



BIONXT REPORTS COMMERCIALIZATION OF ODF CLADRIBINE PRODUCT FOR MS NEXT STEPS

VANCOUVER, BC – March 18, 2024 - BioNxt Solutions Inc. (“**BioNxt**” or the “**Company**”) (CSE: BNXT / OTCQB: BNXTF / FSE: BXT) is pleased to report that based on the recent success of its toxicity and comparative pharmacokinetic (“PK”) studies the Company is advancing towards human comparative bioavailability studies on an expedited basis. 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 upcoming planned human comparative bioequivalence study. Sample manufacturing is planned for Q2 2024 with the European Investigational Medicinal Product Dossier (IMPd) preparation and submission also planned for Q2 2024.

On February 7, 2024, the BioNxt announced positive animal toxicity study results with no adverse clinical abnormalities or indications of toxicity observed in any participants after consecutive days of dosing. On March 13, 2024, the Company announced positive animal PK study results that demonstrated highly comparable rapid absorption and bioequivalence between the Company’s ODF product and the name-brand reference drug for all administered samples. The upcoming planned human comparative bioequivalence study will be carried out by a European contract research organization in accordance with EU medical regulatory guidelines.

BioNxt is developing a 100% owned and proprietary hybrid-generic ODF Cladribine dosage form, directed at the multiple sclerosis (“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 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.

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