

November 25, 2019



Algernon Pharmaceuticals Provides Update on its Planned Phase II Clinical Trial

VANCOUVER, B.C., Nov. 25, 2019 (GLOBE NEWSWIRE) -- Algernon Pharmaceuticals Inc. (CSE: AGN) (FRANKFURT: AGW) (OTCB: BTHCF) (the “**Company**” or “**Algernon**”), a clinical stage pharmaceutical development company, is pleased to provide an update to the market on its planned phase II clinical trial and its additional plans for 2020.

Algernon Business Model Overview

The Company is focused on developing repurposed therapeutic drugs. Drug repurposing (also known as re-profiling, re-tasking or therapeutic switching) is the application of approved drugs and compounds to treat a different disease than what they were originally developed for. The Company’s objective is to minimize costs and drug development risk by taking advantage of drugs with regulatory approval in other jurisdictions and discovering alternative clinical uses.

The drug candidates identified by the Company as having potential to treat other diseases were initially screened in globally accepted *in vivo* animal models in four new disease areas including non-alcoholic steatohepatitis (NASH), chronic kidney disease (CKD), inflammatory bowel disease (IBD), and idiopathic pulmonary fibrosis (IPF). The lead compounds being advanced by the Company have all performed equal to or better than the positive controls used in the Company’s pre-clinical research studies.

The Company plans to advance its lead drug candidates by accelerating them directly into off-label phase II clinical trials (humans) in the country where the drug is currently approved, or in Australia, where a process that allows for the importing of drugs for human trials has been well established. Once a signal is established in a human trial, the Company will focus on the development of the repurposed drug towards obtaining U.S. Food and Drug Administration (FDA) marketing authorization.

Algernon has filed new method of use patents for each of its lead compounds and where Algernon deemed it necessary, the Company has additionally filed new composition of matter patents based on Markush structure patents (derivatives).

Recent Financing

On November 1st, 2019, the Company announced the closing of its marketed short form prospectus offering, which raised gross proceeds of approximately CDN\$2.1M.

Phase II Clinical Trial

With the recent financing completed, the Company has acquired the capital resources

required to launch its first phase II clinical trial using one of its lead drug compounds in one of its four identified key disease areas being NASH, CKD, IBD and IPF. The Company is in the final planning stages for the phase II trial with a targeted start date in Q2, 2020 and will update the market shortly on the following information:

1. The disease area being studied, the name of the lead compound that will be used in the planned phase II trial and the final clinical trial protocol.
2. The name of the contract research organization (CRO) chosen to conduct the phase II trial as well as the study location and the name of the principal investigator.
3. The Company's decision to either synthesize the lead compound or source finished product currently available.
4. Ethics approval of the phase II study.
5. First patient enrolled and projected end of phase II study date.
6. New additions to the Company's Medical Advisory Board.

NP-120 Ifenprodil Research

Out of all of the lead compounds being advanced by the Company, NP-120 (Ifenprodil) is the most studied. NP-120 (Ifenprodil) is an N-methyl-d-aspartate (NMDA) receptor glutamate receptor antagonist specifically targeting the NMDA-type subunit 2B (Glu2NB). NP-120 (Ifenprodil) also exhibits agonist activity for the Sigma-1 receptor, a chaperone protein up-regulated during endoplasmic reticulum stress.

The Company is currently conducting additional mechanism of action (MOA) research to identify biomarkers for NP-120 (Ifenprodil) that will provide additional data on the drug and will be included in the phase II study design in the event that the Company chooses to conduct an IPF phase II trial.

Orphan Designation & U.S. FDA Regulatory Process

If the Company decides to advance NP-120 (Ifenprodil) for an IPF phase II clinical study, the Company will apply for orphan drug designation with the U.S. FDA. Further, if the Company synthesizes NP-120 (Ifenprodil) instead of sourcing the drug that is available on the market in Japan, the Company may be able to use the data generated from its planned phase II trial as part of a future U.S. FDA New Drug Application (NDA). The Company will also request a pre-IND meeting with the U.S. FDA, which may help advance the regulatory approval process in the U.S. more quickly.

LD Micro Conference

The Company will be presenting at the 12th Annual LD Micro Main Event Conference which will be held on December 10th-12th, 2019 at the Luxe Sunset Hotel in Los Angeles, CA. There will be 275 companies presenting to over 1,500 attendees. LD Micro was founded in 2006 with the sole purpose of being an independent resource in the microcap space. In 2015, LD Micro launched ldmicro.com as a portal to provide exclusive intraday information on the entire sector, including the first pure micro-cap index (LDMi) which covers stocks in North America with market capitalizations between \$50 million to \$300 million.

Breathalyzer

The Company has recently terminated its research agreement with the University of Florida due to slower than expected progress on the development of a working prototype device. As a result of limited capital for ongoing research and based on the potential of its lead drug development candidates, the company has now suspended any further research on the breathalyzer device.

About Algernon Pharmaceuticals Inc.

Algernon Pharmaceuticals is a clinical stage pharmaceutical development company focused on advancing its lead compounds for non-alcoholic steatohepatitis (NASH), chronic kidney disease (CKD), inflammatory bowel disease (IBD) and idiopathic pulmonary fibrosis (IPF).

CONTACT INFORMATION

Christopher J. Moreau

CEO

Algernon Pharmaceuticals Inc.

604.398.4175 ext 701

info@algernonpharmaceuticals.com

investors@algernonpharmaceuticals.com

www.algernonpharmaceuticals.com

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Source: Algernon Pharmaceuticals