and are thought to selectively recognize the aberrantly activated, pro-inflammatory immune cells that express this target and also seem to be mediating the cytokine storm leading to respiratory failure and poor outcomes in severe COVID-19 patients.

The cleaved, blood-circulating soluble form of uPAR, suPAR, has been gaining attention as a potentially important prognostic biomarker for severe COVID-19 in several recently published studies. Rovina et al. 2020 showed that patients with elevated levels of suPAR at the time of hospital admission are 17 times more likely to develop severe respiratory failure ($p=0.0000000012$); Arnold et al. 2020 showed suPAR to have the best performance in predicting outcome (such as intensive care unit admission and death) of all the biomarkers examined; and Eugen-Olsen et al. 2020 showed that low levels of suPAR are predictive of mild outcome in COVID-19 patients.

The aim with uPRITs is to bind to and rapidly eliminate the aberrantly activated immune cells, quickly shutting down the cytokine storm. If uPRITs are effective in this setting, they may also be effective in treating other diseases characterized by rapid and severe systemic inflammatory responses, including certain pneumonias and sepsis.

The uPRIT with the most attractive uPAR binding profile was selected to advance into IND-enabling studies. "Selection of a uPRIT candidate allows us to begin preclinical studies, and brings us one step closer to reaching human clinical trials," said Andrew Mazar, Ph.D., Chief Scientific Officer of Monopar. "Even when SARS-CoV2 vaccines are available, treatments will be needed for those who are not vaccinated, or for patients for whom the vaccine is not effective, and who thereby contract severe COVID-19. Successfully combatting COVID-19 over the long term will require a combination of preventive and treatment approaches."

"This rapid advancement of our uPRIT program highlights the innovation and collaborative efforts of Monopar, NorthStar and our partners," stated James Harvey, Ph.D., Senior Vice

President and Chief Scientific Officer of NorthStar. “Selecting a highly specific therapeutic candidate for the potential treatment of severe COVID-19 in short order is a significant achievement.”

About Monopar Therapeutics Inc.
Monopar Therapeutics is a clinical-stage biopharmaceutical company primarily 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 advanced cancers and severe COVID-19. For more information, visit: www.monopartx.com. Follow Monopar on LinkedIn and Twitter.

About NorthStar Medical Radioisotopes, LLC
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: www.northstarnm.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 selected MNPR-101 derived uPRIT’s ability to mediate the cytokine storm which leads to respiratory failure and poor outcomes in severe COVID-19 patients; whether biomarkers in published studies can be repeated in uPRIT preclinical and clinical studies; uPRIT’s ability to be effective in treating other diseases characterized by rapid and severe systemic inflammatory responses, including certain pneumonias and sepsis; and whether uPRITs will be successful in preclinical studies or move forward into clinical trials in patients with severe COVID-19. 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, the requirement for additional capital to complete preclinical and clinical development and for potential commercialization, the uPRIT not being able to kill aberrantly activated cytokine producing immune cells, the uPRIT 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 when vaccines are widely utilized or treatments are approved for marketing and 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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