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A MULTICENTER RANDOMIZED PHASE III STUDY OF KRN125 (PEGFILGRASTIM) IN BREAST CANCER PATIENTS RECEIVING TC CHEMOTHERAPY

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Background: KRN125 (Pegfilgrastim) is a pegylated derivative of Filgrastim, a human granulocyte colony-stimulating factor (G-CSF), which remains in circulation for a prolonged duration. Here, we report the results of phase III study of KRN125 in Japanese breast cancer patients.

Material and methods: A phase III, double-blind, placebo-controlled, multicenter, randomized study designed to evaluate the prophylactic use of KRN125 to reduce the incidence of febrile neutropenia (FN) in breast cancer patients compared with placebo. The main eligibility criteria were at least 20 and under 70 years of age with stage I-III invasive carcinoma and were expected to receive full dose of TC chemotherapy (docetaxel 75 mg/m² and cyclophosphamide 600 mg/m² every 3 weeks for up to 4 cycles) as either neoadjuvant or adjuvant therapy. All patients received TC chemotherapy on day 1 followed by administration of KRN125 or placebo on day 2 every cycle. TC treatment was repeated for 4 to 6 cycles.

Results: 351 patients were enrolled into the study (177 patients in KRN125 group and 174 patients in placebo). Among those, 173 patients in each group who received administration of study drug were evaluable for FAS efficacy analysis and safety analysis. As baseline characteristics, the median age were 51.6 years and 50.8 years in KRN125 group and placebo group. Number of patients 65 years of age or older were 20 (11.6%) and 17 (9.8%), respectively. The ratio of patients who underwent neoadjuvant chemotherapy was 12.7% and 13.9%, respectively. In total, patient characteristics was well balanced in both groups. The result of the primary efficacy endpoint (incidence of FN) was 1.2% (2 of 173 subjects) in KRN125 group versus 68.8% (119 of 173 subjects) in the placebo group (p < 0.001). Adverse events were reported for all patients in both groups. Most adverse events were consistent with those expected for breast cancer subjects receiving TC chemotherapy. The administration of KRN125 in this setting appeared safe and well tolerated.

Conclusion: The administration of KRN125 significantly reduced the incidence of FN compared with placebo and appeared well tolerated.