Why is it important that therapies for psoriasis achieve clear skin?

Psoriasis is a chronic immune-mediated disease characterized by thick and long lasting skin lesions, called plaques, known to cause itching, scaling and pain\textsuperscript{1-3}. This common and distressing condition is not simply a cosmetic problem – even people with very mild symptoms are affected everyday\textsuperscript{1}. Psoriasis is associated with significant impairment of physical and psychological quality of life. People living with the condition are also more likely suffer from a range of conditions that may occur simultaneously such as psoriatic arthritis, heart disease and cancer (lymphoma)\textsuperscript{1-3}. Consequently there is an urgent need for new treatments that achieve clear or almost clear skin, as a proven link exists between this and health-related quality of life\textsuperscript{1-4}.

Measuring psoriasis skin clearance in clinical trials

The Psoriasis Area and Severity Index (PASI) is frequently used to measure outcomes in psoriasis clinical trials and measures the redness, scaling and thickness of psoriatic plaques and the extent of involvement in each region of the body\textsuperscript{5}. During clinical trials, psoriasis treatment efficacy is assessed by the reduction of the score from baseline (week 0)\textsuperscript{5}.

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**PASI Scores**

Measuring Skin Clearance for Psoriasis Patients in Clinical Trials

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**PASI 50**

50% reduction in PASI score – an acceptable measure of efficacy for secondary endpoints in psoriasis clinical trials\textsuperscript{5}

**PASI 75**

75% reduction in PASI score – standard efficacy measure used in most psoriasis clinical studies\textsuperscript{5}

**PASI 90**

90% reduction in PASI score (almost clear skin)

**PASI 100**

Completely clear skin


\textsuperscript{1} PASI 90 AND 100 ARE CONSIDERED THE MOST ROBUST PRIMARY ENDPOINT MEASURES FOR EVALUATING SKIN CLEARANCE\textsuperscript{5}

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**IGA mod 2011:** An alternative measure of psoriasis severity is the Investigator's Global Assessment (IGA). A rating of 0/1 corresponds to clear or nearly clear skin in psoriasis patients.
Clear skin is the desired outcome for most psoriasis patients\(^1\text{-}^4\), establishing a more accurate primary endpoint is critical.

Historically, achieving PASI 75 has been the goal for psoriasis treatments, and as a consequence this measure has been regularly used as the primary endpoint in clinical trials\(^5\). However, there is now a continued focus on the establishment of PASI 90 and PASI 100 as the preferred efficacy measure, as recommended by clinical guidelines and regulatory authorities\(^5\). This is because these measures accurately reflect the patient’s treatment goals, as well as ensuring thorough evaluation of patient progress throughout clinical trials\(^5\).

### Patient Progress with Treatment Over the Course of 36 Weeks

**Baseline**

Patient assessment begins at baseline (week 0).

**PASI 90**

PASI 90 or almost clear skin, was achieved between week 0 and week 24.

**PASI 100**

PASI 100 or clear skin, can be seen at week 36.

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**References**