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## News Release

**Not intended for U.S. and UK Media**

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### **Ultravist™ by Bayer now approved for contrast-enhanced mammography in EU**

- Ultravist™-300, -370 receives green light for indication extension for use in contrast-enhanced mammography (CEM) in a European Workshare Procedure
  - CEM is emerging modality combining digital mammography with the administration of a contrast agent
  - Strategically expands Bayer's portfolio in breast imaging, including contrast agents and injectors
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**Berlin, January 23, 2023** – Bayer announced today that its iodine-based contrast agent Ultravist™-300, -370 is now approved for contrast-enhanced mammography (CEM) in the EU. The product can be used to evaluate and detect lesions of the breast as an adjunct to mammography (with or without ultrasound) or as an alternative when a magnetic resonance imaging (MRI) is contraindicated or unavailable. Following the approval of the European Workshare Procedure (a decentralized mutual recognition process on EU level), the first national approvals in the EU are expected in the first quarter of 2023. CEM is an emerging modality that combines digital mammography with the administration of a contrast agent, such as Ultravist, to support the diagnosis of breast cancer and guide treatment decisions. The approval expands Bayer's radiology portfolio, which includes contrast media, injectors as well as digital and artificial intelligence (AI) enabled solutions, supporting radiologists across a broad range of diseases including breast cancer.

“Breast cancer is the most common cancer worldwide, impacting millions of women and their loved ones around the world,” said Dr. Julia Camps Herrero, Corporate Chief of Breast Health, Ribera Salud Hospitals Spain. “Early detection of cancer can save lives. Imaging options such as contrast-enhanced mammography can help improve diagnostic accuracy, potentially identifying cancers that otherwise might have been missed.”

“The approval of Ultravist-300 and -370 in contrast-enhanced mammography gives physicians a new imaging option where conventional mammography might not be enough,” said Dr. Konstanze Diefenbach, Head of Radiology Research and Development, Bayer. “We are pleased to be able to offer additional options for breast imaging to healthcare professionals, as we aim to support them in their role of providing clear direction from diagnosis to care for patients.”

### **About breast cancer and contrast-enhanced mammography**

In 2020, there were 2.3 million women diagnosed with breast cancer and 685 000 deaths globally, according to the World Health Organization (WHO). Breast cancer treatment can be very effective, especially when the disease is identified early. CEM is a highly sensitive and relatively low-cost breast imaging examination, with an increasing number of independent scientific publications affirming its value as an adjunct to mammography. It is easy to perform in everyday clinical practice and can be used in various clinical settings, such as inconclusive findings in previous imaging procedures, or preoperative assessment of the extent of the disease. It can also be a helpful tool when MRI is unavailable or contraindicated.

Public health education about early detection and imaging options is a key factor in fighting breast cancer. Bayer is committed to driving information about this important topic. The company recently launched a global digital information hub to help encourage women to take an active role and make informed decisions about their health:

<https://letstalkaboutit.bayer.com/>

### **About Ultravist™**

Ultravist™ is an iodine-based contrast medium for X-ray techniques requiring contrast enhancement such as conventional radiography, angiography and computed tomography. Available in more than 100 countries, Ultravist is currently being applied more than 18 million times a year. Depending on the country, Ultravist is approved for use across a vast range of indications such as CT of the head, chest, heart, abdomen, and liver; multi-detector CT for stroke/ischemic damage and imaging of the abdominal viscera; CT angiography of vessels in the head, heart and peripheral parts of the body; conventional radiology for duct systems/body cavities and urography; contrast enhancement of body cavities, e.g., arthrography; and pediatric imaging, including in very young children.

## **About Radiology at Bayer**

As a true life-science company with a heritage of over 100 years in Radiology, Bayer is committed to providing excellence, from innovative products to high-quality services, to support efficient and optimized patient care. Bayer offers a leading portfolio of contrast media for computed tomography (CT), X-Ray, and magnetic resonance imaging (MRI), devices for their precise administration, informatics solutions and a medical imaging platform delivering access to applications, including those enabled by AI. Bayer's Radiology products generated a total of €1.8bn sales in 2021. Based on the company's ambition to outperform the radiology market's average annual growth rate of 5% by 2030, Bayer is highly committed to research and development, which includes leveraging artificial intelligence and driving innovation in medical imaging. Each of these offerings provides effective tools to support radiologists in their mission to deliver treatment-critical answers and a clear direction – from diagnosis to care.

## **About Bayer**

Bayer is a global enterprise with core competencies in the life science fields of health care and nutrition. Its products and services are designed to help people and the planet thrive by supporting efforts to master the major challenges presented by a growing and aging global population. Bayer is committed to driving sustainable development and generating a positive impact with its businesses. At the same time, the Group aims to increase its earning power and create value through innovation and growth. The Bayer brand stands for trust, reliability and quality throughout the world. In fiscal 2021, the Group employed around 100,000 people and had sales of 44.1 billion euros. R&D expenses before special items amounted to 5.3 billion euros. For more information, go to [www.bayer.com](http://www.bayer.com).

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