Protocol Abstract

Title: A Long-Term Non-Interventional Registry to Assess Safety and Effectiveness of Humira® (Adalimumab) in Pediatric Patients with Moderately to Severely Active Crohn's Disease (CD) – *CAPE*
Rationale and Background: This protocol describes a non-interventional registry that will evaluate the long-term safety and effectiveness of Humira as used in routine clinical practice in pediatric patients (between the ages of 6 and 17 years inclusive at the time of enrollment) with moderately to severely active CD, who receive Humira therapy according to the local product label. This registry is part of a post-marketing commitment from AbbVie to the European Medicines Agency (EMA).
Research Question and Objectives: The primary objective of this registry is to evaluate long-term safety of Humira in pediatric patients (between the ages of 6 and 17 years inclusive at the time of enrollment) with moderately to severely active CD who are prescribed and treated in accordance with the approved local Humira product label under the conditions of routine clinical setting. Patients being prescribed and treated with conventional immunosuppressant therapy with no concurrent biologic use will also be enrolled as a reference group. The secondary objective of this registry is to evaluate the long-term effectiveness of Humira in pediatric patients (between the ages of 6 and 17 years inclusive at the time of enrollment) with moderately to severely active CD who are prescribed and treated in accordance with the approved local Humira product label under the conditions of routine clinical setting. Patients being prescribed and treated with conventional immunosuppressant therapy with no concurrent biologic use will be considered a reference group. In addition, the impact of treatment interruptions on the safety and effectiveness of Humira will be evaluated.
Study Design: This is a global, multicenter, non-interventional registry of pediatric patients with moderately to severely active CD treated in a routine clinical setting with Humira or immunosuppressant non-biologic therapy. Patients meeting entry criteria will be enrolled. All patients who consent to take part in the registry will be followed for up to 10 years, providing long-term safety and effectiveness data on Humira or immunosuppressant non-biologic therapy. [redacted]

Study Design (Continued): [redacted]

Population: Male and female pediatric patients (between the ages of 6 and 17 years inclusive at the time of enrollment) who have been diagnosed with moderately to severely active CD and have been prescribed and treated [redacted] in accordance with the local Humira product label or who have been prescribed and treated with immunosuppressant therapy [azathioprine, 6-mercaptopurine or methotrexate].

Variables: Data collected from all patients who receive at least one dose of Humira or at least one dose of conventional immunosuppressant therapy in the registry will be used for analysis of safety and effectiveness in each group.

[redacted]

Data Sources: Patient source data will include patient medical records, health care provider completed questionnaires, and patient reported questionnaires. [redacted]

Study Size: Approximately 1300 pediatric patients with moderately to severely active CD will be enrolled in the European countries and additional countries after Marketing Authorization is obtained in these regions [redacted]

Data Analysis:

Statistical Methods:

Safety is the primary objective for this registry. Safety analyses will be performed for all patients who receive at least one dose of Humira or at least one dose of conventional immunosuppressant therapy in this registry to be used for analysis of safety in each group. The total number and percentage of subjects with treatment-emergent SAEs and AESI will be summarized. The event rate per 100 patient years (PYs) of treatment-emergent SAEs and AESI will also be presented. In addition, observational SAEs and AESI occurring from the first dose of Humira in the registry through the last patient contact will be tabulated.

Redacted information - 20Mar2014

Data Analysis (Continued):

Statistical Methods (Continued):

The secondary objective of this registry is to evaluate the long-term effectiveness of registry therapy in patients with moderately to severely active CD. Effectiveness measures (sh-PCDAI and PGA) and outcomes measures (WPAI-caregivers, IMPACT III, and SIBDQ) will be summarized descriptively at each registry visit.

Prior and concomitant CD medications, duration of exposure, and Baseline characteristics (i.e., race/ethnicity, duration of CD, body mass index [BMI], and prior therapies for CD) will be summarized descriptively.

[redacted]

Milestones:

Start of Data Collection: April 2014

End of Data Collection: April 2030

Study Progress Report: August 2014

Interim Report: Every August from 2015 throughout the registry

Registration in the EU PAS Register: TBC

Final Report of Study Results: October 2030