APIM Therapeutics AS

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A Novel Intervention Point in Cancer Therapy

As pressure from regulatory authorities for the development of safe, efficacious and cost-effective anti-cancer therapies is constantly building up, a new therapeutic approach by APIM Therapeutics (Trondheim, Norway) shows strong development potential in several cancer indications. Specifically targeting a natural stress defense mechanism controlled by PCNA, a master "hub" protein regulator of cell stress responses, APIM's lead drug ATX-101 is able to potentiate the action of more than 15 marketed chemotherapeutic agents in various preclinical assays. This holds promise for the development of novel combinatorial therapies that would benefit human cancer patients (Gilljam et al, 2009, J Cell Biol 186, 645-654, Müller et al, 2013, PLoS One. 2013 Jul 31;8(7)).

APIM's technology, originally developed by Prof. M. Otterlei and co-workers at the Dpt. of Cancer and Molecular Medicine at the Norwegian University of Science and Technology (NTNU), is broadly applicable to several cancer indications. Among most responsive tumor types, specific blood cancer cells (e.g. multiple myeloma) or solid tumors (e.g. bladder and prostate cancer) are particularly sensitive to ATX-101-based therapies. These properties have triggered significant investor interest having led to the recruitment of four investment groups in the company over the last five years (Sarsia Seed, Birk Venture, Ro Invest and Norsk Innovasjonskapital III).

Currently, APIM focuses its development efforts in Non-Muscle Invasive Bladder Cancer (NMIBC), the 5th most prevalent cancer indication globally. Considered a therapeutically under-served disease (only a handful of generic drugs are approved for this indication) that creates a huge socio-economic burden due to continuous disease recurrence and increasing costs of diagnosis & treatment, NMIBC offers an early therapeutic entry point in human patients for ATX-101. Delivered locally via intravesical instillation in combination with Mitomycin-C, the preferred chemotherapeutic agent used for this indication, APIM hopes to establish safety and efficacy of ATX-101 in a pivotal phase I/II clinical study to be initiated in 2015. If successful, the company expects to attract significant corporate and investor interest that will allow further development of ATX-101 for this indication.

Independent of its local delivery approach pursued in NMIBC as a means to achieve early proof-of-concept, APIM's drugs hold significant clinical potential in systemic anti-cancer treatment. For example, a single intravenous injection of ATX-101 suffices to potentiate the anti-cancer effect of cisplatin in animal models of Muscle Invasive Bladder Cancer (MIBC). This property, coupled with chemotherapy potentiation effects observed with a constantly increasing list of drugs, clearly support a "platform" development potential for ATX-101 that could be exploited further in a series of systemic indications including MIBC.

APIM's immediate development plans include execution of regulatory toxicology & safety assays leading to a successful Clinical Trial Application (CTA) in early 2015. The company is hoping to achieve clinical status by dosing its first NMIBC patient in Scandinavia by mid-2015.