December 22, 2020

Monopar Announces Issuance of U.S. Patent Covering Compositions of Matter for a Novel Family of Camsirubicin Analogs

-Issued patent expands and strengthens Monopar's existing camsirubicin IP portfolio
-Phase 2 initiation for camsirubicin in advanced soft tissue sarcoma remains on track for early 2021

WILMETTE, Ill., Dec. 22, 2020 (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 the issuance of a U.S. patent (US 10,450,340) covering compositions of matter for a novel family of camsirubicin analogs. The patent, which expands the Company's camsirubicin intellectual property portfolio, is expected to expire in 2038 not including any patent term extensions.

"The analogs covered in this patent have been designed to retain the potentially favorable non-cardiotoxic chemical backbone of camsirubicin and the potent broad-spectrum antitumor activity of doxorubicin; further, preclinical evidence suggests that this new family of 2-pyrrilino camsirubicin analogs could be active in doxorubicin-resistant tumor cells. This may enable us to address additional cancer types beyond those possible with camsirubicin," said Andrew Mazar, PhD, Monopar's Chief Scientific Officer.

Doxorubicin is FDA approved in 14 different types of cancers including soft tissue and bone sarcomas; metastatic stomach, ovarian, thyroid, lung, and breast cancer; acute myeloid and lymphoblastic leukemia; Hodgkin and non-Hodgkin lymphoma; and neuroblastoma. However, cumulative dose effects of doxorubicin can result in irreversible heart damage and death, which is why a restrictive lifetime cumulative dose limitation has been placed on its use.

"If successful, camsirubicin and its analogs could overcome the restrictive dose limitation and be administered at higher doses and for longer periods of time than doxorubicin," said Chandler Robinson, MD, Monopar's Chief Executive Officer. "This could lead to improved efficacy and better patient outcomes."

Monopar's clinical trial collaboration partner, Grupo Español de Investigación en Sarcomas (GEIS), an internationally renowned non-profit organization focused on the research and development of drugs for sarcomas, is on track to initiate an open-label Phase 2 clinical study in early 2021 evaluating camsirubicin head-to-head against doxorubicin in advanced soft tissue sarcoma (ASTS), where doxorubicin is currently the first-line treatment.

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 the issued patent expands and strengthens Monopar’s existing camsirubicin IP portfolio; whether GEIS will initiate the Phase 2 camsirubicin clinical trial in early 2021, if at all; whether the analogs covered in the patent could retain the potentially favorable non-cardiotoxic chemical backbone of camsirubicin and the potent broad-spectrum antitumor activity of doxorubicin; whether this new family of 2-pyrrilino camsirubicin analogs could be active in doxorubicin-resistant tumor cells which may enable Monopar to address additional cancer types beyond those possible with camsirubicin; and whether camsirubicin and its analogs could overcome the restrictive dose limitation and be administered at higher doses and for longer periods of time than doxorubicin which could lead to improved efficacy and better patient outcomes. The forward-looking statements involve risks and uncertainties including, but not limited to the requirement for additional capital to complete future clinical development beyond the GEIS Phase 2 clinical trial; the safety and efficacy of camsirubicin in the Phase 2 and in future clinical development, if at all; if successful, the potential for commercialization, including uncertainties about levels of demand of camsirubicin; and the significant and 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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