

Neuroprotection Biotech Bionure Reports Successful Phase 1 Study for Lead Candidate BN201

Company is now preparing a Series B funding round to finance the Phase 2 clinical program

Barcelona, Spain, May 7, 2019 - Bionure, a biotech company specialized in neuroprotection, today announces that it has successfully concluded its Phase 1 clinical study with its lead compound, BN201. The study was aimed at investigating safety, tolerability and pharmacokinetics of single and multiple doses of BN201.

The results of the randomized, double-blind, placebo-controlled Phase 1 study performed in the UK in 48 healthy volunteers showed good correlation with pharmacokinetic data generated in animal studies. No drug-related safety or tolerability issues were reported in the tested dose range.

BN201 is a new chemical and first-in-class compound that demonstrated neuroprotective activity i.e. stimulation for axonal protection, remyelination and promotion of neuronal survival in preclinical models, making it an ideal candidate for facilitating neuroprotection from degenerative, ischemic, toxic and inflammatory diseases of the nervous system.

Bionure's initial focus areas are Acute Optic Neuritis (AON) and Multiple sclerosis (MS), for which there still are high unmet medical needs. The current standards of care include anti-inflammatory drugs and/or immunomodulators, both of which reduce inflammation but do not adequately protect the neurons nor repair the nerve damage.

The mechanism of action of BN201 will enable it to ideally address further indications relevant for a neuroprotective agent, including other neurodegenerative disorders, cerebrovascular disease, certain ophthalmic diseases and traumatic central nervous system injuries.

Central Nervous System drugs currently represent a substantial prescription drug-market area with yearly sales exceeding USD 50bn, covering all major diseases including multiple sclerosis, which alone represents approximately USD 20bn.

"I'm delighted about the results of the Phase 1 clinical study that is a clear milestone achievement following our 15 years of research in neuroprotection. We will now prepare the implementation of a Phase 2 program to confirm the potential of BN201 to bring clinical benefits to patients," said Dr. Pablo Villoslada, scientific founder and CSO of Bionure.

"Currently there is a strong need for effective neuroprotectants and no remyelinating drug approved. Since only a handful of programs are in clinical development, this represents a great opportunity for Bionure to become a game changer in the neuroprotective market. We will now prepare a Series B financing round to fund the Phase 2 program," added Laurent Nguyen, CEO of Bionure.

BN201 is covered by Composition of Matter and Method-of-Use patents and has orphan drug designation in the EU and the US for Acute Optic Neuritis.

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Promoting Neuroprotection

About Bionure

Bionure is a biotechnology company, a spin-off from IDIBAPS - Hospital Clinic of the University of Barcelona and the Spanish National Council CSIC (Spain), developing the neuroprotectant BN201. BN201 is a small molecule that has successfully completed a clinical phase 1 study on the safety, tolerability and pharmacokinetics of single and multiple doses of BN201 in healthy volunteers under the approval of MHRA, UK. It was backed by a Series A financing led by Alta Life Sciences. The company plans to start a phase 2 trial in early 2020. The neuroprotective activity and the ability of BN201 to induce remyelination of the neuron, as shown in preclinical studies, provide the basis for future research and clinical experiments for the treatment of several diseases in neurology with high unmet needs, including acute optic neuritis (AON, a rare ophthalmological disease) and multiple sclerosis (MS).

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