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Efficacy and safety of secukinumab in moderate to severe palmoplantar pustular psoriasis over 148 weeks: Extension of the 2PRECISE study

To the Editor: Palmoplantar pustular psoriasis is a debilitating inflammatory disease confined to the palms and/or soles and resistant to treatment.[1] Secukinumab, a fully human monoclonal antibody selectively targeting interleukin 17A, is efficacious in the treatment of moderate to severe psoriasis, with a sustained effect and favorable safety profile.[2]

2PRECISE was a phase 3b multicenter, randomized, double-blind, placebo-controlled, parallel-group study comparing secukinumab 300 mg (n = 79) and 150 mg (n = 80) to placebo (n = 78) in individuals with moderate to severe palmoplantar pustular psoriasis over 52 weeks. The primary objective was a response of at least a 75% reduction in Palmoplantar Pustular Psoriasis Area Severity Index (ppPASI75) with secukinumab at week 16 versus placebo.[3] Baseline patient characteristics, study design, and primary endpoint were previously reported.[3] Extension of treatment after week 52 was possible to up to 148 weeks, with patients who achieved meaningful clinical response in the investigator's judgment either maintained on secukinumab 300 mg (n = 36) or secukinumab 150 mg (n = 31) and placebo nonresponder patients who had switched to secukinumab 300 mg (n = 17) or 150 mg (n = 10) at week 16 of the core study.[3] Missing values were imputed using the last observation carried forward (LOCF).

The mean ppPASI at study baseline was 22.7 (standard deviation, 9.5) in patients who entered the extension period. The ppPASI75 response rates increased during the extension period in all groups (Fig 1). At week 148, the percentages of patients with ppPASI75 response had increased in all groups, with similar levels in the placebo/secukinumab 150 mg group (75.0%), placebo/secukinumab 300 mg group (77.8%), and initial secukinumab 300 mg group (78.3%), and 100% responders in the initial secukinumab 150 mg group. At the end of the extension treatment period at week 148, the mean ppPASI in the placebo/secukinumab 150 mg group remained at the same level, at 9.75, whereas it had decreased in all other groups (initial secukinumab 150 mg, 1.01; initial secukinumab 300 mg, 3.43; and placebo/secukinumab 300 mg, 4.19) (Fig 2). The overall incidence of adverse events in the extension treatment period was slightly lower under secukinumab 150 mg (61.0%) than under secukinumab 300 mg (69.8%), and no new or unexpected adverse events were observed. During the extension period, there were 5 discontinuations in the secukinumab 150 mg group (16.1%), 5 in the secukinumab 300 mg group (13.9%), 4 in the placebo/secukinumab 150 mg group (40.0%), and 4 in the placebo/secukinumab 300 mg group (23.5%).

The low numbers of patients in each group warrant caution in interpreting these results and render unfeasible any further analysis of efficacy by patient characteristics on entering the extension study. The apparently greater benefit observed for the 150-mg dose compared to the 300-mg dose may also be due to small group numbers and discontinuations. However, these data suggest a sustained clinical benefit and an acceptable safety and tolerability profile of extended treatment with secukinumab 300 mg or 150 mg in patients with

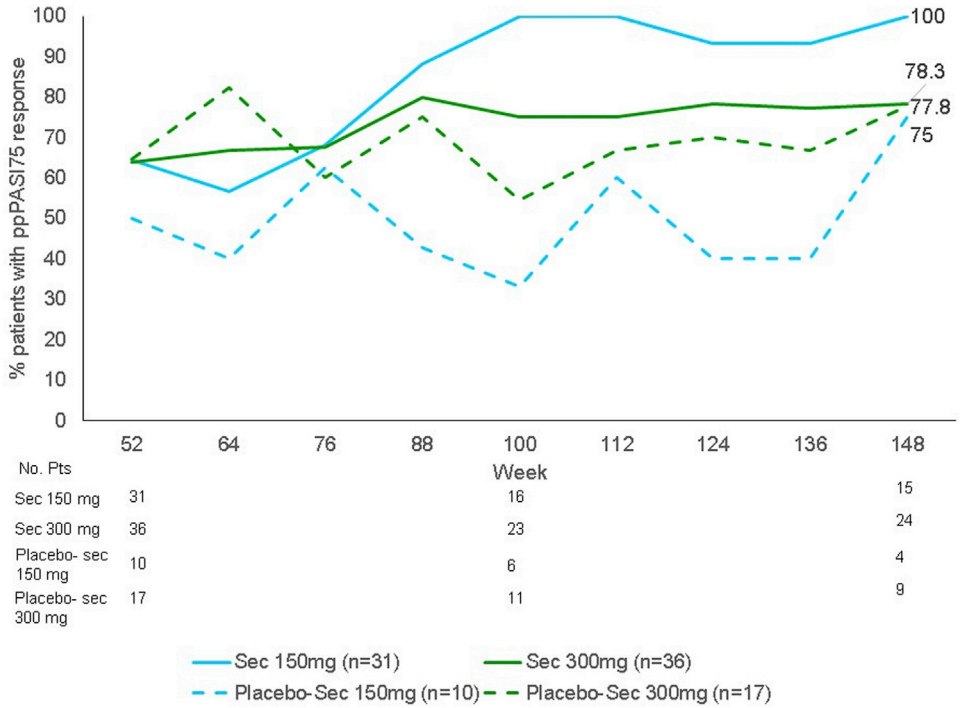

Fig 1. Time course of ppPASI75 response rate during extension treatment period (full analysis set, last observation carried forward). *ppPASI75*, 75% or greater reduction in Palmoplantar Pustular Psoriasis Area Severity Index; *Pts*, patients; *Sec*, secukinumab.

