Nxera Pharma Operational Highlights and Consolidated Results for the Fourth Quarter and Full Year 2024

Tokyo, Japan and Cambridge, UK, 14 February 2025 – Nxera Pharma Co., Ltd. ("Nxera" or "the Company"; TSE 4565) provides an update on operational activities and reports its consolidated results for the fourth quarter and 12 months ended 31 December 2024. The full report can be viewed here.

Chris Cargill, President & CEO of Nxera, commented: "2024 was a transformational year for Nxera during which we made excellent progress under our new company name and brand towards becoming a leading technology driven biopharmaceutical company bringing new medicines to patients in Japan and globally.

"We made fantastic commercial progress, with two products – PIVLAZ™ and QUVIVIQ™ (partnered with Shionogi) – recently launched in Japan driving top line revenue growth. We plan to make these products available to patients in South Korea shortly, in addition to other key APAC markets (ex-China).

"Furthermore, and importantly, we saw significant advances across our partnered pipeline in 2024, with multiple programs moving towards late-stage clinical development and generating approximately US$90 million in upfront and milestone payments. These programs address some of the fastest growing therapeutic areas of unmet need, including neurology/neuropsychiatry, metabolic diseases and immunology and inflammation. The progress made by partner Neurocrine to advance its muscarinic agonist portfolio during the year has been particularly exciting and will lead to the first Nxera-designed molecule entering Phase 3 trials in 2025.

"Our three wholly owned programs are also advancing as planned in early clinical development, with several important milestones expected over the next 12-18 months. Further, the continued investment in our NxWave™ platform, alongside our collaborations with cutting-edge technology companies, is generating exciting new discovery opportunities within the GPCR target universe, and potentially beyond to other important transmembrane target classes, such as ion channels or transporters. In addition, it allows us to explore new modalities against GPCR targets of interest, such as peptides and antibodies, broadening our capabilities and opportunities even more.

"Going into 2025, Nxera is well capitalized and very well positioned – with multiple clinical data readouts and other potential catalysts expected during the year – to build on the tremendous work done by our exceptional and dedicated team, as we continue our mission to bring innovative therapies to patients in Japan and around the world."

Operational Highlights for Q4 2024

- **Significant growth in PIVLAZ® (clazosentan sodium) 150mg sales in Japan during first full year of Nxera ownership**
  - Rapidly becoming standard of care in Japan with neurosurgeons for prevention of cerebral vasospasm in patients with aneurysmal subarachnoid haemorrhage (aSAH)
  - Market share increased from 57% in 2023 to 69% in 2024
  - Q4 2024 net sales of JPY 4,282 million, FY 2024 net sales of JPY 12,651 million (US$83.5 million, representing 14% growth vs FY 2023)

- **QUVIVIQ™ (daridorexant) 25 and 50 mg launched in Japan for the treatment of adult patients with insomnia**
  - Insomnia affects about 20% of Japanese adults and is recognized as an important national issue impacting both physical and mental health.
  - QUVIVIQ™ is a novel dual orexin receptor agonist that was successfully developed through a Phase 3 trial by Nxera Pharma Japan ("NPJ," a wholly owned subsidiary of Nxera Pharma).
  - QUVIVIQ™ was launched in December 2024 under a commercial partnership agreement signed in October 2024 with Shionogi, which is solely responsible for distribution and sales of QUVIVIQ™ in Japan. NPJ is responsible in part for provision of drug product.

- **Strategy to expand market for daridorexant underway with start of Phase 3 trial in South Korea**
  - Insomnia affects an estimated 15-25% of the adult population in South Korea, or 6.5-11 million people.
  - The randomized, double-blind, placebo-controlled Phase 3 study in adult and elderly subjects with insomnia is expected to run for 12 months with results expected during 1H 2026.

- **Further progress in sleep/wake disorders made by partner Centessa, which initiated a Phase 2 trial of ORX750**
  - ORX750 is an investigational, orally administered, highly potent and selective orexin receptor 2 agonist, designed using Nxera technology to target the underlying pathophysiology of orexin neuron loss in narcolepsy type 1 and other sleep-wake disorders.

