NON-INTERVENTIONAL STUDY REPORT ABSTRACT

Title: Observational, real-world study of infliximab-dyyb in patients with inflammatory bowel disease (IBD) in the United States and Canada

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Rationale and background: In 2016, the FDA approved the biosimilar infliximab-dyyb for use in inflammatory bowel disease (IBD) patients. To date, there is a dearth of real-world data on clinical, economic and patient-reported outcomes associated with the use of infliximab-dyyb for IBD in the North American population.

Research question and objectives: The objective of this study was to describe the effects of infliximab-dyyb on clinical and patient-reported outcomes in patients with Crohn's disease (CD) and ulcerative colitis (UC) patients, in a real-world setting.

Study design: In this prospective, observational study, patients in the US and Canada initiating treatment with infliximab-dyyb for IBD were recruited between February 2018 and February 2019. Subjects, including biological naive users of infliximab-dyyb and patients switching from RP infliximab or other biologics, were followed for 12 months.

Setting: 24 sites were activated; 15 sites enrolled patients in the US (n=11) and Canada (n=4).

Subjects and study size, including dropouts: 118 total patients were assessed for eligibility. 1 patient was excluded from the study due to not meeting inclusion criteria and 2 did not receive infliximab-dyyb due to being given RP infliximab at their infusion center/pharmacy. 115 patients receiving infliximab-dyyb were included in the study.

Variables and data sources: The primary clinical outcome was the partial Mayo score (pMAYO) and Harvey Bradshaw Index (HBI) for UC and CD patients, respectively, and a measurable clinical response (pMAYO/HBI reduction ≥3 points) or clinical remission (pMAYO <3 or HBI <5). Additionally, baseline and follow-up data collected were: demographics, clinical characteristics, disease-related surgical history, treatment characteristics, laboratory outcomes, patient-reported outcomes, healthcare resource utilization (HCRU)and treatment-related adverse events.

Results: 67 CD and 48 UC patients initiated treatment with infliximab-dyyb (51.3% female; mean age 44.25 years; 87.0% Caucasian; mean BMI 27.86). Of them, 39 patients were biological naive users, 57 were switched from RP infliximab, and 19 were switched from other biologics. Clinical remission status improved significantly in UC subjects that were biological naïve (baseline: 5.6%; 12-months: 90.9%; p=0.0015) and was maintained in UC subjects that were switched from RP infliximab (baseline: 71%; 12-months: 94%; p=0.1007). Clinical remission status was maintained in CD subjects. Patient-reported outcomes

improved significantly from baseline to 12-month follow-up for nearly all outcomes. SIBDQ, EQ-VAS, all domains of WPAI, the effectiveness domain of TSQM, GAD-7, and PHQ-8 scores significantly improved from baseline to 12-months follow-up. Adverse events occurred at a rate consistent with the known adverse event profile for RP infliximab.

Discussion: This study provides real-world evidence to support the use of infliximab-dyyb in IBD. Among biological naïve users, clinical outcomes improved significantly for UC and were maintained for CD patients. Consistent with findings across other immunological diseases, patients who switched from RP infliximab to infliximab-dyyb maintained clinical outcomes and remission status. Patient-reported quality of life and work productivity outcomes improved among biological naïve subjects and were maintained for subjects switched from RP infliximab.

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