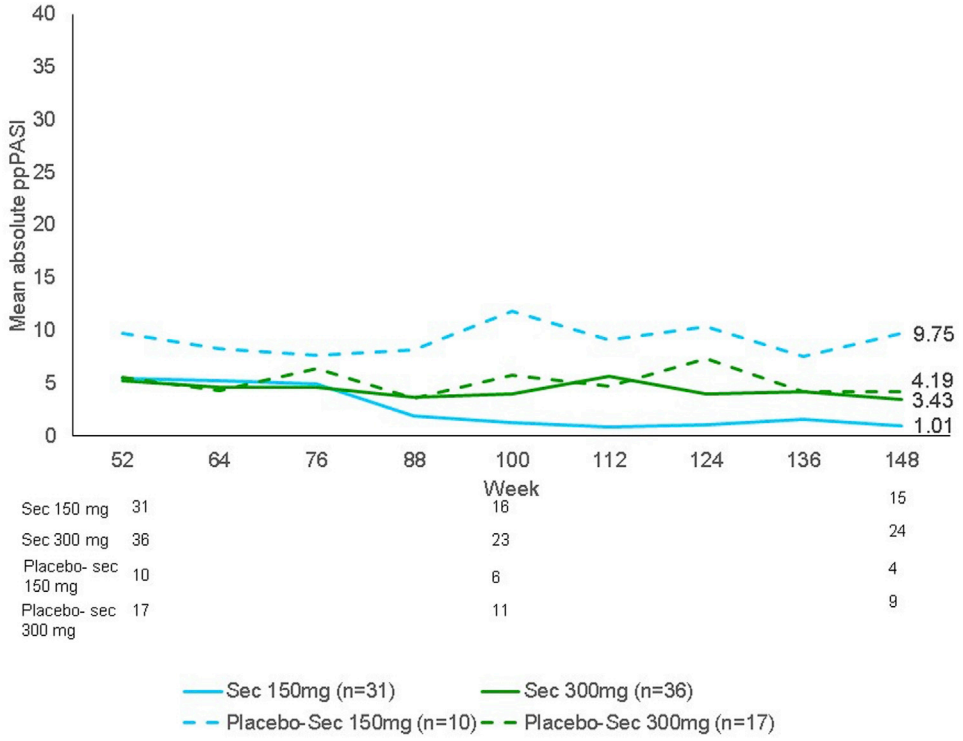

Fig 2. Time course of mean absolute ppPASI score during extension treatment period (full analysis set, last observation carried forward). *ppPASI*, Palmoplantar Pustular Psoriasis Area Severity Index; *Pts*, patients; *Sec*, secukinumab.

palmoplantar pustular psoriasis who had achieved a meaningful clinical response at weeks 16 and 52 when continuing secukinumab up to week 148.

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A pilot study of the impact of facial skin protectants on qualitative fit testing of N95 masks

To the Editor: The COVID-19 pandemic has necessitated prolonged use of N95 masks, leading to superficial wounds, purpura, and indentations on health care workers' faces.[1,2] The use of skin protectants may prevent skin irritation caused by N95 masks[2] by providing a barrier and/or redistributing pressure; however, the impact on respirator fit has not been evaluated. This study assesses the impact of the use of skin protectants on N95 respirator qualitative fit test (QLFT) results and user comfort.

We enrolled adult employees at Brigham Health and Dana-Farber Cancer Institute previously fit-tested for N95 masks (N = 25) via a standardized QLFT protocol[3] (see Supplemental Materials; available via Mendeley at https://doi.org/10.17632/sj6tr3mp9r.1). Each participant underwent QLFT for 5 types of skin protectants on a 3M (St Paul, MN) 1860 N95 mask after self-application using a standardized protocol (Fig 1 and Supplemental Table I; available via Mendeley at https://doi.org/10.17632/sj6tr3mp9r.1). Participants underwent repeated QLFT of their respirator for each dressing and rated dressing comfort (Supplemental Fig 1; available via Mendeley at https://doi.org/10.17632/sj6tr3mp9r.1).

Most participants were female (76%), with an average age of 28 years. QLFT passing rates ranged from 88.0% for Cavilon film (3M) to 56.0% for DuoDERM CGF (ConvaTec, Oklahoma City, OK), with the highest failure rates noted with movement maneuvers (Tables I and II). Overall, 9 (36.0%) participants passed with all 5 materials. Mepitac tape (Mölnlycke, Gothenburg, Sweden) and DuoDERM CGF (88.0% positive rating) were reported to be more comfortable than Cavilon film (22.0%). Cavilon film and DuoDERM CGF had the most negative qualitative comments, with odor and impact on mask fit or seal quality as common concerns, respectively.

In this study, we found that the use of skin protectants to prevent skin irritation may interfere with N95 respirator fit. Mitigation of skin irritation from prolonged N95 use is a concern, but workers should not trade efficacy for comfort. Most fit test failures were observed with movement, suggesting that the impact of skin protectants on fit may not be obvious to the wearer.