NovAccess Global Receives FDA Approval of Orphan Drug Application for TLR-AD1

FDA Expands the Scope of the Company's Submission

Accelerates Path Toward Immunotherapy for Glioblastoma (Brain Cancer)

Cleveland, OH – October 26, 2022 -- NovAccess Global Inc. (OTCQB: XSNX), a biomedical company developing novel immunotherapies for brain tumor patients, today announced the approval of its application with the U.S. Food and Drug Administration (FDA) for Orphan Drug Designation (ODD) for TLR-AD1, a vaccine immunotherapy for the treatment of aggressive brain cancers, including glioblastoma and other high-grade gliomas.

"Orphan Drug Designation is yet another timely milestone achieved by NovAccess Global as we prepare an Investigative New Drug (IND) application for FDA approval to start human clinical trials. We expect to submit the IND in the first half of 2023," said the Company's Chief Executive Officer Dr. Dwain K. Irvin. "We are very pleased to have received this approval, and we believe the promise of our platform technology is underscored by the FDA expanding the scope of our original submission. This has been a team effort and I would like to congratulate our team for its ambitious and comprehensive efforts. The designation represents a critical step forward as we address an important and unmet healthcare challenge in the treatment of brain cancers."

"The FDA approval of our Orphan Drug application for TLR-AD1 is an important step forward," said Dr. Christopher Wheeler, President of StemVax Therapeutics, a wholly owned division of NovAccess Global, and served as Company's lead in interactions with the FDA. "With Orphan Drug Designation status granted by the FDA, TLR-AD1 serves as our vanguard technology in our portfolio in the fight against cancer. It is our first in a platform of novel immunotherapy and innovative technology solutions we intend to bring to market in the service of cancer patients and their families across the globe. The special status afforded to us through the Orphan Drug Designation will enable an acceleration of the development of our therapies for new treatment options to treat a wide range of glioblastoma patients."

Dr. Wheeler continued, “Our therapeutic path involves a transformational process where tumor-killing immune responses for malignant glioma (MG) cells are higher than that of previous immunotherapies. This unique process involves the addition of proprietary substances to create a “cocktail” for more personalized treatment that substantially increases clinical benefits for patients. We look forward to advancing this novel immunotherapy into the clinic.”

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 five 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. 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, and the receipt of orphan drug designation status does not change the regulatory requirements or process for obtaining marketing approval from the FDA.

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 in the first half 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 press release may 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 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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