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# Monopar Advances Dosing of Camsirubicin to Higher Level Than Tested In Any Previous Clinical Trial

WILMETTE, Ill., Dec. 08, 2021 (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 the positive recommendation from its safety review committee to escalate to the second dose level in its camsirubicin Phase 1b trial in patients with advanced soft tissue sarcoma (ASTS). This decision was made following a review of safety data from the patients in the first dose cohort and will allow evaluation of a higher dose level of camsirubicin than has been administered in any prior clinical trial.

“Camsirubicin belongs to a class of drugs, anthracyclines, that have repeatedly demonstrated a dose-dependent anti-tumor response,” said Andrew Mazar, PhD, Monopar’s Chief Scientific Officer. “Camsirubicin has already shown potential signs of anti-tumor activity in a traditional all-comer advanced cancer Phase 1 and in a pilot Phase 2 study in ASTS, so the ability to achieve a higher dose than previously used in those studies is an important milestone for the company.”

“We are pleased with the swift progress accomplished to date, rapidly moving from regulatory trial allowance to first site activated to clearing the first dose level in only a few months,” said Chandler Robinson, MD, Monopar’s Chief Executive Officer. “We are eager to continue evaluating progressively escalating dose levels of camsirubicin, which may demonstrate increasing anti-tumor activity.”

Further information about this actively enrolling, open-label, dose-escalation Phase 1b clinical trial is available at www.ClinicalTrials.gov under study identifier **NCT 05043649.**

**About Camsirubicin**

Camsirubicin is a novel proprietary analog of the widely used cancer drug doxorubicin. It has been investigated in ASTS patients in a Phase 1 and a single-arm Phase 2 clinical trial. In these studies, no camsirubicin-treated patients developed the irreversible cardiotoxicity common to doxorubicin at higher cumulative doses. The most frequent adverse event observed in the Phase 1 study was neutropenia, which was mitigated in the Phase 2 study using prophylactic G-CSF. Based on encouraging clinical results to date, the current Phase 1b trial is designed to test camsirubicin at progressively higher doses than previously administered while using concomitant prophylactic G-CSF to prevent neutropenia.

**About Soft Tissue Sarcoma**

Soft tissue sarcomas (STS) are a diverse type of cancer that typically develop in the connective tissue of the body. According to the American Cancer Society, in 2021, an

estimated 13,460 new STS cases will be diagnosed in the US alone, and about 5,350 people will not survive their disease. These tend to be the advanced cases; those with sarcomas that are unresectable and/or have metastasized. The average life expectancy from time of diagnosis for those patients with advanced disease (ASTS) is about 12 to 15 months. Doxorubicin is the current standard of care in the 1$^{st}$-line setting for ASTS, and has been for decades, since there have been no 1$^{st}$-line therapeutic advancements that have improved overall survival for this patient population.

**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® 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, 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 we will be able to continue evaluating progressively escalating dose levels of camsirubicin, which may demonstrate increasing anti-tumor activity. The forward-looking statements involve risks and uncertainties including, but not limited to: whether the Phase 1b camsirubicin trial will successfully enroll sufficient patients to accomplish trial goals; whether camsirubicin will show comparable anti-tumor activity to doxorubicin without any signs of irreversible heart damage; that camsirubicin may not prove to be clinically efficacious; that the Company will need to raise additional funds in 2022 to develop camsirubicin beyond Phase 1b; 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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