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Phase I Pharmacokinetic and Pharmacodynamic Dose-Escalation Study of RG7160 (GA201), the First Glycoengineered Monoclonal Antibody Against the Epidermal Growth Factor Receptor, in Patients With Advanced Solid Tumors

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Abstract

Purpose

We conducted a phase I dose-escalation study to characterize the safety, efficacy, pharmacokinetic (PK), and

pharmacodynamic properties of RG7160 (GA201), a humanized and glycoengineered immunoglobulin G₁ anti-epidermal growth factor receptor (EGFR) monoclonal antibody with enhanced antibody-dependent cell-mediated cytotoxicity.

Patients and Methods

Seventy-five patients with advanced EGFR-positive solid tumors received RG7160 (50 to 1,400 mg) administered every week, every 2 weeks, or every 3 weeks. Dose

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escalation followed a three-plus-three trial design.

Results

No maximum-tolerated dose was reached for any dosing schedule. Common adverse events (AEs) included rash (80% of patients), infusion-related reactions (77%), and hypomagnesemia (56%). Grades 3 and 4 AEs were rash (grade 3, 25%), infusion-related reaction (grade 3, 7%; grade 4, 1%), paronychia (grade 3, 3%), and hypomagnesemia (grade 3, 1%; grade 4, 1%). RG7160 exposure increased greater than proportionally over the 50- to 400-mg dose range (with greater than proportional decline in clearance) and approximately dose proportionally above 400 mg (where clearance plateaued). A marked reduction in circulating natural killer cells and increased infiltration of immune effector cells into skin rash were seen. Clinical efficacy included one complete response and two partial responses in patients with colorectal cancer

(including one with *KRAS* mutation) and disease stabilization in 27 patients.

Conclusion

RG7160 had an acceptable safety profile with manageable AEs and demonstrated promising efficacy in this heavily pretreated patient cohort. On the basis of modeling of available PK parameters, the RG7160 dose selected for part two of this study is 1,400 mg on days 1 and 8 followed by 1,400 mg every 2 weeks.

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