13th International Conference on THROMBOSIS & HEMOSTASIS ISSUES in CANCER
April, 17-19th, 2026
Bergamo, Italy

ANTITHROMBOTIC DRUGS

SUB-ANALYSIS OF INTERIM RESULTS FROM A PHASE 2 STUDY INVESTIGATING REGN9933^{A2} AND REGN7508^{CAT} FOR THE PREVENTION OF CONTACT-MEDIATED VENOUS THROMBOEMBOLISM IN PATIENTS WITH ACTIVE CANCER UNDERGOING PERIPHERALLY INSERTED CENTRAL CATHE

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Introduction. Thrombosis is a common complication of PICC placement. Available anticoagulants can increase bleeding risk and are rarely used for thromboprophylaxis in patients (pts) with PICC lines. Factor XI (FXI) inhibition may reduce thrombosis risk after PICC placement without increased bleeding risk in pts with cancer at enhanced risk of clotting and bleeding. REGN9933^{A2} and REGN7508^{CAT} are human monoclonal antibodies binding the A2 and catalytic FXI domains, respectively. The Phase 2 ROXI-CATH study (NCT06299111) evaluated REGN9933^{A2} and REGN7508^{CAT} for preventing contact-mediated VTE after PICC placement.

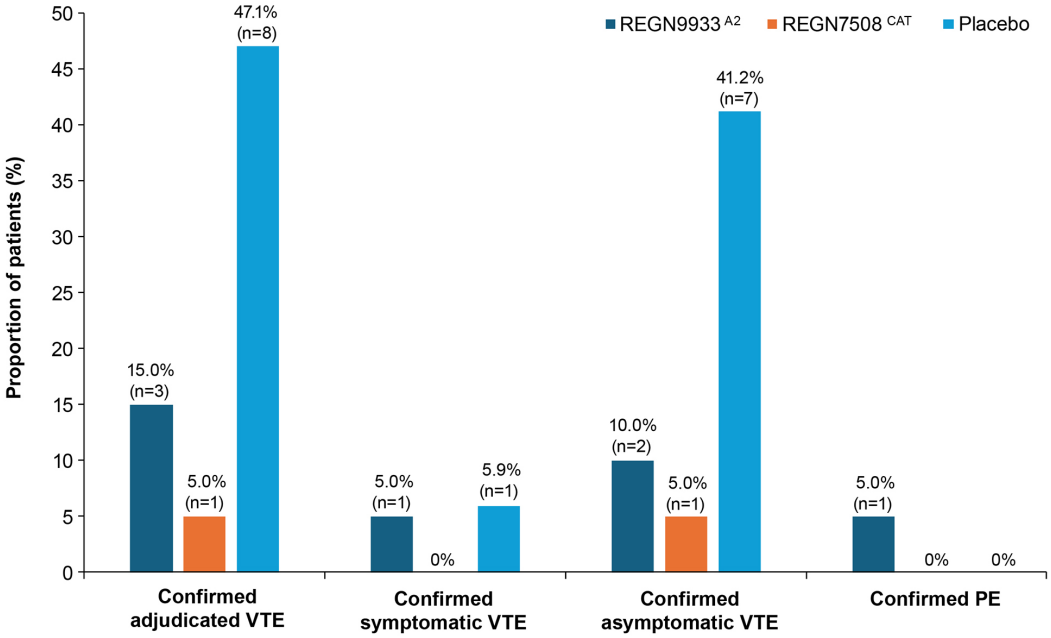
Aim. To assess the efficacy and safety of REGN9933^{A2} and REGN7508^{CAT} in pts from ROXI-CATH with active cancer undergoing PICC placement.

Materials and Methods. In this ongoing double-blind study, pts ≥18 years undergoing PICC placement (in place for ≥14 days) were randomized 1:1:1 to receive intravenous REGN9933^{A2} 300 mg, REGN7508^{CAT} 250 mg, or placebo ≤24 hours of PICC placement. Ultrasound of the upper extremity ipsilateral to the PICC was performed on Day 7 and Day 14 (±2 days) for thrombosis assessment. Co-primary endpoints were the incidence of confirmed VTE until Day 14 after PICC placement and incidence and severity of treatment-emergent adverse events (TEAEs). A sub-analysis at ~50% enrollment of pts with active cancer is presented.

Results. As of July 30, 2025, 58 pts with active cancer were enrolled and treated (REGN9933^{A2}, n=20; REGN7508^{CAT}, n=20; placebo, n=18). In the efficacy analysis set (n=57), VTE occurred in 3 (15.0%) pts receiving REGN9933^{A2}, 1 (5.0%) receiving REGN7508^{CAT}, and 8 (47.1%) receiving placebo (Figure). Odds ratios for VTE for REGN9933^{A2} and REGN7508^{CAT} vs placebo were 0.29 (90% CI 0.06–0.73) and 0.13 (90% CI 0.02–0.36), respectively. No major bleeding occurred (safety analysis set, n=58); clinically relevant non-major bleeding occurred in one pt receiving REGN9933^{A2} and one receiving placebo. Treatment-related TEAEs occurred in one pt receiving REGN9933^{A2} (anemia and epistaxis) and one receiving REGN7508^{CAT} (overdose); none occurred in the placebo group.

Conclusions. FXI inhibition may be effective for preventing contact-mediated VTE in pts with active cancer, with lower VTE rates in those receiving REGN9933^{A2} or REGN7508^{CAT} than placebo. FXI inhibition represents a novel potential anticoagulant approach to preventing PICC-associated thrombosis in pts with cancer without substantially increasing the bleeding risk.

Figure. Incidence of confirmed VTE* in patients with cancer



*VTE included asymptomatic or symptomatic surveillance ultrasound-detected PICC-associated VTE, or confirmed PE, including PE-related death.

PE, pulmonary embolism; PICC, peripherally inserted central catheter; VTE, venous thromboembolism.