Nxera Pharma Operational Highlights and Consolidated Results for the First Quarter 2025

Tokyo, Japan and Cambridge, UK, 2 May 2025 – Nxera Pharma ("the Company" or "Nxera"; TSE: 4565) provides an update on operational activities and reports its consolidated results for the first quarter ended 31 March 2025. The full report can be found here.

Chris Cargill, President and CEO of Nxera, commented: "As we mark one year since our transformation from Sosei Heptares to Nxera Pharma, I am incredibly proud of the progress we've made and how we have evolved. Our new identity has unified the Group and helped clarify our mission while clearly signalling our intent to lead the next era of biopharmaceutical innovation in Japan and globally. The strides we've made over the past year is a testament to the strength of our people, our partnerships, and the power of our NxWave™ platform to deliver promising new candidates for development across major disease areas with great unmet need.

"We expect 2025 to be an important year across both for our partnered and in-house portfolios. With key data readouts anticipated from multiple clinical trials and several new studies due to commence, we are well positioned to deliver significant value for patients and shareholders alike."

Operational Highlights for Q1 2025

Development and commercialization agreements

- Assignment of Japan and Asia-Pacific (ex-China) rights for cenerimod, a promising S1P1 receptor modulator for autoimmune diseases, to Viatris
  - Receipt of upfront payment of US$10 million, with additional milestone and royalty potential
- Agreement signed with Holling Bio-Pharma Corp. ("Holling") to commercialize daridorexant, a dual orexin receptor antagonist, for sleep disorders in Taiwan
  - Nxera will be responsible for the supply of drug product and Holling will be responsible for regulatory, commercial and distribution activities and will hold all regulatory approvals
  - Filing in Taiwan is expected in 2025, with a potential launch in 2026

Progress with partnered programs

- Neurocrine Biosciences, Inc. outlined clinical development plans for the partnered muscarinic agonist portfolio in 2025, including
  - Initiation of Phase 3 registrational studies with NBI-1117568 (an oral, muscarinic M4-selective agonist) in schizophrenia in 1H 2025
  - Initiation of a Phase 2 study with NBI-1117568 in bipolar mania in 2H 2025
  - Initiation of a Phase 2 study with NBI-1117570 (a dual M1 / M4 agonist) in schizophrenia in 2H 2025
  - Data readouts for NBI-1117570, NBI-1117567 (M1-preferring), and NBI-1117569 (M4-preferring) expected in 2025, all of which are being advanced in Phase 1 trials targeting neurological and neuropsychiatric conditions

- Tempero Bio initiated a Phase 2 trial of TMP-301 for alcohol use disorder
  - TMP-301, a potent, selective and orally available mGluR5 negative allosteric modulator (NAM), was discovered using Nxera's NxWave™ platform and is also in development for cocaine use disorder

Corporate highlights

- Changes to Board of Directors
  - Ms. Naoko Shimura and Ms. Nicola Rabson appointed as new External Directors
  - Mr. Shinichi Tamura, Chairman and founder of the Company, Mr. Tomohiro Tohyama and Mr. Kuniaki Kaga, former External Directors, also retired from the Board of Directors

Post-period events

- Neurocrine initiated a Phase 3 registrational program of NBI-1117568 as a potential treatment for schizophrenia in May 2025 supported by positive top-line data from the Phase 2 study, which met its primary endpoint for the once-daily 20 mg dose (as reported in August 2024).
  - The Phase 3 study is a global double-blind, placebo-controlled trial evaluating NBI-'568 in adults with a primary diagnosis of schizophrenia who are experiencing an acute exacerbation or relapse of symptoms.
  - The study is expected to enroll approximately 280 patients.
  - The primary endpoint of the study is a reduction from baseline in the Positive and Negative Syndrome Scale (PANSS).
  - The key secondary endpoint is improvement in the Clinical Global Impression of Severity (CGI-S) scale.
- Executive appointments
  - Mr. Kiyoshi Kaneko appointed as Chief Commercial Officer and Ms. Mariko Nakafuji promoted to Chief Legal Officer

Financial Highlights for the Three-month Period ended 31 March 2025

- Revenue totalled JPY 6,644 million (US$43.5 million*), an increase of JPY 2,033 million (US$12.5 million) vs. the prior year. This increase was primarily due to the inclusion of sales of QUVIVIQ® following its launch in the fourth quarter of 2024, as well as the occurrence of one R&D milestone event in the current quarter vs. no R&D milestone events in the prior corresponding period.
- R&D expenses totalled JPY 3,808 million (US$25.0 million), an increase of JPY 645 million (US$3.7 million) vs. the prior year. This increase primarily reflects an increased investment in R&D and the impact of the weaker Yen.
- SG&A expenses totalled JPY 3,701 million (US$24.3 million), an increase of JPY 51 million (a decrease of US$0.3 million) vs. the prior corresponding period. This increase was primarily due to incremental spend on personnel to strengthen organizational capabilities, offset by lower sales-related costs as a result of targeted cost savings.
- Operating loss totalled JPY 2,193 million (US$14.4 million) vs. an operating loss of JPY 3,076 million (US$20.7 million) in the prior year. This improvement in profitability reflects the combined effect of all movements explained above.
- Loss before income tax totalled JPY 2,156 million (US$14.1 million) vs. a loss before income tax of JPY 2,796 million (US$18.8 million) in the prior year. This improvement in profitability reflects the combined effect of all movements explained above.
- Net loss totalled JPY 760 million (US$5.0 million) vs. a net loss of JPY 3,281 million (US$22.1 million) in the prior year. This improvement in profitability reflects the combined effect of all movements explained above.

- Core operating loss** totalled JPY 625 million (US$4.1 million) vs. a core operating loss of JPY 931 million (US$6.3 million) in the prior corresponding period.
- Cash and cash equivalents as at 31 March 2025 amounted to JPY 34,465 million (US$230.0 million) having increased by JPY 2,197 million (US$24.3 million) from the beginning of the year.

**Convenience conversion to US$ at the following rates: FY 2025: 1US$ =152.57 JPY; FY 2024: 1US$ =148.40 JPY; 31 Mar 2025: 1US$ = 149.85 JPY; 31 Dec 2024: 1US$ = 156.83 JPY*
*** Core operating profit / loss is an alternative performance measure which adjusts for material non-cash costs and one-off costs in order to provide insights into the recurring cash generation capability of the core business.*

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About Nxera Pharma
Nxera Pharma 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.

We have built an agile, new-generation commercial business in Japan to develop and commercialize innovative medicines, including several launched products, to address this high value, large and growing market and those in the broader APAC region.

Behind that, and powered by our unique NxWave™ discovery platform, 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 of potentially first- and best-in-class candidates is focused on addressing major unmet needs in some of the fastest-growing areas of medicine across neurology/neuropsychiatry, metabolic diseases and immunology and inflammation.

Nxera employs approximately 400 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.