

Monopar and EDNOC Announce Expanded Access Program for MNPR-101-Zr and MNPR-101-Lu in Advanced Cancers

WILMETTE, Ill. and HOUSTON, Texas, June 11, 2025 (GLOBE NEWSWIRE) -- Monopar Therapeutics Inc. ("Monopar," the "Company," "us" and "our") (Nasdaq: MNPR), a clinical-stage biopharmaceutical company focused on developing innovative treatments for patients with unmet medical needs, in collaboration with Excel Diagnostics and Nuclear Oncology Center ("EDNOC"), a premier diagnostic medical imaging and therapeutic nuclear medicine center, today announced that the physician-sponsored Expanded Access Program ("EAP") for the investigational imaging agent MNPR-101-Zr and investigational therapeutic agent MNPR-101-Lu has received authorization to proceed from the U.S. Food and Drug Administration ("FDA").

The MNPR-101 EAP is now open for enrollment to patients with advanced solid tumors at EDNOC in Houston, Texas. EDNOC is among the first private outpatient facilities in the U.S. to be designated as a Radiopharmaceutical Therapy Center of Excellence by the Society of Nuclear Medicine and Molecular Imaging ("SNMMI"). Patients will be treated under the supervision of renowned investigator Ebrahim S. Delpassand, MD, founder and medical director of EDNOC.

"We are pleased to provide patients in the United States with access to MNPR-101-Zr and MNPR-101-Lu, which were developed to target aggressive cancers, such as triple-negative breast, pancreatic, and colorectal cancer," said Andrew Cittadine, Chief Operating Officer of Monopar. "This EAP represents continued progress in our radiopharmaceutical pipeline following last year's initiation of Phase 1 clinical trials in Australia with MNPR-101-Zr and MNPR-101-Lu. We are grateful for the opportunity to work with Dr. Delpassand to make these therapies available to patients on a compassionate use basis," added Mr. Cittadine.

"Our team at Excel Diagnostics looks forward to providing MNPR-101-Zr and MNPR-101-Lu to patients in need," said Dr. Delpassand. "Targeting uPAR-expressing solid tumors will be another promising frontier in radioligand therapy to help patients with 'difficult-to-treat' cancers," continued Dr. Delpassand.

About Expanded Access to MNPR-101-Zr and MNPR-101-Lu

EAPs are intended to serve as a potential pathway for a patient with a serious or immediately life-threatening disease or condition to gain access to an investigational medical product outside of clinical trials preceding FDA approval; this occurs when no comparable or satisfactory alternative treatment is available, and the patient's situation necessitates accessing an unapproved product outside of clinical trials. Healthcare providers and cancer patients who are interested in learning more about the MNPR-101-Zr and MNPR-101-Lu EAP, including eligibility criteria, can visit www.clinicaltrials.gov using the following links: [NCT06980506](https://clinicaltrials.gov/ct2/show/study/NCT06980506) and [NCT06980519](https://clinicaltrials.gov/ct2/show/study/NCT06980519) for the imaging and therapy EAP, respectively.

About MNPR-101-Zr and MNPR-101-Lu

MNPR-101 is Monopar's proprietary antibody targeting the urokinase plasminogen activator receptor ("uPAR"), which is expressed in numerous tumor types, including pancreatic, breast, colorectal, ovarian, and bladder. By selectively targeting uPAR, Monopar aims to image tumors and deliver a targeted radiopharmaceutical therapy that kills cancer cells while minimizing damage to healthy tissue. MNPR-101-Zr is MNPR-101 conjugated to zirconium-89 and designed for the imaging of advanced cancers; MNPR-101-Lu is MNPR-101 conjugated to lutetium-177 and designed as an investigational treatment of advanced solid cancers.

About Monopar Therapeutics Inc.

Monopar Therapeutics is a clinical-stage biopharmaceutical company focused on advancing late-stage ALXN1840 for Wilson disease, and radiopharmaceutical programs including Phase 1-stage MNPR-101-Zr for imaging advanced cancers, and Phase 1a-stage MNPR-101-Lu and late preclinical-stage MNPR-101-Ac for the treatment of advanced cancers. For more information, visit: www.monopartx.com.

About Excel Diagnostics and Nuclear Oncology Center ("EDNOC")

EDNOC is one of the premier diagnostic medical imaging and therapeutic nuclear medicine centers located in Houston, Texas. In addition to standard of care procedures such as MRI, PET/CT scans, SPECT/CT nuclear medicine scans, ultrasound, and bone mineral densitometry ("BMD"), Excel is offering its patients access to several investigational trials so they may benefit from the latest diagnostic and therapeutic nuclear medicine procedures. Excel has been the pioneer of bringing several new diagnostic and therapeutic radiopharmaceuticals for the first time to the United States. EDNOC has been designated as a Radiopharmaceutical Therapy **Center of Excellence** by the Society of Nuclear Medicine and Molecular Imaging ("SNMMI") since 2020. For more information, please visit: www.exceldiagnostics.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: that patients will be treated under the supervision of renowned investigator Ebrahim S. Delpassand; that the team at Excel Diagnostics looks forward to providing MNPR-101-Zr and MNPR-101-Lu to patients in need; that targeting uPAR-expressing solid tumors will be another promising frontier in radioligand therapy; that EAPs are intended to serve as a potential pathway for a patient with a serious or immediately life-threatening disease or condition to gain access to an investigational medical product outside of clinical trials preceding FDA approval; that Monopar aims to deliver a targeted radiopharmaceutical therapy that kills cancer cells while minimizing damage to healthy tissue; and that Excel is offering its patients access to several investigational trials so they may benefit from the latest diagnostic and therapeutic nuclear medicine procedures.

The forward-looking statements involve risks and uncertainties including, but not limited to: the risk that MNPR-101-Zr and/or MNPR-101-Lu may cause unexpected serious adverse effects or fail to be effective against the cancer tumors in humans; the risk that the trials could result in a clinical hold should there be a serious adverse event; the risk that future preclinical, including MNPR-101-Ac, or clinical data may not be as promising as the data to date; uncertainties related to the regulatory process that Monopar intends to initiate related to ALXN1840 and the outcome thereof; the rate of market acceptance and competitiveness in terms of pricing, efficacy and safety, of any products for which Monopar receives marketing approval, and Monopar's ability to competitively market any such products as compared to larger pharmaceutical firms; Monopar's ability to raise sufficient funds in order for the Company to support continued preclinical, clinical, regulatory, precommercial and commercial development of its programs and to make contractual milestone payments, as well as its ability to further raise additional funds in the future to support any existing or future product candidate programs through completion of clinical trials, the approval processes and, if applicable, commercialization; 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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