

# RETRANSMISSION: Defence Receives FDA Approval for Phase I Clinical Trial Targeting Solid Cancer Tumors with AccuTOX(R)

Vancouver, British Columbia--(Newsfile Corp. - December 12, 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 the U.S. FDA issued a "Study May Proceed", this clears its Investigational New Drug (IND) application for a Phase I clinical trial of ACCUM-002™ Dimer CDCA-SV40 commonly named "AccuTOX®", as an injectable anticancer molecule, for the treatment of solid cancer tumors. The approval granted to AccuTOX®, the company's first first-in-class therapy, marks another key advancement for Defence in the immune-oncology field.

The successful filing and safety review by the U.S. FDA of our protocol entitled "Phase 1 trial of ACCUM-002™ administered intratumorally as monotherapy and in combination with Opdualag (fixed IV doses), in patients with unresectable, stage IIIB to IV melanoma refractory to or relapse from standard therapy" marks a significant milestone for the company's strategy featuring diverse pipelines. Alongside its cancer vaccine-related therapies, AccuTOX® will become Defence's flagship asset in the anti-cancer therapeutics field. Defence remains committed to its mission of addressing unmet clinical needs and in pursuing its goals to become a global leader in the development of innovation anti-cancer therapies.

## **About AccuTOX®**

AccuTOX® is a derivative of the initial Accum® backbone molecule. It was initially designed to various cellular processes including endosomal membranes to impair intracellular transport mechanisms, triggering genotoxic effects, blocking DNA repair mechanisms, and eliciting immunogenic cell death to stimulate the immune system. The use of AccuTOX® in preclinical animal models with T-cell lymphoma, melanoma or breast cancer, under Dr. Moutih Rafei supervision, Defence's CSO, resulted in impaired tumor growth with 70% of treated animals showing complete responses.

"We are very proud, thrilled, and we look forward to beginning this Phase I trial as its aim is to test one of our leads and most advanced therapeutic candidate for the treatment of solid tumors for the benefits of the cancer patients. Defence is becoming a clinical stage company," said Sébastien Plouffe, President & CEO of Defence Therapeutics.

The primary objective of this upcoming Phase I clinical trial, is to identify the safest dosing range in order to co-administer AccuTOX® 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 II clinical trial on a basket of tumors. More details about the beginning of the Phase I will be announced in the near future.

According to Data Bridge Market Research, the solid tumors market was valued at USD 209.61 billion in 2021 and is expected to reach USD 901.27 billion by 2029, registering a CAGR of 20.0% during the forecast period of 2022 to 2029.

<https://www.databridgemarketresearch.com/reports/global-solid-tumors-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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### **Cautionary Statement Regarding "Forward-Looking" Information**

This release includes certain statements that may be deemed "forward-looking statements". All statements in this release, other than statements of historical facts, that address events or developments that the Company expects to occur, are forward-looking statements. Forward-looking statements are statements that are not historical facts and are generally, but not always, identified by the words "expects", "plans", "anticipates", "believes", "intends", "estimates", "projects", "potential" and similar expressions, or that events or conditions "will", "would", "may", "could" or "should" occur. Although the Company believes the expectations expressed in such forward-looking statements are based on reasonable assumptions, such statements are not guarantees of future performance and actual results may differ materially from those in the forward-looking statements. Factors that could cause the actual results to differ materially from those in forward-looking statements include regulatory actions, market prices, and continued availability of capital and financing, and general economic, market or business conditions. Investors are cautioned that any such statements are not guarantees of future performance and actual results or developments may differ materially from those projected in the forward-looking statements. Forward-looking statements are based on the beliefs, estimates and opinions of the Company's management on the date the statements are made. Except as required by applicable securities laws, the Company undertakes no obligation to update these forward-looking statements in the event that management's beliefs, estimates or opinions, or other factors, should change.

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