For Immediate Release

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Results of a Clinical Phase III Trial of an Oral Factor Xa Inhibitor, Edoxaban, in Prevention of Post-Operative Venous Thromboembolism

TOKYO, Japan (December 11, 2009) – Daiichi Sankyo Company , Limited announced today the results of a clinical Phase III trial of edoxaban in prevention of venous thromboembolism in patients undergone total knee arthroplasty in Japan and Taiwan.

This trial was performed as a randomized, double-blind and active-controlled trial in order to evaluate the efficacy and safety of edoxaban administered as a once daily dosage of 30 mg compared to enoxaparin sodium 2,000 IU twice daily subcutaneous injection. According to the results, non-inferiority to enoxaparin sodium was confirmed in edoxaban group in terms of the primary endpoint, which was the incidence of venous thromboembolism. No significant difference between edoxaban and enoxaparin sodium groups was observed in the incidence of either major or clinically relevant non-major bleeding.

Daiichi Sankyo is preparing to file its NDA for the prevention of post-operative venous thromboembolism in year 2010 in Japan.

Attachment

1. Edoxaban Overview

Edoxaban is an oral anticoagulant that directly inhibits Factor Xa, a clotting factor in the blood. Daiichi Sankyo is developing edoxaban as a drug for the treatment and prophylaxis of thromboembolism.

2. Trial Summary

Objective	Evaluate the efficacy and safety of a once daily oral dosage of 30 mg of edoxaban in patients undergone total knee arthroplasty
Design	Randomized, double-blind, parallel group, multi- center trial. Enoxaparin sodium, 2,000 IU twice-daily subcutaneous injections, was used as the comparator drug.
Number of patients	716
Treatment period	11 to 14 days
Efficacy	Assess non-inferiority of edoxaban to enopaxarin sodium for the prevention of post-operative venous thromboembolism
Safety	Compare incidence of major and clinically relevant non major bleedings

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