Characterization of Patients With Ulcerative Colitis in a Post-Authorisation Safety Study of Golimumab Based in the Spanish ENEIDA Registry

Joan Fortuny,1 Lawrence Rasouliyan,1 Daniel Mines,2 Anita Tornos,1 Elizabeth Earley,3 Susana Perez-Guthmann,1 Eugeni Domènech,4 Javier P. Gisbert5
1RTI Health Solutions, Barcelona, Catalonia, Spain; 2Merck & Co., Inc., Kenilworth, New Jersey, USA; 3Hospital Universitari Germans Trias i Pujol and CIBERER-Badalona, Barcelona, Catalonia, Spain; 4Hospital Universitari de La Princesa, IIS-IP and CIBERER, Madrid, Spain

BACKGROUND
- Simponi (golimumab) is an anti-tumor necrosis factor alpha (anti-TNFα) agent authorized for the treatment of moderately to severely active ulcerative colitis (UC).
- As part of its risk management plan, Merck & Co. (Ireland) Ltd, a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA as the study sponsor is conducting a post-authorisation safety study (PASS) using data from ENEIDA, a large, prospectively maintained registry of patients with inflammatory bowel disease in Spain in the setting of routine clinical practice. Founded in 2006, ENEIDA has not previously been used in a PASS.

OBJECTIVE
Overall Study Objectives
- At planned completion in 2023 (using data from September 2013 until May 2022), the study intends to provide comparative data on the risk of colorectal dysplasia and of advanced colorectal neoplasia (ACN) in patients with UC treated with golimumab, other anti-TNF agents, or thiopurines.

Objectives for this Presentation
- Using data from September 2013 until May 2017, we present the following:
  - Characteristics of the ENEIDA registry
  - Ongoing study cohorts’ assembly
  - Baseline characteristics of currently enrolled patients with UC
  - Number of study outcomes

METHODS
Data Source
- The main source of data for the study is the Spanish inflammatory bowel disease registry, ENEIDA, owned by the Spanish task force on Crohn’s disease and UC (GETECCU). (See Figure 1 and Box 1 for main characteristics and organization of the registry.)

Study: Among new users of treatments for UC before September 2013 through May 2017 (through May 2022 for the final analyses) were included.

RESULTS

CONCLUSIONS
- Based on the preliminary results presented:
  - The ENEIDA registry is a valuable data source to study patients with UC in Spain.
  - Extended study periods are needed for less common outcomes.