

April 17, 2023



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).

CONTACT INFORMATION

Christopher J. Moreau
CEO

Algernon Pharmaceuticals Inc.

604.398.4175 ext 701

info@algernonpharmaceuticals.com

investors@algernonpharmaceuticals.com

www.algernonpharmaceuticals.com

Neither the Canadian Securities Exchange nor its Market Regulator (as that term is defined in the policies of the Canadian Securities Exchange) accepts responsibility for the adequacy or accuracy of this release.

CAUTIONARY DISCLAIMER STATEMENT: No Securities Exchange has reviewed nor accepts responsibility for the adequacy or accuracy of the content of this news release. This news release contains forward-looking statements relating to product development, licensing, commercialization and regulatory compliance issues and other statements that are not historical facts. Forward-looking statements are often identified by terms such as “will”, “may”, “should”, “anticipate”, “expects” and similar expressions. All statements other than statements of historical fact, included in this release are forward-looking statements that involve risks and uncertainties. There can be no assurance that such statements will prove to be accurate and actual results and future events could differ materially from those anticipated in such statements. Important factors that could cause actual results to differ materially from the Company’s expectations include the failure to satisfy the conditions of the relevant securities exchange(s) and other risks detailed from time to time in the filings made by the Company with securities regulations. The reader is cautioned that assumptions used in the preparation of any forward-looking information may prove to be incorrect. Events or circumstances may cause actual results to differ materially from those predicted, as a result

of numerous known and unknown risks, uncertainties, and other factors, many of which are beyond the control of the Company. The reader is cautioned not to place undue reliance on any forward-looking information. Such information, although considered reasonable by management at the time of preparation, may prove to be incorrect and actual results may differ materially from those anticipated. Forward-looking statements contained in this news release are expressly qualified by this cautionary statement. The forward-looking statements contained in this news release are made as of the date of this news release and the Company will update or revise publicly any of the included forward-looking statements as expressly required by applicable law.



Source: Algernon Pharmaceuticals