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FDA approves Bayer thromboembolic BP drug

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Singapore: Bayer HealthCare has recieved US FDA approval for Adempas (riociguat) tablets for the treatment of adults with persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH) and pulmonary arterial hypertension (PAH) to improve exercise capacity.

In PAH, efficacy was shown in patients on Adempas monotherapy or in combination with endothelin receptor antagonists (ERAs) or prostanoids (inhaled, oral or subcutaneous). Adempas is the only treatment approved in the US for use in two types of pulmonary hypertension. It is the first and only FDA-approved drug therapy for persistent/recurrent CTEPH after surgical treatment or inoperable CTEPH. It is also the only approved oral therapy in PAH with efficacy shown in monotherapy or in combination with ERAs or prostanoids.

For all female patients, Adempas is available only through a restricted program called the Adempas Risk Evaluation and Mitigation Strategy (REMS) Program.

"CTEPH and PAH are serious and life-threatening diseases," said Dr. Nick H. Kim, Associate Clinical Professor of Medicine, Division of Pulmonary and Critical Care Medicine; Director, Pulmonary Vascular Medicine; Director, Fellowship Program; University of California San Diego. "The approval of Adempas equips physicians with a new approach to treating PAH patients, and it gives us the first approved drug treatment for patients with inoperable CTEPH or with persistent/recurrent CTEPH after surgery. While surgery should always be considered as the first treatment option for CTEPH, the fact remains that up to forty percent of CTEPH patients are not eligible for surgery, and ten to thirty-five percent of CTEPH patients have disease that persists after surgery."

PAH is a disease characterized by elevated pressure in the pulmonary arteries. CTEPH is a form of pulmonary hypertension in which blood clots and thromboembolic occlusion of the pulmonary vessels leads to increased pressure in the pulmonary arteries. The standard treatment for CTEPH is pulmonary endarterectomy, a potentially curative surgery that clears clots and scar material from the blood vessels of the lung.

"Bayer is deeply committed to bringing new treatment options to patients with life-threatening diseases. Adempas is an excellent example of this commitment, because it is the result of years of dedicated research in our Bayer laboratories into a new way of treating two forms of pulmonary hypertension," said Ms. Pamela A. Cyrus, Vice President and Head, U.S. Medical, Bayer HealthCare Pharmaceuticals. "We are pleased to bring this new class of treatment to patients with PAH or with inoperable CTEPH or persistent/recurrent CTEPH after surgical treatment."

Ms. Rino Aldrighetti, President and CEO, Pulmonary Hypertension Association added, "From a patient's perspective, living with pulmonary hypertension remains difficult. We know that not all treatments work for all people. We get excited when there is a new treatment option for PAH patients, and we are thrilled there is finally an approved drug treatment for people living with persistent/recurrent CTEPH after surgical treatment or inoperable CTEPH."