

Table SVIII Overview of serious infection episodes by SOC and PT in the four constant^a treatment groups from baseline to EOT or last follow-up

| | Placebo | | | Ustekinumab | | | Brodalumab 140 mg Q2W | | | Brodalumab 210 mg Q2W | | |
|-------------------------------|------------------------------------|---|----------|---------------------------|---|----------|-----------------------------|----|----------|-----------------------------|----|----------|
| | <i>n</i> = 881; 200.2 PYE | | | <i>n</i> = 612; 139.5 PYE | | | <i>n</i> = 1,490; 342.3 PYE | | | <i>n</i> = 1,495; 344.4 PYE | | |
| | Patients with events, <i>n</i> (%) | | | 156 (25.5) | | | 343 (23.0) | | | 421 (28.2) | | |
| | E/100 PY (95% CI) | | | 133.4 (114.9–153.9) | | | 124.4 (112.9–136.9) | | | 157.6 (144.7–171.5) | | |
| Period 1 | <i>n</i> (%) | E | E/100 PY | <i>n</i> (%) | E | E/100 PY | <i>n</i> (%) | E | E/100 PY | <i>n</i> (%) | E | E/100 PY |
| Infections and infestations | 1 (0.1) | 1 | 0.5 | 2 (0.3) | 2 | 1.4 | 7 (0.5) | 7 | 2.0 | 7 (0.5) | 8 | 2.3 |
| Cellulitis | 0 | | | 1 (0.2) | 1 | 0.7 | 2 (0.1) | 2 | 0.6 | 2 (0.1) | 2 | 0.6 |
| Appendicitis | 0 | | | 0 | | | 2 (0.1) | 2 | 0.6 | 1 (0.1) | 1 | 0.3 |
| Diverticulitis | 0 | | | 1 (0.2) | 1 | 0.7 | 1 (0.1) | 1 | 0.3 | 0 | | |
| Gastroenteritis | 0 | | | 0 | | | 1 (0.1) | 1 | 0.3 | 1 (0.1) | 1 | 0.3 |
| <i>Escherichia</i> UTI | 1 (0.1) | 1 | 0.5 | 0 | | | 0 | | | 0 | | |
| Meningitis cryptococcal | 0 | | | 0 | | | | | | 1 (0.1) | 1 | 0.3 |
| Peritonsillar abscess | 0 | | | 0 | | | 1 (0.1) | 1 | 0.3 | 0 | | |
| Pneumonia | 0 | | | 0 | | | 0 | | | 1 (0.1) | 1 | 0.3 |
| Sepsis | 0 | | | 0 | | | 0 | | | 1 (0.1) | 1 | 0.3 |
| UTI | 0 | | | 0 | | | 0 | | | 1 (0.1) | 1 | 0.3 |
| | <i>n</i> = 881; 200.2 PYE | | | <i>n</i> = 612; 432.9 PYE | | | <i>n</i> = 467; 293.3 PYE | | | <i>n</i> = 537; 415.8 PYE | | |
| | Patients with events, <i>n</i> (%) | | | 304 (49.7) | | | 206 (44.1) | | | 293 (54.6) | | |
| | E/100 PY (95% CI) | | | 124.1 (113.8–135.0) | | | 108.4 (96.8–121.0) | | | 134.7 (123.8–146.3) | | |
| Period 2 | <i>n</i> (%) | E | E/100 PY | <i>n</i> (%) | E | E/100 PY | <i>n</i> (%) | E | E/100 PY | <i>n</i> (%) | E | E/100 PY |
| Infections and infestations | 5 (0.8) | 5 | 1.2 | 5 (1.1) | 5 | 1.7 | 9 (1.7) | 10 | 2.4 | 9 (1.7) | 10 | 2.4 |
| Cellulitis | 1 (0.2) | 1 | 0.2 | 1 (0.2) | 1 | 0.3 | 2 (0.4) | 2 | 0.5 | 2 (0.4) | 2 | 0.5 |
| Appendicitis | 0 | | | 0 | | | 1 (0.2) | 1 | 0.3 | 1 (0.2) | 1 | 0.2 |
