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Monopar Announces FDA Clearance to Proceed with Camsirubicin Clinical Trial Targeting Advanced Soft Tissue Sarcoma

WILMETTE, Ill., Aug. 03, 2021 (GLOBE NEWSWIRE) -- Monopar Therapeutics Inc. (Nasdaq: MNPR), a clinical-stage biopharmaceutical company primarily focused on developing proprietary therapeutics designed to extend life or improve the quality of life for cancer patients, today announced clearance from the US Food and Drug Administration (FDA) to proceed under its IND with an open-label Phase 1b dose-escalation trial evaluating camsirubicin plus growth factor support (pegfilgrastim) in patients with advanced soft tissue sarcoma (ASTS). The Company anticipates dosing the first patient in the trial in the fourth quarter of this year.

“By giving concomitant growth factor support to overcome the dose-limiting toxicity of this class of drug, we hypothesize camsirubicin could be dosed even higher and longer than doxorubicin, yielding the chance to demonstrate efficacy superiority over doxorubicin,” said Octavio Costa, MD, Monopar’s Chief Medical Officer.

“We eagerly await reaching each higher dose level in this trial,” said Andrew Mazar, PhD, Monopar’s Chief Scientific Officer. “Camsirubicin is a novel analog of doxorubicin, and doxorubicin is known to work through a dose-dependent mechanism, where higher quantities yield more anti-cancer effect.”

“If successful in ASTS, there are 13 other potential cancer indications for camsirubicin where doxorubicin is already FDA-approved,” said Chandler Robinson, MD, Monopar’s Chief Executive Officer.

About Monopar Therapeutics Inc.

Monopar Therapeutics is a clinical-stage biopharmaceutical company primarily focused on developing proprietary therapeutics designed to extend life or improve the quality of life for cancer patients. Monopar's pipeline consists of Phase 2b/3-stage Validive® for the prevention of chemoradiotherapy-induced severe oral mucositis in oropharyngeal cancer patients; Phase 1b-stage 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: the Company anticipating dosing the first patient in the fourth quarter of this year; that camsirubicin could be dosed even higher and longer than doxorubicin, yielding the chance to demonstrate efficacy superiority over doxorubicin; and if successful in ASTS, there are 13 other potential cancer indications for camsirubicin where doxorubicin is already FDA approved. The forward-looking statements involve risks and uncertainties including, but not limited to: not dosing the first patient in the Phase 1b clinical trial in the fourth quarter of this year, if at all; that camsirubicin may cause unexpected serious adverse effects or lacks meaningful efficacy; the potential for the FDA to put the Phase 1b trial on clinical hold at any time; whether giving concomitant growth factor support will overcome the dose-limiting toxicity of this class of drug and whether camsirubicin will be able to safely achieve any dose level higher than the starting dose level for this Phase 1b trial; camsirubicin not being superior to or as effective as doxorubicin; if successful, camsirubicin not being effective in 13 other cancer indications; 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.

CONTACT:

Monopar Therapeutics Inc.
Investor Relations
Kim R. Tsuchimoto
Chief Financial Officer
kimtsu@monopartx.com

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