# NovAccess Global Announces Filing of Orphan Drug Application for TLR-AD1

*Accelerating on the Path Toward Immunotherapy for Glioblastoma (Brain Cancer)*

Cleveland, OH – July 19, 2022 -- NovAccess Global Inc. (OTC PINK: XSNX), a biomedical company developing novel immunotherapies for brain tumor patients, today announced the filing of an application with the U.S. Food and Drug Administration (FDA) to receive Orphan Drug Designation (ODD) for TLR-AD1, a vaccine immunotherapy for the treatment of aggressive brain cancers, including glioblastoma and other high grade gliomas.

Glioblastoma is a form of aggressive brain cancer that annually impacts approximately 250,000 people globally and is on the rise in many countries, according to NovAccess scientists and published reports. The market data is more alarming, with glioblastoma accounting for approximately 50% of all malignant brain cancers diagnosed in the United States each year, and more than 10,000 Americans dying from this tumor type annually. Less than 5% of people with this cancer live longer than 5-years after their diagnosis. The global glioblastoma treatment market was estimated to be valued in excess of $2 billion in 2020, with projections for a compounded annual growth rate of more than 8% throughout the remainder of the decade.

"We are very excited to announce the filing of an Orphan Drug application for TLR-AD1. If we obtain FDA approval it would grant us special status and enable the acceleration of the development of our therapies to treat glioblastoma patients," Dr. Christopher Wheeler, President of StemVax Therapeutics. "The ODD process supports the development and evaluation of new treatments for rare diseases which is a key priority for both the FDA and for NovAccess Global. Receiving this important designation would represent a milestone in the development of TLR-AD1 and would highlight the need for potential new treatment options for patients with aggressive brain cancers which today have no immunotherapy treatment leaving only the option of highly invasive and complicated surgery."

Dr. Wheeler continued, "Upon receiving ODD, the product will significantly bolster NovAccess Global's intellectual property portfolio, which presently includes the rights to U.S. patent #US9764014B2 granted under the "Cancer Antigens" category related to the "treatment of cancer using vaccination therapy." We are pleased with the progress we are making toward building out our platform for novel immunotherapy for brain tumor patients."

The FDA's Office of Orphan Products Development grants orphan designation status to investigational drugs and therapies addressing rare medical diseases or conditions that affect fewer

than 200,000 people in the United States. Orphan drug designation provides benefits to drug developers which may include assistance in the drug development process, financial incentives to support clinical development, tax credits for clinical costs, exemptions from certain FDA fees and the potential for seven years of post-approval marketing exclusivity.

Sponsors seeking orphan drug designation for a drug must submit a request for designation to the FDA. Orphan drug designation is a separate process from seeking commercial approval or licensing. As such, the receipt of Orphan Drug Designation status does not change the regulatory requirements or process for obtaining marketing approval.

**About TLR-AD1**

TLR-AD1 is designed to activate anti-tumor immune responses against these brain tumors using immune-activating dendritic cells combined with the patient's own tumor proteins. The resulting dendritic cell vaccines are matured with a proprietary combination of Toll-like receptor (TLR) adjuvants to boost their immune-activating potency beyond current vaccine preparations.

NovAccess Global expects to submit an Investigational New Drug (IND) application to the FDA for TLR-AD1 by the first quarter of 2023. In advance of the IND filing, the Company expects to announce a partnership with a clinical manufacturing organization for vaccine testing and production readiness for phase I-II clinical trials of TLR-AD1.

**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 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 existing cancer by strengthening the body's natural defenses against the cancer cells. It is a meaningful technology that 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 email and its attachments 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, 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.

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