BioNxt Solutions Reports Progress on BNT23001 Development for Multiple Sclerosis Treatment

VANCOUVER, BC / December 9, 2024 / BioNxt Solutions Inc. ("BioNxt" or the "Company") (CSE: BNXT) (OTC MARKETS: BNXTF) (FSE: BXT), a bioscience company specializing in advanced drug delivery systems, has achieved key milestones in the development of BNT23001, its proprietary sublingual thin-film (OFD) formulation of Cladribine for the treatment of Multiple Sclerosis (MS). These achievements in 2024 lay the groundwork for clinical trials and regulatory submissions in 2025, reinforcing BioNxt's commitment to advancing patient-centric therapeutic solutions.

2024 Milestones: Establishing a Strong Foundation for Cladribine Thin-Film Development

Preclinical Success: BNT23001 demonstrated high absorption rates of Cladribine through sublingual delivery in pharmacokinetic (PK) studies conducted in animal models. These studies confirmed the product's bioequivalence to the originator therapy, Mavenclad®, and validated the thin-film's rapid absorption and safety profile. Toxicity studies further demonstrated no adverse local effects, highlighting the viability of the sublingual delivery approach.

Advancements in Manufacturing: BioNxt successfully transferred the BNT23001 production process to its GMP-certified manufacturing partner, Gen-Plus GmbH & Co KG in Munich (Germany), ensuring readiness for clinical batch production. This milestone supports the Company's plan to initiate clinical trials in 2025 with reliable, high-quality product supply.

Strengthened Intellectual Property Position: A favorable International Preliminary Report on Patentability (IPRP) confirmed BNT23001's novelty, inventive step, and industrial applicability, underscoring its unique value in MS treatment. The Company has initiated patent nationalization in major jurisdictions, including Europe, the United States, and Canada, with patent grants anticipated in several regions by mid-2025.

2025 Roadmap: Advancing BNT23001 into Clinical Trials

Manufacturing Clinical Batches: BioNxt will complete GMP manufacturing and Qualified Person (QP) release of clinical trial batches in the second quarter of 2025. This step is critical for the successful initiation of human studies.

Regulatory Filings and Approvals: The Company plans to submit the Investigational Medicinal Product Dossier (IMPD) to European regulatory authorities by mid-2025, paving the way for clinical trial approval. These regulatory submissions will include data from preclinical studies and stability assessments conducted at the manufacturing site.

Clinical Study to Validate Performance: BioNxt aims to launch a pilot clinical study in the latter half of 2025. This trial will compare the efficacy, bioavailability, and safety of BNT23001 to Mavenclad®, the originator tablet product, positioning the thin-film formulation as a patient-friendly alternative.

Ongoing Patent Protection: In addition to continuing the patent nationalization process, BioNxt expects granted patents in key regions to strengthen its intellectual property portfolio and provide competitive advantages as the product moves toward commercialization.

BNT23001: Advancing Toward Clinical Validation for MS Treatment

BNT23001 offers a novel approach to MS management by addressing limitations in traditional oral therapies. Its sublingual thin-film format provides:

- **Convenience:** Easy-to-use and portable, ideal for patients with difficulty swallowing or active lifestyles.
- **Rapid Absorption:** Direct delivery through the sublingual mucosa for faster therapeutic action.
- **Improved Compliance:** A patient-friendly alternative designed to enhance adherence to prescribed regimens.

By delivering these advantages, BNT23001 aligns with BioNxt's mission to improve outcomes for patients living with chronic diseases like MS.

About BioNxt Solutions Inc.

BioNxt Solutions Inc. is a bioscience innovator focused on next-generation drug delivery technologies, diagnostic screening systems, and active pharmaceutical ingredient development. The Company's proprietary platforms—Sublingual (Thin-Film), Transdermal (Skin Patch), and Oral (Enteric-Coated Tablets)—target key therapeutic areas, including autoimmune diseases, neurological disorders, and longevity.

With research and development operations in North America and Europe, BioNxt is advancing regulatory approvals and commercialization efforts, primarily focused on European markets. BioNxt is committed to improving healthcare by delivering precise, patient-centric solutions that enhance treatment outcomes worldwide.

BioNxt is listed on the Canadian Securities Exchange: BNXT, OTC Markets: BNXTF and trades in Germany under WKN: A3D1K3. To learn more about BioNxt, please visit www.bionxt.com.

Investor Relations & Media Contact

Hugh Rogers, Co-Founder, CEO and Director
Email: investor.relations@bionxt.com
Phone: +1 780-818-6422

Web: www.bionxt.com
LinkedIn: https://www.linkedin.com/company/bionxt-solutions
Instagram: https://www.instagram.com/bionxt

Cautionary Statement Regarding "Forward-Looking" Information

This press release contains forward-looking statements within the meaning of applicable securities laws, including statements regarding the development, testing, regulatory approval, and commercialization of BNT23001, as well as projected milestones for 2025. These statements are based on current expectations and assumptions but involve risks and uncertainties that could cause actual results to differ materially. These risks include clinical trial outcomes, regulatory delays, manufacturing challenges, intellectual property issues, market competition, and changes in laws or market conditions. The Company undertakes no obligation to update or revise forward-looking statements, except as required by law. For more information, refer to the "Risk Factors" section of the Company's filings at www.sedarplus.ca.