

Nxera Pharma to Receive US\$35 Million from Neurocrine Biosciences upon Positive Phase 2 Data for Partnered Schizophrenia Candidate NBI-1117568

Tokyo, Japan and Cambridge, UK, 2 September 2024 – Nxera Pharma Co., Ltd. (“Nxera” or “the Company”; TSE 4565) – formerly known as Sosei Group or Sosei Heptares – announces that it will receive a US\$35 million payment from Neurocrine Biosciences (‘Neurocrine’), triggered by the successful completion of the Phase 2 trial with NBI-1117568 (NBI-‘568) in adults with schizophrenia, as announced on 28 August 2024. Receipt of the US\$35 million payment will be recognized as one-time revenue in the third quarter of 2024.

The [NBI-‘568-SCZ2028 dose-finding study](#) met its primary endpoint for the once-daily 20 mg dose and was generally safe and well tolerated at all doses studied, supporting Neurocrine’s intentions to advance NBI-‘568 into Phase 3 clinical trials in early 2025. Please refer to “[Nxera Pharma Notes Positive Phase 2 Data for Partnered Schizophrenia Candidate NBI-1117568](#)” dated 28 August 2024 for the full announcement from Nxera on the positive data from the trial.

NBI-‘568 is the first oral, muscarinic M4 selective agonist in development for the treatment of schizophrenia. The candidate is the most advanced from a broad portfolio of novel clinical and preclinical subtype-selective muscarinic M4, M1 and dual M1/M4 receptor agonists discovered by Nxera and advancing under a 2021 global collaboration with Neurocrine for the treatment of major neurological and neuropsychiatric disorders.

To date, Nxera has received multiple, significant payments from Neurocrine including those based on developmental progress of four candidates in clinical trials. Overall, Nxera is eligible to receive up to US\$1.5 billion in development milestone payments through to approvals, plus commercial milestones, which together total up to US\$2.6 billion, plus product royalties, provided the criteria under the agreement are satisfied. Nxera retains rights to develop M1 agonists advancing under this collaboration in Japan in all indications, subject to certain exceptions.

Matt Barnes, EVP, President of Nxera Pharma UK and Head of R&D, commented: “The successful Phase 2 trial with NBI-‘568 delivered positive data in adults with schizophrenia at the 20mg dose. As stated by Neurocrine, these data support advancing NBI-‘568 into Phase 3 trials that would aim to confirm its potential to become a new oral therapy option for patients with a competitive profile based on efficacy, safety and tolerability from a convenient 20mg once-daily administration.”

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About the Agreement with Neurocrine Biosciences

Nxera Pharma and Neurocrine entered a collaboration and licensing agreement in November 2021 to develop a portfolio of novel muscarinic receptor agonists for the treatment of schizophrenia, dementia and other neuropsychiatric disorders.

Under the terms of the agreement, Neurocrine gained development and commercialization rights to a broad portfolio of novel clinical and preclinical subtype-selective muscarinic M4, M1 and dual M1/M4 receptor agonists discovered by Nxera. Neurocrine is responsible for development costs associated with the programs globally, except for M1 agonists being developed in Japan. Nxera retains rights to develop M1 agonists in Japan for any indication, subject to certain exceptions, with Neurocrine receiving co-development and profit share options.

Nxera is eligible to receive R&D funding plus development, regulatory and commercial milestones of up to US\$2.6 billion, with further product royalties, provided the criteria under the agreement are satisfied.

The four candidates progressing from the partnership are:

Compound	Primary Mechanism	Phase	Therapeutic Areas	Potential Areas for Development
NBI-1117568	M4 agonist	2	Psychosis Cognition	Alzheimer's Disease Bipolar Disorder Parkinson's Disease Lewy Body Dementia Schizophrenia
NBI-1117569	M4 agonist	1		
NBI-1117567	M1 agonist	1		
NBI-1117570	M1/M4 dual agonist	1		

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.