1000 mg Q6W until disease progression, discontinuation, or withdrawal.

Results At this third interim analysis of GARNET, the safety population included 605 patients. irAEs were experienced by 32.2%, with 10.1% of patients experiencing grade ≥3 irAEs (table 1). Few, 5.5%, discontinued treatment because of an irAE. No irAEs led to death. Of patients experiencing irAEs, 64.6% were treated with immune modulatory medications (IMMs; referring to steroids, immune suppressant, and/or thyroid therapy); 58.7% of these patients experienced resolution. Average time to resolution was 69 days. For the 35.4% of patients not treated with IMMs, 36.5% experienced a resolution. Average time to resolution was 67 days. The most common irAEs were hypothyroidism (7.6%); 45 of 46 (97.8%) patients treated with thyroid therapy and arthralgia (5.6%); 8 of 34 (23.5%) patients treated with steroids.

Conclusion Across all tumour types evaluated in GARNET, 32.2% of patients experienced irAEs, 68.7% of whom experienced grade 2 events. 58.7% of these patients experienced resolution. Overall discontinuation due to irAEs was low.

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THROMBOPROPHYLAXIS IN SURGICALLY TREATED GYNECOLOGICAL CANCER PATIENTS WITH TINZAPARIN IN HIGHER THAN CONVENTIONAL PROPHYLACTIC DOSE: PRELIMINARY RESULTS FROM THE SONG-TIN STUDY


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Introduction/Background Surgeries for resection of malignant tumors are associated with a particularly high risk of venous thromboembolism (VTE). Certain abdominopelvic cancer surgeries are associated with a six to 10-fold increased risk of DVT versus surgeries for benign disease. Despite increased awareness on VTE risk, improved surgical techniques and use of primary thromboprophylaxis, the incidence of postoperative DVT remains high; it should be evaluated if extended VTE prophylaxis with more intensive doses could improve outcomes in gynecologic cancer surgery.

Methodology Song-Tin is a prospective, phase IV, observational cohort study, evaluating efficacy and safety of tinzaparin use for up to 1 month post hospital discharge, in patients with low bleeding risk, as specified in current clinical practice protocol for postoperative thromboprophylaxis, in high thrombotic risk gynecological cancer patients undergoing surgery.

Results Preliminary results from 69 surgically treated women are reported; one woman was lost to follow up and in 4 cases there were anticoagulant drug modifications (1 change drug, 2 dose increase and 1 dose decrease). ECOG status was: 0:65%, 1:22% and 2:13%; 87% were postmenopausal. Women’ characteristics grouped as cancer, treatment, patient and biomarkers related presented in table 1. Median surgery duration was 2.5 hours (Q1-Q3: 2–3 hours); median blood loss was 400 ml (Q1-Q3: 250–600 ml). Up to report time, median duration of prophylaxis with tinzaparin was 34 days (Q1-Q3: 22–38); no thrombotic events were reported (efficacy: 100%, 95%CI:0–5%). Two major bleeding events and one clinically relevant non major bleeding event occurred. None of these adjudicated as related to anticoagulant; tinzaparin dose remained the same before and after bleeding event.

Conclusion Intensive perioperative thromboprophylaxis with tinzaparin 8,000 Anti-Xa IU, OD for up to 1 month post gynecologic cancer surgery found to be effective and safe. Additional data is needed to confirm these findings.