BioNxt Advances “Melt in Your Mouth” Cladribine Formulation to Improve Treatment for MS Patients with Dysphagia

VANCOUVER, BC / ACCESS Newswire / December 9, 2025 - BioNxt Solutions Inc. (“BioNxt” or the “Company”) (CSE:BNXT) (OTCQB:BNXTF) (FSE:BXT) is advancing the development of a next-generation “Melt in Your Mouth” cladribine formulation, built on the Company’s proprietary oral dissolvable film (ODF) drug-delivery system. The technology is designed for rapid, sublingual (under-the-tongue) absorption of medication and aims to improve treatment access and comfort for people living with multiple sclerosis (MS). BioNxt’s lead program, BNT23001, is being developed as a swallow-free alternative to cladribine tablets, which generated USD 1.28 billion in global sales in 2024.

Cladribine (Mavenclad®) is an established therapy for MS; however, many patients struggle with difficulty swallowing tablets, a symptom that is both common and often under-recognized. For these individuals, pill-based medication can lead to coughing, choking, anxiety, and missed doses - all of which reduce treatment consistency and therapeutic effectiveness.

BioNxt’s “Melt in Your Mouth” ODF is engineered to dissolve in seconds under the tongue, eliminating the need to swallow and offering a needle-free, patient-friendly method of administration. The approach aims to enhance treatment adherence, safety, and overall quality of life for MS patients who face challenges with tablet-based medication.

Swallowing Difficulties: A Hidden Barrier in Multiple Sclerosis Treatment

Swallowing problems (dysphagia) are common in MS but often overlooked. A recent meta-analysis of more than 10,800 MS patients found that approximately 45% experience dysphagia during the course of their disease (2023, Journal of Clinical Neuroscience). Additional clinical studies using instrumental swallowing assessments have reported abnormalities in over 50% of patients, including cases not detected through self-report.

For these individuals, tablets may feel “stuck,” provoke coughing or choking, or require repeated attempts to swallow - turning a simple daily task into a persistent source of stress.

As swallowing becomes more difficult or unsafe, patients may delay doses, avoid medication altogether, or require caregiver assistance. By removing the need to swallow, BioNxt’s “Melt in Your Mouth” cladribine ODF is being developed specifically to address this barrier and help maintain consistent, safe access to cladribine therapy.

Significant Market Opportunity for a Patient-Friendly Cladribine Format

The global cladribine market is expanding rapidly. Merck KGaA’s cladribine tablets (Mavenclad®) generated over USD 950 million in the first three quarters of 2025, reflecting strong, ongoing demand across the U.S. and Europe. The company reported record quarterly sales in 2025 and continues to expect growth in Europe, although a recent U.S. patent decision could open the door to generic competition beginning in 2026.

According to Cladribine Market Research Report 2033 from Dataintelo, the global cladribine market was valued at USD 1.2 billion in 2023 and is projected to reach USD 2.5 billion by 2032, representing a robust 8.5% CAGR driven by rising MS prevalence and interest in innovative drug-delivery formats.

At the same time, the oral transmucosal drug-delivery market - including sublingual and buccal systems - is expected to grow from USD 45.8 billion in 2025 to nearly USD 96.8 billion by 2033. As a low-dose molecule well suited to BioNxt’s Melt in Your Mouth ODF technology, cladribine sits at the intersection of two fast-growing global markets, offering a significant opportunity to modernize and differentiate an established therapy.

“Taking a tablet should not be a barrier to treatment,” said Hugh Rogers, CEO of BioNxt Solutions. *“Our Melt in Your Mouth cladribine film is designed specifically for MS patients who struggle to swallow pills. We are addressing a meaningful unmet need by making an important therapy easier, safer, and more accessible in everyday life.”*

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: +1 778.598.2698

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 news release includes certain statements that may be deemed "forward-looking statements". All statements in this release, other than statements of historical facts, that address events or developments that the Company expects to occur, are forward-looking statements. Forward-looking statements are statements that are not historical facts and are generally, but not always, identified by the words "expects", "plans", "anticipates", "believes", "intends", "estimates", "projects", "potential" and similar expressions, or that events or conditions "will", "would", "may", "could" or "should" occur. Forward-looking information in this news release includes the anticipated filing date of the Annual Filings. Although the Company believes the expectations expressed in such forward-looking statements are based on reasonable assumptions, such statements are not guarantees of future performance and actual results may differ materially from those in the forward-looking statements. Factors that could cause the actual results to differ materially from those in forward-looking statements include regulatory actions, market prices, and continued availability of capital and financing, and general economic, market or business conditions. Investors are cautioned that any such statements are not guarantees of future performance and actual results or developments may differ materially from those projected in the forward-looking statements. Forward-looking statements are based on the beliefs, estimates and opinions of the Company's management on the date the statements are made. Except as required by applicable securities laws, the Company undertakes no obligation to update these forward-looking statements in the event that management's beliefs, estimates or opinions, or other factors, should change.