Defence's Successful Submission of an Investigational New Drug (IND) Application for AccuTOX(R) as an Injectable Anticancer Treatment for Solid Tumors

Vancouver, British Columbia--(Newsfile Corp. - November 14, 2023) - Defence Therapeutics Inc. (CSE: DTC) (OTC Pink: DTCFF) (FSE: DTC) ("**Defence**" or the "**Company**"), one of the leading Canadian biotechnology companies working in the field of immune-oncology is pleased to announce that it has successfully submitted on November 9, 2023 an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) for its ACCUM-002™ Dimer CDCA-SV40 commonly named "AccuTOX®", an injectable anticancer molecule, for the treatment of solid cancer tumors.

AccuTOX® is a derivative of the initial Accum® molecule, which has been reported to target cancer on multiple fronts. AccuTOX® disrupts endosomal membranes resulting in impaired intracellular transport mechanisms. AccuTOX® also triggers genotoxic effects, blocks DNA repair mechanisms normally used by cancer cells to repair its damaged genome and induces a form of immunogenic cell death capable of turning "ON" the immune system. When previously tested in preclinical animal models under the supervision of Dr. Moutih Rafei, AccuTOX® impaired tumor growth resulting in "70-100% survival" of animals with solid T-cell lymphoma, melanoma or breast cancer.

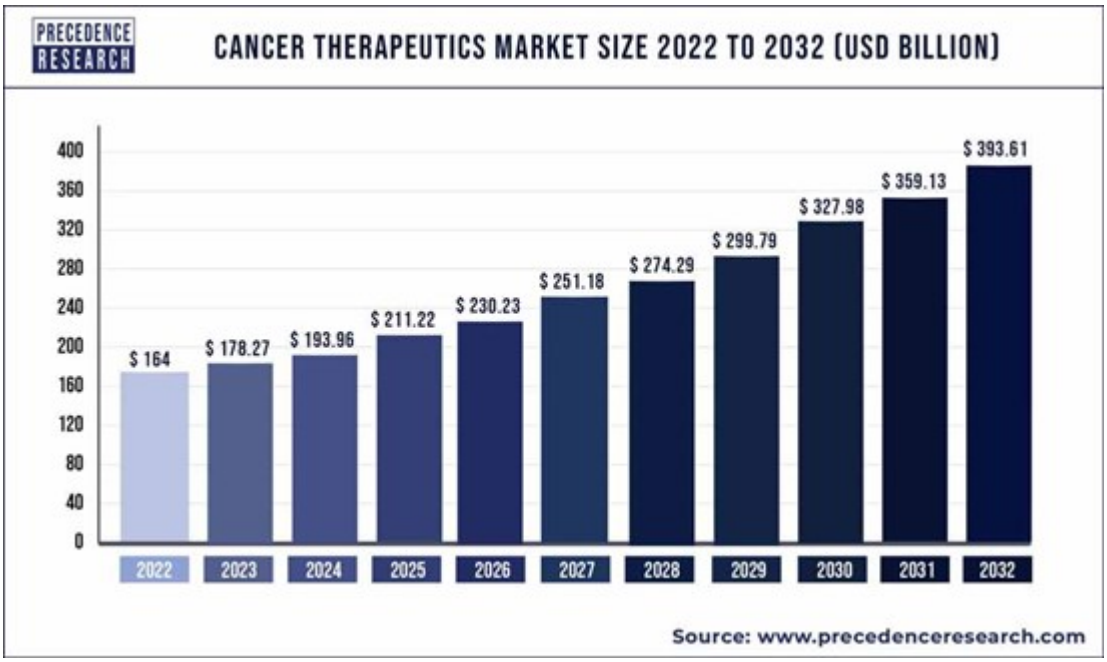
The IND application includes data, reports and overview summaries of numerous studies to evaluate the pharmacology, pharmacokinetics, and toxicology of AccuTOX® both *in vitro* and *in vivo*, including cancer models. In addition, the application describes the manufacture of the drug substance and drug product to be used in human clinical trials. The main purpose of the IND is to share with the FDA the extensive non-clinical data supporting an acceptable safety profile when AccuTOX® will be first administered to humans. The FDA will review the application and determine the acceptability of the data before Defence begins the Phase I clinical trial, which could be as early as Q1-Q2 2024.

"We are thrilled and excited that Defence has achieved a successful submission on its first IND, which represents an important milestone towards advancing AccuTOX® into the clinic. We look forward to work with clinical investigators at City of Hope to study this important and novel candidate for the treatment of melanoma and potentially other solid tumors," said Sébastien Plouffe, President & CEO of Defence Therapeutics. "With the continued difficulties encountered in the oncology clinic, we believe that the therapeutic use of AccuTOX® provides a novel and powerful approach to combat cancer," he added.

The primary objective of this upcoming Phase I clinical trial, when approved, is to identify the best therapeutic dosing range that would allow clinicians to co-administer the AccuTOX® compound with Opdulag®, a BMS product containing both anti-LAG3 and anti-PD-1. Several other secondary parameters including therapeutic efficacy will be monitored in treated patients in preparation for a Phase IIa trial on a basket of tumors.

According to Precedence Research, the global cancer therapeutics market size is expected to be worth around US$ 393.61 billion by 2032 from at US$ 164 billion in 2022, growing at a CAGR of 9.20% during the forecast period 2023 to 2032.

https://www.precedenceresearch.com/cancer-therapeutics-market



Cancer Therapeutics Market Size 2022 to 2032 (USD Billion)

To view an enhanced version of this graphic, please visit:
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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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