Safety of Imprime PGG, a Novel Innate Immune Modulator, in Adults With Stage IV Non-Small Cell Lung Cancer (NSCLC)

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Purpose: To assess the ORR of Imprime PGG in combination with carboplatin/paclitaxel and cetuximab in patients with first-line advanced NSCLC.

Inclusion criteria:
- Age ≥18 years
- Histology of NSCLC
- Stage IV NSCLC
- Performance status of 0 or 1
- Life expectancy > 3 months
- ECOG performance status of 0 or 1
- No previous chemotherapy for NSCLC
- No prior or concurrent biological agents for NSCLC

Exclusion criteria:
- Prior or concurrent use of immunomodulatory agents
- Active or progressive cancer
- Presence of co-morbid conditions

Methods:
- Phase 3 study
- Randomization: Imprime PGG group (n=29) vs. control group (n=46)
- Treatment: Imprime PGG 140 mg/m² IV weekly for 6 cycles with carboplatin/paclitaxel
- Cetuximab 400 mg/m² IV weekly for 6 cycles in patients with EGFR-expressing tumors

Endpoints:
- ORR
- Overall survival (OS)
- Progression-free survival (PFS)
- Safety

Results:
- ORR: 34% reduction in the risk of death with Imprime PGG
- OS: 10.2 months in the Imprime PGG group vs. 7.4 months in the control group
- PFS: 3.6 months in the Imprime PGG group vs. 2.9 months in the control group
- Safety: Rates of overall and severe (CTCAE grade 3 or 4) AEs were similar between groups.

Conclusions:
- Imprime PGG demonstrated a significant improvement in ORR and survival with acceptable safety.
- It holds promise as an adjunct to anti-EGFR therapy in NSCLC.

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Disclosures:
- No conflicts of interest.
- Imprime PGG is the subject of U.S. Patent 6,700,504 and other patents pending.
- The authors are employed by Biothera and hold stock options/grants.

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