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Novaremed Announces Completion of All Patient Visits in NIH-Funded Phase 2b Trial of Non-Opioid Nispomeben for Treating Chronic Pain Associated with Diabetic Peripheral Neuropathy

- *Last patient last visit (LPLV) was reached for the 127 adult and elderly patients enrolled into the 12-week placebo-controlled trial with nispomeben (NRD.E1)*
- *Topline results are expected in November 2025*
- *The trial builds on Phase 2a double-blind, randomized, dose-finding study comparing nispomeben to placebo with results showing a clinically meaningful placebo-corrected reduction in pain and favorable tolerability of nispomeben in patients with painful DPN [1]*

Basel, Switzerland, 2 September 2025 – Novaremed AG, a privately held clinical-stage biopharmaceutical company, announces completion of the last patient last visit (LPLV) in the National Institutes of Health (NIH)-funded Phase 2b EN21-01 trial (ClinicalTrials.gov identifier NCT05480228). The trial evaluates Novaremed's non-opioid investigational drug nispomeben for the oral treatment of chronic pain associated with painful diabetic peripheral neuropathy (DPN). It is funded by the NIH Helping to End Addiction Long-term Initiative, or NIH HEAL Initiative, and conducted by the HEAL Early Phase Pain Investigation Clinical Network (EPPIC-Net). Topline Phase 2b data are expected in November 2025.

The Phase 2b trial is a 12-week, multicenter, randomized, double-blind, placebo-controlled clinical trial with the primary objective to evaluate whether a once-daily oral dose of nispomeben 80 mg is superior to placebo in relieving chronic pain among patients with painful DPN. The trial further assesses safety, tolerability, pharmacokinetics, and the compound's impact on sleep and quality of life. With LPLV achieved, database lock and prespecified statistical analyses are the next steps. Topline readout is scheduled for November 2025.

"Chronic pain associated within diabetic peripheral neuropathy affects about 20% of diabetes patients and is the most common form of neuropathic pain. Patients with painful DPN are in high unmet need of safe, effective, and non-addictive treatments," commented **Jessica Robinson-Papp, MD, MS, FAAN, Lead Primary Investigator and Professor at the Icahn School of Medicine at Mount Sinai (New York, USA)**. "Reaching last patient last visit in this trial with nispomeben is a major milestone for the program and for everyone who contributed to this rigorous study. We are deeply grateful to the study participants and to all collaborating sites. We now look forward to completing analyses and sharing the results."

"We are pleased that all patient visits have been completed in this important study with nispomeben. The Phase 2b trial is supported by the NIH, which selected nispomeben as the only oral agent for inclusion in the EPPIC-Net platform protocol to assess treatments for painful DPN," said **Camilla Mittelholzer, PhD, CSO and Head of R&D at Novaremed**. "We are preparing for the continued development of nispomeben for the treatment of patients suffering from painful DPN."

About nispomeben

Nispomeben (formerly NRD.E1 or NRD135S.E1), an orally active small molecule with a novel mechanism of action, is being developed to treat chronic pain associated with diabetic peripheral neuropathy. The mechanism of action of nispomeben is different from that of approved pain therapies and it does not bind to opioid receptors or other receptors associated with opioid mode of action. The US FDA has granted Fast Track designation to nispomeben for the treatment of painful DPN. FDA Fast Track is a process designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need. The purpose is to get important new drugs to the patient earlier. Completed clinical studies with nispomeben include Phase 1 studies and one Phase 2a proof-of-concept, randomized, double-blind, placebo-controlled, dose-finding study [1, 2]. The Phase 2a trial showed clinically relevant placebo-corrected pain reductions in patients with moderate to severe painful DPN over a 3-week treatment period. Nispomeben was well tolerated with no serious, severe, or dose-related adverse events (AE). No AEs suggestive of drug abuse, dependence or withdrawal were identified.

About the NIH HEAL Initiative and EPPIC-Net Program

The *NIH HEAL Initiative* is an NIH-wide effort to speed scientific solutions to the overdose epidemic, including opioid and stimulant use disorders, and the crisis of chronic pain. HEAL programs include those focused on identifying, developing, and testing new safe, effective, and non-addictive pain therapies. The *EPPIC-Net (Early Phase Pain Investigation Clinical Network)* is part of the NIH HEAL Initiative and seeks to enhance the management of acute and chronic pain and reduce the need for opioid medications by accelerating early-phase clinical trials of non-addictive treatments for pain. For more information: https://heal.nih.gov and https://heal.nih.gov/research/clinical-research/eppic-net

About painful diabetic peripheral neuropathy (painful DPN)

Peripheral nerve injury from various etiologies may ultimately result in chronic and severe intractable neuropathic pain. Painful DPN is a frequent complication of diabetes and represents the most common form of neuropathic pain with a high unmet medical need. Worldwide, two-thirds or an estimated 5-8 million (in US, Europe and Japan) of patients suffering from painful DPN do not obtain sufficient pain relief with current therapies. Many of the currently available products for the treatment of chronic neuropathic pain have limited efficacy and are often not well tolerated. The increasing prevalence of diabetes as well as the limitations of the available therapies make the prevention and treatment of painful DPN a condition of high unmet medical need.

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 nispomeben, an orally active non-opioid small molecule with a novel mechanism of action, has FDA Fast Track Designation and is being studied in an NIH-funded Phase 2b clinical trial for the treatment of painful DPN as part of the NIH HEAL Initiative. Novaremed aims to address high unmet patient and societal needs for better relief from pain and peripheral neuropathy associated with diabetes by providing novel, non-opioid chronic pain therapies and countering overreliance on addictive treatments. For more information: www.novaremed.com.

References:

[1] Tiecke E., Rainisio M., Eisenberg E., Wainstein J., Kaplan E., Silverberg M., Hochman L., Mangialaio S. (2022) NRD.E1, an innovative non-opioid therapy for painful diabetic peripheral neuropathy – a randomized proof of concept study. *European Journal of Pain* (https://onlinelibrary.wiley.com/doi/10.1002/ejp.1989).

[2] Tiecke E., Rainisio M., Guentert T., Müller S., Hochman L., Kaplan E., Mangialaio S. (2022). First-in-human single-ascending-dose, multiple-dose and food interaction studies of NRD.E1, an innovative non-opioid therapy for painful diabetic peripheral neuropathy. *Clinical Pharmacology in Drug Development (CPDD)* (https://accp1.onlinelibrary.wiley.com/doi/10.1002/cpdd.1103).

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