

BI gets USFDA nod for drug reversing anticoagulant effects

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Singapore: Global pharmaceutical company, Boehringer Ingelheim, has received USFDA approval for Praxbind (idarucizumab), indicated for patients treated with Pradaxa (dabigatran etexilate), when reversal of the anticoagulant effects of dabigatran is needed for emergency surgery/urgent procedures or in life-threatening or uncontrolled bleeding.

"We are very pleased to offer Praxbind, the first specific reversal agent for a novel oral anticoagulant, now approved by the FDA," said Professor Jörg Kreuzer, vice president medicine, Therapeutic Area Cardiovascular, Boehringer

Ingelheim. "With this approval, Boehringer Ingelheim is leading the evolution of anticoagulation care, as we did with the introduction of Pradaxa. While we anticipate that Praxbind will be rarely used in clinical practice, the availability of a specific reversal agent has the potential to give physicians and patients added confidence in choosing Pradaxa."

The FDA granted Praxbind breakthrough therapy designation and the application received priority review.

"The emergence of novel oral anticoagulants, or NOACs, marked a significant advancement in anticoagulation care. While general management strategies for NOAC-related bleeding are available, until today, there was no option for specific and immediate reversal of the anticoagulant effect of a NOAC in a patient in rare emergencies where speed matters, such as life threatening bleeding or the need to quickly perform surgery or interventions," said Dr Charles Pollack, lead investigator, REVERSE AD, professor of Emergency Medicine, Sidney Kimmel Medical College, Thomas Jefferson University, Philadelphia, USA. "The availability of Praxbind now provides a unique option for reversing anticoagulation in patients taking Pradaxa."