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XIENCE V™ Everolimus-Eluting Coronary Stent System: A Preclinical Assessment

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Abstract

Background: *The XIENCE V™ everolimus-eluting coronary stent system is a second-generation drug-eluting stent designed for safety and efficacy in the interventional treatment of coronary artery disease and in preventing in-stent restenosis. A comprehensive preclinical program was completed to aid in the scientific design and to demonstrate the safety of XIENCE V.*

Methods: *Studies evaluating clinical dose selection, pharmacokinetics, single and overlapping stent safety, polymer safety, and maximum dose (8× everolimus) safety were conducted in the porcine coronary arterial model at 28, 90, 180 days, and 1 and 2 years. Additionally, a subset of studies was conducted in the rabbit iliac arterial model.*

Results: *Morbidity and mortality rates for all preclinical studies were exceptionally low, being less than 1%. The arterial response observed in the clinical dose selection study and in all safety studies was typified by benign neointimal hyperplasia with endothelialization by 28 days. Everolimus was released in a controlled manner for 120 days and remained primarily localized within the stented arterial region, which was evidenced histologically as peristrut fibrin. The temporal presence of peristrut fibrin matched the everolimus-elution profile. Thrombosis, malapposition, medial loss, or other adverse effects were not observed in any preclinical studies.*

Conclusion: *XIENCE V has demonstrated safety via an extremely comprehensive preclinical program published to date for a DES system, with data generated in two species to 2 years. The preclinical data, along with the SPIRIT clinical trial data, demonstrate the excellent safety and potential efficacy profile of XIENCE V.*

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