September 13, 2021

# Monopar Expands Phase 2b/3 VOICE Clinical Trial to Europe

- ***Trial launch in Europe coincides with the Company's upcoming presentation at the European Society for Medical Oncology Congress***

WILMETTE, Ill., Sept. 13, 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 it has received authorization to proceed with the Phase 2b/3 VOICE clinical trial in France. The trial, which began earlier this year in the US, is evaluating Validive® (clonidine HCl MBT) to prevent the onset of severe oral mucositis (SOM) in oropharyngeal cancer (OPC) patients treated with chemoradiotherapy. The trial's rationale and design will be presented at the upcoming European Society for Medical Oncology (ESMO) Congress 2021. Monopar anticipates reaching the interim of the Phase 2b/3 VOICE trial in the first half of 2022.

"Building on the numerous clinical sites we have activated in the US, we are pleased to receive authorization to proceed with the VOICE trial in France," said Octavio Costa, MD, Chief Medical Officer of Monopar. "Expansion to Europe marks another important milestone in this late-stage trial, and we anticipate dosing patients in France in the not too distant future with additional European countries to follow."

"SOM is a painful, debilitating side effect of chemoradiotherapy that results in patients' inability to drink and/or eat, and it has no approved preventative or treatment options," said Andrew Mazar, PhD, Monopar's Chief Scientific Officer. "We are pleased to share the rationale and design for our Phase 2b/3 VOICE clinical trial with the European oncology community as we continue in our efforts to prevent this life-altering condition."

ESMO Congress poster presentation details are as follows:

**e-Poster:** 1729TiP. "Rationale and design of the Phase 2b/3 VOICE trial of clonidine MBT for the prevention of severe oral mucositis in patients with OPC receiving chemoradiotherapy."

**Presenting Author:** Dr. Andrew P. Mazar, Chief Scientific Officer of Monopar Therapeutics

**Session:** 247-15 e-Poster Display

**Date:** 16 Sept 2021 8:30 AM CEST, virtual meeting website channel 7

**About Validive®**

Validive (clonidine mucobuccal tablet; clonidine MBT) is a novel mucobuccal tablet (MBT) formulation. The mucobuccal tablet provides for prolonged and enhanced local delivery of clonidine to the regions of oral mucosal radiation damage in OPC patients. The tablet is self-

administered once daily in the patient's home setting with the patient placing it under the upper lip where it adheres to the gums and dissolves over several hours, continuously releasing clonidine into the saliva. Clonidine agonizes the alpha-2 adrenergic receptor on macrophages (white blood cells present in the immune tissues of the oropharynx), decreasing the macrophages' expression of the destructive cytokines that are released in response to radiotherapy. A completed double-blind, randomized, placebo-controlled Phase 2 clinical trial of Validive showed reduced incidence compared to placebo (absolute decrease of 26%, relative decrease of 40%) in OPC patients treated with Validive 100 µg, a safety profile similar to placebo, and a high rate of treatment compliance (over 90%). Monopar expects to continue activating sites in the US and abroad for this adaptive Phase 2b/3 VOICE clinical trial. Further information about the trial in the US is available at www.ClinicalTrials.gov under study identifier **NCT 04648020**.

**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: Monopar anticipating reaching the interim of the Phase 2b/3 VOICE trial in the first half of 2022; and Monopar anticipating dosing patients in France in the not too distant future with additional European countries to follow. The forward-looking statements involve risks and uncertainties including, but not limited to: that Monopar may not reach the interim by the first half of 2022; that the VOICE trial may not yield similar or better results than the Phase 2 trial or be statistically significant; that Monopar may not continue to successfully recruit and complete the VOICE trial; not receiving regulatory approval to market Validive or failure to successfully launch Validive upon approval; that Monopar may not be successful in raising additional capital to complete the Phase 3 portion of the VOICE trial nor the potential second confirmatory Phase 3 clinical trial, if required by the regulators and, if successful, to commercialize Validive; not being able to ensure volumes of Validive can be manufactured and scaled up to meet potential demand; uncertainties about levels of demand if and when Validive is approved for commercialization; 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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