August 11, 2022

Monopar Therapeutics Reports Second Quarter 2022 Financial Results and Recent Program Developments

Validive® Phase 2b/3 VOICE Trial Continues Adding Sites in the U.S. and Europe and Enrolling Patients Toward Interim Analysis Anticipated in Q1 2023 Camsirubicin Phase 1b Dose-Escalation Trial Now Dosing 4th Level

WILMETTE, Ill., Aug. 11, 2022 (GLOBE NEWSWIRE) -- Monopar Therapeutics Inc. (Monopar or the Company) (Nasdaq: MNPR), a clinical-stage biopharmaceutical company focused on developing proprietary therapeutics designed to extend life or improve the quality of life for cancer patients, today announced second quarter 2022 financial results and summarized recent program developments.

Recent Program Developments

Validive – International Phase 2b/3 VOICE Clinical Trial, Actively Recruiting

- The VOICE trial continues to enroll patients and add additional clinical sites in the U.S. and Europe (now at 58 active sites). Based on findings extracted from public reporting of recently completed severe oral mucositis (SOM) trials that led to subsequent enhancements being made to Monopar's interim analysis, the Company anticipates the interim analysis to occur in Q1 2023.

Camsirubicin – Phase 1b Dose-Escalation Clinical Trial, Actively Recruiting

- Monopar has cleared the third dose-level and is currently dosing the fourth dose-level cohort. The fourth dose-level is approximately double the highest dose of camsirubicin ever tested in a prior trial.

- Early signs of clinical benefit have been observed with camsirubicin in this Phase 1b trial.

MNPR-101 Radioimmunotherapeutic

- Monopar is actively evaluating pathways to initiate a first-in-human study with the MNPR-101-PCTA radioimmunotherapeutic/radiodiagnostic candidate that Monopar generated with its partner NorthStar Medical Radioisotopes, LLC.

MNPR-202

- Monopar's collaborator, the Cancer Science Institute of Singapore at the National University of Singapore, tested MNPR-202 in preclinical cancer models with promising

results and is currently conducting additional preclinical studies. The aim is to submit an abstract of the results to one or more scientific/medical conferences within the coming months.

Results for the Second Quarter Ended June 30, 2022, Compared to the Second Quarter Ended June 30, 2021

Cash and Net Loss

Cash and cash equivalents as of June 30, 2022 were $16.5 million. Monopar anticipates that its current cash and cash equivalents will fund: the completion of the Phase 2b portion of the VOICE clinical trial; the commencement of the Phase 3 portion of the VOICE clinical trial; and the Phase 1b camsirubicin clinical trial through at least September 2023. The Company plans to raise additional funds and/or engage a partner within the next 12 months to complete the VOICE clinical program and continue camsirubicin clinical development through and beyond the ongoing open-label, dose escalation Phase 1b clinical trial.

Net loss for the second quarter of 2022 was $2.8 million or $0.22 per share compared to net loss of $2.1 million or $0.17 per share for the second quarter of 2021.

Research and Development (R&D) Expenses

R&D expenses for the three months ended June 30, 2022 were $2,078,000, compared to $1,476,000 for the three months ended June 30, 2021. The increase of $602,000 is attributed to (1) an increase of $473,000 in camsirubicin clinical trial expenses including patient dosing and manufacturing-related expenses, (2) an increase of $302,000 in Validive clinical trial-related and clinical material manufacturing-related expenses, and (3) a $9,000 net increase in other R&D expenses (4) offset by a decrease of $182,000 in R&D personnel costs.

General and Administrative (G&A) Expenses

G&A expenses for the three months ended June 30, 2022 were $685,000, compared to $616,000 for the three months ended June 30, 2021. The increase of $69,000 is primarily the result of an increase in G&A personnel expenses.

About Monopar Therapeutics

Monopar Therapeutics is a clinical-stage biopharmaceutical company focused on developing proprietary therapeutics designed to extend life or improve the quality of life for cancer patients. The Company's pipeline consists of Validive for the prevention of chemoradiotherapy-induced severe oral mucositis in oropharyngeal cancer patients; camsirubicin for the treatment of advanced soft tissue sarcoma; a late-stage preclinical antibody, MNPR-101, for advanced cancers and severe COVID-19; and an early-stage camsirubicin analog, MNPR-202, 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: Monopar’s plans to continue to enroll patients and add additional Validive clinical sites in the U.S. and Europe; that the VOICE trial is on track for reaching interim analysis in Q1 2023; Monopar aims to submit an abstract of the MNPR-202 results to one or more scientific/medical conferences within the coming months; and that Monopar anticipates its current cash and cash equivalents will fund completion of the Phase 2b portion of the VOICE clinical trial, the commencement of the Phase 3 portion of the VOICE clinical trial, and the Phase 1b camsirubicin clinical trial at least through September 2023. The forward-looking statements involve risks and uncertainties including, but not limited to: not successfully recruiting patients and opening additional clinical trial sites for the VOICE clinical trial or the camsirubicin Phase 1b clinical trial within expected timeframes, if at all; the Company’s inability to raise sufficient funds or engage a partner to complete the Phase 3 portion of the VOICE clinical trial and continue the camsirubicin clinical program through and beyond the Phase 1b clinical trial; whether early signs of clinical benefit observed with camsirubicin in this Phase 1b trial will continue; and the significant general risks and uncertainties surrounding the research, development, regulatory approval, and commercialization of 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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Source: Monopar Therapeutics Inc.