



## **BIONXT SIGNS CLINICAL STUDY AGREEMENT AND COMMENCES MANUFACTURE OF CLINICAL SAMPLES FOR STUDY OF TRANSDERMAL ROTIGOTINE PATCH FOR PARKINSON'S DISEASE**

**VANCOUVER, BC – March 1, 2023** - BioNxt Solutions Inc. ("**BioNxt**" or the "**Company**") (CSE: BNXT / OTC: BNXTF / FSE: BXT) is pleased to report that it has executed an agreement to carry out its comparative drug absorption study for the Company's transdermal ("**TDS**") Rotigotine patch for the treatment of Parkinson's disease. BioNxt has also commenced the manufacture of clinical samples for use in the study which is planned for early Q2 2023.

Further to BioNxt's press release dated February 13, 2023, the Company has finalized its plans for the human bioavailability study to be carried out by a qualified European contract research organization. The comparative study is designed as a randomized, crossover, two-period, single dose pilot study to assess the relative bioavailability, skin adhesion and skin tolerance of BioNxt's new formulation compared to the name brand product. The study will be carried out in Europe in accordance with Good Clinical Practice (GCP) and the European Medical Agency (EMA) Guideline on quality of transdermal patches. The Company has also commenced the manufacture of transdermal clinical samples based on the TDS platform technology developed by its wholly owned German subsidiary, Vektor Pharma TF GmbH ("**Vektor**").

BioNxt is working to develop in-house commercial manufacturing capabilities at its German drug development facility. This will include EU GMP-approved manufacturing and packaging equipment as well as a certified manufacturing line capable of producing pivotal trial materials compliant with commercial regulatory approval applications and final commercial products (transdermal and oral dissolvable). The Company expects to make further announcements regarding its commercialization capabilities over the coming months.

Rotigotine is a non-ergoline dopamine agonist approved for the treatment of Parkinson's disease and restless legs syndrome (RLS) in Europe and the United States. The active pharmaceutical ingredient is not well absorbed via oral delivery and is formulated as a once-daily TDS patch to increase bioavailability and provide a controlled and steady supply of the drug over the course of 24 hours. The therapeutic market for Parkinson's disease is over 10 million people worldwide and growing. The top selling name brand product launched by the originator in 2007 independently sold over US\$375 million of its Rotigotine TDS patches in 2021. According to Wissen Market Research, total global sales for Rotigotine patches were approximately US\$518 million in 2021 with the market expected to surpass US\$766 million by 2030.

BioNxt's Rotigotine transdermal patch is one product based on its 100% owned platform technology which represents a scalable opportunity for additional TDS drug development and manufacturing programs. According to Research and Markets, the global transdermal skin patch market had a value of nearly US\$6.5 billion in 2020 while Kuick Research, Pharmaceutical and Healthcare, estimates the market will reach approximately US\$20 billion by 2028.



BioNxt's wholly owned subsidiary, Vektor, is a German narcotics manufacturer, developer, and researcher located in the district of Biberach, Baden-Württemberg, Germany. For over a decade, the company and its team have been leaders in the design, testing and manufacture of innovative, non-invasive drug delivery systems, particularly transdermal patches and sub-lingual strips for the delivery of active pharmaceutical ingredients for the treatment of pain and neurological conditions. According to Precedence Research, the global drug delivery market was valued at US\$1,476 billion in 2021 and is expected to grow to US\$2,047 billion by 2030.

### **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.

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### **Cautionary Statement Regarding "Forward-Looking" Information**

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