BioNxt Solutions Expands Patent Protection for Drug Delivery Innovations Backed by Positive IPRP

VANCOUVER, BC / ACCESSWIRE / December 19, 2024 / 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 announce the expansion of its intellectual property portfolio with the filing of new international patents for sublingual delivery technologies targeting autoimmune neurodegenerative diseases.

Building upon the positive International Preliminary Report on Patentability (IPRP) issued by the European Patent Office (EPO) in September 2024, BioNxt has initiated national-level filings in key jurisdictions, including the United States, Canada, Europe, and Japan. These patents are designed to protect the Company's proprietary sublingual formulations of anticancer drugs repurposed for the treatment of conditions such as Multiple Sclerosis (MS).

"Securing robust intellectual property rights across major markets is a critical component of our strategy to bring innovative, patient-friendly therapies to individuals affected by autoimmune neurodegenerative diseases," stated Hugh Rogers, CEO of BioNxt Solutions. "Our sublingual delivery platform offers significant advantages in terms of rapid absorption and ease of administration, particularly for patients experiencing difficulty swallowing."

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 to existing oral therapies, with plans underway to commence clinical trials in 2025, subject to regulatory approval.

In addition to MS, the Company is advancing sublingual Cladribine formulations for Myasthenia Gravis (MG), addressing a significant unmet need in this patient population. The global MG market is projected to reach USD 6.7 billion by 2032 (Clinical Trials Arena), highlighting the substantial opportunity for innovative treatments.

Strategic Vision for 2025 and Key Milestones

As BioNxt enters 2025, the Company has set a series of critical milestones to advance its sublingual drug delivery platform and bring its innovative therapies closer to commercialization. Key objectives for 2025 include:

- Initiation of Clinical Trials: Launching comparative bioequivalence trials for BNT23001, BioNxt’s proprietary sublingual Cladribine formulation for Multiple Sclerosis (MS).
- Regulatory Submissions: Preparing and submitting clinical trial applications (CTAs) in key jurisdictions to support clinical trial activities.
- Partnership Development: Pursuing strategic partnerships with pharmaceutical and biotech companies to accelerate development and commercialization pathways.

- Pipeline Expansion: Advancing the development of sublingual therapies and exploring additional applications for its sublingual delivery technology.
- Investor and Industry Engagement: BioNxt's management will actively participate in key industry conferences throughout 2025, to meet with industry leaders, engage with investors, and explore potential strategic partnerships.

Industry Collaboration and Strategic Alliances

To foster industry collaboration and partnership development, BioNxt's management team, including CEO, Hugh Rogers, and Director of Business Development, Dr. Oleksandr Zabutkin, will attend key global conferences in 2025, to meet with industry leaders, potential partners, and investors. These engagements aim to strengthen the Company's strategic alliances, identify co-development and licensing opportunities, and highlight BioNxt's role in advancing sublingual drug delivery technologies.

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.