BitNile Holdings Announces That Alzamend Neuro Receives FDA “Study May Proceed” Letter for Phase I/IIA Clinical Trial Under Its Investigational New Drug Application for an Immunotherapy Vaccine (ALZN002) to Treat Alzheimer’s Disease

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ALZN002 is believed to be the first autologous dendritic cell-based active immunotherapy vaccine candidate to be tested in humans to treat Alzheimer’s

LAS VEGAS--(BUSINESS WIRE)-- BitNile Holdings, Inc. (NYSE American: NILE), a diversified holding company (“**BitNile**” or the “**Company**”) today announced that Alzamend Neuro, Inc. (Nasdaq: ALZN) (“**Alzamend**”), an early clinical-stage biopharmaceutical company focused on developing novel products for the treatment of Alzheimer’s disease (“**Alzheimer’s**”), bipolar disorder, major depressive disorder and post-traumatic stress disorder, received a “study may proceed” letter from the U.S. Food and Drug Administration (“**FDA**”) for a Phase I/IIA clinical trial under Alzamend’s Investigational New Drug (“**IND**”) application for an immunotherapy vaccine (ALZN002) to treat mild to moderate dementia of the Alzheimer’s type.

ALZN002 is believed to be the first candidate autologous (uses the patient’s own cells) dendritic cell-based Alzheimer’s immunotherapy vaccine to be tested in humans that potentially fosters tolerance to treatment (for safety) while providing durable active immunity potential and fewer physician visits compared to passive (foreign to the patient) immunity treatments.

Alzamend reported that it expects to initiate the clinical trial in the first quarter of 2023. BitNile is a significant beneficial owner of Alzamend common stock.

About ALZN002

ALZN002 is a proprietary “active” immunotherapy product, which means it is produced by each patient’s immune system. It consists of autologous dendritic cells (“**DCs**”), which are activated white blood cells taken from each individual patient that are then engineered outside of the body to attack Alzheimer’s-related amyloid-beta proteins. These DCs are pulsed with a novel amyloid-beta peptide designed to bolster the ability of the patient’s immune system to combat Alzheimer’s. The goal of this treatment approach is to foster tolerance to treatment for safety purposes while stimulating the immune system to reduce the brain’s beta-amyloid protein burden, resulting in reduced Alzheimer’s signs and symptoms.

The ALZN002 DC treatment is, by definition, an individual-patient-specific therapy since these autologous DCs are administered to the same patient from whom they were removed. Each patient will undergo leukapheresis, i.e., removal and return to the body of white blood cells. This procedure will isolate each patient’s peripheral blood monocytes from the obtained white blood cells. These are subsequently differentiated outside the body into DCs that are engineered to induce immunogenicity (search and destroy capability) towards amyloid, the protein associated with

Alzheimer's in the patient's body, but to be otherwise tolerated as natural to the body to avoid adverse side effects.

Compared to passive immunization treatment approaches that use foreign blood products (such as monoclonal antibodies), active immunization with ALZN002 is anticipated to offer a more robust and long-lasting effect on the clearance of amyloid. This is expected to provide a safe and effective treatment for Alzheimer's sufferers that requires considerably less frequent treatment visits compared to passive immunity approaches.

The IND supports initial deployment of a Phase I/IIA clinical trial, ALZN002-01, a first-in-human, randomized, double-blind, placebo-controlled, parallel-group study. The purpose of this trial will be to assess the safety, tolerability, and efficacy of multiple ascending doses of ALZN002 compared with that of placebo in 20 to 30 subjects with mild to moderate dementia of the Alzheimer's type. Also, the trial will be designed to determine the optimal dosage of ALZN002 for treatment of patients with Alzheimer's in a larger Phase IIB efficacy and safety clinical trial (ALZN002-02), which Alzamend expects to initiate within three months of receiving data from the initial trial.

Milton "Todd" Ault, III, the Company's Executive Chairman and the Founder and Chairman Emeritus of Alzamend, stated, "I could not be more pleased with the FDA's 'Study May Proceed' allowing Alzamend to begin to test its immunotherapy vaccine in patients with Alzheimer's. It has been a life-long goal of mine to help people suffering from Alzheimer's. I believe that a vaccine will play the biggest role in the fight against Alzheimer's."

The Company has certain beneficial ownership and rights to further invest in Alzamend. The Company beneficially owns approximately 10.4 million shares and has the right to acquire 3.4 million shares of Alzamend common stock upon the exercise of warrants. In addition, the Company's wholly owned subsidiary, Ault Lending, LLC, has the right to purchase up to an additional 6.67 million shares at $1.50 per share with warrants to purchase 3.3 million of shares of Alzamend common stock at an exercise price of $3.00 per share.

Should the Company exercise all warrants and options to invest, it would own approximately 23.8 million shares with an average cost of $2.02 per share of common stock, representing 22% of Alzamend's issued and outstanding common stock.

For more information on BitNile and its subsidiaries, BitNile recommends that stockholders, investors, and any other interested parties read BitNile's public filings and press releases available under the Investor Relations section at www.BitNile.com or available at www.sec.gov.

About BitNile Holdings, Inc.

BitNile Holdings, Inc. is a diversified holding company pursuing growth by acquiring undervalued businesses and disruptive technologies with a global impact. Through its wholly and majority-owned subsidiaries and strategic investments, BitNile owns and operates a data center at which it mines Bitcoin and provides mission-critical products that support a diverse range of industries, including oil exploration, defense/aerospace, industrial, automotive, medical/biopharma, karaoke audio equipment, hotel operations and textiles. In addition, BitNile extends credit to select entrepreneurial businesses through a licensed lending subsidiary. BitNile's headquarters are located at 11411 Southern Highlands Parkway, Suite 240, Las Vegas, NV 89141; www.BitNile.com.

Forward-Looking Statements

This press release contains "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. These forward-looking statements generally include statements that are predictive in

nature and depend upon or refer to future events or conditions, and include words such as “believes,” “plans,” “anticipates,” “projects,” “estimates,” “expects,” “intends,” “strategy,” “future,” “opportunity,” “may,” “will,” “should,” “could,” “potential,” or similar expressions. Statements that are not historical facts are forward-looking statements. Forward-looking statements are based on current beliefs and assumptions that are subject to risks and uncertainties. Forward-looking statements speak only as of the date they are made, and the Company undertakes no obligation to update any of them publicly in light of new information or future events. Actual results could differ materially from those contained in any forward-looking statement as a result of various factors. More information, including potential risk factors, that could affect the Company’s business and financial results are included in the Company’s filings with the U.S. Securities and Exchange Commission, including, but not limited to, the Company’s Forms 10-K, 10-Q and 8-K. All filings are available at www.sec.gov and on the Company’s website at www.BitNile.com.

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