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Monopar Announces Initial Data for First Patient Dosed in Radiopharma Phase 1 Clinical Trial of MNPR-101-Zr

WILMETTE, Ill., Aug. 14, 2024 (GLOBE NEWSWIRE) -- Monopar Therapeutics Inc. (Nasdaq: MNPR), a clinical-stage radiopharma company focused on developing innovative treatments for cancer patients, today announced the successful dosing of the first patient in its open-label Phase 1 imaging and dosimetry clinical trial of its uPAR-targeted imaging radiopharmaceutical MNPR-101-Zr.

MNPR-101-Zr was well-tolerated with no serious adverse reactions reported through the last imaging timepoint and the corresponding initial safety review. Preliminary analysis of MNPR-101-Zr's pharmacokinetics and biodistribution suggests the low radiation dose to healthy tissue aligns with what was anticipated based on the previously presented MNPR-101-Zr preclinical biodistribution data. Dosimetry analysis showed absorbed organ doses were well below accepted safety limits; for example, the radiation dose to red bone marrow was about 14 mGy, which is around 150 times less than the generally accepted limit of 2-to-3 Gy. No unanticipated or excessive uptake of MNPR-101-Zr was observed in any critical organs through the end of the subject's imaging period. The patient has metastatic disease from a cancer type not known for high uPAR expression. The study aims to include several patients with cancers known to express high levels of uPAR to gain insight into MNPR-101-Zr's tumor uptake profile, in addition to patients with cancers of unknown uPAR expression.

"The safety profile observed thus far, along with the encouraging biodistribution data, gives us an increased confidence as we continue to advance our Phase 1 study and prepare to launch our therapeutic study," said Andrew Cittadine, Monopar's Chief Operating Officer.

Further information about the ongoing MNPR-101-Zr trial is available at www.ClinicalTrials.gov under study identifier **NCT06337084**.

About Monopar Therapeutics Inc.

Monopar Therapeutics is a clinical-stage radiopharmaceutical company focused on developing innovative treatments for cancer patients, including Phase 1-stage MNPR-101-Zr for imaging advanced cancers and late preclinical-stage MNPR-101 radio-immuno-therapeutic (RIT) for the treatment of advanced cancers, as well as early development programs against solid cancers. 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 statements concerning: that the study aims to enroll several patients with cancers known to express high levels of uPAR to gain insight into MNPR-101-Zr's tumor uptake profile, in addition to patients with cancers of unknown uPAR expression; and that the safety profile observed thus far, along with the encouraging biodistribution data, gives Monopar an increased confidence as it continues to advance its Phase 1 study and launch its therapeutic study. The forward-looking statements involve risks and uncertainties including, but not limited to: the Phase 1 imaging and dosimetry clinical trial in advanced cancer patients with MNPR-101-Zr may not yield satisfactory results, if at all; that future preclinical or clinical data will not be as promising as the data to date; that MNPR-101-Zr and/or MNPR-101 conjugated to a therapeutic radioisotope may cause unexpected serious adverse effects or fail to image or be effective against the cancer tumors in humans; that Monopar may not advance its Phase 1 study and launch its therapeutic study; that Monopar may not regain compliance with Nasdaq listing standards within any extended Nasdaq deadline; that Monopar may expend available funds sooner than anticipated or require additional funding due to change in circumstances or unanticipated events; 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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