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Monopar Therapeutics

Monopar Announces First Patient Dosed in its Phase 2b/3 VOICE Trial Evaluating Validive® for the Prevention of Chemoradiotherapy-Induced Severe Oral Mucositis (SOM) in Oropharyngeal Cancer (OPC)

There are currently no FDA-approved drugs to prevent or treat chemoradiotherapy-induced SOM

WILMETTE, Ill., Feb. 16, 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 dosed the first patient in its Phase 2b/3 VOICE trial of Validive® for the prevention of chemoradiotherapy-induced severe oral mucositis in patients with oropharyngeal cancer (VOICE).

Validive's mucoadhesive buccal tablet formulation allows for prolonged and enhanced local delivery of drug to the regions of mucosal radiation damage, and its easy application under the upper lip allows for convenient once-daily self-administration in the patient's home setting.

"With this important milestone accomplished we are excited to be one step closer to bringing Validive to the approximately 40,000 OPC patients per year in the US that have no effective options for preventing or treating their chemoradiotherapy-induced SOM," said Chandler Robinson, MD, Chief Executive Officer of Monopar. "SOM is a painful and debilitating severe adverse effect of chemoradiotherapy (CRT) treatment and can have significant negative impacts on clinical outcomes as well as quality of life in both the short and long term."

"The number of newly diagnosed individuals with oropharyngeal cancer is growing," said Andrew Mazar, PhD, Chief Scientific Officer of Monopar. "CRT is the standard of care for OPC, but unfortunately 60-70% of OPC patients undergoing CRT will develop severe oral mucositis in the course of their treatment."

The completed Validive Phase 2 trial showed that administering a single, once daily 100µg Validive tablet resulted in a 40% reduction in the incidence of SOM compared to placebo in OPC patients undergoing CRT treatment. Up to approximately 260 patients will be enrolled in the current multi-center, randomized, double-blind, placebo-controlled, adaptive design Phase 2b/3 VOICE trial.

Further information about the Validive Phase 2b/3 VOICE trial is available at

www.ClinicalTrials.gov under study identifier **NCT 04648020.**

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 they release 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 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; and a late-stage preclinical antibody, MNPR-101, for advanced cancers and severe COVID-19. 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 whether Monopar will successfully continue to enroll its Validive Phase 2b/3 VOICE clinical trial; whether Validive will benefit OPC patients in the VOICE trial; whether the VOICE trial will yield results similar to the Phase 2 clinical trial in OPC patients; and whether the incidence of OPC will continue to grow and continue to be treated with CRT. The forward-looking statements involve risks and uncertainties for Monopar including, but not limited to, the requirement for additional capital to complete the

VOICE trial beyond the interim analysis and for potential commercialization; the VOICE trial not yielding statistically significant results; if successful, 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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