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Novaremed announces publication of pharmacological profile of MP-101, a clinical development candidate for the prevention of chemotherapy-induced peripheral neuropathy

Basel, Switzerland, January 31, 2023 – Novaremed AG, a privately held clinical-stage biopharmaceutical company focused on innovative non-opioid treatment options for chronic pain management, announces the publication of the pharmacological profile of MP-101, which is in Phase 2 clinical development as a non-opioid treatment for the prevention of chemotherapy-induced peripheral neuropathy (CIPN), including neuropathic pain.

"We are delighted with the publication of these data on MP-101," said **Eva Tiecke, PhD, Chief Scientific Officer and Head of R&D of Novaremed**. "The study demonstrated that MP-101, a non-racemic enantiomeric mixture containing three parts of R-dimiracetam and one part of S-dimiracetam, is pharmacologically more potent than racemic dimiracetam in several animal models of neuropathic pain, cognition, and depression. The demonstrated efficacy of MP-101 in the oxaliplatin-induced peripheral neuropathic pain model, together with the preclinically and clinically established safety and tolerability profile of racemic dimiracetam, strongly support the development of MP-101 for the prevention of symptoms of peripheral neuropathy, including neuropathic pain induced by chemotherapy, an area with a high unmet medical need."

In this study [1], the effects of dimiracetam, its R- or S-enantiomers, and the R:S 3:1 nonracemic mixture, designated as MP-101, were compared. In vitro, dimiracetam was more potent than its R- or S-enantiomers in reducing the N-methyl-D-aspartate (NMDA)-induced [3H]D-aspartate release in rat spinal cord synaptosomes. Similarly, acute oral administration of dimiracetam was more effective than a single enantiomer in the sodium monoiodoacetate (MIA) paradigm of painful osteoarthritis. Then, the in vitro effects of a broad range of non-racemic enantiomeric mixtures on the NMDA-induced [3H]D-aspartate release were compared. Dimiracetam was a more potent blocker than each isolated enantiomer but the R:S 3:1 non-racemic mixture (MP-101) was even more potent than dimiracetam, with an IC50 in the picomolar range. In the chronic oxaliplatin-induced neuropathic pain model, MP-101 showed a significantly improved anti-neuropathic profile, and its effect continued one week after treatment suspension. MP-101 also performed better than dimiracetam in animal models of cognition and depression. Based on the benign safety and tolerability profile previously observed with racemic dimiracetam, MP-101 appears to be a novel, promising clinical candidate for the prevention and treatment of several neuropathic and neurological disorders.

Reference:

[1] Bonifacino, T.; Micheli, L.; Torazza, C.; Ghelardini, C.; Farina, C.; Bonanno, G.; Milanese, M.; Di Cesare Mannelli, L.; Scherz, M.W. Pharmacological profile of MP-101, a novel non-racemic mixture of R- and S-dimiracetam with increased potency in rat models of cognition, depression and neuropathic pain. *Cells 2022*, 11, 4027. https://doi.org/10.3390/cells11244027

About MP-101 and the prevention of chemotherapy-induced peripheral neuropathy (CINP)

The Phase 2 clinical candidate MP-101 is an orally available modulator of glutamate signaling. It works by preventing or reversing the ramped-up signaling that occurs in the spine and brain as a result of damaged peripheral nerves. MP-101 is a patented non-racemic mixture of the dimiracetam enantiomers with patent protection until 2038. In previous Phase 1 and Phase 2 clinical studies, in a total of 176 human subjects, a benign safety and tolerability profile comparable to placebo was noted for dimiracetam, and no signs or symptoms of sedation, dependence or withdrawal symptoms emerged. Based on pre-clinical proof of concept studies and pre-IND discussions with the FDA, MP-101 is being developed for the prevention and treatment of chemotherapy-induced neuropathy and neuropathic pain.

About Novaremed

Novaremed AG, a privately held clinical-stage biopharmaceutical company, is developing a pipeline of innovative medications for chronic pain management to address the high unmet medical need for better pain relief and as an alternative to opioids. Its lead product is NRD.E1, an orally active non-opioid small molecule with a novel mechanism of action, has FDA Fast Track Designation is being studied in an NIH-sponsored Phase 2b clinical trial for the treatment of painful diabetic peripheral neuropathy (PDPN) as part of the NIH HEAL (Helping to End Addiction Long-term^{SM}) initiative. The earlier stage pipeline includes clinical candidate MP-101 (Phase 2) being developed for the prevention of chemotherapy-induced peripheral neuropathy (CIPN), and MP-103 (preclinical) targeting CIPN and other peripheral neuropathy indications. Novaremed aims to address high unmet patient and societal needs for better relief from pain and peripheral neuropathy associated with diabetes and cancer chemotherapy by providing novel, non-opioid chronic pain therapies and countering overreliance on addictive treatments. For more information: www.novaremed.com.

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