August 5, 2021

Monopar Reaches Target Number of Clinical Sites in Phase 2b Portion of 2b/3 Validive® VOICE Trial

WILMETTE, Ill., Aug. 05, 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 it has successfully reached its target of 20 activated clinical trial sites in the Phase 2b portion of the VOICE trial.

Validive® is a small, easy-to-use mucobuccal tablet that can be self-administered in the patient's home setting. The VOICE study evaluates Validive® for the prevention of severe oral mucositis (SOM) in oropharyngeal cancer patients. SOM results from the chemoradiation used to treat oropharyngeal cancer (OPC). There is no FDA-approved preventative or treatment option for the estimated >40,000 OPC patients in the US annually who are at-risk of developing SOM.

"We are very pleased to reach this clinical milestone and to achieve clinical site enrollment rates that have exceeded our base case projections to date," said Octavio Costa, MD, Monopar's Chief Medical Officer. "We are proud of our clinical team's efforts and grateful for the support from participating patients and staff at our clinical sites, who are joining us in our focus to prevent this painful, debilitating condition that results in patients losing the ability to drink and/or eat."

"In planning for success and the Phase 3 portion of the VOICE trial, and as a result of strong interest from sites in joining the trial, we are going to expand the number of sites beyond the original 20 targeted," said Chandler Robinson, MD, Monopar's Chief Executive Officer. "Because of interest outside the US, we are also looking at activating sites in additional countries, potentially later this year."

Monopar anticipates reaching the interim analysis of the Phase 2b/3 Validive® VOICE trial in the first half of 2022. Further information about the trial is available at www.ClinicalTrials.gov under study identifier **NCT 04648020**.

About Severe Oral Mucositis

Severe oral mucositis (SOM) is a painful and debilitating inflammation and ulceration of the mucous membranes lining the oral cavity and oropharynx in response to insults such as chemoradiation treatment (CRT). SOM is the most frequent major side effect experienced by oropharyngeal cancer patients, experienced by a majority of those undergoing CRT. SOM impacts both quality of life and clinical outcomes for these patients. SOM prevents patients from drinking and/or eating, and can lead to severe weight loss, opiate usage, and the use of feeding tubes as well as intravenous supplementation to keep alive. Patients who develop SOM can become hospitalized, and symptoms can force patients to prematurely stop cancer

treatment, reducing treatment efficacy and long-term survival.

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 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: Monopar’s plan to expand the number of sites beyond the original 20 targeted, including the Company’s plan to activate sites in additional countries, potentially later this year; and that Monopar anticipates reaching the interim analysis of the Phase 2b/3 Validive VOICE trial in the first half of 2022. The forward-looking statements involve risks and uncertainties including, but not limited to: Monopar’s inability to enroll the VOICE trial as planned; Monopar not reaching the interim analysis of the Phase 2b/3 Validive VOICE trial within the anticipated timeframe, if at all; the Company’s inability to complete the VOICE trial; that Validive may not prove to be clinically efficacious; 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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