Interim Report on the ANNEXA-4 Study: Andexanet For Reversal of Anticoagulation in Factor Xa - Associated Acute Major Bleeding

Purpose: To evaluate the effectiveness of andexanet alfa to treat acute major bleeding in patients receiving a factor Xa inhibitor.

Trial Design: Phase 3. Interim report. Open-label, not-randomized or controlled, single arm. N=227 patients with active, major bleeding who took a Factor X inhibitor; treated with andexanet – iv bolus and 2-hour infusion.

Primary Efficacy Endpoints: % of patients where major bleed stopped @ 12 hours after receiving andexanet alfa; anti-Factor Xa inhibitor activity reduction

Primary Safety Endpoint: thrombus, 30-day mortality

andexanet		
Efficacy	83% stopped bleeding @ 12 hours CI = 0.75-0.89	Anti-Factor Xa inhibitor activity reduction: rivaroxaban – 88% reduction apixaban – 91% reduction enoxaparin – 75% reduction
Safety	Thrombus @ 3 days – 2.6% Thrombus by 30 days – 11%	Death – 12% by 30 days

Single-arm interim analysis results from this ongoing clinical trial suggest safety (death, stroke, MI, peripheral thrombus) and efficacy (reduction in anti-Factor Xa inhibitor activity, clinical hemostasis) in reversing major bleeding while taking a Factor Xa inhibitor.

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