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Algernon Pharmaceuticals Begins Manufacturing of Repirinast and Launches New Chronic Kidney Disease Research Program

VANCOUVER, British Columbia, Feb. 23, 2022 (GLOBE NEWSWIRE) -- Algernon Pharmaceuticals Inc. (the "Company" or "Algernon") (CSE: AGN) (FRANKFURT: AGWO) (OTCQB: AGNPF) a clinical stage pharmaceutical development company is pleased to announce that it has awarded a contract to Zhejiang Ausun Pharmaceutical CO, LTD of China to begin the manufacturing of a cGMP supply of its repurposed drug candidate NP-251 ("Repirinast") and has initiated a new chronic kidney disease ("CKD") research program.

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.

Repirinast was approved in Japan for patients with bronchial asthma in 1987, to prevent attacks when administered regularly. A pediatric formulation was also approved in 1990. Unlike most allergy medications, Repirinast does not have a direct antihistaminic effect. The drug acts on mast cells and inhibits the release of chemical mediators by IgE-related antigen antibody interactions.

Repirinast is one of several repurposed drug candidates that were part of Algernon's acquisition of NASH Pharmaceuticals Inc. ("NASH") on October 22, 2018.

Repirinast, in a unilateral ureteral obstruction (UUO) mouse model of kidney fibrosis conducted by NASH, reduced fibrosis by 50% with statistical significance. It also showed a modest, but significant, synergistic improvement in combination with telmisartan, which is a blood pressure lowering medication and is considered a front line standard of care treatment for CKD. As part of the new CKD research program, the Company will also investigate the use of Repirinast in acute interstitial nephritis.

"Current treatment of CKD usually consists of measures to help control signs and symptoms, reduce complications, and slow progression of the disease, but there is no cure and new treatment options are needed," said Christopher J. Moreau, CEO of Algernon. "The pre-clinical data is showing that Repirinast may represent a promising new potential therapy and we look forward to advancing it as quickly as possible into human trials."

Preclinical Data

Data from the 2019 UUO study demonstrated that clinically relevant doses resulted in statistically significant improvements in the reduction in fibrosis as measured by Sirius Red

staining over untreated controls:

- Telmisartan (3 mg/kg), a positive control, reduced fibrosis by 32.6% ($p<0.001$)
- Cenicriviroc (40 mg/kg) a CCR2/5 chemokine receptor antagonist with reported anti-fibrotic activity, reduced fibrosis by 31.9% ($p=0.00032$).
- Repirinast (90 mg/kg) reduced fibrosis by 50.6% ($p<0.000001$).
- Repirinast (30 mg/kg) reduced fibrosis by 20.8% ($p>0.05$).
- The combination of Repirinast (30 mg/kg) and telmisartan (3 mg/kg) reduced fibrosis by 54.2% ($p<0.000001$). In addition, the mass of the fibrotic kidney was lower than the negative control ($p<0.001$).

About Chronic Kidney Disease ("CKD")

CKD is a condition in which the kidneys are damaged or cannot filter blood as well as healthy kidneys, often because of fibrosis. As a result, excess fluid and waste from the blood remain in the body and may cause other health problems.

While there is no known cure, kidney disease complications can be controlled to make patients more comfortable. Treatments are focussed on managing symptoms and complications that include high blood pressure, swelling and anemia.

The global market for CKD drugs continues to grow at a significant pace, driven by the increasing number of CKD patients and the growing need for novel treatments to improve patients' quality of life. The global CKD drug market stood at US$11.5 Billion in 2015. Growing at a CAGR of 3.60% between 2016 and 2024, the market's opportunity is expected to reach US$15.8 Billion by the end of 2024.

Manufacturing

Since Mitsubishi was the single supply source of cGMP Repirinast and has since discontinued its manufacturing, Algernon has retained Zhejiang Ausun Pharmaceutical CO, LTD located in Zhejiang China, to begin manufacture of a cGMP supply. The Company believes the manufacturing will be completed in approximately five months.

Algernon's Clinical Research Plan

The Company is in the early planning stages of its clinical research program and is considering the option of conducting its initial trial in Australia. Research conducted in Australia would be reimbursed under the Australian Scientific Research Tax Credit Program at a rate of 43.5%.

The Company has retained its Asia Pacific CRO partner Novotech to conduct a feasibility study for the Company's Repirinast CKD clinical research plan.

The Company is also planning to conduct trials in the U.S. and will accordingly file a pre-IND application with the U.S. Food and Drug administration.

Since there is no current Repirinast finished product to use as a comparator for Algernon's planned new cGMP supply, the Company will conduct a bridging sub-acute toxicology study when the Repirinast cGMP synthesis is completed. The sub-acute toxicology study is expected to take approximately 90 days.

Additionally, the Company is planning to conduct a small Phase 1 study in Q4, 2022, to determine the bioavailability of its newly planned Repirinast finished product.

Algernon CKD Program Lead Consultant

Dr. Chirag Parikh, MD, PhD, FACP

Dr. Parikh is the Director, Division of Nephrology and Professor of Medicine at Johns Hopkins University. He is board-certified in both Nephrology and Internal Medicine. He conducts an active patient-oriented research program investigating the translational and epidemiological aspects of acute kidney injury (AKI) and other kidney related disorders.

Dr. Parikh has authored more than 250 peer-reviewed papers, 50 book chapters and reviews, and he has given more than 50 invited lectures at scientific meetings and academic institutions around the world. He has received several awards, including the National Junior Physician Investigator Award from the American Federation of Medical Research and the Outstanding Investigator Award from the Society of Clinical Investigation.

CRO's

In addition to Novotech, Algernon has also retained CRO Clinical Development Solutions to support all aspects of the investigational brochure, study protocol and Pre-IND and IND applications and will provide high-level oversight and management of all clinical trials.

Intellectual Property

Algernon's patent applications for Repirinast include the treatment of CKD as well as dosing and in combination with several cholesterol-lowering or antihypertensive drugs.

About Algernon Pharmaceuticals Inc.

Algernon is a drug re-purposing company that investigates safe, already approved drugs, including naturally occurring compounds, for new disease applications, moving them efficiently and safely into new human trials, developing new formulations and seeking new regulatory approvals in global markets. Algernon specifically investigates compounds that have never been approved in the U.S. or Europe to avoid off label prescription writing.

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