

# NovAccess Global, Inc. Announces Successful Completion of Pre-IND Meeting with FDA

**CLEVELAND, OH / ACCESSWIRE / June 28, 2021 /** NovAccess Global Inc. (OTC PINK:XSNX) announced today that it received a productive response from the U.S. Food and Drug Administration (FDA) on its pre-investigational new drug (IND) meeting request regarding the development plan for Glioblastoma Multiforme (GBM) patients, including the clinical study design and dosing strategy for the initial phase 1/phase 2 protocol.

The FDA recommended conducting an initial Phase I trial to evaluate product feasibility, toxicity and activity arising from NovAccess Global's novel DC maturation procedures, but also provided specific current good manufacturing practice (cGMP) compliance guidance in the case that the Company proposes a Phase II or later stage clinical trial.

"We are excited that we have received positive input from the FDA, which may allow us to shorten our timeline for trials. The FDA tentatively agreed that further animal (toxicology) studies are not needed and generally accepted our enrollment plan, dosing regimen, and adverse event monitoring plan. They provided specific guidance on our data safety monitoring plan, inclusion of surrogate consent, and manufacturing specifics in light of current good manufacturing practice (cGMP) compliance. We will strategically evaluate the FDA's recommendations and guidance as we prepare our IND submission." Dr. Wheeler, President of StemVax Therapeutics, Inc, a NovAcess Global Company. We anticipate submitting the IND by end of calendar 2021.

According to iHealthcareAnalyst, Inc, the global *Glioblastoma multiforme* (GBM) drugs market is expected to reach nearly \$1.8 billion by 2027, expanding at a CAGR of 12.8% during the forecast period, driven by rising geriatric population and growing incidence.

Brain and other nervous system cancers are the 10th leading cause of death for men and women. Globally, over 150,000 people die each year as a result of brain or nervous system cancer, with GBM being the most common form of the disease. Given the limitation of all current therapeutics (surgery, chemotherapy and/or radiation), development of novel approaches to treating glioblastoma remains a great unmet need.

## **About NovAccess Global**

NovAccess Global is a biomedical company accelerating novel cancer diagnostics and

therapeutics. Our goal is to discover, develop and bring to market novel and innovative medicine and medical devices to improve the quality of care for cancer and neurological patients.

NovAccess Global is a currently developing a cancer vaccine therapy that enhances the patient's immune response against brain tumors. Our company has a novel immunotherapeutic approach to treat brain tumor patients with glioblastoma multiforme, the most common adult brain tumor with a 15-month median survival after diagnosis. Our patented technology is designed to combine a dendritic cell-based immunotherapeutic approach with a unique combination of Toll-like receptor (TLR) adjuvants, TLR-AD1, to help promote an enhanced immune response against the patient's tumor. Our platform technology focuses on enhancing the patient's immune cells to fight their unique cancer by utilizing the antigens specific to the patient's tumor. The company owns a cancer vaccine, which is a medication that stimulates or restores the immune system's ability to fight an existing cancer by strengthening the body's natural defenses against the cancer cells. It is a meaningful technology which could significantly improve the quality of life and prognosis for the many people who suffer from brain tumors. For more information, please visit novaccessglobal.com.

### **Forward-Looking Statement**

This press release contain "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and such forward-looking statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. "Forward looking statements" describe future expectations, plans, results, or strategies and are generally preceded by words such as "may," "future," "plan" or "planned," "will" or "should," "expected," "anticipates," "draft," "eventually" or "projected." You are cautioned that such statements are subject to a multitude or risks and uncertainties that could cause future circumstances, events, or results to differ materially from those projected in the forward-looking statements, including the risks that actual results may differ materially from those projected in the forward-looking statements as a result of various factors, and other risks identified in the Company's disclosures or filings with the Securities Exchange Commission and/or OTC Markets, Inc. You are further cautioned that penny stocks and stocks of smaller companies like NovAccess Global Inc. are inherently volatile and risky and that no investor should buy this stock unless they can afford the loss of their entire investment. The Company disclaims any obligation to update any forward-looking statements to reflect events or circumstances after the date thereof.

#### **Broker, and Analyst Contact:**

Chesapeake Group +1 (410) 825-3930 info@chesapeakegp.com

#### **Investor Relations Contact:**

Satya Chillara
Darrow Associates
(510) 396 -2776
schillara@darrowassociates.com