

# **Monopar Therapeutics, Inc. Announces Acquisition of GPX-150, a Broad Spectrum Phase II Cancer Drug Candidate, Closing on \$9.7M in Financing, and Filing of Form 10 Registration Statement**

**-Proceeds from the financing will be used largely to initiate Validive® Phase III registration program for radiation induced severe oral mucositis in patients with head and neck cancer**

CHICAGO, Nov. 14, 2017 /PRNewswire/ -- Monopar Therapeutics, Inc., an emerging biopharmaceutical company focused on developing innovative drug candidates to improve clinical outcomes in cancer patients, today announced the acquisition of GPX-150 from privately held Gem Pharmaceuticals concurrent with \$9.7 million of new financing.

"GPX-150 fits nicely into our growing portfolio of oncology drug candidates that range from our preclinical antitumor antibody MNPR-101 (formerly huATN-658) to our Phase III-ready Validive® program to prevent and treat severe oral mucositis in patients receiving radiation treatment for head and neck cancer," said Dr. Chandler Robinson, Monopar's CEO. "Having just closed on nearly \$10 million in new financing, and with the recent filing of our Form 10 as a path toward the public listing of Monopar's securities, we are well on our way to becoming an active new contributor in the oncology therapeutic space."

## **About GPX-150**

GPX-150 has been engineered specifically to retain the anticancer activity of doxorubicin while minimizing the potential for irreversible damage to the heart. Doxorubicin is currently approved by the FDA for use in 14 different cancer types. However, the ability to provide patients with optimal treatment exposure to doxorubicin is limited due to the risk of patients developing irreversible cardiotoxicity.

"Extensive clinical data support the benefit of higher doses of doxorubicin for longer periods of time," said Dr. Andrew Mazar, Monopar's CSO. "Based on the data generated by Gem's studies to date, we believe that GPX-150 has the potential to provide all the therapeutic potential of higher cumulative dose doxorubicin while reducing or even eliminating its known cardiotoxic risks."

Decreased cardiotoxicity of GPX-150 compared to doxorubicin and other anthracyclines has been demonstrated in preclinical studies and several early clinical studies, supporting the safety and efficacy of GPX-150. A Phase I dose escalation study conducted at the University of Iowa enrolled 24 patients at five different dose levels of GPX-150 ranging from

14-265 mg/M<sup>2</sup>. No evidence of cardiotoxicity was observed in any of these patients, including four patients that had received prior anthracycline treatment. Fifty-three percent of patients showed disease stabilization, including three out of four patients with leiomyosarcoma.

Based on these favorable results, a multi-institutional single-arm Phase II clinical trial was conducted in patients with soft tissue sarcoma (STS). GPX-150 monotherapy demonstrated anticancer efficacy similar to that observed historically for doxorubicin in this indication, but with no evidence of irreversible cardiotoxicity.

Overall, GPX-150 showed a superior safety profile to that observed historically with doxorubicin. Monopar plans to leverage the favorable safety profile of GPX-150 to advance its development as a combination therapy in cancer indications where doxorubicin demonstrates a strong antitumor activity but its use has been restricted due to cardiotoxicity.

### **About Monopar Therapeutics, Inc.**

Monopar Therapeutics is an emerging biopharmaceutical company focused on developing innovative drug combinations to improve clinical outcomes in cancer patients. Monopar is building a drug development pipeline through the licensing and acquisition of oncology therapeutics at the late preclinical through advanced clinical development stage that have demonstrated good antitumor efficacy and safety when used in combination. Monopar recently announced an exclusive worldwide license to develop, register, commercialize and manufacture Validive®, a Phase III-ready first-in-class prevention of and treatment for radiation induced severe oral mucositis (SOM) in head and neck cancer. Monopar currently has three compounds in development: Phase III-ready Validive® (clonidine mucobuccal tablet; clonidine MBT); Phase II-stage GPX-150 (a novel non-cardiotoxic anthracycline); and near-to-the-clinic MNPR-101, a humanized monoclonal antibody that targets the urokinase plasminogen activator receptor (uPAR). MNPR-101 is being developed in collaboration with Cancer Research UK, which is funding MNPR-101's development through Phase Ib clinical trials. [www.monopartherapeutics.com](http://www.monopartherapeutics.com)

**Forward Looking Statements:** *Statements in this press release which are not purely historical, including statements regarding Monopar Therapeutics' intentions, hopes, beliefs, expectations, representations, projections, plans or predictions of the future are forward-looking statements within the meaning of Section 21E of the United States Securities Exchange Act of 1934, as amended, and Section 27A of the United States Securities Act of 1933, as amended. The forward-looking statements involve risks and uncertainties including, but not limited to the risk that the programs do not have significant upside potential. Factors that could cause actual results to differ materially include, but are not limited to, uncertainties associated with completing preclinical and clinical trials for our technologies; the early stage of product development; the significant costs to develop our products as all of our products are currently in development, preclinical studies or clinical trials; obtaining additional financing to support our operations and the development of our products; obtaining regulatory approval for our technologies; anticipated timing of regulatory filings and the potential success in gaining regulatory approval and complying with governmental regulations applicable to our business. Risks facing the company and our programs are set forth in our filings with the SEC. The company cautions investors not to place undue reliance on the forward-looking statements contained in this press release. Monopar Therapeutics,*

*Inc. disclaims any obligation, and does not undertake to update or revise any forward-looking statements in this press release.*

View original content:<http://www.prnewswire.com/news-releases/monopar-therapeutics-inc-announces-acquisition-of-gpx-150-a-broad-spectrum-phase-ii-cancer-drug-candidate-closing-on-97m-in-financing-and-filing-of-form-10-registration-statement-300555632.html>

SOURCE Monopar Therapeutics, Inc.