August 10, 2023

Monopar Therapeutics Reports Second Quarter 2023 Financial Results and Recent Developments

Camsirubicin Phase 1b Trial Currently at 5th Dose-Level (650 mg/m^2), Generating Encouraging Results
MNPR-101 Radiopharma Program Advancing Toward First-in-Human Studies

WILMETTE, Ill., Aug. 10, 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 second quarter 2023 financial results and summarized recent developments.

Recent Developments

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

- As recently reported, both of the advanced soft tissue sarcoma (ASTS) patients so far in the fifth dose-level cohort (650 mg/m^2) have experienced tumor size reductions – of 18% and 20%, respectively – after the first two cycles of camsirubicin treatment. These patients are set to receive additional cycles of camsirubicin treatment, which may result in further tumor size reduction.

- Phase 1b clinical trial data continue to support Monopar's dose-response hypothesis with camsirubicin. The best response seen prior to the current 650 mg/m^2 dose level was a 21% reduction in tumor size in a patient after receiving six cycles of camsirubicin treatment at the immediately prior dose level (520 mg/m^2). This patient's cancer was unresectable at study entry, but after the tumor size reduction, the patient was able to undergo a successful surgical removal of the cancer with clear margins. All three patients at this prior dose level (520 mg/m^2) achieved stable disease with either a net reduction or no overall change in tumor size per RECIST 1.1 while on study drug.

- No drug-related cardiotoxicity has been observed in the trial to date as evaluated by the industry standard left ventricular ejection fraction (LVEF). This compares favorably to the well-documented cumulative dose-restricting cardiotoxicity experienced with doxorubicin, the current first-line treatment for ASTS.

MNPR101 for Radiopharmaceutical Use – Promising Preclinical Studies Support First in Human Study

- MNPR-101 is a uPAR-targeting antibody being developed in collaboration with NorthStar Medical Radioisotopes LLC as a precision radiopharmaceutical for both imaging and treatment of cancer. Both the imaging and therapeutic agents are showing

promise in preclinical studies and are advancing toward first-in-human (FIH) studies potentially as early as the end of this year.

- MNPR-101-Zr is a cancer imaging agent radiolabeled with ^{89}Zirconium, a positron emission tomography (PET) imaging isotope. Recent preclinical imaging studies have shown selective, high, and enduring tumor uptake across multiple aggressive cancers including pancreatic, colorectal, and triple negative breast cancers.

- MNPR-101-RIT is a cancer therapeutic agent radiolabeled with ^{225}Actinium, a powerful alpha-emitting isotope. Preclinical studies show a favorable biodistribution and a strong, dose-dependent anti-tumor effect in triple-negative breast cancer models.

- Monopar and the Cancer Science Institute at the National University of Singapore (NUS) recently announced a collaborative effort to investigate uPAR expression levels in subtypes of ASTS as a means to identify the most promising subtypes to pursue in subsequent human clinical trials using MNPR-101-Zr and MNPR-101-RIT.

MNPR202 Promising Preclinical Data Ignite Further Research

- MNPR202 is a camsirubicin analog designed to retain the same potentially non--cardiotoxic backbone as camsirubicin but is modified at other positions which may enable it to work in cancers that are resistant to doxorubicin, one of the most commonly-used cancer drugs worldwide.

- In collaboration with Dr. Anand Jeyasekharan at NUS, preclinical studies are showing that MNPR-202 has a similar cytotoxic potency to doxorubicin but that it works in a distinct way and against doxorubicin-sensitive cancers as well as doxorubicin-resistant ones.

- Preclinical work comparing the cardiotoxic effects of doxorubicin to MNPR-202 is currently underway using well-established models of doxorubicin cardiotoxicity.

Results for the Second Quarter Ended June 30, 2023 Compared to the Second Quarter Ended June 30, 2022

Cash and Net Loss

Cash, cash equivalents and short-term investments as of June 30, 2023 were $10.2 million. Monopar expects that its current funds will be sufficient for Monopar to 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), advance the Company's MNPR-101 radiopharmaceutical program into its first-in-human clinical trial, and close out Monopar's terminated Validive Phase 2b/3 (VOICE) clinical program. The Company estimates its cash, cash equivalents and short-term investments will fund the Company's planned operations at least through September 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 second quarter of 2023 was $2.2 million or $0.16 per share compared to net loss of $2.8 million or $0.22 per share for the second quarter of 2022.

Research and Development (R&D) Expenses

R&D expenses for the three months ended June 30, 2023 were $1,595,000, compared to $2,078,000 for the three months ended June 30, 2022. This represents a decrease of $483,000 primarily attributed to (1) a decrease of $606,000 in camsirubicin clinical trial expenses and manufacturing-related expenses, and (2) a decrease of $68,000 in Validive clinical trial and manufacturing-related expenses. These decreases were partially offset by (1) a $99,000 increase in non-clinical studies related to MNPR-101-Zr and MNPR-101-RIT activity, and (2) an increase of $112,000 in R&D personnel and consulting expenses.

General and Administrative (G&A) Expenses

G&A expenses for the three months ended June 30, 2023 were $733,000, compared to $685,000 for the three months ended June 30, 2022. This represents an increase of $48,000 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; MNPR101, a late-stage preclinical antibody for radiopharmaceutical use in advanced cancers; and MNPR202, 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 both Phase 1b camsirubicin patients are set to receive additional cycles of camsirubicin treatment, which may result in further tumor size reduction; that both the MNPR-101 imaging and therapeutic agents are showing promise in preclinical studies and moving toward first-in-human studies potentially as early as the end of this year ; the timing and cost of the Phase 1b camsirubicin clinical trial, MNPR-101 radiopharma program and MNPR-202; and that the Company’s cash, cash equivalents and short-term investments will be sufficient to fund planned operations at least through September 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 partners; the effects of general economic and market conditions on Monopar’s operations and ability to raise funding, including potential ramifications due to recent instability in the banking industry; whether the Company will remain in compliance

with Nasdaq listing standards with regard to its stock price and if the Company becomes non-compliant, whether the Company will regain compliance within Nasdaq's time limits and requirements and its effect on the Company's ability to raise funds; 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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Source: Monopar Therapeutics Inc.