- **New multi-target partnership and licensing agreement with UK techbio company Antiverse to design antibodies for validated but challenging GPCR targets**
  - The collaboration combines Antiverse's generative AI antibody design expertise with Nxera's NxWave™ platform, with Nxera retaining exclusive rights to develop and commercialize any resulting candidates.

- **Experienced Pharma Executive Makoto Sugita, M.D., Ph.D., MBA, Appointed as Chief Medical Officer and President of NPJ**
  - Dr. Sugita was formerly Vice President, Head of R&D for Bristol Myers Squibb in Japan – he brings nearly 20 years' experience in R&D and commercial roles working within the Japanese businesses of global pharmaceutical companies.

- **Nxera Pharma won Biotech Company of the Year and Financing Deal of the Year at the Citeline Japan Awards 2024**
  - Awards recognize outstanding advancements and innovations in the Japanese pharma and biotech sector.

Post-period Events

- **Clinical development progress with partnered muscarinic agonist portfolio noted by Neurocrine at 43rd Annual J.P. Morgan Healthcare Conference**

  NBI-1117568 (an oral, muscarinic M4-selective agonist)
  - End of Phase 2 meeting with the US Food & Drug Administration completed and reiteration of plans to begin Phase 3 studies in schizophrenia in 1H 2025.
  - Initiate Phase 2 study in bipolar mania in 2H 2025.

  NBI-1117570 (a dual M1 / M4 agonist)

- Initiate Phase 2 study in schizophrenia in 2H 2025.

NBI-1117567 (an M1-preferring agonist) and NBI-1117569 (an M4-preferring agonist)
- Phase 1 trials underway targeting neurological and neuropsychiatric conditions with data readouts anticipated during 2025.

Operational Highlights for Full Year 2024

Corporate highlights

- **Nxera Pharma, the new name for Sosei Heptares, came into effect on 1 April 2024** along with the launch of a new corporate brand and identity designed to capture the Group's ambition to be at the forefront of the next era of biopharmaceuticals and medicine
- **Senior team strengthened with appointments of experienced biopharma executives** Toshihiro Maeda as Chief Operating Officer and senior strategy consultant Patrick Branch as Head of Business Development for Japan and APAC

Progress with in-house programs

- **Approval of QUVIVIQ™ (daridorexant) 25 and 50 mg** by the Ministry of Health, Labour and Welfare of Japan for the treatment of adult patients with insomnia received in September 2024
- **First subject dosed in a Phase 1 trial with NXE0033744**, a novel, potent, selective and gut-restricted EP4 receptor agonist in development for the treatment of Inflammatory Bowel Disease (IBD)
- **Full ownership of NXE0027477 regained from GSK** – NXE-477 is a clinic-ready, highly selective, first-in-class, oral GPR35 agonist in development as a potential new treatment for IBD.
- **Nxera and PrecisionLife expanded their 2022 strategic R&D partnership** into autoimmune disorders with the aim of identifying new drug targets and subsequently potential precision targeted therapies for complex, chronic conditions.

Progress with partnered programs

- **Approximately US$70 million in milestone payments received by Nxera based on progress made across multiple partnered programs**
  - Neurocrine presented positive Phase 2 data for schizophrenia candidate NBI-'568 and announced its intention to advance it into Phase 3 trials in 2025, triggering a US$35 million payment to Nxera.
  - Successful completion of long-term preclinical toxicity program with NBI-'568, supporting its chronic dosing in future clinical trials, triggered a US$15 million payment from Neurocrine
  - First R&D milestone reached under a multi-target discovery collaboration with AbbVie in neurological diseases resulted in a payment of US$10 million to Nxera
  - Progress made by Centessa advancing ORX750 into and through Phase 1 development resulted in a milestone payment to Nxera of US$4.6 million
  - US$2.5 million milestone payment received from Formosa Pharmaceuticals for US approval of APP13007 for the treatment of post-operative inflammation and pain following ocular surgery
- **New global collaboration and exclusive option-to-license agreement signed with Boehringer Ingelheim to develop first-in-class treatments targeting all symptoms of schizophrenia**
  - Single-target agreement focused on development of novel, small molecule agonists of GPR52 discovered by Nxera with the potential to simultaneously address positive, negative and cognitive symptoms of schizophrenia
  - Nxera received EUR 25 million upfront from Boehringer Ingelheim and is eligible for an option exercise payment of EUR 60 million and further milestone payments totalling up to EUR 670 million plus tiered royalties

