

## News Release

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## **Merck KGaA, Darmstadt, Germany, Provides Update on Xevinapant Program in Locally Advanced Head and Neck Cancer**

Darmstadt, Germany, June 24, 2024 – Merck KGaA, Darmstadt, Germany, a leading science and technology company, today announced the discontinuation of the Phase III randomized TrilynX study evaluating xevinapant plus chemoradiotherapy (CRT) in patients with unresected locally advanced squamous cell carcinoma of the head and neck (LA SCCHN). The decision follows a pre-planned interim analysis performed by the study's Independent Data Monitoring Committee, which found that the trial would be unlikely to meet its primary objective of prolonging event-free survival. Top-line safety data were overall compatible with the chemo-radio sensitizing properties of xevinapant. The company will conduct an in-depth review of the data and will share the results in a peer-reviewed forum.

LA SCCHN has proven to be a difficult-to-treat form of cancer. CRT has remained the standard of care for decades, despite multiple studies designed to improve outcomes with new treatment approaches, including multiple immunotherapy trials.

"We sincerely thank the patients, caregivers and clinical investigators who participated in this trial," said Danny Bar-Zohar, Global Head of Research & Development and Chief Medical Officer for the Healthcare business sector of Merck KGaA, Darmstadt, Germany. "While we are disappointed by these results, we remain



## News Release

steadfast in our commitment to develop transformative medicines within our oncology portfolio for areas of high unmet need.”

Given the totality of the data, the company decided to also stop the Phase III clinical trial X-Ray Vision (xevinapant plus radiotherapy, compared to placebo plus radiotherapy) in patients who underwent resection of locally advanced head and neck cancer.

Merck KGaA, Darmstadt, Germany, is working to develop and deliver new treatment options that exploit the vulnerabilities of tumor cells. The company is exploring modalities including antibody drug conjugates (ADCs) and DNA damage response (DDR) inhibitors, across multiple tumor types, including many that have proven difficult to treat where there are significant unmet needs for patients. The company’s support for the head and neck cancer community remains steadfast with Erbitux<sup>®\*</sup>, which the company commercializes outside of the U.S. and Canada. Erbitux is approved in Europe in combination with radiotherapy for the treatment of locally advanced SCCHN. Erbitux continues to be studied in more than 200 active clinical trials, including at least 15 Phase III studies.

\* Merck KGaA, Darmstadt, Germany, licensed the right to market Erbitux, a registered trademark of ImClone LLC, outside the U.S. and Canada from ImClone LLC, a wholly owned subsidiary of Eli Lilly and Company, in 1998.

### **About Xevinapant**

Xevinapant (formerly known as Debio 1143) is an investigational potent oral small-molecule IAP (inhibitor of apoptosis protein) inhibitor. In March 2021, Merck KGaA, Darmstadt, Germany, gained exclusive rights from Debiopharm International SA to develop and commercialize xevinapant worldwide. Xevinapant is not approved for any use anywhere in the world.

### **Advancing the Future of Cancer Care**

At Merck KGaA, Darmstadt, Germany, we strive every day to improve the futures of people living with cancer. Our research explores the full potential of promising mechanisms in cancer research, focused on synergistic approaches designed to hit cancer at its core. We are determined to maximize the impact of our standard-of-care treatments and to continue pioneering novel medicines. Our vision is to create a world where more cancer patients will become cancer survivors. Learn more at [www.emdserononcology.com](http://www.emdserononcology.com)

### **About Merck KGaA, Darmstadt, Germany**

Merck KGaA, Darmstadt, Germany, a leading science and technology company, operates across life science, healthcare and electronics. Around 63,000 employees work to make a positive difference to millions of people’s lives every day by creating more joyful and sustainable ways to live. From providing products and services that accelerate drug development and manufacturing as well as discovering unique ways to treat the most challenging diseases to enabling the intelligence of devices – the company is everywhere. In 2023, Merck KGaA, Darmstadt, Germany, generated sales of € 21 billion in 65 countries.

## News Release

The company holds the global rights to the name and trademark "Merck" internationally. The only exceptions are the United States and Canada, where the business sectors of Merck KGaA, Darmstadt, Germany, operate as MilliporeSigma in life science, EMD Serono in healthcare and EMD Electronics in electronics. Since its founding in 1668, scientific exploration and responsible entrepreneurship have been key to the company's technological and scientific advances. To this day, the founding family remains the majority owner of the publicly listed company.

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