PSORIASIS

NINE-YEAR INTERIM REAL-WORLD SAFETY AND EFFECTIVENESS OF ADALIMUMAB FOR MODERATE TO SEVERE PSORIASIS FROM THE ESPRIT REGISTRY

D Thaçi [(1)] - Y Poulin [(2)] - W Valdecantos [(3)] - M Bereswill [(4)] - D Arikan [(3)] - D Guo [(3)] - H Kupper [(4)] - K Papp [(5)]

Institute And Comprehensive Center For Inflammation Medicine, University Of Lübeck, Dermatology, Lübeck, Germany [(1)] - Centre De Recherche Dermatologique Du Québec Métropolitain And Laval University, Dermatologique, Québec City, Canada [(2)] - Abbvie Inc, Dermatology, North Chicago, United States [(3)] - Abbvie Deutschland Gmbh & Co Kg, Dermatology, Ludwigshafen, Germany [(4)] - K Papp Clinical Research And Probity Medical Research, University Of Western Ontario, Dermatology, Waterloo, Canada [(5)]

Introduction and Objective: ESPRIT is a 10-year international prospective observational registry evaluating the long-term safety and effectiveness of originator adalimumab in adults with moderate-to-severe chronic plaque psoriasis. We report results over the registry's initial 9 years.

Materials and Methods: Enrolled patients have continued adalimumab treatment from a current prescription or previous study participation, or initiated adalimumab ≤4 weeks of registry entry. The All-Treated Population (All-Rx) received ≥1 adalimumab dose in this registry. Evaluations were at 3 and 6 months post-enrollment, then every 6 months up to 10 years. Data for this interim analysis were collected 26 September 2008 through 30 November 2017. Incidence rates (IR) for all treatment-emergent adverse events (All-TEAEs) for All-Rx are reported as events per 100 patient years (E/100PY) of total adalimumab exposure, including pre-registry exposure.

Results: 6016 All-Rx patients were analyzed. After 9 years, median duration of total adalimumab exposure was 1427.5 days (range 14–5526). Registry discontinuation rate was 44.0%; most frequently due to loss to follow up (19.5%). IR (E/100PY) for All-TEAEs was overall 22.1, serious AEs 4.6, malignancies 1.2, serious infections (SI) 1.0, and for All-TEAEs leading to death, 0.2. Standardized mortality ratio was 0.35 (95% CI: 0.26, 0.46), indicating that the observed number of deaths was below expected in an age-, sex- and country-matched population.
All-Rx patients (n/N [%]) achieving Physician's Global Assessment of 'clear' is reported at each 12-month interval (12-108 months), as observed: 1114/4614 (24.1%), 1047/4042 (25.9%), 938/3535 (26.5%), 953/3243 (29.4%), 905/2965 (30.5%), 703/2238 (31.4%),

556/1595 (34.9%), 256/635 (40.3%), and 12/25 (48.0%), respectively.

Conclusions: Through 9 years of the registry, no new safety signals were observed, safety was consistent with the known profile, the IR of SI and malignancies remained stable, and TE deaths were below the expected rate. As-observed rates of adalimumab effectiveness remained stable through 108 months.