| Diverticulitis | 1 (0.2) | 1 | 0.2 | 1 (0.2) | 1 | 0.3 | 0 | | | 0 | | |
| UTI | 0 | | | 0 | | | 2 (0.4) | 2 | 0.5 | 2 (0.4) | 2 | 0.5 |
| Cholecystitis infective | 0 | | | 0 | | | 1 (0.2) | 1 | 0.2 | 1 (0.2) | 1 | 0.2 |
| Coccidioidomycosis | 0 | | | 0 | | | 1 (0.2) | 1 | 0.2 | 1 (0.2) | 1 | 0.2 |
| Furuncle | 0 | | | 0 | | | 1 (0.2) | 1 | 0.2 | 1 (0.2) | 1 | 0.2 |
| Gastroenteritis | 0 | | | 0 | | | 1 (0.2) | 1 | 0.3 | 0 | | |
| Herpes zoster | 0 | | | 0 | | | 1 (0.2) | 1 | 0.3 | 0 | | |
| Kidney infection | 0 | | | 0 | | | 0 | | | 1 (0.2) | 1 | 0.2 |
| Meningitis cryptococcal | 0 | | | 0 | | | 1 (0.2) | 1 | 0.2 | 1 (0.2) | 1 | 0.2 |
| Perichondritis | 1 (0.2) | 1 | 0.2 | 0 | | | 0 | | | 0 | | |
| Tick-borne viral encephalitis | 1 (0.2) | 1 | 0.2 | 0 | | | 0 | | | 0 | | |
| Tube-ovarian abscess | 1 (0.2) | 1 | 0.2 | 0 | | | 0 | | | 0 | | |
| | <i>n</i> = 612; 432.9 PYE | | | <i>n</i> = 467; 529.5 PYE | | | <i>n</i> = 537; 869.7 PYE | | | <i>n</i> = 537; 869.7 PYE | | |
| | Patients with events, <i>n</i> (%) | | | 83.3 (75.7–91.4) | | | 102.9 (96.3–109.9) | | | 87.8 (85.6–90.0) | | |
| | E/100 PY (95% CI) | | | 124.1 (113.8–135.0) | | | 108.4 (96.8–121.0) | | | 134.7 (123.8–146.3) | | |
| Period 3 | <i>n</i> (%) | E | E/100 PY | <i>n</i> (%) | E | E/100 PY | <i>n</i> (%) | E | E/100 PY | <i>n</i> (%) | E | E/100 PY |
| Infections and infestations | 6 (1.3) | 6 | 1.1 | 6 (1.3) | 6 | 1.1 | 13 (2.4) | 15 | 1.7 | 13 (2.4) | 15 | 1.7 |
| Appendicitis | 1 (0.2) | 1 | 0.2 | 1 (0.2) | 1 | 0.2 | 3 (0.6) | 3 | 0.3 | 3 (0.6) | 3 | 0.3 |
| Cellulitis | 1 (0.2) | 1 | 0.2 | 1 (0.2) | 1 | 0.2 | 2 (0.4) | 2 | 0.2 | 2 (0.4) | 2 | 0.2 |
| Gastroenteritis | 2 (0.4) | 2 | 0.4 | 2 (0.4) | 2 | 0.4 | 0 | | | 0 | | |
| UTI | 0 | | | 0 | | | 2 (0.4) | 2 | 0.2 | 2 (0.4) | 2 | 0.2 |
| Cholecystitis infective | 0 | | | 0 | | | 1 (0.2) | 1 | 0.1 | 1 (0.2) | 1 | 0.1 |
| Coccidioidomycosis | 0 | | | 0 | | | 1 (0.2) | 1 | 0.1 | 1 (0.2) | 1 | 0.1 |
| Diverticulitis | 1 (0.2) | 1 | 0.2 | 1 (0.2) | 1 | 0.2 | 0 | | | 0 | | |
| Furuncle | 0 | | | 0 | | | 1 (0.2) | 1 | 0.1 | 1 (0.2) | 1 | 0.1 |
| Herpes zoster | 1 (0.2) | 1 | 0.2 | 1 (0.2) | 1 | 0.2 | 0 | | | 0 | | |
| Kidney infection | 0 | | | 0 | | | 1 (0.2) | 1 | 0.1 | 1 (0.2) | 1 | 0.1 |
| Meningitis cryptococcal | 0 | | | 0 | | | 1 (0.2) | 1 | 0.1 | 1 (0.2) | 1 | 0.1 |
| Periodontitis | 0 | | | 0 | | | 1 (0.2) | 1 | 0.1 | 1 (0.2) | 1 | 0.1 |
| Peritonitis bacterial | 0 | | | 0 | | | 1 (0.2) | 1 | 0.1 | 1 (0.2) | 1 | 0.1 |
