SUSTAINED IMPROVEMENT IN SKIN DISEASE-SPECIFIC QUALITY OF LIFE IN PATIENTS WITH MODERATE TO SEVERE PSORIASIS RECEIVING USTekeniumab MAINTENANCE THERAPY: LONG-TERM RESULTS FROM PRE-EMPT STUDY 1
Leonardi C1, Papp K2, Schanberg K3, Zhao N1, Yelding N1, Kimball A1
1St. Louis University, St. Louis, MO, USA, 2Pfizer Medical Research, Waterlo, ON, Canada, 3Johnson & Johnson Pharmaceutical Services, LLC, Horsham, PA, USA
OBJECTIVES: To assess the long-term impact of ustekeniumab (UST) on quality of life (QoL) among patients responding to therapy at wk40. METHODS: In PHEINEX-1, patients with psoriasis were randomized to UST45 mg (n = 255), UST90 mg (n = 256), or placebo (n = 255). Placebo patients crossed over to receive UST45 mg or 90 mg at wk12. At wk40, UST PASI75 responders were re-randomized to continue the same dose of UST q12 wks or be withdrawn from treatment. After losing 50% of the improvement gained while on UST, patients withdrawn from treatment re-initiated UST at the same dose previously received. The DLQI assessed skin disease-specific QoL (lower scores indicating better QoL) through 3 yrs of change. RESULTS: 162 patients were re-randomized to UST at wk40 (n = 77.45 mg; n = 85.90 mg); 320 patients were withdrawn from UST at wk40 (n = 141.45 mg; n = 179.90 mg). Among patients re-randomized to UST, mean change from baseline in DLQI score for the 45 mg and 90 mg groups [mean(SD)] was: −9.1(7.0) and −10.0(6.11) at wk 4 and −8.6(6.9) and −9.7(6.2) at Year 3, respectively. Among patients withdrawn, mean change from baseline in DLQI score for the UST45 mg and 90 mg groups [mean(SD)] was: −1.4(5.8) and −4.2(4.7) at wk76 and 0.9(2.2) and −2.8(0.9) at Year3, respectively. At wk76 and Year3, 64.0% and 74.7%, and 66.6% and 65.4% of patients in the 45 mg and 90 mg groups, respectively, achieved a DLQI score of ≤10; at wk76 and Year3, 10.9% and 19.2%, and 3.1% and 13.9% of patients withdrawn from 45 mg and 90 mg, respectively, achieved these results. In those re-randomized to UST, the proportion of patients in the 45 mg and 90 mg groups who experienced a ≥5 point improvement in DLQI was 73.3% and 78.5% at wk76, and 70.8% and 78.3% at Year 3; in the withdrawal group, 16.6% and 20.9%, and 0.78% and 1.3%, of patients from 45 mg and 90 mg, respectively, achieved these results. In conclusion: Clinically meaningful QoL improvements are sustained through Year 3 among patients responding at wk40 who continued to receive UST q12 wks.