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DEFENCE'S LUNG CANCER GLP TOX STUDY ON ITS INTRANASAL ACCUTOX™ FORMULATION ADVANCES

Vancouver, BC, Canada, January 31st, 2023 - Defence Therapeutics Inc. ("Defence" or the "Company"), a Canadian biopharmaceutical company specialized in the development of immunology vaccines and drug delivery technologies is pleased to announce the start of its GLP studies on a new intranasal AccuTOX™ formulation. This milestone is crucial to initiate a Phase I trial for this drug in the context of lung cancer.

AccuTOX™: the past, the present and the future.

The AccuTOX™ molecule can eradicate cancer cells via different mechanisms including the initiation of immunogenic cells death, endoplasmic reticulum stress and by causing direct damages to DNA. When tested in three different animal models of solid tumors (lymphoma, melanoma and breast), the compound-controlled tumor growth and synergized with different commercially-used immune-checkpoints (anti-PD-1, anti-CTLA4 and anti-CD47). Building upon this success, Defence designed a new non-invasive formulation allowing the drug to be delivered intranasally to reach lung-established tumors. Lung cancer is the deadliest cancer worldwide, accounting for 1.79 million deaths in 2020.

<https://www.statista.com/statistics/288580/number-of-cancer-deaths-worldwide-by-type/#:~:text=Lung%20cancer%20is%20the%20deadliest,by%20stomach%20and%20liver%20cancer.>

"Although most of our efficacy studies delivered AccuTOX™ directly into solid tumors, our objective was to find new ways to target other deadly and difficult to treat ailments such as lung cancer" says Dr. Rafei, the VP research and development of Defence.

For that purpose, a series of maximum tolerated dose (MTD) studies were conducted to identify the best regimen for intranasal AccuTOX™ delivery. These studies showed that AccuTOX™ is well tolerated up to 3 mg/kg (5-6 times lower than the injectable dose) and could be delivered up to 6 times over a period of 2 weeks. The translation of this dosing regimen to mice with lung cancer decreased by over 50% the number of cancer nodules when delivered as a combo with the anti-PD1 immune-checkpoint inhibitor. The next step is now to test the safety and the tolerability of the intranasal Defence's AccuTOX™ formulation in a series of GLP tox studies prior to its therapeutic use on patients in clinical trial.

Next step: GLP studies

Defence signed a service agreement with Adgyl Life Sciences, a leading Good Laboratory Practice Drug Development and Toxicology Contract Research Organization, to test its intranasal AccuTOX™ formulation using a medical spray device. The studies will be conducted in both rats and dogs. More specifically, Defence intends to: **i)** assess the eye irritation potential of AccuTOX™ using reconstructed human cornea-like epithelium, **ii)** evaluate the skin corrosion potential of AccuTOX™, **iii)** determine the plasma PK and bioavailability of AccuTOX™ following a single dose intranasal administration in rats and dogs, **iv)** determine the toxicity potential and kinetics of AccuTOX™ when administered on alternate days for 7 days (Days 1, 3, 5 and 7) as intranasal drops or intranasal spray (using a spray device) in rats and dogs, and finally **v)** evaluate multiple parameters such as food consumption, body weight, hematological parameters and histopathology in rats and dogs.

"The completion of these GLP tox studies in parallel to the initiation of a Phase I trial on AccuTOX™ as an injectable for solid tumors will allow Defence to achieve important inflection points with major milestones to be accomplished in 2023. By demonstrating great safety and tolerability profiles using both AccuTOX™ formulation (injectable and intranasal), Defence is poised to become a leading biotech in the field of immuno-oncology and cancer therapeutics with a lead compound possessing a wide scope of therapeutic applications", says Mr. Plouffe, the CEO of Defence Therapeutics.

The global lung cancer therapeutics market size was estimated at USD 27.57 billion in 2021 and it is expected to surpass around USD 55.6 billion by 2030 with a registered CAGR of 8.11% from 2022 to 2030 according to Precedence Research.

<https://www.precedenceresearch.com/lung-cancer-therapeutics-market>

About Defence:

Defence Therapeutics is a publicly-traded biotechnology company working on engineering the next generation vaccines and ADC products using its proprietary platform. The core of Defence Therapeutics platform is the ACCUM™ technology, which enables precision delivery of vaccine antigens or ADCs in their intact form to target cells. As a result, increased efficacy and potency can be reached against catastrophic illness such as cancer and infectious diseases.

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