

# Approaches to immunomodulation in relapsing multiple sclerosis

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The BCD-132 and BCD-054 (JSC BIOCAD, Russia) are novel immunomodulating therapeutic options for relapsing form of multiple sclerosis (MS) treatment. The BCD-054 is a conjugate of recombinant human interferon  $\beta$ 1a and linear polyethylene glycol (PEG) with a molecular weight of 30kDA. Such conjugation

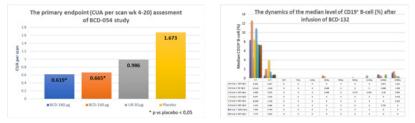
decreases renal clearance, increases half-life of drug and, consequently, allows to prolong the duration of action and reduce the frequency of injections compared with non-pegylated forms of interferon.

The interim 20-week results of BCD-054 III phase study showed significant reduction in brain MRI disease activity on PEG interferon  $\beta$ 1a therapy compared with placebo. It was proven, what two studied doses of BCD-054 superior to placebo for the primary efficacy endpoint represented by combined unique active (CUA) lesion counts. Assessment of clinical performance demonstrated the reduction of relapse rate: BCD-054 180 µg - 10, 62%, BCD-054 240 µg - 6,14%, low dose interferon  $\beta$ 1a (LIB) - 15,93%, placebo - 15,79%.

Another potential treatment of MS is BCD-132, an innovative the 3rd generation humanized afukosylated anti-CD20 antibodies. It has increased affinity for FcyRllla, thereby effectively induces antibody-dependent cytotoxicity and antibody dependent phagocytosis.

Direct strictly specific effect of BCD-132 on B lymphocyte in a wide range of doses (100-1000 mg) was established by dynamic assessment of such cells lever in phase I clinical trial after intravenous administration of increasing doses in two dosage regimens.

The obtained data shows that BCD-132 has an expected pharmacodynamic effect of long-term depletion of CD19+ and CD20+ B cell lineage and an acceptable safety profile when used to treat patients with MS in all studied doses.



#### Biography

Alexei Boyko gained his MD and PhD from the Russian State Medical University, Moscow and has been Professor of the Department of Neurology and Neurosurgery at this university since 1997. He was the Chief Neurologist of the Department of Health Care of the Government of Moscow in 2001-2015, Director of the Moscow Multiple Sclerosis Center in 2004-2014 and Director of the MS Clinical and Research Center of Neuroclinic since 2015, Director of the Neuroimmunological Department of the Federal Center CVPS. Professor Boyko has been a member of the "Oslo International Think-tank on MS Epidemiology, Analytical Approaches to Study of the Aetiology" at the Center for Advanced Studies of the Norwegian Academy of Science and Letters in 1994-1995, and worked at UBC MS Center in 1998 (Vancouver, Canada). He is also a member of the Presidium of the All-Russian Society of Neurologists, Co-ordinator of the Medical Consulting Boards of Moscow and All-Russian MS Societies, President of RUCTRIMS, member of ECTRIMS Council.

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