



## **BIONXT REPORTS SUCCESSFUL RESULTS FROM ODF CLADRIBINE PK STUDY**

**VANCOUVER, BC – March 13, 2024** - BioNxt Solutions Inc. ("**BioNxt**" or the "**Company**") (CSE: BNXT / OTCQB: BNXTF / FSE: BXT) is pleased to report that the comparative pharmacokinetic ("PK") study for its oral dissolvable film ("ODF") based proprietary Cladribine product for the treatment of Multiple Sclerosis ("MS") has been completed and results received by the Company. The animal PK study results are highly promising and demonstrated comparable rapid absorption and systemic exposure between the Company's ODF product and the name-brand reference drug in all samples.

"These results are a significant milestone for BioNxt. We have demonstrated that our ODF platform is an effective drug delivery system for cytostatic drugs via transmucosal absorption," said Hugh Rogers, CEO of BioNxt. "With our recently obtained toxicology data, the PK results allow us to strengthen the Company's Cladribine ODF patent position and proceed immediately to a PK study in humans. These exciting results validate the potential for BioNxt to immediately expand into additional ODF drug formulations for similar, high-value and highly toxic drugs."

BioNxt is developing a 100% owned and proprietary hybrid-generic ODF 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 annual sales in excess of one billion USD. Cladribine tablets are approved for several indications, namely highly active forms of relapsing-remitting MS and certain forms of leukemia. 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 expected to top USD 41 billion by 2033 according to Market.us.

The comparative PK study was carried out by a European contract research organization in accordance with EU medical regulatory guidelines using animal models and a single administration of either sublingual (ODF) or oral (tablet) Cladribine. Blood testing and analysis was carried out pre-dose and at up to six time points after administration using blood aliquots. The animal PK study results closely follows the unanimously successful results of the ODF Cladribine animal toxicity study, announced February 7, 2024: positive results were observed in all study participants with no adverse clinical abnormalities or indications of toxicity observed in the study after consecutive days of dosing.

BioNxt has accelerated its Cladribine ODF program in a priority manner with GMP product development and batch production planned for Q1 and Q2 2024 with the European Investigational Medicinal Product Dossier (IMPD) preparation and submission planned for Q2 2024.

The Company has filed Cladribine ODF-related provisional patent applications with three to four patent applications expected to be on file in major international jurisdictions by late 2024 to early



2025 with potential patent protection extending to 2044.

BioNxt's wholly owned subsidiary is a German narcotics manufacturer, developer, and researcher located in the district of Biberach, Baden-Württemberg, Germany. For over a decade, the company and its team have been leaders in the design, testing and manufacture of innovative, non-invasive drug delivery systems, particularly transdermal patches and sublingual strips for the delivery of active pharmaceutical ingredients for the treatment of pain and neurological conditions. According to Precedence Research, the global pharmaceutical drug delivery market size was valued at USD 1,525 billion in 2022 and expected to surpass approximately USD 2,047 billion by 2030.

### **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.

### **BioNxt Solutions Inc.**

Hugh Rogers, CEO and Director

Email: [info@bionxt.com](mailto:info@bionxt.com)

Phone: +1 780-818-6422

### **Cautionary Statement Regarding "Forward-Looking" Information**

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