August 9, 2024

Monopar Therapeutics Reports Second Quarter 2024 Financial Results and Recent Developments

Initiated and Enrolling Patients into MNPR-101-Zr First-in-Human Phase 1 Radiopharma Clinical Trial
MNPR-101 radio-immuno-therapeutic (RIT) Clinical Trial on Track to Initiate in Q4 2024

WILMETTE, Ill., Aug. 09, 2024 (GLOBE NEWSWIRE) -- Monopar Therapeutics Inc. (Monopar or the Company) (Nasdaq: MNPR), a clinical-stage radiopharmaceutical company focused on developing innovative treatments for cancer patients, today announced second quarter 2024 financial results and summarized recent developments.

Recent Developments

MNPR-101 for Radiopharmaceutical Use

- MNPR-101 is a uPAR-targeting antibody being developed as a precision radiopharmaceutical for both imaging and treatment of various cancers.
- MNPR-101-Zr is a cancer imaging agent radiolabeled with Zirconium-89, a positron emission tomography (PET) imaging isotope. Preclinical imaging studies have shown selective, high, and enduring tumor uptake across multiple uPAR-expressing cancers including pancreatic, colorectal, and triple negative breast cancers. An open-label Phase 1 imaging and dosimetry clinical trial of MNPR-101-Zr was recently initiated and is currently active and enrolling patients.
- An open-label Phase 1 clinical trial for Monopar's therapeutic radiopharmaceutical MNPR-101-RIT is on track to initiate as early as Q4 2024. Preclinical in vivo studies of therapeutic radioisotopes, such as actinium-225 and lutetium-177, bound to MNPR-101 have shown near complete elimination of uPAR-expressing tumors after just a single injection.
- Monopar's MNPR-101-RIT abstract was selected as a Top-Rated Oral Presentation at the European Association of Nuclear Medicine (EANM) 2024 Annual Congress that will be held in Hamburg, Germany in October 2024.
- A long-term supply agreement with NorthStar Medical Radioisotopes LLC was entered into under which NorthStar agreed to provide actinium-225 for Monopar's development stage and potential future commercial stage programs.
- The NorthStar collaboration agreement was amended, with one primary impact being Monopar gaining full ownership and title to its lead MNPR-101 radiopharmaceutical platform.

Reverse Stock Split

- On August 5, 2024, the stockholders approved the reverse stock split proposal at the Annual Meeting of Stockholders, which provided the Board of Directors with authority to effect a reverse split within the range of ratios approved by stockholders. Subsequently, the Board of Directors approved a reverse stock split of 1 for 5 shares of the Company's common stock in an attempt to regain compliance with the Nasdaq's continued listing requirements. The Company expects that the reverse stock split will become effective at 5:00 pm on Monday, August 12, 2024, and its common stock will begin trading on a split-adjusted basis at the open of trading on Tuesday, August 13, 2024.

Results for the Second Quarter Ended June 30, 2024 Compared to the Second Quarter Ended June 30, 2023

Cash and Net Loss

Cash, cash equivalents and short-term investments as of June 30, 2024, were $7.1 million. Monopar projects that its current funds will be sufficient to continue operations at least through August 31, 2025, including to continue to conduct and conclude our first-in-human clinical trial with our MNPR-101-Zr radiopharmaceutical imaging program and to advance our MNPR-101-RIT program into the clinic. We are in the process of winding down the camsirubicin Phase 1b clinical trial and the preclinical development of MNPR-202 due to focusing our finite financial resources on our radiopharmaceutical programs. We will require additional funding to further advance our clinical and preclinical programs, and we anticipate that we will seek to raise additional capital within the next 12 months to fund our future operations.

Net loss for the second quarter of 2024 was $1.7 million, or $0.10 per share, compared to net loss of $2.2 million, or $0.16 per share, for the second quarter of 2023.

Research and Development (R&D) Expenses

R&D expenses for the quarter ended June 30, 2024 were $1,131,000, compared to $1,595,000 for the quarter ended June 30, 2023. This represents a decrease of $464,000 attributed to (1) a decrease of $636,000 in Validive clinical trial-related expenses due to the closure of the trial in March 2023, and (2) decrease in camsirubicin manufacturing costs of $138,000. These decreases were partially offset by a net increase of $310,000 due to other R&D expenses attributable to MNPR-101 for radiopharma use.

General and Administrative (G&A) Expenses

G&A expenses for the quarter ended June 30, 2024 were $658,000, compared to $733,000 for the quarter ended June 30, 2023. This represents a decrease of $75,000 primarily attributed to (1) a decrease in stock-based compensation to the board of directors of $64,000 as no equity awards were issued to the board of directors to-date in 2024, and (2) a net decrease in consulting, tax services and other G&A expenses of $11,000.

Principal Effects of the Pending Reverse Stock Split

The number of shares authorized remains at 40,000,000. After effectiveness of the

anticipated reverse stock split, the unaudited proforma number of shares issued and outstanding will be approximately 3,520,366. The par value will remain unchanged at $0.001 per share.

About Monopar Therapeutics

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, 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 is on track to initiate a Phase 1 clinical study in advanced cancers with its therapeutic radiopharmaceutical MNPR-101-RIT as soon as Q4 2024; that NorthStar will provide actinium-225 for Monopar’s development stage and potential future commercial stage programs; that current funds will be sufficient for Monopar to continue operations at least through August 31, 2025, including to continue to conduct and conclude its first-in-human clinical trial with Monopar’s MNPR-101-Zr radiopharmaceutical program, and to advance the preclinical MNPR-101-RIT therapeutic program into the clinic; and that the Company expects that the reverse stock split at a ratio of 1 for 5 shares of common stock will become effective at 5:00 pm on Monday, August 12, 2024 and its common stock will begin trading on a split-adjusted basis at the open of trading on Tuesday, August 13, 2024. The forward-looking statements involve risks and uncertainties including, but not limited to: that we may expend available funds sooner than anticipated or require additional funding due to change in circumstances or unanticipated events; that future preclinical or clinical data will not be as promising as the preclinical data to date; not enrolling sufficient patients in the MNPR-101-Zr Phase 1 clinical trial; 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; the effects of general economic and market conditions on Monopar’s operations and ability to raise funding; whether the Company effects the reverse stock split as expected and whether the Company is able to regain compliance with Nasdaq’s requirements within required timeframes or at all; 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.

Contact
Karthik Radhakrishnan
Chief Financial Officer
karthik@monopartx.com

Follow Monopar on social media for updates:
Twitter: @MonoparTx LinkedIn: Monopar Therapeutics

Source: Monopar Therapeutics Inc.