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## News Release

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### Chronic Thromboembolic Pulmonary Hypertension (CTEPH)

## **FDA grants breakthrough device designation to artificial intelligence software for CTEPH pattern recognition from Bayer and MSD**

The software in development intends to support clinical decision-making of chronic thromboembolic pulmonary hypertension – a progressive and life-threatening condition

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**Berlin, December 3, 2018** – Bayer announced today that the U.S. Food and Drug Administration (FDA) granted Breakthrough Device Designation to the Artificial Intelligence Software for Chronic Thromboembolic Pulmonary Hypertension (CTEPH) Pattern Recognition, which Bayer is currently developing jointly with MSD (tradename of Merck & Co., Inc., Kenilworth, N.J., USA).

A rare form of pulmonary hypertension, CTEPH affects an estimated 8 to 40 people per million globally. CTEPH can be difficult to diagnose because its symptoms are similar to those of other lung diseases. Being a rare disease, physicians may not always recognize CTEPH due to factors including a lack of clinical awareness and complex findings involving the heart, lung and pulmonary vessels. Computed tomography pulmonary angiography (CTPA) as well as a ventilation/perfusion scan (V/Q scan) are common diagnostic modalities to detect CTEPH. Radiologists may have the first opportunity to identify CTEPH in patients; therefore it is vital that they recognize CTEPH indicators on CTPA images.

Development of the software will rely on using deep learning methodology to support radiologists by identifying signs of CTEPH in CTPA scans. The software processes image findings of cardiovascular, lung perfusion and pulmonary vessel analyses in combination with the patient's history of pulmonary embolism. If the development is successful, the software could be deployed via Bayer's Radimetrics™, an informatics technology platform

that connects contrast medium with injector and scan information to provide important insights.

“Bayer is looking forward to leveraging our expertise in Radiology to develop a software to support radiologists and treating physicians in the complex diagnostic decision making process of this rare disease,” said Prof. Dr. Olaf Weber, Head of Radiology Research & Development of Bayer AG’s Pharmaceuticals Division. “We hope that greater awareness of CTEPH in conjunction with a decision-support tool will eventually assist in diagnosing patients earlier and more reliably, thereby allowing earlier treatment.”

The FDA Breakthrough Device Program is intended to help patients have more timely access to devices and breakthrough technologies that provide for more effective treatment or diagnosis for life-threatening or irreversibly debilitating diseases by expediting their development, assessment, and review. While the FDA Breakthrough Device Designation is expected to expedite the software’s assessment and review, its development remains complex given the nature of the disease and technology.

### **About Chronic Thromboembolic Pulmonary Hypertension (CTEPH)**

CTEPH is a progressive type of pulmonary hypertension, in which it is believed that thromboembolic occlusion (organized blood clots) of pulmonary vessels gradually builds up and subsequently leads to an increased blood pressure in the pulmonary arteries, resulting in an overload of the right heart. CTEPH may evolve after prior episodes of acute pulmonary embolism (PE). The standard and potentially curative treatment for CTEPH is pulmonary thromboendarterectomy (PTE), a surgical procedure in which the blood vessels of the lungs are cleared of clot and scar material. However, a considerable number of patients with CTEPH (20%-40%) are not operable and in up to 35 percent of patients, the disease persists or reoccurs after PTE.

As many as 1 out of every 25 people who had a PE (even if they were treated with at least 3 months of anticoagulants) could go on to develop CTEPH. Symptoms of CTEPH include shortness of breath, edema, fatigue, and chest pain and are therefore similar to other, more common diseases, resulting in an often delayed diagnosis of CTEPH.

Bayer and MSD are in a worldwide collaboration in the field of sGC modulators with the goal to fully evaluate this therapeutic class in areas of unmet medical need.

### **About Bayer's Radimetrics™**

Bayer's Radimetrics™ intelligently connects contrast, injector and scan information into a Seamlessly Smart™ solution to provide critical insights to radiology teams. This helps deliver more personalized care and achieve reproducible quality, in line with radiation standards and regulation. As a true multi-modality solution, spanning Magnetic Resonance Imaging (MRI), Computed Tomography (CT), Nuclear Medicine (NM), X-ray, ultrasound and mammography, it helps radiology departments and practices generate diagnostic quality images more safely, consistently and efficiently. Radimetrics seamlessly integrates with the existing IT infrastructure and radiology equipment through respective interfaces.

### **About Bayer**

Bayer is a global enterprise with core competencies in the Life Science fields of health care and agriculture. Its products and services are designed to benefit people and improve their quality of life. At the same time, the Group aims to create value through innovation, growth and high earning power. Bayer is committed to the principles of sustainable development and to its social and ethical responsibilities as a corporate citizen. In fiscal 2017, the Group employed around 99,800 people and had sales of EUR 35.0 billion. Capital expenditures amounted to EUR 2.4 billion, R&D expenses to EUR 4.5 billion. For more information, go to [www.bayer.com](http://www.bayer.com).

### **About MSD**

For more than a century, MSD, a leading global biopharmaceutical company, has been inventing for life, bringing forward medicines and vaccines for many of the world's most challenging diseases. MSD is a trade name of Merck & Co., Inc., with headquarters in Kenilworth, N.J., U.S.A. Through our prescription medicines, vaccines, biologic therapies and animal health products, we work with customers and operate in more than 140 countries to deliver innovative health solutions. We also demonstrate our commitment to increasing access to health care through far-reaching policies, programs and partnerships. Today, MSD continues to be at the forefront of research to advance the prevention and treatment of diseases that threaten people and communities around the world - including cancer, cardio-metabolic diseases, emerging animal diseases, Alzheimer's disease and infectious diseases including HIV and Ebola. For more information, visit [www.msd.com](http://www.msd.com) and connect via [Twitter](#), [LinkedIn](#) and [YouTube](#)

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