



BIONXT REPORTS SUCCESSFUL RESULTS FROM ODF CLADRIBINE TOXICITY STUDY

VANCOUVER, BC – February 7, 2024 - BioNxt Solutions Inc. (“**BioNxt**” or the “**Company**”) (CSE: BNXT / OTCQB: BNXTF / FSE: BXT) is pleased to report that the toxicity 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 study was unanimously successful with positive results in all study participants with no adverse clinical abnormalities or indications of toxicity observed in the study after consecutive days of dosing.

BioNxt is developing a proprietary hybrid-generic ODF Cladribine dosage form, primarily directed at the MS market. Cladribine tablets are approved for use in over 75 countries, including by the United States Food and Drug Administration (“FDA”) and the European Medicines Agency (“EMA”), 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 oral toxicity study was carried out by a European contract research organization in accordance with EU medical regulatory guidelines using animal models for five consecutive days of sublingual ODF dosing. Animals were observed daily for general health, clinical indications, and qualitative food intake, while body weight was recorded twice throughout the study. In addition, careful examination of the application site was done four times/day. The Company’s Cladribine ODF did not cause any sign of treatment-related toxicity either at the site of application or within the oral cavity of the animals. There were no health or clinical abnormalities observed at any time during the study.

Comparative pharmacokinetic studies in animal models have commenced in Europe with results expected in Q1 2024. GMP product development and batch production is 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

Phone: +1 780-818-6422

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