June 24, 2021

Monopar to Present Results from Analysis of Oropharyngeal Cancer Patients in Completed Phase 2 Validive® Trial at MASCC/ISOO

WILMETTE, Ill., June 24, 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 that it will present its oropharyngeal cancer (OPC) patient population analysis of the Phase 2 Validive® (clonidine HCl MBT) trial for the prevention of chemoradiotherapy-induced severe oral mucositis in head and neck cancer at the Multinational Association of Supportive Care in Cancer and International Society of Oral Oncology (MASCC/ISOO) 2021 annual meeting. This analysis provided the rationale for the design of Monopar's Phase 2b/3 VOICE trial, which is open and accruing oropharyngeal cancer patients in the US.

"We are excited to share the data from our analysis at this pre-eminent multidisciplinary conference dedicated to supportive care in cancer and for the opportunity to continue working towards providing a treatment for this debilitating condition," said Andrew Mazar, PhD, Chief Scientific Officer of Monopar.

Session Title: Mucositis - New Dimensions in Research and Clinical Practice, Oral Proffered Paper 2

Presentation Title: Subgroup Analysis of Head and Neck Cancer Patients Treated with Clonidine Mucobuccal Tablet in a Randomized, Double-Blind Phase 2 Trial (Study BA2009-28-01) Supports Further Clinical Development in Patients with Oropharyngeal Cancer

Author: Andrew Mazar, PhD, Chief Scientific Officer of Monopar Therapeutics

Date and Time: The Company's presentation will be available on demand for registered attendees starting Friday, June 25, 2021 at 8:00am EDT. For information on registration, visit: https://www.mascc.org/2021-registration

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%).

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: the Company's excitement for the opportunity to continue working towards providing a treatment for severe oral mucositis; and the Phase 2 trial supporting further clinical development in patients with oropharyngeal cancer. The forward-looking statements involve risks and uncertainties including, but not limited to: that the Phase 2 trial analysis will not provide successful rationale for the conduct and design of Monopar's Phase 2b/3 VOICE trial; that Monopar may not provide a treatment for severe oral mucositis; that Validive's Phase 2b/3 VOICE trial may not yield similar results as the Phase 2 trial or successful clinical results; that Monopar may not successfully recruit and complete the Phase 2b/3 VOICE trial; the requirement for additional capital to complete the Phase 3 portion of the VOICE trial and potentially a second smaller confirmatory Phase 3 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 a treatment is available 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.

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