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AstraZeneca and Daiichi Sankyo's Datroway Approved in US, Cuts Cancer Progression Risk by 37%

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TROPION-Breast01 trial results pave the way for Datroway (Dato-DXd) as a new treatment option for metastatic HR-positive, HER2-negative breast cancer, marking AstraZeneca's eighth breakthrough medicine toward its 2030 goal.



First approval in the US for AstraZeneca and Daiichi Sankyo's Datroway based on TROPION-Breast01 results showing 37% reduction in the risk of disease progression or death vs. chemotherapy

Datroway is the eighth new medicine of the 20 AstraZeneca has set out to deliver by 2030

Datroway (datopotamab deruxtecan or Dato-DXd) has been approved in the US for the treatment of adult patients with unresectable or metastatic hormone receptor (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. The approval by the US Food and Drug Administration (FDA) was based on results from the TROPION-Breast01 Phase III trial.

Aditya Bardia, MD, MPH, Program Director of Breast Oncology and Director of Translational Research Integration at the UCLA Health Jonsson Comprehensive Cancer Center and Global Principal Investigator for TROPION-Breast01, said: "Despite considerable progress in the HR-positive, HER2-negative metastatic breast cancer treatment landscape, new therapies are still needed to tackle the frequent and complex challenge of disease progression after endocrine and initial chemotherapy. The approval of datopotamab deruxtecan, a novel TROP2-directed antibody drug conjugate, marks a major therapeutic milestone and provides patients with metastatic breast cancer a new treatment alternative to conventional chemotherapy."

Dave Fredrickson, Executive Vice President, Oncology Haematology Business Unit, AstraZeneca, said: "With this first approval of *Datroway* in the US, we continue to deliver on our ambition for antibody drug conjugates to improve upon and replace conventional chemotherapy for the treatment of multiple cancers. We are proud to bring *Datroway* to people living with metastatic HR-positive, HER2-negative breast cancer, and this approval marks the eighth new medicine of the 20 we have set out to deliver across AstraZeneca by 2030."

Ken Keller, Global Head of Oncology Business, and President and CEO, Daiichi Sankyo, Inc., said: “The approval of *Datroway* provides patients with HR-positive, HER2-negative breast cancer previously treated with endocrine-based therapy and traditional chemotherapy with the opportunity to be treated with a new TROP2-directed antibody drug conjugate earlier in the metastatic setting. *Datroway* is the latest addition to our portfolio of innovative cancer treatments and marks the fourth medicine from our oncology pipeline to receive approval in the US.”

Caitlin Lewis, Senior Vice President of Strategy & Mission, Living Beyond Breast Cancer, said: “Only one in three patients with metastatic HR-positive, HER2-negative breast cancer live more than five years following diagnosis, highlighting the urgent need for additional effective therapies. The approval of *Datroway* is a significant advance, offering patients with metastatic HR-positive breast cancer a new and much-needed treatment option.”

In TROPION-Breast01, *Datroway* significantly reduced the risk of disease progression or death by 37% compared to investigator’s choice of chemotherapy (hazard ratio [HR] 0.63; 95% confidence interval [CI] 0.52-0.76; $p<0.0001$) in patients with HR-positive, HER2-negative metastatic breast cancer as assessed by blinded independent central review (BICR). Median progression-free survival (PFS) was 6.9 months in patients treated with *Datroway* versus 4.9 months with chemotherapy.

The safety profile of *Datroway* was consistent with the known profile of this medicine with no new safety concerns identified. In the *Datroway* arm, the interstitial lung disease (ILD) rate was 4.2% and the majority of events were low grade.

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

Additional regulatory submissions for *Datroway* in breast cancer are under review in the EU, China and other regions.