BioNxt Solutions Prepares For Human Bioequivalence Study For MS

VANCOUVER, BC / ACCESSWIRE / April 23, 2025 / BioNxt Solutions Inc. ("BioNxt" or the "Company") (CSE:BNXT) (OTC PINK:BNXTF) (FSE:BXT), a bioscience innovator specializing in advanced drug delivery systems, is pleased to report advanced preparation for its human bioequivalence study for its lead Multiple Sclerosis (MS) treatment.

BioNxt's lead product, BNT23001, is a proprietary sublingual thin-film formulation of Cladribine for the treatment of MS. Preclinical studies, as reported in internal research data and third-party evaluations, have demonstrated high absorption rates and bioequivalence compared to existing oral tablet therapies. The Company has purchased Cladribine active pharmaceutical ingredient which is necessary to complete the technology transfer process with Gen-Plus, its European Contract Research and Development Organization (CRDO), in Munich, Germany. Once commenced, the bioequivalence study is relatively short, scheduled for less than 30 days from start to finish.

The Company plans to make further updates in the coming weeks regarding its bioequivalent study preparation and scheduling, as well integration of its research and development operations with Gen-Plus.

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.

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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 BioNxt's sublingual drug products, as well as projected milestones, anticipated partnerships, and potential market opportunities. Forward-looking statements are inherently subject to significant risks, uncertainties, and assumptions, many of which are beyond BioNxt's control. Factors that could cause actual results to differ materially include, but are not limited to, delays in regulatory approvals, negative outcomes from clinical trials, changes in market demand, fluctuations in funding availability, or disruptions in supply chains. Readers are cautioned not to place undue reliance on these forward-looking statements, as actual results may differ materially from those expressed or implied. BioNxt undertakes no obligation to update or revise forward-looking statements, except as required by law. Factors that could cause actual results to differ materially from those projected include changes in market demand, regulatory developments, delays in clinical trials, fluctuations in financing availability, supply chain disruptions, and unforeseen competitive pressures.