



## **BIONXT ACCELERATES CLADRIBINE ODF CLINICAL AND COMMERCIALIZATION STRATEGY FOR MULTIPLE SCLEROSIS TREATMENT**

**VANCOUVER, BC – November 20, 2023** - BioNxt Solutions Inc. (“**BioNxt**” or the “**Company**”) (CSE: BNXT / OTCQB: BNXTF / FSE: BXT) is pleased to provide further details on its clinical and commercialization strategy for its recently announced 100% Cladribine IP acquisition and related clinical programs. BioNxt has accelerated development of a proprietary oral dissolvable film (“ODF”) based Cladribine product for the treatment of Multiple Sclerosis (“MS”).

Preclinical work is underway with comparative pharmacokinetic and local toxicity studies in animal models having already 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. An agreement has been signed with a European contract research organization for a human comparative bioequivalence pilot study which is currently scheduled for Q3 2024.

“Accelerated development of a proprietary Cladribine ODF formulation for the treatment of MS has become a top priority for BioNxt,” said Hugh Rogers, CEO & Director of BioNxt. “In just a few years the Cladribine tablet market has reached greater than \$1 billion dollars in annual sales and we see several potential advantages for an ODF product versus tablets. These include improved dosing efficiency and precision due to immediate absorption in the oral cavity, as well as greater convenience and access for MS patients that are unable to swallow tablets.”

The Company has filed Cladribine ODF-related preliminary 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.

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. The global MS drug market is expected to top US\$ 41 Billion by 2033 according to Market.us.

### **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

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