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Tildrakizumab significantly improves genital psoriasis in an interim data of the phase IV ZODIPSO study until 52 weeks

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Introduction & Objectives:

Genital psoriasis is considered a high-burden topography with both physical and emotional impact. Not routinely subjected to clinical examination, this topography is often underdiagnosed, despite being a significant contributor to patients having lower quality of life. The generation of data assessing the effectiveness of current treatments is therefore crucial to optimize the management of genital psoriasis. The 52-weeks interim data presenting here evaluates the effectiveness of tildrakizumab, an inhibitor of the interleukin-23p19, in routine care among patients with psoriasis in high impact areas including genital area.

Materials & Methods:

The ZODIPSO study is an ongoing 52-week, phase IV observational multicentric study in France, involving adult patients with moderate-to-severe plaque psoriasis affecting at least one of the following areas: scalp, nails, palms, and/or genital regions. The decision to initiate treatment with tildrakizumab was made during routine clinical care, according to the summary of product characteristics. Effectiveness outcomes included improvement in patients' Psoriasis Area and Severity Index (PASI) score and static Physician's Global Assessment of Genitalia (sPGA-G). Patient reported outcomes were the Pruritus Numeric Rating Scale (PNRS), the Dermatology Life Quality Index (DLQI) and the treatment satisfaction measured with a Satisfaction Numerical Rate Scale (S-NRS). In these interim results, 122 patients were included and 89 were followed until 52 weeks.

Results:

A total of 122 patients were included (58.2% male, mean [SD] age of 51.3 [16.4] years). 49 patients had genital psoriasis sometimes in conjunction with other high impact areas like scalp (n=39), nail (n=27) or palmoplantar (n=17) psoriasis. Among patients with genital psoriasis the mean [SD] PASI decreased from 12.5 [7.3] at baseline to 1.7 [4.3] at week 52 ($p<0.001$). The percentage of patients with sPGA-G of 0-1 increased from 12.2% at baseline to 69,4% and 83,8% at weeks 28 and 52, respectively. Mean [SD] patient DLQI decreased from 12.6 [7.1] to 4.7 [5.7] at week 28 and 4.7 [6.0] at week 52 ($p<0.001$). Patient pruritus improved with a mean PNRS [SD] scored at 6.9 [3.2] at baseline, 2.2 [2.6] at week 28 and 2.77 [2.96] at week 52. Overall, the mean [SD] S-NRS of patients was 7.8 [2.7] at week 28 and 8.4 [2.3] at week 52. Tildrakizumab was well tolerated and patients were highly satisfied with the treatment.

Conclusion:

Tildrakizumab significantly improved genital psoriasis in a real-world study evaluating treatment effectiveness in patients with psoriasis in high-impact areas. All scores improved from baseline to 28 and 52 weeks. These results can contribute to enhancing the physician's confidence in their therapeutic options when discussing this sensitive challenge with the patient.