**Introduction**

- Moderate to severe psoriasis impacts patients both physically and emotionally, leading to major health-related quality of life (HRQoL) impairment.
- Pruritus is one of the most frequent and bothersome symptoms of psoriasis and significantly impacts HRQoL.
- Improvements in HRQoL and disease symptoms have been reported with several psoriasis therapies.
- Given the chronic nature of psoriasis, treatment options should aim to provide long-term improvements.
- Tofacitinib is an oral Janus kinase inhibitor that is being investigated for psoriasis. Two Phase 3 studies, OPT Pivotal 1 and OPT Pivotal 2, reported the efficacy and safety of tofacitinib up to Week 48.
- The aim of this analysis was to report the effect of tofacitinib treatment on HRQoL, and disease symptoms up to 52 weeks in OPT Pivotal 1 and 2.

**Methods**

- OPT Pivotal 1 (NCT0137900) and 2 (NCT0130977) were identical, double-blind, placebo-controlled Phase 3 studies up to 52 weeks (Figure 1).
- Patients were randomized 2:1 to receive tofacitinib 5 or 10 mg or placebo twice daily (BID).
- At Week 16, patients receiving placebo were re-randomized to tofacitinib 5 or 10 mg BID.
- At Week 28, in patients that did not achieve 75% improvement tofacitinib 5 or 10 mg BID vs placebo twice daily (BID).

**Results**

**Patients**

- A total of 1,838 patients were randomized and received treatment in OPT Pivotal 1 and 2.
- Patient demographics and baseline disease characteristics are shown in Table 1. Baseline PRO values indicated a considerable burden of psoriasis on patient HRQoL.

**Itch Severity Item**

- Improvements in ISI were rapid for both tofacitinib doses, reaching significance in patients by Day 2 (p < 0.001; Figure 3a).
- Tofacitinib 10 mg BID provided significantly greater improvements in ISI vs 5 mg BID from Day 3 in OPT Pivotal 1 (p < 0.001), and Day 10 in OPT Pivotal 2 (p = 0.036).
- Improvements in ISI were maintained through Week 2 (Figure 3b).
- At Week 16, a significantly greater proportion of patients treated with tofacitinib plus placebo reported an ISI score of 0 (representing no pruritus) (p < 0.001, Figure 3c).
- A greater proportion of patients achieved IS0 with tofacitinib 10 mg BID vs 5 mg BID (p < 0.001).

**Patient's Global Assessment**

- At Week 16, a greater proportion of patients achieving PGA response of ‘clear’ or ‘almost clear’ with tofacitinib vs placebo reported an ISI score of 0 (representing no pruritus) (p < 0.001, Figure 3d).
- Improvement were maintained through Week 52.

**Dermatology Life Quality Index**

- At Week 16, significantly greater improvements from baseline in DLQI scores were observed with tofacitinib 5 and 10 mg BID vs placebo (p < 0.001; Figure 4).
- Tofacitinib 10 mg BID provided significantly greater improvements in DLQI vs 5 mg BID from Day 3 in OPT Pivotal 1 (p < 0.001), and Day 10 in OPT Pivotal 2 (p = 0.036).
- DLQI scores were observed with tofacitinib 5 and 10 mg BID vs placebo at Week 16 (p < 0.001).
- Almost clear – Tofacitinib 10 mg BID provided significantly greater improvements in DLQI vs 5 mg BID from Day 3 in OPT Pivotal 1 (p < 0.001), and Day 10 in OPT Pivotal 2 (p = 0.036).
- DLQI scores were observed with tofacitinib 5 and 10 mg BID vs placebo at Week 16 (p < 0.001).

**Patient satisfaction**

- At Week 16, a greater proportion of patients satisfied with tofacitinib 5 and 10 mg BID vs placebo (p < 0.001; Figure 5).
- Overall, >79% of patients were ‘very satisfied’ or ‘somewhat satisfied’ with treatment at Week 52.

**Conclusions**

- PRO values at baseline indicated a considerable burden of illness on patient HRQoL.
- In both studies, tofacitinib consistently resulted in significant PRO improvements vs placebo, which were sustained through 52 weeks.
- DLQI improvement of at least the MCID was seen in >60% of tofacitinib-treated patients.
- ID improvements were particularly rapid (Day 2).
- PGA of ‘clear’ or ‘almost clear’ was achieved by significantly more patients with tofacitinib vs placebo.
- >79% of patients were satisfied with tofacitinib after 52 weeks of treatment.
- Tofacitinib 10 mg BID consistently provided greater improvements in HRQoL vs 5 mg BID.
- Tofacitinib represents a potential new oral treatment option, providing long-term HRQoL improvement for patients with moderate to severe psoriasis.

**References**


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**Disclosure of interest**

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