BioPortfolio

PCI Biotech: Publication of the fimaporfin (Amphinex) first-in-man Phase I study in Lancet Oncology

Oslo, 28 July 2016 - PCI Biotech (PCIB) a cancer focused Norwegian biopharmaceutical company, reported today that the first-in-man Phase I study with PCI Biotech's proprietary drug fimaporfin (AmphinexTM) performed at University College Hospital in London in patients with various advanced solid tumours has been published in Lancet Oncology, the premier publication worldwide for original clinical trials research in oncology. The article has the title "Disulfonated tetraphenyl chlorin (TPCS2a)-induced photochemical internalization of bleomycin in patients with solid malignancies: A first-in-man phase I dose escalation clinical trial".

Principal Investigator, Dr. Colin Hopper commented: "The promising tumour responses seen in this heavily pre-treated, difficult to treat patient population with different advanced solid tumours clearly signifies the broad potential of the PCI treatment. The acceptance of this study for publication in this prestigious journal shows the quality of this work, and is an indication of the need for new treatment approaches and the interest in the PCI-application."

CEO Per Walday commented: We are very pleased to have this first clinical validation of the fimaCHEM treatment approach published in this prestigious clinical cancer journal. This publication underscores our belief that the fimaCHEM technology has a role in the treatment of cancer indications with unmet local treatment needs."

In this clinical phase I study PCI Biotech's proprietary photosensitiser fimaporfin was given at escalating doses in combination with the cytotoxic drug bleomycin to 22 patients with advanced and recurrent cancer. The treatment was found safe and tolerable, and significant anti-tumour effect were seen at all dose levels in this patient population with aggressive cutaneous and sub-cutaneous tumours.

About PCI Biotech PCI Biotech is a cancer focused biopharmaceutical company headquartered in Norway and listed on the Oslo Stock Exchange (Axess). The company is developing therapeutic products based on

its proprietary photochemical internalisation (PCI) technology. The PCI technology works by inducing triggered endosomal release and may be used to unlock the true potential of a wide array of therapeutic modalities, such as small molecules, vaccines and nucleic acids.

The company has a clinical Phase I/II program in bile duct cancer, which is an orphan indication without approved medicinal products and a high need for better local treatments. The indication is well suited for PCI treatment, with easy light access through routine endoscopic methods and an active generic drug (gemcitabine) significantly enhanced by PCI.Â

The company is also developing PCI as a vaccination technology. When applied in the emerging field of cancer immunotherapy, PCI can be used to enhance the important cytotoxic effect of therapeutic cancer vaccines.

The PCI technology is also very well suited for intracellular delivery of nucleic acids, such as RNA therapeutics. By releasing nucleic acid compounds from endosomes where they are trapped following administration, PCI addresses one of the major bottlenecks facing this emerging and exciting field.

For more information visit: www.pcibiotech.com

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