Nxera Pharma and Cancer Research UK Announce First Patient Dosed in Phase 2a Trial of Investigational Cancer Immunotherapy HTL0039732

- HTL0039732 (also known as NXE0039732) is Nxera's novel oral EP4 antagonist being investigated to treat a wide range of solid cancers in combination with other immunotherapies
- Cancer Research UK's Centre for Drug Development is sponsoring and managing the ongoing Phase 1/2a trial of HTL0039732

Tokyo, Japan and Cambridge and London, UK, 17 September 2025 – Nxera Pharma Co., Ltd. ("Nxera" or "the Company"; TSE 4565) and Cancer Research UK announce that the first patient has been dosed in a Phase 2a clinical trial (NCT05944237) evaluating Nxera's investigational immunotherapy drug HTL0039732 (also known as NXE0039732) for advanced solid tumors.

The decision to advance to Phase 2a follows the successful completion of the Phase 1 part of the trial, which identified a safe and well-tolerated dose of HTL0039732 – a novel EP4 antagonist – in combination with checkpoint inhibitor atezolizumab that achieves good engagement of the intended target EP4, without significantly engaging EP2.

Study participants had advanced solid tumors that were resistant or refractory to standard therapy, and the Phase 1 trial showed encouraging early efficacy including two confirmed partial responses in two distinct tumor types when administered in combination use with atezolizumab. The Phase 1 trial results to date will be presented at the European Society for Medical Oncology Congress (ESMO) 2025 in October.

HTL0039732 is an oral small molecule drug candidate that blocks the signalling through the prostaglandin E2 (PGE2)-type prostanoid receptor 4 (EP4). PGE2 acts in the tumor microenvironment to trigger cancer cells to evade the immune system.

Targeting EP4 to block the effects of PGE2 increases the ability of the immune system to detect and control cancer cells and makes HTL0039732 a potential candidate to treat patients with cancers that generally do not respond well to current immunotherapies.

Cancer Research UK's Centre for Drug Development is sponsoring and managing the trial, which is led by Chief Investigator Dr Bristi Basu, University of Cambridge, and Co-Chief Investigator Dr Debashis Sarker, King's College London. The trial's lead site is Addenbrooke's Hospital, Cambridge, and it is open for recruitment across several other sites across the Experimental Cancer Medicine Centre (ECMC) network.

The Phase 2a trial will be expanded to four cohorts of patients with microsatellite stable colorectal cancer (MSS CRC), gastric or gastroesophageal junction (GOJ) adenocarcinoma, clear cell renal cell carcinoma, and metastatic castration-resistant prostate cancer. Nxera Pharma holds a license to the results generated

under the trial to continue the clinical development and commercialisation of HTL0039732.

Dr Matt Barnes, Chief Scientific Officer and President of Nxera Pharma UK, said: “We are proud to reach this important milestone in the development of HTL0039732 and to continue our productive collaboration with Cancer Research UK. The initiation of the Phase 2a trial marks a significant step forward in our efforts to bring this promising drug to patients with difficult-to-treat cancers. The encouraging data from the Phase 1 study provide a strong foundation for continued clinical investigation, and we look forward to sharing further updates as the trial progresses.”

Dr Bristi Basu, Chief Investigator, University of Cambridge, said: “It is exciting to move to the next phase of assessing this new inhibitor of an important receptor EP4, which is implicated in suppression of the antitumor immune response. We hope that by combining it with immunotherapy, we will build on some of the promising early data we have seen in patients treated in the Phase 1 trial.”

Dr Lars Erwig, Director of the Centre for Drug Development, Cancer Research UK, said: “The dosing of the first patient in the Phase 2a trial of HTL0039732 is a significant step forward in the Centre for Drug Development’s collaboration with Nxera Pharma, which exemplifies the power of partnership in accelerating the development of groundbreaking therapies. The need for novel immunotherapies is more pressing than ever, as many cancers continue to evade current treatments. We look forward to continuing this journey and bringing hope to patients and their families.”

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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 obesity and metabolic disorders, neurology/neuropsychiatry 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
LinkedIn: @NxeraPharma | X: @NxeraPharma | YouTube: @NxeraPharma

About Cancer Research UK's Centre for Drug Development

Cancer Research UK has an impressive record of developing novel treatments for cancer. The Cancer Research UK Centre for Drug Development has been pioneering the development of new cancer treatments for 30 years, taking over 170 potential new anti-cancer agents into clinical trials in patients. Six of these new agents have made it to market, including temozolomide for brain cancer, abiraterone for prostate cancer and rucaparib for ovarian cancer. Two other drugs are in late development Phase 3 trials. Thirteen agents remain in active development with the potential to reach the market. It currently has a portfolio of 16 projects in preclinical development, Phase 1 or early Phase 2 clinical trials. www.cruk.org.uk/cdd

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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.