Hepion Pharmaceuticals' CRV431 Demonstrates Efficacy in Human Idiopathic Pulmonary Fibrosis Translational Research Study

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EDISON, NJ / ACCESSWIRE / March 12, 2020 / Hepion Pharmaceuticals, Inc. (NASDAQ:HEPA, "Hepion"), a biopharmaceutical company focused on the development of therapeutic drugs for the treatment of liver disease arising from non-alcoholic steatohepatitis ("NASH"), today announced positive findings from a translational research study investigating the effects of Hepion's drug candidate, CRV431, on lung tissue obtained from a patient with idiopathic pulmonary fibrosis ("IPF").

IPF is a rare, progressive, fibrotic lung disease with an unknown cause and poor prognosis. The goal of the study was to determine if the anti-fibrotic activity of CRV431, which has been previously observed in many experimental models of liver disease, could potentially extend to fibrotic diseases affecting other organs.

In the study, conducted by FibroFind Ltd. (Newcastle, UK), diseased lung tissue was obtained from an IPF patient undergoing a lung transplant and maintained for 6 days *ex vivo* by specialized, precision-cut culture techniques. CRV431 was administered to lung tissue samples at concentrations of 1 or 5 µM on the final 4 days of culture. Additional lung samples were treated with pirfenidone (2.5 mM) or nintedanib (2.5 µM), which are the two approved standard-of-care drugs for IPF that slow but do not halt disease progression. Drug effects were evaluated by daily measurement of secreted markers of fibrosis and inflammation (collagen 1α1, TIMP1, MMP7, hyaluronic acid, IL-6, and MCP-1) and by measurement of gene expression (RNA levels of collagen 1α1, TIMP1, αSMA, TGFβ1, IL-6, and MCP-1).

In this study, CRV431 dose-dependently decreased gene expression and secretion of every evaluated disease marker. CRV431 at 5 µM decreased gene expression by an average of 45% (range 20-84% reduction), which was similar to the effects observed with pirfenidone (46% average reduction) dosed at concentrations 500-times greater than CRV431. The daily average decrease in secreted disease markers produced by 5 µM CRV431 was 28% (range 5-61%). Notably, 5 µM CRV431 had similar potency to pirfenidone and nintedanib in decreasing secretion of the fibrosis markers, collagen 1α1 and TIMP1. The most potent secretion effect of 5 µM CRV431 was a 61% reduction in the daily average production of the IPF biomarker, MMP7, which was twice the magnitude of nintedanib (31% reduction) and similar to pirfenidone (65% reduction). In summary, the results demonstrate that CRV431 exerted similar or greater effects than pirfenidone and nintedanib across many disease markers.

"This study represented a rare opportunity to test CRV431 on diseased, IPF tissue. Several previous studies in animal models and human liver tissues demonstrated therapeutic effects of CRV431 in the liver, but this is the first study to show that CRV431 can attenuate disease markers in tissue from another organ," stated Dr. Daren Ure, Chief Scientific Officer of Hepion Pharmaceuticals. "The results reinforce that CRV431 has direct-acting anti-fibrotic activity that may be applicable to a range of fibrotic diseases and disorders, potentially even certain cancers. Having previously observed anti-fibrotic activities of CRV431 in isolated cells from an IPF lung, the current study extends those observations to intact, IPF tissue, which is significantly more relevant."

Dr. Robert Foster, CEO of Hepion Pharmaceuticals, added "Although our main focus remains on treating NASH-related fibrosis, we investigated lung fibrosis to further pressure test CRV431, whose mechanism of action is through inhibition of cyclophilins that play a role in collagen formation and cross-linking. The results of this IPF lung study support this mechanism of action and suggest that CRV431 may work across many different tissues and organs. Depending on resources, we may choose to pursue one or more of these indications in addition to NASH-related fibrosis, but may also be open to collaboration."

Hepion is developing CRV431 for NASH, fibrosis and other liver diseases. A Phase 1, single ascending dose study previously showed CRV431 to be safe and well-tolerated in humans. Currently, CRV431 is being administered in a 28-day multiple ascending dose study.

About Hepion Pharmaceuticals

Hepion Pharmaceuticals is a clinical-stage biopharmaceutical company focused on the development of targeted therapies for liver disease arising from non-alcoholic steatohepatitis (NASH) and other types of hepatitis. The Company's lead drug candidate, CRV431, reduces liver fibrosis and hepatocellular carcinoma tumor burden in experimental models of NASH. Preclinical studies also have demonstrated antiviral activities towards HBV, HCV, and HDV through several mechanisms. These diverse therapeutic activities result from CRV431's potent inhibition of cyclophilins, which are involved in many disease processes. Currently, in clinical phase development, CRV431 shows the potential to play an important role in the overall treatment of liver disease - from triggering events through to end-stage disease.

Forward-Looking Statements

Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of forward-looking words such as "anticipate," "believe," "forecast," "estimated," and "intend," among others. These forward-looking statements are based on Hepion Pharmaceuticals' current expectations and actual results could differ materially. There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, substantial competition; our ability to continue as a going concern; our need for additional financing; uncertainties of patent protection and litigation; uncertainties with respect to lengthy and expensive clinical trials, that results of earlier studies and trials may not be predictive of future trial results; uncertainties of government or third-party payer reimbursement; limited sales and marketing efforts and dependence upon third parties; and risks related to failure to obtain FDA clearances or approvals and noncompliance with FDA regulations. As with any drug candidates under development, there are significant risks in the development, regulatory approval, and commercialization of new products. There are no guarantees that future clinical trials discussed in this press release will be completed or successful, or that any product will receive regulatory approval for any indication or prove to be commercially successful. Hepion Pharmaceuticals does not undertake an obligation to update or revise any forward-looking statement. Investors should read the risk factors set forth in Hepion Pharmaceuticals' Form 10-K for the year ended December 31, 2018 and other periodic reports filed with the Securities and Exchange Commission.

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