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Evaluation of biosimilar Bevacizumab in the treatment of Indian patients with non-small-cell lung cancer

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Statement of the Problem: The role of bevacizumab in combination with carboplatin/paclitaxel chemotherapy has been established in patients with non-small-cell lung cancer (NSCLC). This trial was designed to evaluate the effect of Zydus biosimilar bevacizumab compared to innovator's bevacizumab in Indian patients with NSCLC.

Methodology: A multicentre, prospective, randomized, open-label, active controlled study was carried out on 248 patients with advanced, unresectable, recurrent or metastatic NSCLC at 28 sites across India. Patients were randomized in 2:1 (169:79) ratio to receive intravenous infusion of 15 mg/kg of test bevacizumab or reference bevacizumab, plus paclitaxel 175 mg/m2 and carboplatin (AUC 5 mg/mL×min) every three weeks for six cycles. Overall response rate (ORR) after treatment of 6 cycles was assessed by using response evaluation criteria in solid tumors (RECIST 1.1). Pharmacokinetics (Cmax and AUC0-t), safety and tolerability, and immunogenicity were also assessed.

Findings: All patients were of Asian origin and males comprised >70% of the population in both the groups. The mean age was 57±9.71 years in test bevacizumab and 58±11.35 years in reference bevacizumab. Baseline characteristics were balanced and no statistically significant difference was observed between both the groups. The ORR was 60.82% (59 out of 97 subjects) in Bevacizumab (Zydus) group and 58.82% (30 out of 51 subjects) responders in the reference Bevacizumab and 90% confidence interval for the difference of overall response rate fell within the ±20% equivalence margin (-11.96, 15.97). The pharmacokinetic assessment of the In-transformed bevacizumab after Cycle-1 data showed the 90% confidence intervals for the ratio of the Test geometric least square mean to reference geometric least square mean within the 80.00% to 125.00% limits for Cmax (87.99%;120.41%) and AUC0-t (90.70%;122.03%). The incidence of immunogenicity in the test product treated group was marginally lower compared to the reference drug product treated subjects (72.16% vs. 76.47%).

Conclusion: The results demonstrated biosimilarity between Zydus bevacizumab and innovator's bevacizumab with respect to efficacy, tolerability and safety in Indian patients with NSCLC.

Biography

Deven V Parmar is Head and Vice President, Clinical R&D, Cadila Healthcare Limited, has his expertise in clinical drug development and biosimilar development. He is a Clinical Pharmacologist by training, with 25 years of clinical research experience work across various geographies

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