May 7, 2020

Monopar Therapeutics Reports First Quarter 2020 Financial Results and Business Updates

Validive clinical trial design adapted for current COVID-19 pandemic challenges

CHICAGO, May 07, 2020 (GLOBE NEWSWIRE) -- Monopar Therapeutics Inc. (Monopar or the Company) (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 first quarter 2020 financial results and business updates.

First Quarter and Recent Highlights

Validive Phase 2b/3 Clinical Trial

- Monopar, in response to the current COVID-19 pandemic and its effects on clinical trials, has modified the original adaptive design Phase 3 clinical trial to be a Phase 2b/3 clinical trial to better fit the types of trials which can enroll patients in the current environment.

- The primary endpoint, absolute incidence of severe oral mucositis, remains the same, but the touch points with the healthcare system have been minimized.

- The Validive program will now consist of a randomized Phase 2b/3 clinical trial anticipated to start in the second half of 2020, which will have an unblinded data readout after the Phase 2b portion (estimated to be in the second half of 2021), and shortly thereafter the Phase 3 portion will commence subject to the Company's ability to raise additional funding or find a suitable pharmaceutical partner.

Camsirubicin Phase 2 Clinical Trial

- Camsirubicin clinical program continues to make progress with its collaboration with Grupo Español de Investigación en Sarcomas (GEIS), an internationally renowned non-profit organization focused on the research and development of drugs for sarcoma cancers, which is sponsoring the approximately 170-patient camsirubicin Phase 2 clinical trial for the treatment of advanced soft tissue sarcoma, anticipated to begin in the second half of 2020.

"We are excited to move our clinical development programs forward, especially in light of the challenges that the COVID-19 pandemic has created for many biopharmaceutical companies. Addressing the needs of oncology patients is our highest priority and we look forward to entering the clinic in the second half of this year," said Andrew Mazar, Ph.D., Monopar's Chief Scientific Officer.

First Quarter Summary Financial Results

Results for the Quarter Ended March 31, 2020 Compared to the Quarter Ended March 31, 2019

Cash and cash equivalents as of March 31, 2020 were $12.6 million. Net loss for the three months ended March 31, 2020 was $1.1 million or $0.10 per share compared to net loss of $1.4 million or $0.15 per share in the comparable period in 2019.

Research and Development (R&D) Expenses

R&D expenses for the three months ended March 31, 2020 were $0.3 million, compared to $0.8 million, for the three months ended March 31, 2019. This represents a decrease of $0.5 million primarily attributed to a decrease in Validive clinical trial planning and accrued material costs.

General and Administrative (G&A) Expenses

G&A expenses for the three months ended March 31, 2020 were $0.8 million, compared to $0.6 million, for the three months ended March 31, 2019. This represents an increase of $0.2 million primarily attributed to increases in professional fees and G&A cash and stock-based (non-cash) compensation.

About Monopar Therapeutics

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. The Company'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 more information, and links to SEC filings that contain detailed financial 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 the clinical development timing of Validive and the potential of camsirubicin and the timing of the GEIS clinical trial. The forward-looking statements involve risks and uncertainties including, but not limited to, not commencing the Validive Phase 2b/3 clinical trial and Phase 2 GEIS-sponsored camsirubicin clinical trial in the second half of 2020, if at all, not obtaining the Validive Phase 2b unblinded data readout in the second half of 2021, if at all, and not commencing the Validive Phase 3 portion subject to fundraising and partnership efforts, if at all. 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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Source: Monopar Therapeutics Inc.