

Algernon Pharmaceuticals Announces Russian Athletic Performance Enhancing Drugs Bemethyl (NP-135) and Bromantane (NP-160) Exhibited Potent Anti-Fibrotic Activity in NASH and CKD Studies

VANCOUVER, British Columbia, July 31, 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 report that its lead drugs for non-alcoholic steatohepatitis (NASH) and chronic kidney disease (CKD) are **Bemethyl (NP-135)** and **Bromantane (NP-160)**. They are representative of a class of drugs called “actoprotectors” developed during the Soviet Union era to improve performance of their military, cosmonauts and national athletes under extreme physical conditions.

The Company confirmed, in multiple animal studies conducted by independent laboratories, that NP-135 (Bemethyl) and NP-160 (Bromantane), exhibited highly statistically significant anti-fibrotic activity in both NASH and CKD disease models and out performed known anti-fibrotic agents Telmisartan and Cenicriviroc.

“We are currently planning off-label phase II clinical trials for both drugs and pending the data, the company will begin the process for regulatory approval with the USFDA,” said Christopher J. Moreau, CEO of Algernon. “We also intend to publish our data in a peer-reviewed journal shortly. It is intriguing to think that drugs developed by the Soviet Union during the cold war could end up being viable treatment options for both NASH & CKD on a global scale.”

About NP-135 (Bemethyl)

NP-135 (Bemethyl: 2-(Ethylthio) benzimidazole) is a drug developed in the USSR in the 1970s, and after initial tests on Soviet cosmonauts and soldiers in extreme conditions (fatigue, high altitude) the drug was used to improve athletic performance, including preparing the USSR national team for the Olympic Games. NP-135 (Bemethyl) remains registered as a drug in only three countries: Ukraine, Republic of Moldova, and Georgia (commercial names: Bemetil, Metaprot, and Bemaktor). Owing to its activity, the World Anti-Doping Agency (WADA) included NP-135 (Bemethyl) in its 2018 monitoring program.

About NP-160 (Bromantane)

NP-160 (Bromantane: N-2-adamantil-N-(para-bromophenyl-amine) was also developed in the Soviet Union in the 1980s and has been manufactured in Russia (commercial name:

Ladasten) since 1997. Most recently the drug was manufactured by Pharmstandard, a large Russian domestic pharmaceutical company, until the end of 2018. Similar to NP-135 (Bemethyl), NP-160 (Bromantane), also improved performance under extreme conditions and was later repurposed as a more general treatment for neurasthenia. The drug is currently on the WADA list of banned substances.

NASH Study Data Summary

- **NP-135 (Bemethyl)** (200 mg/kg, QD) showed a 1.1 point drop in the NAFLD/NAS score vs controls ($p>0.05$) **and a 84.4% reduction ($p<0.0001$) in fibrosis area.**
- **NP-160 (Bromantane)** (40 mg/kg, QD) showed a 1.25 point drop in the NAFLD/NAS score vs controls ($p<0.05$) **and a 59.9% reduction ($p<0.0001$) in fibrosis area.**
- Cenicriviroc (40 mg/kg, QD) both a positive control and comparator arm in the study showed a 1.5 point drop in the NAFLD/NAS score vs controls ($p<0.01$) and 54.1% ($p<0.0001$) reduction in fibrosis area. (Cenicriviroc is a repositioned anti-HIV compound that was acquired by Allergan from Tobira for a deal value of up to US\$1.7B.)

CKD Study Data Summary

- **NP-135 (Bemethyl)** (200 mg/kg, QD) reduced fibrosis **by 52.1% ($p<0.000001$)**
- **NP-160 (Bromantane)** (40 mg/kg, QD) reduced fibrosis **by 57.6% ($p<0.000001$)**
- Telmisartan, a positive control in the study and a current standard of care for CKD, reduced fibrosis by 42.2% ($p=0.004$)

While the Company has not determined the exact mechanism of action, it may involve the ability of the drugs to improve physical performance under low oxygen conditions such as hypoxia, which is a known major contributor to fibrosis.

Algernon has filed several patent applications protecting their intellectual property rights with respect to both NP-135 (Bemethyl) and NP-160 (Bromantane).

About Algernon

The Algernon business model is to repurpose safe, approved generic drugs that are not available in the US or Europe, screen them in globally accepted animal models for new diseases, file new intellectual property rights and then move them into an off label phase II trial in the country where they are currently approved. Once a signal is established in a human trial, the company will begin to advance the drug through a USFDA registration.

The Company is preparing multiple compounds for phase II trials for the disease areas of non-alcoholic steatohepatitis (NASH), inflammatory bowel disease (IBD), chronic kidney disease (CKD) and idiopathic pulmonary fibrosis (IPF).

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Source: Algernon Pharmaceuticals