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Noema Pharma Receives FDA Orphan Drug Designation for Basimglurant for the Treatment of Trigeminal Neuralgia

BASEL, Switzerland, Nov. 16, 2026 (GLOBE NEWSWIRE) -- Noema Pharma AG, a clinical-stage biotech company targeting debilitating central nervous system (CNS) disorders, today announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation (ODD) to basimglurant (formerly known as NOE-101) for the treatment of trigeminal neuralgia (TN). Basimglurant is an orally administered, highly potent, cell-penetrant mGluR5 negative allosteric modulator (NAM) designed to modulate both central and peripheral pain pathways implicated in neuropathic pain. Basimglurant previously received FDA Fast Track Designation for TN.

“Receiving Orphan Drug Designation for basimglurant marks an important milestone as we advance the program toward Phase 3 development,” said Ilise Lombardo, M.D., Chief Executive Officer of Noema Pharma. “Affecting an estimated 150,000 people in the U.S., TN is one of the most severe and debilitating chronic neuropathic pain disorders, yet patients have seen limited therapeutic innovation in nearly six decades. This designation supports our efforts to advance basimglurant as a potential first-in-class non-opioid therapy for people living with trigeminal neuralgia.”

The FDA grants ODD to support the development of drugs for rare diseases or orphan conditions, generally those affecting fewer than 200,000 people in the United States. Designation requires a medically plausible basis for expecting the drug to be effective in the proposed indication. Potential benefits include seven years of U.S. orphan drug exclusivity if the FDA approves the drug for the designated indication and applicable requirements are met, as well as tax credits for qualified clinical trials and exemption from certain FDA user fees. ODD is separate from FDA marketing approval.

About Basimglurant
Basimglurant (formerly known as NOE-101) is an investigational, orally administered, highly selective metabotropic glutamate receptor 5 (mGluR5) negative allosteric modulator (NAM) being developed for severe neuropathic pain disorders, including trigeminal neuralgia. Through its unique cell-penetrant mechanism, basimglurant is designed to modulate both intracellular and cell-surface mGluR5 signaling pathways implicated in chronic neuropathic pain. Basimglurant is an

investigational non-opioid treatment with no known abuse potential, and has demonstrated robust and durable reductions across multiple pain domains with a favorable tolerability profile in a Phase 2 clinical study.

About Trigeminal Neuralgia
Trigeminal neuralgia (TN) is a rare, chronic neuropathic pain disorder affecting the trigeminal nerve, characterized by sudden, severe episodes of electric shock-like facial pain that can be triggered by routine daily activities such as eating, drinking, speaking, brushing teeth, shaving, or even light touch or exposure to cold air. Affecting an estimated 150,000 people in the United States, TN is widely considered one of the most painful neurological disorders and can significantly impair quality of life and daily functioning, contributing to substantial psychological burden. Despite its severity, treatment options remain limited, with carbamazepine as the only FDA-approved therapy and no significant therapeutic innovations in decades, leaving patients with a high unmet medical need.

About Noema Pharma
Noema is developing a late-stage portfolio of oral, small molecule therapeutics for neurological and other disorders. The Company is advancing programs across orphan and large-market indications, targeting therapeutic areas of high unmet need. Noema was founded by the leading venture capital firm Sofinnova Partners and is backed by the current investors including EQT, Forbion, Gilde Healthcare, Invus, Jeito Capital, Polaris Partners and UPMC Enterprises. Learn more at www.noemapharma.com.

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