

NEWS RELEASE

Nxera Pharma's Partner Centessa Announces Positive Interim Phase 1 Clinical Data with its Novel Orexin Receptor 2 (OX2R) Agonist, ORX750, in Acutely Sleep-Deprived Healthy Volunteers

2024-09-11

- ORX750 showed clinically meaningful and statistically significant improvements in mean sleep latency and had a favorable safety and tolerability profile with no observations of frequently reported adverse events
- Centessa plans to rapidly advance ORX750 into Phase 2 studies beginning in the fourth quarter of 2024

Tokyo, Japan and Cambridge, UK, 11 September 2024 – Nxera Pharma Co., Ltd. (“Nxera” or “the Company”; TSE 4565) – formerly known as Sosei Group or Sosei Heptares – notes the announcement by Centessa Pharmaceuticals on 10 September 2024 reporting positive interim clinical data from its Phase 1 clinical trial with ORX750 in acutely sleep-deprived healthy volunteers. The full announcement from Centessa can be found by [clicking here](#).

ORX750 is an investigational, orally administered, highly potent and selective orexin receptor 2 (OX2R) agonist designed using Nxera technology to directly target the underlying pathophysiology of orexin neuron loss in narcolepsy type 1 (NT1), with potential applicability to narcolepsy type 2 (NT2), idiopathic hypersomnia, and other sleep-wake disorders with normal orexin levels.

Centessa reported that ORX750 showed clinically meaningful and statistically significant improvements in mean sleep latency at the first two doses evaluated (1.0 mg and 2.5 mg) in the Maintenance of Wakefulness Test (MWT) compared to placebo. More specifically, the 2.5 mg dose was shown to restore normative wakefulness with a mean sleep latency of 32 minutes as measured by the MWT.

ORX750 was also shown to have a favorable safety and tolerability profile with no observations of frequently

reported on-target adverse events (AEs) associated with other OX2R agonists, and no cases of hepatotoxicity or visual disturbances across all three dose levels tested (1.0 mg, 2.0 mg, and 2.5 mg), as of the data cutoff date.

Based on the interim data, Centessa plans to rapidly advance ORX750 into Phase 2 studies in patients with narcolepsy type 1 (NT1), narcolepsy type 2 (NT2), and idiopathic hypersomnia (IH) beginning in the fourth quarter of 2024.

Nxera will disclose if a milestone event is reached that results in a material payment from Centessa to Nxera.

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About Nxera Pharma

Nxera Pharma (formerly Sosei Heptares) is a technology powered biopharma company, in pursuit of new specialty medicines to improve the lives of patients with unmet needs in Japan and globally.

In addition to several products being commercialized in Japan, we are advancing an extensive pipeline of over 30 active programs from discovery through to late clinical stage internally and in partnership with leading pharma and biotech companies. This pipeline is focused on addressing major unmet needs in some of the fastest-growing areas of medicine across neurology, GI and immunology, metabolic disorders and rare diseases, and leverages the power of our unique and industry leading GPCR-targeted structure-based drug discovery NxWave™ platform to provide a sustainable source of best- or first-in-class candidates.

Nxera employs over 350 talented people at key locations in Tokyo and Osaka (Japan), London and Cambridge (UK), Basel (Switzerland) and Seoul (South Korea) and is listed on the Tokyo Stock Exchange (ticker: 4565).

For more information, please visit www.nxera.life

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Forward-looking statements

This press release contains forward-looking statements, including statements about the discovery, development, and commercialization of products. Various risks may cause Nxera Pharma Group's actual results to differ materially from those expressed or implied by the forward looking statements, including: adverse results in clinical development programs; failure to obtain patent protection for inventions; commercial limitations imposed by patents owned or controlled by third parties; dependence upon strategic alliance partners to develop and commercialize products and services; difficulties or delays in obtaining regulatory approvals to market products and services resulting from development efforts; the requirement for substantial funding to conduct research and development and to expand commercialization activities; and product initiatives by competitors. As a result of these factors, prospective investors are cautioned not to rely on any forward-looking statements. We disclaim any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

Source: Nxera Pharma