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**AstraZeneca and Daiichi Sankyo announce clinical collaboration
with Summit Therapeutics to evaluate *Datroway* in combination
with ivonescimab across multiple tumour types**

***Builds on recently announced clinical collaboration between AstraZeneca
and Summit to advance leading ADC combination strategy in cancer***

AstraZeneca and Daiichi Sankyo have entered into a clinical collaboration agreement with Summit Therapeutics Inc. to evaluate *Datroway* (datopotamab deruxtecan) in combination with ivonescimab across multiple tumour types including lung and breast cancers. The companies intend to begin with a Phase III trial in 1st-line triple-negative breast cancer (TNBC).

Datroway is a specifically engineered TROP2-directed DXd antibody drug conjugate (ADC) discovered by Daiichi Sankyo and being jointly developed and commercialised by AstraZeneca and Daiichi Sankyo.

Susan Galbraith, Executive Vice President, Oncology Haematology R&D, AstraZeneca, said: “Central to our strategy to transform cancer outcomes is harnessing the power of immunotherapy and antibody drug conjugate combinations to drive deeper, more durable responses. We believe the combination of *Datroway* and ivonescimab has the potential to make a meaningful difference in multiple tumour types including lung and breast cancers.”

Dr. Maky Zanganeh, President and Co-Chief Executive Officer of Summit Therapeutics, said: “We believe this collaboration with Daiichi Sankyo and AstraZeneca reflects increasing conviction in ivonescimab’s potential as a foundational next-generation immunotherapy and advances our ambition for ivonescimab to become the global PD-1 / VEGF partner of choice for novel combinations. Beginning with a Phase III study in first-line triple negative breast cancer, this collaboration represents an important expansion of Summit’s global development program into breast cancer and a path for additional solid tumour settings.”

John Tsai, Global Head, R&D, Daiichi Sankyo, said: “At Daiichi Sankyo, we are focused on maximising the potential of our DXd antibody drug conjugate portfolio through innovative combinations and strategic collaborations that support the continued advancement of our pipeline. We are encouraged by the opportunity to explore ivonescimab in combination with *Datroway* to potentially deliver clinically meaningful benefit to patients.”

Under the terms of this agreement, each company will contribute their respective medicine for the planned combination trials which will be sponsored by AstraZeneca or Daiichi Sankyo. AstraZeneca, Daiichi Sankyo and Summit will each contribute to trial costs and each company will retain development and commercial rights to their respective medicines.

AstraZeneca also [recently announced](#) an equity investment which will help in part to support clinical collaborations evaluating combinations with ivonescimab including this agreement for *Datroway*, AstraZeneca’s separate agreement with Summit for combinations with sonesitaturg vedotin (Sone-Ve), and planned future clinical collaborations intended to evaluate combinations with other AstraZeneca cancer medicines, including additional ADCs.

Ivonescimab is a novel, potential first-in-class bispecific antibody combining the effects of immunotherapy via a blockade of PD-1 with the anti-angiogenesis effects associated with blocking VEGF into a single molecule. Ivonescimab is approved to treat certain patients with non-small cell lung cancer (NSCLC) in China, and a Biologics License Application (BLA)

seeking approval in EGFR-mutated NSCLC is under review by the US Food and Drug Administration (FDA). Ivonescimab is currently being studied in Phase III clinical trials in NSCLC, small cell lung cancer, biliary tract cancer, bladder cancer, TNBC, head and neck squamous cell carcinoma, colorectal cancer, and pancreatic cancer.

Notes

Datroway

Datroway (datopotamab deruxtecan; datopotamab deruxtecan-dlnk in the US only) is a TROP2-directed ADC. Designed using the proprietary DXd ADC Technology of Daiichi Sankyo, *Datroway* is one of seven DXd ADCs in the oncology pipeline of Daiichi Sankyo, and one of the most advanced programmes in AstraZeneca's ADC scientific platform. *Datroway* is comprised of a humanised anti-TROP2 IgG1 monoclonal antibody, developed in collaboration with Sapporo Medical University, attached to a number of topoisomerase I inhibitor payloads (an exatecan derivative, DXd) via tetrapeptide-based cleavable linkers.

Datroway is approved in more than 30 countries/regions worldwide for the treatment of adult patients with unresectable or metastatic TNBC who are not candidates for PD-1/PD-L1 inhibitor therapy based on the results from the [TROPION-Breast02](#) trial.

Datroway is also approved in more than 45 countries/regions worldwide for the treatment of adult patients with unresectable or metastatic HR-positive, HER2-negative (IHC 0, IHC 1+ or IHC 2+/ISH-) breast cancer who have received prior endocrine-based therapy and chemotherapy for unresectable or metastatic disease based on results from the [TROPION-Breast01](#) trial.

Datroway is approved in the US and several other countries for the treatment of adult patients with locally advanced or metastatic *EGFR*-mutated non-small cell lung cancer (NSCLC) who have received prior *EGFR*-directed therapy and platinum-based chemotherapy based on results from the [TROPION-Lung05](#) and [TROPION-Lung01](#) trials. Continued approval for this indication in the US may be contingent upon verification and description of clinical benefit in a confirmatory trial.

***Datroway* clinical development programme**

A comprehensive global clinical development programme is underway with more than 20 trials evaluating the efficacy and safety of *Datroway* across multiple cancers, including NSCLC, TNBC and urothelial cancer. The programme includes eight Phase III trials in lung cancer, five Phase III trials in breast cancer, one Phase III trial and one Phase II/III trial in urothelial cancer evaluating *Datroway* as a monotherapy and in combination with other cancer treatments in various settings.

Daiichi Sankyo collaboration

AstraZeneca and Daiichi Sankyo entered into a global collaboration to jointly develop and commercialise *Enhertu* (trastuzumab deruxtecan) in [March 2019](#) and *Datroway* in [July 2020](#), except in Japan where Daiichi Sankyo maintains exclusive rights for each ADC. Daiichi Sankyo is responsible for the manufacturing and supply of *Enhertu* and *Datroway*.

AstraZeneca in oncology

AstraZeneca is leading a revolution in oncology with the ambition to provide cures for cancer in every form, following the science to understand cancer and all its complexities to discover, develop and deliver life-changing medicines to patients.

The Company's focus is on some of the most challenging cancers. It is through persistent innovation that AstraZeneca has built one of the most diverse portfolios and pipelines in the

industry, with the potential to catalyse changes in the practice of medicine and transform the patient experience.

AstraZeneca has the vision to redefine cancer care and, one day, eliminate cancer as a cause of death.

AstraZeneca

AstraZeneca (LSE/STO/NYSE: AZN) is a global, science-led biopharmaceutical company that focuses on the discovery, development, and commercialisation of prescription medicines in Oncology, Rare Disease, and BioPharmaceuticals, including Cardiovascular, Renal & Metabolism, and Respiratory & Immunology. Based in Cambridge, UK, AstraZeneca's innovative medicines are sold in more than 125 countries and used by millions of patients worldwide. Please visit astrazeneca.com and follow the Company on Social Media [@AstraZeneca](https://twitter.com/AstraZeneca).

Contacts

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