November 12, 2021

# Monopar Therapeutics Reports Third Quarter 2021 Financial Results and Recent Clinical Developments

***First Patients Dosed in Camsirubicin Phase 1b Clinical Trial in U.S.***
***Validive® Phase 2b/3 VOICE Trial Cleared to Enroll in Europe and on Track for Reaching Interim in H1 2022***

WILMETTE, Ill., Nov. 12, 2021 (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 third quarter 2021 financial results and summarized recent clinical developments.

**Recent Clinical Developments**

***Validive***

- Monopar received clearance in multiple European countries to conduct its Phase 2b/3 VOICE clinical trial of Validive (clonidine HCl mucobuccal tablet) for the prevention of severe oral mucositis (SOM) in patients undergoing chemoradiotherapy (CRT) for oropharyngeal cancer.
- Monopar continues to actively initiate additional clinical sites in both the U.S. and the EU for the Phase 2b clinical trial, which is on track to reach the interim in the first half of 2022.
- There remains no FDA-approved prevention or treatment for CRT-induced SOM.

***Camsirubicin***

- Camsirubicin, a propriety doxorubicin analog, has been engineered specifically to retain the anticancer activity of doxorubicin while minimizing the toxic effects on the heart.
- In August 2021, Monopar received clearance from the U.S. Food and Drug Administration to proceed under an Investigational New Drug (IND) application with an open-label Phase 1b dose-escalation clinical trial evaluating camsirubicin plus growth factor support (pegfilgrastim/G-CSF) in patients with advanced soft tissue sarcoma.
- In September 2021, Monopar initiated the Phase 1b clinical trial, and in October 2021, dosed the first patients.
- Monopar continues to work on activating additional clinical sites in the U.S. for the Phase 1b clinical trial.

***Results for the Third Quarter Ended September 30, 2021, Compared to the Third Quarter Ended September 30, 2020***

***Cash and Net Loss***

Cash and cash equivalents as of September 30, 2021, were $22.3 million. Monopar anticipates that its current cash and cash equivalents will fund: 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 December 2022. 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 beyond the Phase 1b clinical trial.

Net loss for the third quarter of 2021 was $2.5 million or $0.20 per share compared to net loss of $1.6 million or $0.15 per share for the third quarter of 2020.

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

R&D expenses for the third quarter of 2021 were $1.8 million compared to $1.2 million for the third quarter of 2020. This increase of $0.6 million was primarily due to increases of $0.5 million for VOICE clinical trial expenses and $0.2 million for R&D personnel expenses offset by a decrease of $0.1 million for Phase 1b camsirubicin clinical trial expenses.

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

G&A expenses for the third quarter of 2021 were $0.6 million, compared to $0.4 million for the third quarter of 2020. This increase of $0.2 million was primarily due to 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 activate Validive clinical sites in both the U.S. and the EU; that the VOICE trial is on track for reaching interim in the first half of 2022; that Monopar continues to activate additional clinical sites in the U.S. for the camsirubicin Phase 1b clinical trial; and that Monopar anticipates its current cash and

cash equivalents will fund 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 December 2022. 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 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 beyond the Phase 1b clinical trial; 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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