NSCLC, metastatic

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IG-001 IN THE TREATMENT OF LUNG CANCER: RESULTS OF A POST-MARKETING SURVEILLANCE STUDY
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Aim: Abraxane® is a Cremophor-free (CF), albumin-encapsulated nanoparticle formulation of paclitaxel approved globally for metastatic breast cancer (MBC), non-small cell lung cancer (NSCLC), and pancreatic cancer. IG-001 (Genexol®-PM) is a CF, non-biologic, micellar formulation of paclitaxel composed of a biodegradable di-block copolymer of methoxy poly (ethylene glycol)-poly (lactide). IG-001 is approved in Korea for MBC, ovarian cancer, and NSCLC. IG-001 is being developed as bioequivalent to Abraxane. The availability of two similar clinical stage, CF nanoparticle formulations of paclitaxel allows us to compare and confirm clinical activities of CF paclitaxel formulations in NSCLC.

Methods: Bioequivalence of IG-001 was demonstrated by comparing preclinical tumor efficacy data, in vitro dissolution data, and animal pharmacokinetic data. Clinical comparison to Abraxane was examined by comparing the preapproval and PMS studies of IG-001 + cisplatin in NSCLC. This PMS was a single-arm study of IG-001, 230 mg/m² plus cisplatin 60 mg/m² once every 3 weeks in patients (pts) with lung cancer.

Results: 316 pts were treated for up to 9 cycles. Of the 316, 64% had NSCLC, 77.2% were male. Mean age = 59.44 ± 9.43 years. 76%, 23%, and 1% had stages IV, III, and I/II disease, respectively. Best overall response: 0.66% of pts had complete response (CR), 43.85% had partial response (PR), 26.91% had stable disease, 21.93% had progressive disease, and 6.64% were not assessable for a total 44% efficacy (CR + PR). AEs were reported in 83.23% of pts. Serious AEs were reported in 11.1% of pts, with the most frequent being dyspnea (2.5%), pneumonia (1.9%), leukopenia (1.9%), febrile neutropenia (1.9%), neutropenia (1.6%), and lung neoplasm malignant (1.3%). None of the factors assessed were deemed to selectively affect outcomes.

Conclusions: IG-001 in combination with cisplatin for the treatment of lung cancer is effective with an acceptable safety profile. The response rate for IG-001 (44%) compares favorably to historical data for Abraxane (33%) and Taxol® (25%). The IG-001 safety profile is similar to historical safety data for Abraxane. The data suggest that IG-001 may be an alternative to Abraxane for NSCLC.

Disclosure: R.H. Murdock: Both authors are clinical research professionals and employees of Sorrento Therapeutics, a pharmaceutical company developing IG-001 for marketing approval; V. Trieu: The authors are clinical research professionals and employees of Sorrento Therapeutics, a pharmaceutical company developing IG-001 for marketing approval.