



BIONXT PROVIDES UPDATE ON CLADRIBINE PROGRAM FOR MULTIPLE SCLEROSIS, SUBLINGUAL NEURODEGENERATIVE DISEASE PATENT, AND INVESTOR RELATIONS ACTIVITIES

VANCOUVER, BC – September 26, 2024 - BioNxt Solutions Inc. (“**BioNxt**” or the “**Company**”) (CSE: BNXT / OTC: BNXTF / FSE: BXT) is pleased to provide an update on its flagship sublingual Cladribine drug formulation program for the treatment of Multiple Sclerosis (“**MS**”), broad sublingual patent application for the use of anticancer drugs for the treatment of autoimmune neurodegenerative diseases, and investor relations activities.

BioNxt’s lead program is the development of a 100% owned and proprietary sublingual Cladribine dosage form, directed at the MS market. Cladribine tablets are currently approved for use in over 75 countries, including by the United States Food and Drug Administration (“**FDA**”) and the European Medicines Agency (“**EMA**”), with 2023 annual sales in excess of one billion USD according to Merck KGaA. Cladribine tablets are approved for several indications, namely highly active forms of relapsing-remitting MS. MS represents the largest market segment for the sale of Cladribine with approximately 2.3 million people living with MS worldwide, with the highest prevalence in North America and Europe, noted by Atlas of MS. The global Multiple Sclerosis drug market is anticipated to top USD 41 billion by 2033 according to Market.us. BioNxt’s sublingual Cladribine product is expected to yield a significant advantage over the tablet form for patients suffering from Dysphagia (difficulty swallowing), which is a common symptom among MS patients.

In the first half of 2024, the Company announced positive results for both its sublingual Cladribine animal toxicity study and animal pharmacokinetics (“**PK**”) studies. The animal toxicity study results demonstrated zero adverse clinical abnormalities or indications of toxicity in any participants after consecutive days of dosing. The PK study results demonstrated highly comparable rapid absorption and bioequivalence between the Company’s sublingual product and the name-brand reference drug for all administered samples. The next steps in the development and commercialization process include technology and process transfer, upscaling of manufacturing capability, analytical method development and validation, and clinical sample manufacturing preparation, manufacturing, and product release for use in the human comparative bioequivalence study planned for early Q1 2025. The bioequivalence study will be carried out with a European contract research organization in accordance with EU medical regulatory guidelines.

On September 9, 2024, BioNxt reported that the European Patent Office (“**EPO**”) issued a positive international examination report for the Company’s comprehensive patent application



for sublingual delivery of anticancer drugs for the treatment of autoimmune neurodegenerative diseases, such as MS. The Company expects the EU patent to be granted within four weeks and to rapidly enter the national phase of the Patent Cooperation Treaty (“PCT”) patent process with submissions planned for the US, Canada, China, Japan, Australia, and other jurisdictions.

BioNxt plans to continue development of and extend its patent portfolio regarding sublingual drug products containing highly potent anticancer compounds for neurodegenerative diseases. The Company intends to file several related provisional patent applications in the EU with three to four patents expected to be on file in multiple major international jurisdictions by late 2025 to early 2026 with potential patent protection extending to 2045.

Further to the Company’s MS program, BioNxt confirms that its second clinical indication using anticancer compounds in a sublingual drug delivery system will be Myasthenia Gravis (“MG”). MG is an autoimmune and neuromuscular disease characterised by muscle weakness and fatigue. MG patients also commonly experience Dysphagia whereby a sublingual product is expected to yield a significant advantage over conventional tablet forms. The global MG market is expected to reach USD 6.7 billion by 2032 according to Clinical Trials Arena.

In general, the expectation of continued increasing prevalence of Central Nervous System (“CNS”) pathologies will drive investment into new drugs and new drug delivery systems capable of targeting these diseases. The market size for drugs to treat CNS diseases is growing and expected to reach USD 238.8 billion by 2032 according to GMI Market Insights.

BioNxt is also pleased to report that it has engaged two individual consultants (the “Consultants”) to provide Promotional Activity pursuant to Policy 7 of the Canadian Securities Exchange for a period of six months commencing on October 1, 2024. The investor relations activities will include working to increase the shareholder base, market liquidity, and share price through distribution of company information and direct communication with contacts in their respective investor networks, including qualified investors, investment advisors, financial analysts, newsletter writers, and media outlets. Each of the Consultants, Rob Grace, Delta, Canada, and Lance Fortt, Angus, Australia, will receive 12,500 CAD cash per month, 500,000 share purchase options exercisable into common shares of the Company at \$0.25 per share, and 500,000 share purchase options exercisable into common shares of the Company at \$0.30 per share (the “Options”). The Options are exercisable for two years and will vest in stages over a 12-month period with 25% vesting every three months from the date of issuance.

About BioNxt Solutions Inc.

BioNxt Solutions Inc. is a bioscience accelerator focused on next-generation drug formulations and delivery systems, diagnostic screening tests, and new active pharmaceutical production



and evaluation, including: precision transdermal and oral dissolvable drug formulations; rapid, low-cost infectious disease and oral health screening tests; and standardization and clinical evaluation of emerging active pharmaceutical ingredients for neurological applications. The Company has research and development operations in North America and Europe, with an operational focus in Germany, and is currently focused on regulatory approval and commercialization of medical products for European markets.

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