Nxera Pharma Notes Successful Development Progress of Partnered Schizophrenia Candidate NBI-1117568

- NBI-1117568 is an oral, selective muscarinic M4 receptor agonist advancing through Phase 2 clinical development under a multi-program collaboration with Neurocrine Biosciences

- Successful completion of a long-term preclinical toxicity program to support safe, chronic dosing of NBI-1117568 in future clinical trials triggers a $15 million payment to Nxera from Neurocrine Biosciences

Tokyo, Japan and Cambridge, UK, 16 April 2024 – Nxera Pharma Co., Ltd. ("Nxera" or "the Company; TSE 4565) – formerly known as Sosei Group or Sosei Heptares – has been notified by its partner Neurocrine Biosciences Inc. ("Neurocrine"; Nasdaq: NBIX) that NBI-1117568, an oral selective muscarinic M4 receptor agonist being advanced in Phase 2 clinical trials by Neurocrine for the treatment of schizophrenia and other neuropsychiatric disorders, has successfully completed a long-term preclinical toxicity program that meets US FDA requirements to allow for safe, chronic (i.e. long-term) dosing in future clinical trials. The achievement of this important safety development milestone triggers a $15 million payment to Nxera from Neurocrine.

NBI-1117568 is the most advanced candidate 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 the 2021 global collaboration with Neurocrine for the treatment of major neurological disorders. These candidates have potential to address a range of neurological and neuropsychiatric conditions and include:

- NBI-1117568 (an M4 selective agonist) in Phase 2 trials with top-line data expected in H2 2024
- NBI-1117570 (an M1/M4 selective dual agonist) in Phase 1
- NBI-1117569 (an M4-preferring agonist) in Phase 1
- NBI-1117567* (an M1-preferring agonist) expected to enter Phase 1 in 2024

Matt Barnes, EVP, President of Nxera Pharma UK and Head of R&D, commented: "We are delighted that NBI-1117568 has successfully achieved this important safety development milestone. These results will support the safe, long-term use of this novel clinical candidate, which is consistent with a desired product profile for schizophrenia and other neurological diseases where patients often need therapy over many years. We are extremely pleased at the progress being made under our highly productive partnership with Neurocrine and look forward to reporting further progress and upcoming clinical data readouts, including the top-line Phase 2 data on NBI-1117568, which is expected in the second half of 2024."

**Nxera retains rights to develop M1 agonists advancing under this collaboration in Japan in all indications.*

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About Muscarinic Receptors
Muscarinic receptors are G protein-coupled receptors (GPCRs) found in multiple tissues including the brain, cardiovascular system, and gastrointestinal tract. Selective activation of M4 and M1 receptors in the brain is a clinically validated approach to treating cognitive and neuropsychological symptoms of neurological diseases, including Schizophrenia, dementia associated with Alzheimer's disease, Parkinson's disease, and others.

Until now, attempts to develop medicines that selectively target M4 and M1 receptors have been unsuccessful because of side effects caused by the activation of M2 and M3 receptors. Highly selective M4 or M1 agonists that do not activate M2 or M3 therefore are highly sought after and expected to have the potential to address major unmet medical needs with blockbuster potential.

About NBI-1117568
NBI-1117568 is an oral, selective muscarinic M4 receptor agonist discovered by Nxera Pharma and being developed in Phase 2 clinical trials by Neurocrine for the treatment of schizophrenia and other neuropsychiatric disorders. As a selective M4 orthosteric agonist, NBI-1117568 offers the potential to deliver therapeutic effects without the need of combination therapy to minimize side effects, as required with non-selective muscarinic agonists, whilst also avoiding the requirement for cooperativity with acetylcholine (ACh) when compared to positive allosteric modulators. Clinical studies completed to date have shown NBI-1117568 to be generally well tolerated.

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

Under the terms of the agreement, Neurocrine gains 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, 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.

About Neurocrine Biosciences
Neurocrine Biosciences is a leading neuroscience-focused, biopharmaceutical company with a simple purpose: to relieve suffering for people with great needs, but few options. We are dedicated to discovering and developing life-changing treatments for patients with under-addressed neurological, neuroendocrine, and neuropsychiatric disorders. The company's diverse portfolio includes FDA-approved treatments for tardive dyskinesia, chorea associated with Huntington's disease, endometriosis* and uterine fibroids*, as well as a robust pipeline including multiple compounds in mid- to late-phase clinical development across our core therapeutic areas. For three decades, we have applied our unique insight into neuroscience and the interconnections between brain and body systems to treat complex conditions. We relentlessly pursue medicines to ease the burden of debilitating diseases and disorders, because you deserve brave science. For more information, visit neurocrine.com, and follow the company on LinkedIn, X (Formerly Twitter), and Facebook.
(**in collaboration with AbbVie*)

Nxera

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.