Risk of infection
- Data were collected from June 20, 2007, through August 23, 2014
- 12,095 patients (40388 PY) has been enrolled in PSOLAR at 301 sites in North America, Europe and Latin America.
- Other biologics (n=4251) vs nonbiologics showed an elevated risk for infections (HR 1.96, CI95% 1.57-2.44), no increased risk for ustekinumab (n=4364) vs nonbiologics

- OBSERVE-5 was phase-IV, prospective, multicenter surveillance registry of patients with psoriasis.
- OBSERVE-5 enrolled 2510 patients at 375 sites (37 Canada, 338 United States)
- No increased risk of infection

- Data were collected from September 26, 2008 through November 30, 2013
- 6059 patients were observed for 19,242.8 patient-years, with a median duration of 1118 days
- 188 events of any serious infection, 1.0 event per 100 patient-years, does not appear to be elevated

- Prospective meta-analysis from Italy, Spain, and Israel
- 17,739 patients, 10,095 on nonbiologics and 7644 on TNF inhibitors
- Does not indicate an increased risk of serious infections if on TNF inhibitors vs non-biologics

- Data were pooled from 4 phase 2 and 6 phase 3 secukinumab psoriasis studies
- Analysis included 3993 subjects
- No increased infections on secukinumab except for mild Candida infections

- Integrated 7 clinical trials and analyzed 3 data sets: induction period (12 weeks), maintenance period (60 weeks), all ixekizumab exposures
- 4209 patients received ixekizumab
- No increased infections on ixekizumab except for mild Candida infections

- Signal of increased incidence of Candida infections
Risk of malignancy

- PSOLAR, OBSERVE-5, ESPRIT showed no increased risk of cancer for the respective biologics

  - No increased risk of cancer

  - No increased risk of cancer

  - No increased risk of cancer