January 26, 2023

Monopar Therapeutics

Monopar Announces Projected Timeline of Upcoming Q1 2023 Data Events for Validive, Camsirubicin, and MNPR-101 RIT

WILMETTE, Ill., Jan. 26, 2023 (GLOBE NEWSWIRE) -- Monopar Therapeutics Inc. (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 it is planning to report over the next two months (1) the interim go/no-go analysis for its Validive Phase 2b/3 VOICE trial, (2) clinical data from its camsirubicin Phase 1b trial, and (3) a preclinical progress update on its MNPR-101 RIT program.

February 2023:

Camsirubicin Phase 1b Clinical Trial Data Update

- In addition to the previously reported improvement in median progression free survival over the prior camsirubicin Phase 2 study, Monopar plans to provide details of the Phase 1b trial's improved toxicity and safety observed to date compared to doxorubicin.

MNPR-101 Radioimmunotherapeutic (RIT) Preclinical Data Update

- Monopar plans to report an update on recently generated preclinical data and anticipated next steps with partner NorthStar Medical Radioisotopes.

March 2023:

Interim Go/no-go Analysis for Validive Phase 2b/3 VOICE Trial

- Monopar expects to have the interim analysis completed and to report out the go/no-go decision during March 2023; in the intervening time, patient enrollment and addition of new sites continue in preparation for a potentially positive interim.

About Monopar Therapeutics Inc

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. Monopar's pipeline consists of Validive® (Phase 2b/3) for the prevention of chemoradiotherapy-induced severe oral mucositis in oropharyngeal cancer patients; camsirubicin (Phase 1b) 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, visit: www.monopartx.com.

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 planning to report over the next two months various data events; that Monopar plans to provide details of the Phase 1b trial’s improved toxicity and safety observed to-date compared to doxorubicin; that Monopar plans to report an update on recently generated data on MNPR-101 RIT; that the VOICE trial’s interim analysis is anticipated to be reached during March 2023. The forward-looking statements involve risks and uncertainties including, but not limited to: unanticipated delays causing us not to report some or all of the data over the next two months on our expected timeline; not successfully recruiting additional 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 VOICE clinical trial not reaching interim analysis by end of March 2023; negative or ambiguous data are generated by the clinical and preclinical programs; 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; that MNPR-101 RIT may not find a pathway to initiating a first-in-human study; 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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