



BioNevia and NeuroMax Announce Completion of Enrollment in Phase 2b Clinical Trial of BNV-222

Boston, and Moscow, May 16, 2016 -- BioNevia LLC and its development partner, NeuroMax Ltd, today announced the completion of enrollment in NM-ARI-231, a Phase 2b randomized, double-blind, placebo-controlled twelve month, chronic efficacy and safety study of BNV-222 (diepalrestat) in adult subjects with diabetic peripheral neuropathy. Four hundred (400) subjects were enrolled in 27 sites in Russia. The ongoing Phase 2b clinical trial evaluates efficacy on motor nerve conduction velocity, clinical outcomes, and visual acuity.

Diabetes affects more than 380 million patients worldwide, more than 29 million in the US alone and 12 million in Russia. It is estimated that nearly 70 percent of Type 2 diabetes patients will develop diabetic peripheral neuropathy.

"While there are many drugs available to patients and physicians for the treatment of the symptoms of this disease, there are no therapies available to change the rate of progression of the underlying disease. This drug holds the promise to have a meaningful effect on the outcome of the major complications of Type 2 diabetes," said Vera Bril, MD, Professor of Medicine (Neurology) at the University of Toronto, Director of Neurology at Mount Sinai Hospital, and the Principal Investigator of the Phase 2b study.

"The mechanism of aldose reductase inhibition is likely the only near term therapy under investigation which holds the potential to arrest the progression of this devastating disease. Assuming a positive trial outcome, BioNevia is targeting an End of Phase 2 Meeting with the FDA for the second half of 2017 when we hope to establish a clinical path forward for approval in the US," said Timothy Barberich, Chairman of BioNevia.

"Based on several long-term studies of epalrestat, a related compound, including a successful five year study conducted in Japan by Dr. Nigishi Hotta, together with previously conducted supporting preclinical and clinical studies of BNV-222 which showed a favorable safety profile, the companies believe that the compound may be the only potential disease-modifying therapy currently under development for peripheral neuropathy", said Julia Moskot, NeuroMax Program Director. "We anticipate that the current Phase 2b trial results will enable the filing and approval for marketing in Russia. The Company estimates that product launch in Russia and CIS countries could occur as early as first half 2018, and we are currently in discussions with potential marketing partners for the CIS Territories."

About BNV-222

BNV-222 is a potential disease modifying, first-in-class treatment for slowing or arresting diabetic neuropathy, a progressive disease. BNV-222 is a novel extended release formulation of diepalrestat, a cocrystal of epalrestat, a reversible aldose reductase inhibitor (ARI) which blocks the breakdown of excess blood glucose into sorbitol, preventing long-term nerve and tissue damage.

About BioNevia

BioNevia LLC is a clinical stage biotechnology company focused on developing drugs for the treatment of diabetes-associated diseases. The company was founded in 2007 and is based in Boston, Massachusetts.

About NeuroMax

NeuroMax Ltd is a private biotechnology company, founded in 2010, to develop, market and launch innovative products for the treatment of central and peripheral nervous system diseases in Russia. Diepalrestat (BNV-222) is being developed within the framework of international cooperation with BioNevia LLC.

About Maxwell Biotech Venture Fund

Maxwell Biotech Venture Fund (MBVF) is the first Russian venture fund fully dedicated to investment in the life sciences sector. The fund has been created with the participation of the Russian Venture Company (RVC). MBVF portfolio companies have nine innovative clinical stage drug candidates in development, four of them in Phase 2.

###

CONTACTS**BioNevia LLC**

Judy Caron, Ph.D., Vice President, Clinical Development
781-429-8058
judy.caron@bionevia.com

Robert Palladino, Chief Financial Officer
617-669-0059
rpalladino@bionevia.com