PRESS RELEASE
PledPharma AB
Stockholm, March 28, 2018

PledPharma receives European approval of the composition of matter patent for PledOx® and Aladote®

PledPharma AB has received an approval* letter from European Patent Office (EPO) regarding composition of matter patent for the active ingredient in PledOx® and Aladote®.

The decision from EPO is based on PledPharma's application for calmangafodipir with the title "Calmangafodipir, a New Chemical Entity, and Other Mixed Metal Complexes, Methods of Preparation, Compositions, and Methods of Treatment". The expiry date for the patent is December, 2032.

"An approval of a composition of matter patent for PledOx® and Aladote® gives us a strong intellectual property protection in Europe and is of a great value for PledPharma. This composition of matter patent is central in our deep and strong intellectual property portfolio", said Nicklas Westerholm, CEO, PledPharma.

The composition of matter patent has previously been approved in the US, Japan, China and Russia with December, 2032 as the expiry date.

At the beginning of March, 2018, PledPharma did receive an EPO approval for an additional patent (which covers the use of pharmaceuticals in combination with manganese and non-manganese containing PLED-complexes to minimize the risk for accumulation of manganese in the brain), embodies both PledOx® and Aladote®. The patent is entitled "Pharmaceutical Compositions and Therapeutic Methods Employing a Combination of a Manganese Complex Compound and a Non-Manganese Complex Form of the Compound" and expires in 2030.

**Pending patentfee registration*

PledPharma

Overview, patent portfolio

Patent	Expiry	Country									
		AU	CA	CN	EU	IL	JP	KR	MX	RU	US	ZA
1. Compounds for use in the treatment of cancer	2028	✓	●	✓	✓	✓	✓	✓	●	✓	✓	●
2. Pharmaceutical composition and therapeutic methods employing a combination of a manganese complex compound a non-manganese complexed form of the compound	2030	✓	✓	●	✓	✓	✓	●	✓	✓	●	✓
3. Calmangafodipir, a new chemical entity, and other mixed metal complexes, methods of preparation, composition, and methods of treatments	2032	●	●	✓	✓	●	✓	●	●	✓	✓	●
4. Cancer treatment methods	2033	●	●	●	●	●	●	●	●	●	●	●
5. Methods and formulations for treatment of acute liver failure and other hepatotoxic conditions	2037	●	●	●	●	●	●	●	●	●	●	●
Trademarks												
PledOx®		✓		✓	✓		✓			✓	✓	
Aladote®				✓	✓					✓	✓	

Country codes
AU: Australia, **CA:** Canada, **CN:** China, **EU:** Germany, France, UK, Italy, Spain, Sweden, **IL:** Israel, **JP:** Japan, **KR:** South Korea, **MX:** Mexico, **RU:** Russia, **US:** USA, **ZA:** South Africa

✓ Approved
● Application published

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About PledOx®

PledOx® is a "first in class" drug candidate developed to provide patients, that are treated adjuvantly or for metastatic colorectal cancer, prevention against the nerve damage that can occur in conjunction with chemotherapy treatment. The results from a completed Phase IIb trial (PLIANT), where patients with metastatic colorectal cancer were treated with the chemotherapy combination FOLFOX and PledOx®, indicates that the patients who received PledOx® had a lower risk than the placebo group to suffer from nerve damage during the chemotherapy. The presence of the investigator reported sensory nerve damage, the primary endpoint, was after treatment 38% lower in the group of patients treated with PledOx® compared with the placebo group ($p = 0.16$). This was not statistically significant, but a difference of this magnitude is considered to be clinically relevant. After completion of chemotherapy, the patient-reported incidence of moderate and severe neuropathy was 77% lower in patients treated with PledOx® compared to the placebo group (exploratory analysis; $p = 0.014$). This is considered valuable for the success of the forthcoming POLAR studies, where patient-reported symptoms after completion of treatment will be the primary efficacy parameter. No apparent negative effect on the efficacy of the cancer treatment was observed.

About chemotherapy induced peripheral neuropathy (CIPN)

Peripheral neuropathy symptoms are caused by damages to sensory nerves, most commonly in hands and feet. Certain chemotherapies, including oxaliplatin, can cause such damages, which is then called chemotherapy induced peripheral neuropathy (CIPN). This can be a debilitating adverse reaction of the cancer treatment and may occur at any time after the initiation of chemotherapy. The symptoms often increase as the chemotherapy treatment continues and may often causes discontinuation of the chemotherapy. In many patients, the symptoms are resolved after discontinuing the chemotherapy, but up to 20-30% of the patients have sustained symptoms such as numbness, tingling and pain in hands and feet. Patients with CIPN may have difficulties with fine motor skill, such as buttoning buttons, challenges using a computer key board and become hypersensitive to cold. The sensory loss in the feet's may increase the risk of falls. There is currently no approved drug to prevent or treat CIPN.

About PledPharma

PledPharma develops new drugs that protect the body against oxidative stress – a potentially debilitating and sometimes life-threatening condition that can be caused by chemotherapy treatment and following acetaminophen (paracetamol) overdose. The company's most advanced project PledOx® is being developed to reduce nerve damage associated with chemotherapy. A phase IIb study has been conducted and will serve as the basis for the continued development. The drug candidate Aladote® is being developed to reduce the risk of acute liver failure associated with acetaminophen poisoning. PledPharma (STO: PLED) is listed on Nasdaq First North. Erik Penser Bank is the company's Certified Adviser (tel +46 8 463 80 00). For more information, see http://www.pledpharma.se/