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ASIA EDITION

Pradaxa gets EU approval for DVT

June 10, 2014 | Regulatory | By BioSpectrum Bureau

Singapore: Boehringer Ingelheim has recieved Euroean approval for Pradaxa (dabigatran etexilate) for the treatment and prevention of recurrence of deep vein thrombosis (DVT) and pulmonary embolism (PE).

"We are delighted with the European Commission's decision to approve Pradaxa for DVT and PE patients, confirming the well-studied efficacy and safety profile of Pradaxa, which has been established in a clinical trial programme in close to 10,000 patients for DVT and PE, and over 40,000 patients across different indications," commented Professor Klaus Dugi, chief medical officer, Boehringer Ingelheim. "Access to this new treatment option is critical for patients as we know that PE as a consequence of a DVT is still the leading cause of preventable death in hospital."

The approval by the European Commission follows the positive opinion issued by the Committee for Medicinal Products for Human Use of the European Medicines Agency, and is based on results from three phase III clinical trials.

"This approval for dabigatran is a major advance for DVT and PE patients and their physicians," said Professor Dr Stavros Konstantinides, deputy scientific director of the Centre for Thrombosis and Haemostasis of Johannes Gutenberg University, Mainz, Germany. "Clinical trial results show that dabigatran has a favourable safety profile compared to warfarin, while offering similar efficacy for the treatment and prevention of recurrence of DVT and PE. The added benefits of convenience and a simple fixed dose regimen will appeal to patients and their physicians alike."

Pradaxa is convenient for patients as it does not require routine dose monitoring, nor a mandatory dose change during the course of treatment. DVT and PE patients can start taking Pradaxa in a simple fixed dose regimen after initial treatment with an injectable anticoagulant such as low-molecular-weight heparin (LMWH).

Clinical experience of Pradaxa equates to over 2.9 million patient-years in all licensed indications worldwide. Pradaxa has already been available for more than six years and is approved in over 100 countries to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation (NVAF).