

## Immunitor initiates Phase II trial of oral immunotherapy vaccine to treat glioblastoma brain cancer

HONG KONG, HONG KONG, April 23, 2019 /EINPresswire.com/ -- Immunitor China Ltd. (Hong Kong) announces launching immunotherapeutic V-Boost vaccine trial in patients with most common form of brain tumor – glioblastoma multiforme (GBM). The open-label Phase II trial (NCT03916757), which is now recruiting, is expected to enroll at least 20 patients with newly

diagnosed or recurrent glioblastoma who may have undergone surgical removal of their tumor.



We currently have off-theshelf version of allogeneic vaccine, but at the same time we are capable of making individualized, autologous vaccine in as short as one-week time" Aldar Bourinbaiar Glioblastoma multiforme (GBM) is a high-grade glioma and the deadliest astrocytic tumor, composed of variously differentiated neoplastic astrocytes - a subtype of brain cells forming the central nervous system (CNS). Glioblastoma is clinically classified as grade IV astrocytoma and differs from anaplastic astrocytoma (grade III) due to the presence of necrotic tissue and hyperplastic blood vessels. In recent years, glioblastoma became more familiar to the public due to extensively-publicized

association with names of senators Ted Kennedy and John McCain, and Joe Biden's son Beau. The estimated 15,000 people in the USA are diagnosed with glioblastoma annually and have a median survival of 12 to 15 months; less than 5% are alive after five years. Almost every patient with this malignant cancer faces poor survival odds since yearly death rate is the same as the annual incidence.

Finding an effective, but at the same time non-toxic treatment, for brain tumors has been a major challenge. The FDA approved drugs temozolomide, bevacizumab, dinutuximab, lomustine and carmustine wafers have shown modest improvements in progression-free or overall survival, but insignificant percentage of complete remissions. The dozens of drug candidates evaluated in the past decade have failed to improve survival beyond the standard of care. Various immunotherapies and cancer vaccines tested in last few years made no meaningful progress, although research is underway with hope of finding cure.

Immunitor's V-Boost is a stable-at-room-temperature cancer vaccine derived from a pool of patients' own cancer cells circulating in their blood and samples of tumor tissues, which are hydrolyzed and formulated into proprietary oral tablet to be taken once-daily. Tumor antigens are delivered via antigen-presenting cells lining the gut – the largest immune organ in a human body that can play a role like that of dendritic cells. Prior studies have shown V-Boost educated immune cells can pass blood-brain barrier and found to be effective and free of harmful inflammation. It is believed that V-Boost performs better than vaccines based on dendritic cells as these represent only a minor fraction of cells involved in immune regulation.

Over the course of the Phase II trial, participants will receive daily pill of V-Boost in addition to standard of care, which may include surgery, chemotherapy, radiation, or checkpoint inhibitors. The trial's main goal is to evaluate effect on tumor shrinking and assess overall or progression-free survival as secondary endpoints. "The response we see in some patients with brain disorders is very encouraging, it is not limited to GBM only, which equals to global market size

USD <u>1.15 billion</u> by 2024 – representing the tiny proportion of CNS therapeutics worth <u>\$128.9 billion</u>", says Dr Allen Bain, the Director of Vancouver-based Immunitor Inc. "We look forward to outcome of Phase II trial to confirm our preliminary findings. The potential will be substantial since brain cancers are in unmet need category", said Dr. Aldar Bourinbaiar – CEO of Immunitor holding company. "Our V-Boost vaccine has been clinically validated starting some years ago; given familiarity with excellent safety and efficacy of this product in patients with neurodegenerative diseases it will facilitate our effort of seeking approval for tumor cancers. We currently have off-the-shelf version of allogeneic vaccine, but at the same time we are capable of making individualized, autologous vaccine in as short as one-week time", added Dr. Bourinbaiar.

## **About Immunitor**

Immunitor is a commercial stage biopharmaceutical company registered in Hong Kong with subsidiaries in Beijing, Ulaanbaatar, Moscow, Johannesburg, and Vancouver. Immunitor's strength and leading position resides in its affordable oral vaccine's platform validated by multiple clinical trials conducted over last two decades. Immunitor markets 22 oral immunotherapy products addressing major health problems, i.e., in infectious diseases area; a variety of autoimmune and metabolic diseases; and recently in immuno-oncology space. Immunitor has successfully launched advanced trials for hepatocellular carcinoma, cholangiocarcinoma, and pancreatic cancer. Last year, Immunitor started five Phase 2 trials in patients with endometriosis, uterine fibroids, cervical, ovarian, and breast cancer. These and additional immunotherapy studies for other indications are still ongoing.

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