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Monopar and NorthStar Announce Expanded Radiopharma Program, Positive Preclinical Results, and Visibility Toward Human Trials

WILMETTE, Ill. and BELOIT, Wis., Feb. 27, 2023 (GLOBE NEWSWIRE) -- Monopar Therapeutics Inc. (Nasdaq: MNPR) (Wilmette, Ill.) and NorthStar Medical Radioisotopes, LLC (Beloit, Wis.), today announced an expansion of their radiopharmaceutical collaboration along with a new radiolabeled MNPR-101 imaging candidate designated as MNPR-101-Zr. Based on promising recently generated preclinical imaging results with MNPR-101-Zr showing high uptake across multiple tumor types, the companies also committed to additional funding with the aim of initiating a first-in-human imaging study with MNPR-101-Zr as early as the end of this year.

MNPR-101-Zr is a zirconium-89 labeled version of MNPR-101, a highly selective antibody against the urokinase plasminogen activator receptor (uPAR). Positron emission tomography (PET) imaging of preclinical mouse models for triple-negative breast, colorectal, and pancreatic tumors displayed high and selective uptake of MNPR-101-Zr in these uPAR-expressing tumors.

These proof-of-concept studies provide support for a first-in-human PET imaging study with MNPR-101-Zr and a future therapeutic study using the previously announced actinium-225 labeled radioimmunotherapeutic version of MNPR-101. Overall, the imaging results demonstrate the potential utility of MNPR-101 as a precision targeting agent for both imaging and therapy in multiple cancer indications.

“We are excited about these recent developments, about our expanded partnership with NorthStar, and about our increasing involvement in the radiopharma space. The Monopar team believes this personalized medicine and precision approach to imaging and treating cancer patients holds tremendous promise,” said Chandler Robinson, MD, CEO of Monopar Therapeutics.

“Our continued partnership with Monopar shows our commitment to being a leader in the radiopharmaceutical field through the supply of advanced radionuclides as well as specialized development support for promising precision radiopharma programs like MNPR-101,” said Stephen Merrick, CEO of NorthStar Medical Radioisotopes.

About Radiopharmaceuticals

Radiopharmaceuticals are an emerging class of cancer drugs designed to target a tumor and deliver radiation directly while minimizing damage to normal tissue. Radiopharmaceuticals are formed by attaching radioactive isotopes, a process also known as radiolabeling, to targeting molecules (e.g., an antibody) that bind specifically to tumors. Depending on the

radioactive isotope selected, the radiopharmaceutical can image or treat the targeted cancers.

About Monopar Therapeutics Inc.

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® (Phase 2b/3) for the prevention of chemoradiotherapy-induced severe oral mucositis in oropharyngeal cancer patients; camsirubicin (Phase 1b) for the treatment of advanced soft tissue sarcoma; a late-stage preclinical antibody, MNPR-101, for radiopharmaceutical use in advanced cancers; and an early-stage camsirubicin analog, MNPR-202, for various cancers. For more information, visit: www.monopartx.com.

About NorthStar Medical Radioisotopes, LLC

NorthStar Medical Radioisotopes is a commercial-stage nuclear medicine company focused on advancing patient care by providing diagnostic and therapeutic radioisotopes, novel radiopharmaceuticals and customized radiopharmaceutical development services. Its proven management team and state-of-the-art, environmentally preferable and non-uranium based technologies have made it an emerging leader at the forefront of U.S. medical radioisotope and radiopharmaceutical production. NorthStar is the sole domestic producer of molybdenum-99 (Mo-99), used to generate the standard-of-care diagnostic imaging radioisotope for assessing heart disease and cancer. It is expanding its industry-leading position in the growing area of therapeutic radioisotopes, used in targeted radiopharmaceutical therapy to treat cancer and other serious diseases, and is poised to be the first commercial-scale producer of non-carrier added (n.c.a.) actinium-225 (Ac-225) and copper-67 (Cu-67). NorthStar's Radiopharmaceutical Contract Development and Manufacturing Organization (CMDO/CMO) services unit will provide customized service offerings and specialized radiopharmaceutical expertise to help biopharmaceutical companies rapidly advance their development and commercialization programs. For more information about NorthStar's comprehensive portfolio and patient-focused services, 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 companies' plans for future studies and the timing thereof, as well as the potential of MNPR-101-based imaging or therapeutic agents. The forward-looking statements involve risks and uncertainties including, but not limited to: the lack of any human clinical activities to date with respect to MNPR-101 and related conjugates; the requirement for additional capital to complete preclinical and clinical development of a therapeutic or imaging agent utilizing MNPR-101, and if successful, commercialization; if funding is available, not being able to successfully develop a therapeutic or imaging agent utilizing MNPR-101; not being able to ensure volumes of

MNPR-101 conjugates can be manufactured and scaled up to meet potential demand; uncertainties about levels of demand if and when a therapeutic or imaging agent utilizing MNPR-101 are available for commercialization and the significant general risks and uncertainties surrounding the research, development, regulatory approval and commercialization of pharmaceuticals. 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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