PSORIASIS

EVALUATION OF THE USABILITY AND ACCEPTABILITY OF A NOVEL, SELF-INJECTION DEVICE FOR THE TREATMENT OF MODERATE-TO-SEVERE PSORIASIS: RESULTS FROM THE PHASE III ORION SELF-DOSE STUDY

L Ferris [1] - E Ott [2] - G Jiang [3] - C Han [2] - Hc Hong [4] - W Baran [5]

University Of Pittsburgh, Dermatology, Pittsburgh, United States [1] - Janssen Research & Development, Llc, Clinical, Spring House, United States [2] - Janssen Research & Development, Llc, Clinical Biostatistics, Spring House, United States [3] - University Of British Columbia, Dermatology And Skin Science, Surrey, Canada [4] - Wroclaw Medical University, Dermatology, Venereology, And Allergology, Wroclaw, Poland [5]

Introduction/Objective: To evaluate the usability and acceptability of a novel self-injection-device in patients with moderate-to-severe psoriasis.

Materials/Methods: ORION is a Phase 3, multicenter, randomized, double-blind, PBO-controlled study evaluating guselkumab (GUS) administered with a subcutaneous, prefilled, self-injection-device. Patients (≥18 years old, psoriasis for ≥6 months, IGA score ≥3, PASI score ≥12, BSA ≥10%, and candidates for/may have received systemic therapy/phototherapy) were randomized to PBO (n=16) at wks0, 4, 12 then GUS 100mg at wks16, 20, 28, or GUS (n=62) at wks0, 4, 12, 20, 28. Usability at week 0 was assessed using a 3-step Observer Injection Checklist (OIC: removal of cap/position of device/completion of injection). Acceptability was assessed using a self-injection assessment questionnaire [SIAQ: 6 domains (feelings about injections/self-image/self-confidence/pain and skin reactions during or after the injection/ease of use of the self-injection device/satisfaction with self-injection), 0=worst to 10=best experience, rated post-injection at wks0, 4, and 12; 3 domains (feeling about self-injections, self-confidence, and satisfaction with self-injection) also rated pre-injection at wk0] and a 3-question self-dose patient questionnaire about speed of injection/handle design and ease of identifying completion of injection at wk12.

Results: The proportion of patients with successful, problem-free injections assessed by OIC was 98.7 % (77/78 patients). Overall mean SIAQ scores at wk0 prior to first injection (6.59–8.23) remained high or increased over time in both groups. SIAQ post-injection domain scores were generally favorable (overall means 7.63–9.84) and comparable between treatment groups through week 12 across all 6 domains. Overall score for pain and

skin reactions during or after injection (≥9.8) indicated no reactions. Most patients (≥94.7%) favorably viewed speed of injection, handle design, and completion of injection.

Conclusions: GUS administered with the self-injection device was associated with successful, problem-free injections and favorable acceptability scores, suggesting that patients had a favorable experience and impression of the device.