Supportive Information

Article Title
Post-marketing analysis for biosimilar CT-P13 in inflammatory bowel disease compared with external data of originator infliximab in Japan

Journal
Journal of Gastroenterology and Hepatology

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### Table S1
Persistence of CT-P13 treatment and reasons for drug discontinuation in PMS

| Treatment persistence     | CD (n=327) | UC (n=313) |
|---------------------------|------------|------------|
| **Continued patients**    | 219 (67.0%)| 172 (55.0%)|
| **Discontinued patients** | 108 (33.0%)| 141 (45.0%)|
| **Reason for discontinuation** | (n=108) | (n=141) |
| Remission                 | 5 (4.6%)   | 5 (3.5%)   |
| Adverse drug reaction     | 21 (19.4%) | 41 (29.1%) |
| Insufficient efficacy     | 33 (30.6%) | 52 (36.9%) |
| Other medical reason      | 10 (9.3%)  | 3 (2.1%)   |
| Hospital transfer         | 17 (15.7%) | 27 (19.1%) |
| Hospital policy           | 4 (3.7%)   | 2 (1.4%)   |
| Personal reasons          | 12 (11.1%) | 4 (2.8%)   |
| No visiting                | 6 (5.6%)   | 7 (5.0%)   |
Table S2
Incidence of ADRs leading to discontinuation of CT-P13 in 640 IBD patients in PMS during an observation period of 742.7 person-years

| Category of ADRs                        | Number of patients (N=640) | Incidence per total number of patients | Incidence per 100 person-years | ADR leading to drug discontinuation                                      |
|----------------------------------------|---------------------------|---------------------------------------|--------------------------------|--------------------------------------------------------------------------|
| Infusion related reaction              | 35                        | 5.47%                                 | 4.71                           | Infusion related reaction                                                |
| Blood system disorders                 | 3                         | 0.47%                                 | 0.40                           | Anemia, Granulocyte count decreased, Platelet count increased            |
| Gastrointestinal disorders             | 2                         | 0.31%                                 | 0.27                           | Mesenteric vein thrombosis, Retroperitoneal hemorrhage                   |
| General disorders                      | 3                         | 0.47%                                 | 0.40                           | Asthenic conditions, Malaise, Pyrexia                                   |
| Hepatobiliary disorders                | 4                         | 0.63%                                 | 0.54                           | ALT/AST increased, Hepatic steatosis, Hyperbilirubinemia, Liver disorder  |
| Infections and infestations            | 6                         | 0.94%                                 | 0.81                           | CMV infection, EBV infection, Folliculitis, Meningitis tuberculosis, Pneumonia(2), Sepsis, Tuberculosis, Muscle abscess |
| Neoplasms                              | 1                         | 0.16%                                 | 0.13                           | Cutaneous T-cell lymphoma                                               |
| Nervous system disorders               | 1                         | 0.16%                                 | 0.13                           | Hypoesthesia                                                            |
| Respiratory disorders                  | 4                         | 0.63%                                 | 0.54                           | Eosinophilic pneumonia (2), Interstitial lung disease (2)               |
| Skin and subcutaneous tissue           | 6                         | 0.94%                                 | 0.81                           | Alopecia, Pruritus, Pustular psoriasis(3), Rash                         |
| Total number of patients with ADRs     | 62                        | 9.69%                                 | 8.35                           |                                                                         |