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A PHASE II OPEN LABEL STUDY OF NEIHULIZUMAB, ANTI-CD162 (PSGL-1) ANTIBODY, IN PATIENTS WITH MODERATELY TO SEVERELY ACTIVE, ANTI-TNF ALPHA AND/OR ANTI-INTEGRIN REFRACTORY ULCERATIVE COLITIS

Inflammatory Bowel Diseases

IBD: Uncontrolled Therapeutic Observations in Humans Biologic

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Author(s): David T. Rubin, Scott D. Lee, Lucky Flores, Gustavo Albizu-Angulo, Ellen J. Scherl, Surinder Saini, Shipra Patel, Yi-Lin I. Cheng, Ting-Ying Cheng, Shih-Yao Lin

Background: Neihulizumab is a humanized monoclonal antibody which binds to human CD162 (PSGL-1) and preferentially induces apoptosis of late stage activated T cells, and has been/is being tested in T-cell mediated inflammatory diseases including psoriasis, psoriatic arthritis and GvHD. We conducted a Phase II trial to evaluate the efficacy and safety of neihulizumab in anti-TNFα and/or anti-Integrin refractory ulcerative colitis.

Methods
Patients with moderately to severely active UC refractory to anti-TNFα and/or anti-integrin inhibitors were enrolled. Two regimens were tested: 5 weekly doses plus 3 bi-weekly doses of 9 mg/kg AbGn-168H (5+3 regimen); and 8 weekly doses plus 2 bi-weekly doses of 9 mg/kg AbGn-168H (8+2 regimen). The primary outcome is the proportion of patients with clinical response at W12. Key secondary outcomes include the proportion of patients with clinical remission and the proportion of patients with mucosa healing at W12.

Results
10 patients were enrolled in the 5+3 regimen (median age 38.5 yo (range 22–66)) and 11 patients were enrolled in the 8+2 regimen (median age 33.0 yo (range 23–62)). In the 5+3 regimen, among the 8 W12 evaluable patients, 1/8 patients (13%) exhibited clinical response and 1/8 patients (13%) showed mucosa healing at W12. In the 8 + 2 regimen, out of 9 patients having reached W12, 5 patients (56%) exhibited clinical response, 2 patients (22%) showed clinical remission, and 2 patients (22%) showed mucosa healing at W12. 100% of patients fulfill the criteria of responders, and 40% of patients fulfill the criteria of remission at their best response. All drug-related AEs are mild to moderate in severity. The most frequent drug-related AE observed is mild headache. No cytokine release syndrome or local/systemic hypersensitivity or drug-related SAEs were reported. No significant CBC changes were observed throughout the study.

Conclusions
We demonstrate the efficacy and safety of the first anti-CD162 therapy in medically resistant UC. Studies of this unique mechanism are ongoing

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Corp/Syneos: Consulting; Check-cap: Consulting; Dizal Pharmaceuticals: Consulting; GalenPharma/Atlantic: Consulting; Genetech/Roche: Consulting; Gilead Sciences: Consulting; Glenmark Pharmaceuticals: Consulting; GSK (GlaxoSmithKline Services): Consulting; Janssen Pharmaceuticals: Consulting; Lilly: Consulting; Mahana Therapeutics: Consulting; Narrow River Mgmt: Consulting; Pfizer: Consulting; Prometheus Laboratories: Consulting; Reistone: Consulting; Seres Therapeutics: Consulting; Shire: Consulting; Takeda: Consulting; Target PharmaSolutions, Inc.: Consulting; S. D. Lee: Abbvie: Consulting; Eli Lilly: Consulting; Janssen: Consulting; Takeda: Consulting; UCB: Consulting; L. Flores: No Conflicts; G. Albizu-Angulo: No Answer; E. J. Scherl: Janssen: Advisory Committees or Review Panels; Pfizer: Advisory Committees or Review Panels; Takeda: Speaking and Teaching; UCB: Advisory Committees or Review Panels; S. Saini: No Conflicts; S. Patel: Parexel International: Other Activities Not in List; Y. I. Cheng: AbGenomics International: Employment; T. Cheng: No Conflicts; S. Lin: AbGenomics International Inc: Employment, Employment;