| Wound infection | 0 | | | 0 | | | 1 (0.2) | 1 | 0.1 | 1 (0.2) | 1 | 0.1 |
| | <i>n</i> = 467; 529.5 PYE | | | <i>n</i> = 467; 551.0 PYE | | | <i>n</i> = 537; 869.7 PYE | | | <i>n</i> = 537; 869.7 PYE | | |
| | Patients with events, <i>n</i> (%) | | | 83.3 (75.7–91.4) | | | 102.9 (96.3–109.9) | | | 87.8 (85.6–90.0) | | |
| | E/100 PY (95% CI) | | | 124.1 (113.8–135.0) | | | 108.4 (96.8–121.0) | | | 134.7 (123.8–146.3) | | |
| Period 4 | <i>n</i> (%) | E | E/100 PY | <i>n</i> (%) | E | E/100 PY | <i>n</i> (%) | E | E/100 PY | <i>n</i> (%) | E | E/100 PY |
| Infections and infestations | 6 (1.3) | 6 | 1.1 | 6 (1.3) | 6 | 1.1 | 13 (2.4) | 15 | 1.7 | 13 (2.4) | 15 | 1.7 |
| Appendicitis | 1 (0.2) | 1 | 0.2 | 1 (0.2) | 1 | 0.2 | 3 (0.6) | 3 | 0.3 | 3 (0.6) | 3 | 0.3 |
| Cellulitis | 1 (0.2) | 1 | 0.2 | 1 (0.2) | 1 | 0.2 | 2 (0.4) | 2 | 0.2 | 2 (0.4) | 2 | 0.2 |
| Gastroenteritis | 2 (0.4) | 2 | 0.4 | 2 (0.4) | 2 | 0.4 | 0 | | | 0 | | |
| UTI | 0 | | | 0 | | | 2 (0.4) | 2 | 0.2 | 2 (0.4) | 2 | 0.2 |
| Cholecystitis infective | 0 | | | 0 | | | 1 (0.2) | 1 | 0.1 | 1 (0.2) | 1 | 0.1 |
| Coccidioidomycosis | 0 | | | 0 | | | 1 (0.2) | 1 | 0.1 | 1 (0.2) | 1 | 0.1 |
| Diverticulitis | 1 (0.2) | 1 | 0.2 | 1 (0.2) | 1 | 0.2 | 0 | | | 0 | | |
| Furuncle | 0 | | | 0 | | | 1 (0.2) | 1 | 0.1 | 1 (0.2) | 1 | 0.1 |
| Herpes zoster | 1 (0.2) | 1 | 0.2 | 1 (0.2) | 1 | 0.2 | 0 | | | 0 | | |
| Kidney infection | 0 | | | 0 | | | 1 (0.2) | 1 | 0.1 | 1 (0.2) | 1 | 0.1 |
| Meningitis cryptococcal | 0 | | | 0 | | | 1 (0.2) | 1 | 0.1 | 1 (0.2) | 1 | 0.1 |
| Periodontitis | 0 | | | 0 | | | 1 (0.2) | 1 | 0.1 | 1 (0.2) | 1 | 0.1 |
| Peritonitis bacterial | 0 | | | 0 | | | 1 (0.2) | 1 | 0.1 | 1 (0.2) | 1 | 0.1 |
| Wound infection | 0 | | | 0 | | | 1 (0.2) | 1 | 0.1 | 1 (0.2) | 1 | 0.1 |

^aConstant treatment groups included all patients exposed to the same planned treatment during the full length of a treatment period. Four time periods were identified: Period 1, the initial double-blind, placebo- and ustekinumab-controlled 12-week induction phase; Period 2, the ustekinumab-controlled 52-week period; and Periods 3 and 4, which covered the open-label extension trials up to the EOT or last follow-up. CI, confidence interval; E, number of events; E/100 PY, event rate per 100 patient-years; EOT, end of treatment; PT, preferred term; PYE, patient-years of exposure; Q2W, every 2 weeks; SOC, system organ class; UTI, urinary tract infection.