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Algernon Pharmaceuticals Announces Notice of Allowance for Method of Use U.S. Patent Application

VANCOUVER, British Columbia, April 17, 2023 (GLOBE NEWSWIRE) -- Algernon Pharmaceuticals Inc. (the "Company" or "Algernon") (CSE: AGN) (FRANKFURT: AGW0) (OTCQB: AGNPF), a clinical stage pharmaceutical development company, is pleased to announce that it has received a Notice of Allowance from the United States Patent and Trademark Office (USPTO) for patent application 17/258,402 entitled "Compositions and Methods for Treating Non-Alcoholic Steatohepatitis" for its lead chronic kidney Disease (CKD) program drug NP-251 (Repirinast). The Company has also filed corresponding patent applications in Canada, Europe, China and Japan.

The invention claims treating non-alcohol fatty liver disease (NAFLD), including non-alcoholic steatohepatitis (NASH) and NASH-derived hepatocellular carcinoma, with Repirinast. The company previously disclosed that Repirinast, in a widely used STAM™ mouse model of NASH from SMC Laboratories (Japan):

- Reduced hepatic fibrosis by 57% compared to vehicle ($p < 0.0001$)
- Reduced the NAFLD score, a composite histopathological measure of inflammation, steatosis and ballooning, by 31% compared to vehicle (3.125 vs 4.5 points, $p = 0.059$)
- In the same model, telmisartan, a positive control and the standard of care for NASH, reduced fibrosis by 27% ($p = 0.014$)

Repirinast is the Company's lead candidate for the treatment of CKD based on data showing it reduced fibrosis by 51% with statistical significance and showed an additive benefit to telmisartan (a medicine used to treat high blood pressure, heart failure, and diabetic kidney disease) in a unilateral ureteral obstruction (UUO) mouse model. Because patients with NAFLD have a two-fold increased risk of CKD, even when controlling for other comorbidities such as obesity, type 2 diabetes mellitus and insulin resistance, Repirinast is a strong candidate for both indications.

Algernon's intellectual property strategy for its repurposed drug program includes protecting its compounds by filing patent applications including method of use, dosing, and formulations, and for new composition of matter patents based on novel salt forms.

"This is the first allowance notice received from the USPTO by Algernon for one of the drugs being investigated under our innovative drug repurposing program and is further validation of our intellectual property strategy," said Christopher J. Moreau, CEO of Algernon Pharmaceuticals.

About NP-251 (Repirinast)

Repirinast was originally developed by Mitsubishi Tanabe Pharma ("Mitsubishi") and was sold and marketed in Japan under the brand name Romet™ for the treatment of Asthma. Romet™ was marketed for over 25 years in Japan. Mitsubishi discontinued manufacturing and sales of the drug in 2013. Accordingly, Algernon has retained Zhejiang Ausun Pharmaceutical in Zhejiang, China to manufacture a cGMP Repirinast supply.

Mast cells are recruited to sites of cellular damage, and degranulation of mast cells leads to release of a myriad of proinflammatory chemical mediators which lead to tissue damage in a self-propagating cascade. NP-251 binds to receptors on mast cells and prevents their degranulation, which the Company believes could help prevent fibrosis in multiple organ classes including the kidneys and the liver.

About Algernon Pharmaceuticals

Algernon Pharmaceuticals is a Canadian clinical stage drug development and repurposing company investigating multiple drugs for unmet global medical needs. Algernon Pharmaceuticals has active research programs for IPF with chronic cough, and chronic kidney disease, and is the parent company of a newly created private subsidiary called Algernon NeuroScience, that is advancing a psychedelic program investigating a proprietary form of psychedelic DMT for stroke and traumatic brain injury (TBI).

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Source: Algernon Pharmaceuticals