Financial Highlights for the 12-month Period ended 31 December 2024

- Revenue totalled JPY 28,835 million (US$190.4 million*), an increase of JPY 16,069 million (US$99.6 million) vs. the prior year. This increase was primarily due to the inclusion of NPJ in the scope of consolidation from July 2023 resulting in twelve months of PIVLAZ® sales being included in 2024 compared to circa five months in 2023, as well as signing one new R&D partnership agreement and the occurrence of five R&D milestone events in the current year vs. no upfront fees and the occurrence of three R&D milestone events in the prior year.
- R&D expenses totalled JPY 11,816 million (US$78.0 million), an increase of JPY 1,741 million (US$6.3 million) vs. the prior year. This increase primarily reflects an increased investment in R&D plus the impact of the weaker Yen. JPY 1,483 million (US$9.8 million) has been included for R&D expenses relating to NPJ/NPK.
- SG&A expenses totalled JPY 16,015 million (US$105.8 million), an increase of JPY 6,050 million (US$34.8 million) vs. the prior corresponding period. This increase was primarily due to an increase in SG&A expenses relating to the NPJ/NPK businesses, including an amortization charge on Idorsia related intangible assets. JPY 8,972 million (US$59.3 million) has been included for SG&A expenses relating to NPJ/NPK.
- Operating loss totalled JPY 5,423 million (US$35.8 million) vs. an operating loss of JPY 9,526 million (US$67.8 million) in the prior year. This improvement in profitability reflects the combined effect of all movements explained above.
- Loss before income tax totalled JPY 4,662 million (US$30.8 million) vs. a loss before income tax of JPY 10,680 million (US$76.0 million) in the prior year. This improvement in profitability reflects the combined effect of all movements explained above.
- Net loss for the year ended 31 December 2024 totalled JPY 4,838 million (US$31.9 million) vs. a net loss of JPY 7,193 million (US$51.2 million) in the prior year. This improvement in profitability reflects the combined effect of all movements explained above.
- Core operating profit** totalled JPY 3,606 million (US$23.8 million) vs. a core operating loss of JPY 3,076 million (US$21.9 million) in the prior corresponding period.
- Cash and cash equivalents as at 31 December 2024 amounted to JPY 32,268 million (US$205.8 million) having decreased by JPY 16,797 million (decreased by US$142.1 million) from the beginning of the year.

**Convenience conversion to US$ at the following rates: FY 2024: 1US$ =151.43 JPY; FY 2023: 1US$ =140.53 JPY; 31 Dec 2024: 1US$ = 156.83 JPY; 31 Dec 2023: 1US$ = 141.03 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.*

–END–

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.

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
LinkedIn: @NxeraPharma | X: @NxeraPharma | YouTube: @NxeraPharma

Enquiries:

Nxera – Media and Investor Relations
Kentaro Tahara, VP Investor Relations and Corporate Strategy
Shinichiro Nishishita, VP Investor Relations, Head of Regulatory Disclosures
Maya Bennison, Communications Manager
+81 (0)3 5210 3399 | +44 (0)1223 949390 | IR@Nxera.life

MEDiSTRAVA (for International Media)
Mark Swallow, Frazer Hall, Erica Hollingsworth
+44 (0)203 928 6900 | Nxera@medistrava.com

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.