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Monopar Therapeutics

Monopar Receives Clearance to Proceed with First-in-Human Phase 1 Trial of Novel Radiopharmaceutical MNPR-101-Zr in Advanced Cancers

WILMETTE, Ill., Feb. 20, 2024 (GLOBE NEWSWIRE) -- Monopar Therapeutics Inc. (Nasdaq: MNPR), a clinical-stage biopharmaceutical company focused on developing innovative treatments for cancer patients, today announced it has received Human Research Ethics Committee (HREC) clearance in Australia to commence a Phase 1 dosimetry trial of its novel radiopharmaceutical MNPR-101-Zr.

The MNPR-101-Zr Phase 1 dosimetry clinical trial will enroll patients with advanced cancers and will utilize positron emission tomography (PET) imaging to assess tumor uptake, normal organ biodistribution, and safety.

MNPR-101-Zr is a zirconium-89 (imaging radioisotope) labeled version of MNPR-101, Monopar's proprietary first-in-class humanized monoclonal antibody that is highly selective against the urokinase plasminogen activator receptor (uPAR). PET imaging studies in preclinical xenograft models of triple-negative breast, colorectal, and pancreatic cancers displayed high and selective uptake of MNPR-101-Zr in these uPAR-expressing tumors. The imaging results, along with corresponding *in vivo* efficacy studies with actinium-225 (Ac-225, a powerful alpha-emitting therapeutic radioisotope) bound to MNPR-101 in preclinical xenograft tumor models, support the development MNPR-101 as a targeted radiopharmaceutical for multiple advanced cancer indications.

"This is a significant milestone for Monopar," said Chandler Robinson, MD, Monopar's Chief Executive Officer. "Following more than 18 months of extensive preclinical development, we believe we are well-positioned in this space. This is our first human clinical trial using our uPAR targeting agent. There has been quite impressive clinical data generated in the radiopharma sector of late, such as against PSMA and SSTR2 expressing cancers, and we believe this to be just the beginning."

If the tumor uptake, biodistribution, and safety look encouraging in this Phase 1 clinical trial, which is anticipated to enroll around 12 patients and to initiate in the near future, the plan is to evaluate the efficacy in humans of a therapeutically radio-labeled version of MNPR-101 bound to an isotope such as Ac-225.

About Monopar Therapeutics Inc.
Monopar Therapeutics is a clinical-stage biopharmaceutical company primarily focused on developing innovative treatments for cancer patients. Monopar's pipeline consists of Phase 1b-stage camsirubicin for the treatment of advanced soft tissue sarcoma; Phase 1-stage MNPR-101 for radiopharmaceutical use in advance cancers; and an early-stage camsirubicin analog, MNPR-202. For more information, visit: www.monopartx.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: that MNPR-101-Zr Phase 1 dosimetry clinical trial will enroll patients with advanced cancers and will utilize positron emission tomography (PET) imaging to assess tumor uptake, normal organ biodistribution, and safety; that the Phase 1 clinical trial is anticipated to enroll around 12 patients in the near future; and that the plan is to evaluate the efficacy in humans of a therapeutically radio-labeled version of MNPR-101 bound to an isotope such as Ac-225. The forward-looking statements involve risks and uncertainties including, but not limited to: not initiating and enrolling the Phase 1 clinical trial in 2024, if at all; that MNPR-101-Zr may cause unexpected serious adverse effects or fails to image the cancer tumors in humans; the potential for the HREC to put the Phase 1 trial on clinical hold at any time; and the significant general risks and uncertainties surrounding the research, development, regulatory approval, and commercialization of imaging agents and 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 undertakes 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 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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