Imprime PGG, a Novel Innate Immune Modulator, in the 1st-Line Treatment of Stage IV NSCLC: Results From a Randomized, Controlled, Multicenter Phase 2 Study

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Background

Standard treatment for advanced or metastatic NSCLC consists of platinum-based doublet chemotherapy, but does not result in cell- or complement-mediated cytotoxicity and is approved in Europe and the United States in combination with cetuximab.

Objective

To evaluate the safety, tolerability, and efficacy of Imprime PGG in combination with bevacizumab in patients with previously untreated stage IV non-squamous NSCLC.

Methods

This was a multicenter, open-label, randomized (2:1) phase 2 trial. Simon 2-stage optimal flexible stratification was used. The primary endpoint was duration of response (DoR) measured from the start of combination therapy until disease progression or death. Secondary endpoints included overall response rate (ORR), progression-free survival (PFS), overall survival (OS), safety, and tolerability. The study included 56 patients (28 per arm) aged 18-75 years with measurable disease and ECOG performance status of 0-2.

Results

At the primary analysis, 30 patients (52.5%) in the Imprime PGG group compared to 15 patients (26.9%) in the control group had a sustained overall response (RR=0.79; ECOG4599). The median duration of response was 12.3 months and overall survival was 25.0 months.

Conclusion

Imprime PGG in combination with bevacizumab significantly improved ORR, duration of response, and overall survival in previously untreated stage IV non-squamous NSCLC compared to control. Further studies are warranted.

References