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# Monopar Therapeutics Reports Third Quarter 2023 Financial Results and Recent Developments

## MNPR-101 Radiopharma Program to Enter First-in-Human Studies Potentially As Early As December of This Year Camsirubicin Phase 1b Trial Efficacy and Safety Data Highlighted at the 2023 CTOS Annual Meeting

WILMETTE, Ill., Nov. 09, 2023 (GLOBE NEWSWIRE) -- Monopar Therapeutics Inc. (Monopar or the Company) (Nasdaq: MNPR), a clinical-stage biopharmaceutical company focused on developing innovative treatments for cancer patients, today announced third quarter 2023 financial results and summarized recent developments.

**Recent Developments**

***MNPR-101 for Radiopharmaceutical Use – First-in-Human Study to Start Potentially As Early As December of This Year***

- Monopar continues to advance its MNPR-101 radiopharmaceutical program towards a first-in-human study in patients with advanced solid tumors. MNPR-101 is a highly selective antibody against uPAR, a promising target overexpressed in multiple solid tumors, being developed as a precision radiopharmaceutical for both imaging and treatment of cancer. Much of the work with MNPR-101 is being done in collaboration with NorthStar Medical Radioisotopes LLC.

- Preclinical data with MNPR-101 labeled with zirconium-89 (imaging radioisotope) as well as actinium-225 (a powerful alpha-emitting therapeutic radioisotope) so far have shown selective, high, and durable tumor uptake across multiple aggressive cancers including pancreatic, colorectal, and triple negative breast cancers. In addition, a strong, dose-dependent anti-tumor effect has been seen in *in vivo* pancreatic and triple-negative breast cancer models with favorable biodistribution profiles.

***Camsirubicin – Phase 1b Dose-Escalation Trial, Treating Fifth Dose-Level Cohort (650 mg/m$^2$)***

- The Phase 1b open-label, dose-escalating clinical trial of camsirubicin in patients with advanced soft tissue sarcoma (ASTS) is in the fifth dose-level cohort (650 mg/m$^2$), which is nearly 2.5x the highest dose evaluated in any prior camsirubicin clinical trial (265 mg/m$^2$). We have dosed to date two patients in the fifth dose cohort, and both experienced tumor size reductions, one of approximately 18% and the other of approximately 20%.

- At the 2023 Connective Tissue Oncology Society (CTOS) Annual Meeting, Monopar presented Phase 1b clinical trial results to-date. So far, 9 out of the 14 enrolled ASTS patients have had stable disease (SD, as defined by RECIST 1.1 criteria) after camsirubicin treatment, including all patients in the fourth and fifth dose cohorts. No dose-limiting toxicity, as defined in the protocol, has been observed to-date. A medically complex patient in the fifth dose cohort has an ongoing left ventricular ejection fraction ("LVEF") decrease and is being assessed for potential anthracycline (camsirubicin) induced cardiotoxicity. This patient has a BMI of 42.5, one kidney, hypertension, a long-standing heart murmur, and a maternal history of heart failure.

***MNPR-202 - Encouraging Preclinical Results Support Further Research***

- MNPR-202 is a camsirubicin analog that retains the same potentially non-cardiotoxic backbone as camsirubicin but is modified at other positions which may enable it to work against cancers that are resistant to doxorubicin, one of the most commonly-used cancer drugs worldwide.

- In collaboration with Dr. Anand Jeyasekharan at National University of Singapore, preclinical studies are showing that MNPR-202 has a similar cytotoxic potency to doxorubicin but that it works in a distinct way as compared to doxorubicin.

- In a preclinical study using a human iPSC cardiomyocyte model to evaluate heart toxicity, cells treated with MNPR-202 maintained a greater contractile amplitude and a more consistent and regular beat rate relative to doxorubicin-treated cells, indicating that MNPR-202 has a broader therapeutic window than doxorubicin with respect to cardiotoxicity.

**Results for the Third Quarter Ended September 30, 2023 Compared to the Third Quarter Ended September 30, 2022**

***Cash and Net Loss***

Cash, cash equivalents and short-term investments as of September 30, 2023 were $8.5 million. Monopar expects that its current funds will be sufficient for Monopar to advance the Company's MNPR-101 radiopharmaceutical program into its first-in-human clinical trial, obtain topline results from its ongoing open-label Phase 1b camsirubicin clinical trial by mid-2024 (but this may not be the case if camsirubicin reaches even higher dose levels than anticipated and topline results are deferred as dosing continues beyond mid-2024), and continue preclinical studies of MNPR-202. The Company estimates its cash, cash equivalents and short-term investments will fund the Company’s planned operations at least through November 2024. Monopar will require additional funding to advance its clinical and preclinical programs beyond that and anticipates seeking to raise additional capital within the next 12 months to fund its future operations.

Net loss for the third quarter of 2023 was $2.0 million or $0.14 per share compared to net loss of $2.4 million or $0.19 per share for the third quarter of 2022.

***Research and Development (R&D) Expenses***

R&D expenses for the three months ended September 30, 2023 were $1,317,000,

compared to $1,732,000 for the three months ended September 30, 2022. This represents a decrease of $415,000 primarily attributed to a decrease of $673,000 in Validive clinical trial-related and clinical material manufacturing-related expenses offset by (1) an increase of $161,000 in non-clinical studies related to the MNPR-101 radiopharmaceutical program, (2) an increase of $78,000 in camsirubicin clinical trial expenses including patient dosing and manufacturing-related expenses, and (3) a net increase of $19,000 due to other R&D expenses.

***General and Administrative (G&A) Expenses***

G&A expenses for the three months ended September 30, 2023 were $749,000, compared to $675,000 for the three months ended September 30, 2022. This represents an increase of $74,000 primarily attributed to an increase in G&A salaries and benefits.

**About Monopar Therapeutics**

Monopar Therapeutics is a clinical-stage biopharmaceutical company focused on developing innovative treatments for cancer patients. Monopar's pipeline consists of camsirubicin (Phase 1b) for the treatment of advanced soft tissue sarcoma; MNPR-101, a late-stage preclinical antibody for radiopharmaceutical use in advanced cancers; and MNPR-202, an early-stage camsirubicin analog for various cancers. For more information, and links to SEC filings that contain detailed financial information, visit: https://ir.monopartx.com/quarterly-reports.

**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 Monopar continues to advance its MNPR-101 radiopharmaceutical program towards the first-in-human study in patients with advanced solid tumors; that Monopar anticipates commencing a first-in-human clinical trial for its MNPR-101 radiopharmaceutical program potentially as early as December of this year; and that the Company’s cash, cash equivalents and short-term investments will be sufficient to fund planned operations at least through November 2024. The forward-looking statements involve risks and uncertainties including, but not limited to: not successfully recruiting patients and initiating additional clinical trial sites for the camsirubicin Phase 1b clinical trial within expected timeframes, if at all; the camsirubicin trial data being inconclusive or negative; the Company’s inability to raise sufficient funds or engage a partner to continue the camsirubicin clinical program through and beyond the Phase 1b clinical trial and to further develop MNPR-101-Zr and MNPR-101-RIT with its collaboration partner; not regaining Nasdaq listing compliance; the effects of general economic and market conditions on Monopar’s operations and ability to raise funding, including potential ramifications of the threat of or actual delisting from Nasdaq; and the significant general risks and uncertainties surrounding the research, development, regulatory approval, and commercialization of therapeutics and imaging agents. 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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