PCI Biotech and eTheRNA immunotherapies initiate research collaboration

Exploring synergies between PCI and TriMix technologies to further enhance the effect of novel oncologic therapies

Oslo (Norway) and Niel (Belgium), 8 December 2016 —PCI Biotech (OSE: PCIB), a cancer focused biopharmaceutical company, and eTheRNA immunotherapies NV, a VUB spin-off company backed by strong life science investors to continue the development of mRNA-based immunotherapies, today announced that they are initiating a preclinical research collaboration.

The partnership is governed by a preclinical research collaboration agreement. In brief, the collaborators will evaluate technology compatibility and synergy based on *in vivo* studies. The companies will evaluate results achieved from this research collaboration and then explore the potential for a further partnership.

Per Walday, CEO of PCI Biotech, said: "I'm very pleased to announce another research agreement in the field of nucleic acid therapeutics. We believe that the PCI technology has the potential to play a role in the realisation of several new therapeutic modalities. We look forward to explore synergies with eTheRNA' s unique and innovative mRNA based TriMix technology. "

Dirk Reyn, CEO of eTheRNA immunotherapies, commented: "Encouraged by the impressive phase I/IIa study results with our *ex vivo/*cell version of our TriMix technology, we are focusing on the off-the shelf variant that can be applied intranodally, intradermally or by direct injection in the tumour and that represent a more convenient and cost effective product. While we are now about to initiate our second clinical trial with this *in vivo* formulation of TriMix, we continue to evaluate new technologies that may further enhance the efficacy of this mode of application. We are very pleased about the potential of the PCI platform and the opportunities of this research agreement."

About PCI Biotech

PCI Biotech is a biopharmaceutical company focusing on development and commercialisation of novel therapies for the treatment of cancer through its innovative photochemical internalisation (PCI) technology platform. PCI is applied to three distinct anticancer paradigms: **fima*CHEM*** (enhancement of chemotherapeutics for localised treatment of cancer), **fima*VACC*** (T-cell induction technology for therapeutic vaccination), and **fima*NAc*** (nucleic acid therapeutics delivery).

Photochemical internalisation induces triggered endosomal release that is used to unlock the true potential of a wide array of therapeutic modalities. The company's lead **fima*CHEM*** programme consists

of a clinical Phase I/II clinical study in bile duct cancer, an orphan indication with a high unmet need and without approved products. **fima*VAcc*** applies a unique mode of action to enhance the essential cytotoxic effect of therapeutic cancer vaccines, which works in synergy with several other state-of-the-art vaccination technologies. **fima*NAc*** utilises the endosomal release to provide intracellular delivery of nucleic acids, such as mRNA and siRNA therapeutics, thereby addressing one of the major bottlenecks facing this emerging and promising field.

About eTheRNA immunotherapies

Founded in January 2013 as a spin-off of the VUB Laboratory for Molecular and Cellular Therapy (LMCT) headed by Prof K. Thielemans, *eTheRNA immunotherapies* (Belgium) is a ground-breaking global pioneer in the development of mRNA-based immunotherapies for different cancers and certain infectious diseases. *eTheRNA* is focusing on therapies that prepare and activate the immune system by programming dendritic cells (DC) with synthetic mRNA. For this purpose, eTheRNA continues to develop its proprietary TriMix platform comprising three mRNA molecules that jointly have a boost effect on the activation and maturation of dendritic cells, leading to potent population of both helper T-cells and cytotoxic T-cells.

Encouraged by the impressive complete response rate (>20%) of the combination therapy including TriMix-DC (the *ex-vivo* autologous version) and ipilimumab in patients with pre-treated advanced melanoma *(Neyns et al, 2016 - Journal Clinical Oncology),* the company is committed to establish its TriMix technology as the gold standard in the wider area of onco-immunotherapy - both as a monotherapy product in adjuvant settings and in combination with checkpoint inhibitors or other targeted therapies. *eTheRNA* has made significant preclinical progress in developing TriMix not merely as an *ex vivo* product, but also as an *in vivo* formulation that can be made available 'off the shelf'. eTheRNA is initiating phase I/II clinical studies with an *in vivo* injectable TriMix product in melanoma and triple negative breast cancer.

As of 2017, *eTheRNA immunotherapies* will operate a state-of-the-art GMP-approved manufacturing unit which is amongst the top 3 in Europe.

Contact information:

PCI Biotech Holding ASA, Ullernchausséen 64, N-0379 Oslo, Norway. www.pcibiotech.com
Per Walday, CEO, pw@pcibiotech.no, Mobile: +47 917 93 429.

eTheRNA immunotherapies NV, Galileilaan 19, 2845 Niel, Belgium. www.etherna.be
Contact person: Dirk Reyn, CEO, dirk.reyn@etherna.be, Mobile +32 475 96 52 57