November 8, 2024

Monopar Therapeutics Reports Third Quarter 2024 Financial Results and Recent Developments

In-licensed ALXN-1840 (a Late-Stage Wilson Disease Drug Candidate) from Alexion, AstraZeneca Rare Disease
Two Novel Radiopharma Clinical Trials now Active and Enrolling Patients with Advanced Solid Cancers

WILMETTE, Ill., Nov. 08, 2024 (GLOBE NEWSWIRE) -- Monopar Therapeutics Inc. ("Monopar" or the "Company") (Nasdaq: MNPR), a clinical-stage biotechnology company focused on developing innovative treatments for patients with unmet medical needs, today announced third quarter 2024 financial results and summarized recent developments.

Recent Developments

ALXN-1840 for Wilson disease – Late Stage

- On October 23, 2024, the Company entered into an exclusive license with Alexion, AstraZeneca Rare Disease whereby the Company gained worldwide rights to develop and commercialize ALXN-1840 (bis-choline tetrathiomolybdate). ALXN-1840 is a drug candidate for Wilson disease that is in late-stage development, having already completed a Phase 3 clinical trial. Monopar will be assembling a regulatory package and initiating discussions with the FDA, with an initial focus on Wilson disease patients with more severe symptoms. More details on this transaction can be found here (link).

MNPR-101 for Radiopharmaceutical Use – Phase 1

- In August 2024, the Company received regulatory clearance in Australia to commence a first-in-human Phase 1a therapeutic clinical trial of its novel urokinase plasminogen activator receptor (uPAR)-targeted radiopharmaceutical therapy MNPR-101-Lu (MNPR-101 conjugated to lutetium-177) in patients with advanced solid cancers. The Company activated its first clinical trial site and launched the study in October 2024; the trial is currently active and recruiting patients.
- In September 2024, the Company announced positive early clinical data from its ongoing open-label Phase 1 imaging and dosimetry clinical trial of MNPR-101-Zr that validate the tumor-targeting ability of MNPR-101-Zr. In October, the Company presented additional clinical data at the European Association of Nuclear Medicine Annual Congress 2024. The data demonstrate clear and durable tumor uptake of MNPR-101-Zr in a patient with advanced ovarian cancer and show favorable biodistribution with low off-target binding.
- The Company is also actively exploring opportunities to expand its radiopharmaceutical pipeline primarily through internal development efforts. In October 2024, the Company announced the filing of a provisional patent application for new

radiopharmaceutical compounds and a family of linkers used to connect radioisotopes with targeting agents, including its uPAR-targeting antibody MNPR-101. This provisional patent could enable the Company to use these linkers to create new proprietary radiopharmaceuticals to pursue well-established, high-value cancer targets of interest.

Capital Raise

- On October 30, 2024, the Company completed a registered public offering of 1,181,540 shares of the Company's common stock at $16.25 per share, generating net proceeds of approximately $17.7 million, after deducting placement agent fees and other estimated offering expenses.

Results for the Third Quarter Ended September 30, 2024 Compared to the Third Quarter Ended September 30, 2023

Cash and Net Loss

Cash and cash equivalents as of September 30, 2024, were $6.0 million. As noted above, the Company completed a registered public offering on October 30, 2024 that yielded net proceeds to the Company of approximately $17.7 million, after deducting placement agent fees and other estimated offering expenses.

Monopar projects that its current funds will be sufficient to continue operations at least into the first half of 2026, including to: (1) assemble a regulatory package and initiate discussions with the FDA on ALXN-1840 for Wilson disease; (2) continue to conduct and conclude its first-in-human imaging and dosimetry Phase 1 clinical trial with MNPR-101-Zr; (3) continue to conduct its first-in-human therapeutic radiopharma clinical trial with MNPR-101-Lu; (4) advance its preclinical MNPR-101-Ac program into the clinic, and (5) invest in internal R&D projects to expand its radiopharma pipeline.

Net loss for the third quarter of 2024 was $1.3 million, or $0.37 per share, compared to net loss of $2.0 million, or $0.69 per share, for the third quarter of 2023.

Research and Development (R&D) Expenses

R&D expenses for the three months ended September 30, 2024 were $984,000, compared to $1,317,000 for the three months ended September 30, 2023. This represents a decrease of $333,000 attributed to (1) a decrease in camsirubicin manufacturing costs of $301,000 due to the Company's decision to wind down that program, and (2) a decrease of $218,000 in Validive clinical trial related expenses due to the closure of the trial in March 2023. These decreases were partially offset by a net increase of $186,000 due to other R&D expenses attributable to MNPR-101 for radiopharmaceutical use.

General and Administrative (G&A) Expenses

G&A expenses for the three months ended September 30, 2024 were $591,000, compared to $749,000 for the three months ended September 30, 2023. This represents a decrease of $158,000 primarily attributed to (1) a reduction of stock based compensation expenses of $146,000 due to the full vesting of the 2020 grants in the fourth quarter of 2023, and (2) a decrease in stock-based compensation to the CEO and the board of directors of $64,000 as

no equity awards have been issued to the CEO and the board of directors to date in 2024, partially offset by a net increase in consulting and other G&A expenses of $52,000.

About Monopar Therapeutics

Monopar Therapeutics Inc. is a clinical-stage biotechnology company with late-stage ALXN-1840 for Wilson disease, and radiopharma 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-Ac225 for the treatment of advanced 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 will be assembling a regulatory package and initiating discussions with the FDA, with an initial focus on Wilson disease patients with more severe symptoms;
that Monopar is actively exploring opportunities to expand its radiopharmaceutical pipeline primarily through internal development efforts; that the provisional patent could enable the Company to use these linkers to create new proprietary radiopharmaceuticals to pursue well-established, high-value cancer targets of interest; and that Monopar projects that its current funds will be sufficient to continue operations at least into the first half of 2026. The forward-looking statements involve risks and uncertainties including, but not limited to: Monopar’s ability to raise sufficient funds in order for the Company to support continued clinical, regulatory and commercial development of its programs and to make contractual upfront and future 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; uncertainties related to the regulatory discussions that Monopar intends to initiate related to ALXN-1840 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; 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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