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BI announces Dabigatran's safety and efficacy for management of VTE in children

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Pradaxa is not approved in any country for paediatric patients with VTE.

Boehringer Ingelheim has announced results from two paediatric studies of dabigatran etexilate, which were presented at the International Society on Thrombosis and Haemostasis (ISTH) 2019 Congress in Melbourne, Australia.

The data showed dabigatran to be as effective and have a comparable safety profile to the current standard of care (SOC) for the treatment of acute venous thromboembolism (VTE) in children. A favourable safety profile for dabigatran was also established in a second study, the first of its kind to assess direct oral anticoagulant (DOAC) for the prevention of recurrent VTE in children with persistent VTE risk factors.

Current SOC for treatment and prevention of recurrent VTE in children have several limitations, including the need for frequent monitoring and non-oral means of administration. The aim of these new dabigatran studies was to provide additional insight and knowledge on anticoagulation in paediatric patients with VTE or at risk of recurrent VTE.

“The diagnosis and incidence of VTE has risen dramatically over the years, and childhood VTE is associated with considerable morbidity. Although treatments are currently available to help manage VTE, there is still a need for effective, safe and more convenient options that have been investigated in children. We therefore wanted to assess if dabigatran’s established safety and efficacy, in treating adults with VTE, also translated through to paediatric patients,” said Prof. Dr Martina Brückmann, Global Head of Clinical Development Cardiovascular, Cardiometabolic Medicine, Boehringer Ingelheim. “It is therefore encouraging that these studies suggest a comparable safety profile and efficacy for dabigatran for the potential treatment and prevention of recurrent VTE in children.”

Pradaxa is not approved in any country for paediatric patients with VTE. The studies form part of the ongoing commitment from Boehringer Ingelheim to expanding scientific knowledge of thrombosis care. The safety and efficacy profile of dabigatran in adults has been proven and well-documented in the extensive RE-VOLUTION clinical trial programme.

About the DIVERSITY study, Ablisetti M et al

Open-label, randomised, multicentre, Phase IIb/III trial evaluated the efficacy and safety of dabigatran vs SOC (low molecular weight heparin or vitamin K antagonist) in children aged from birth to <18 years old with acute VTE requiring anticoagulation therapy for 3 months.

The combined efficacy endpoint was the proportion of children with recurrent VTE, VTE-related death, and thrombus resolution. The secondary endpoints included safety as determined by bleeding events, and pharmacokinetic/pharmacodynamic relationships.

The results from the DIVERSITY trial demonstrated that dabigatran was non-inferior to SOC for paediatric patients at high risk of VTE, with comparable bleeding rates.

About the secondary VTE prevention study, Brandao L et al.

Open-label, single-arm, prospective cohort, Phase III trial is the first study of its kind to describe outcomes in children treated with a direct oral anticoagulant for secondary VTE prevention. In the study, approximately 200 children received dabigatran for up to 12 months. The primary endpoints for this study included VTE recurrence, bleeding events, and mortality at 6 and 12 months.

The study showed a low overall frequency of recurrent VTEs and any major bleeding events. Based on these results, the authors concluded that this trial showed “favourable safety results” with dabigatran in children with VTE and persistent thrombosis risk factors.