STUDY | **LIMMitless trial: Long-term safety and efficacy of risankizumab in patients with moderate-to-severe plaque psoriasis**

Population
LiMMitless:
N = 897 (706 ongoing)

Endpoints: Safety outcomes up to Week 304; TEAEs, defined as AEs with onset or worsening after first dose; efficacy outcomes up to Week 256; PASI 90/PASI 100; PASI <3 and mean improvement in PASI from baseline; sPGA score 0/1; DLQI score 0/1; ≥4-point improvement in DLQI from baseline.

Eligibility: Adult patients with history of moderate-to-severe plaque psoriasis; completed one of the preceding studies that included a continuous risankizumab arm*; at least 3 years of continuous risankizumab treatment.

TRIAL DESIGN

Phase III ongoing, single-arm, multicenter open-label extension study

Base studies

Risankizumab | 150 mg/day

Included patients who completed prior placebo-controlled phase II/III studies*, and initially randomized to receive Risankizumab

LIMMitless trial

Risankizumab | 150 mg/day

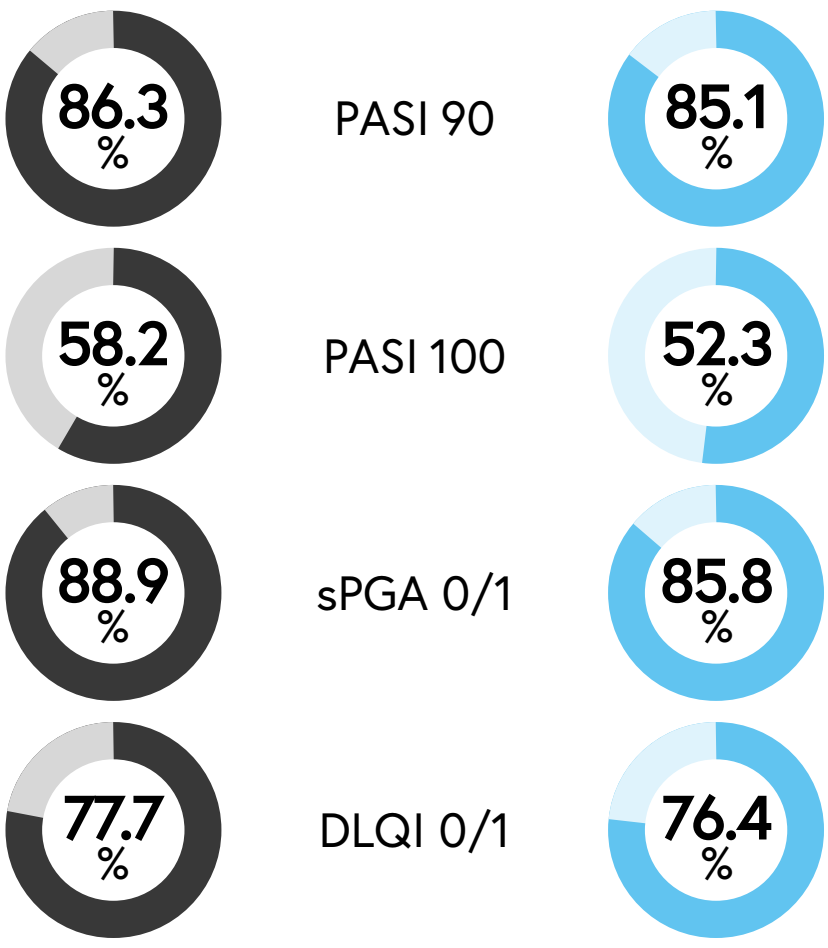
Every 12 weeks for 252 weeks

Assessments undertaken every 12 weeks until Week 156 and then every 24 weeks thereafter.

*UltIMMa-1 (NCT02684370), UltIMMa-2 (NCT02684357), SustaIMM (NCT03000075, NCT03255382), IMMvent (NCT02694523), or IMMhance (NCT02672852).

EFFICACY

Base (52 weeks) N = 897 | **LIMMitless** (256 weeks) N = 897



90.3% Absolute PASI <3

≥95% Mean change in PASI from baseline (Week 28–256)

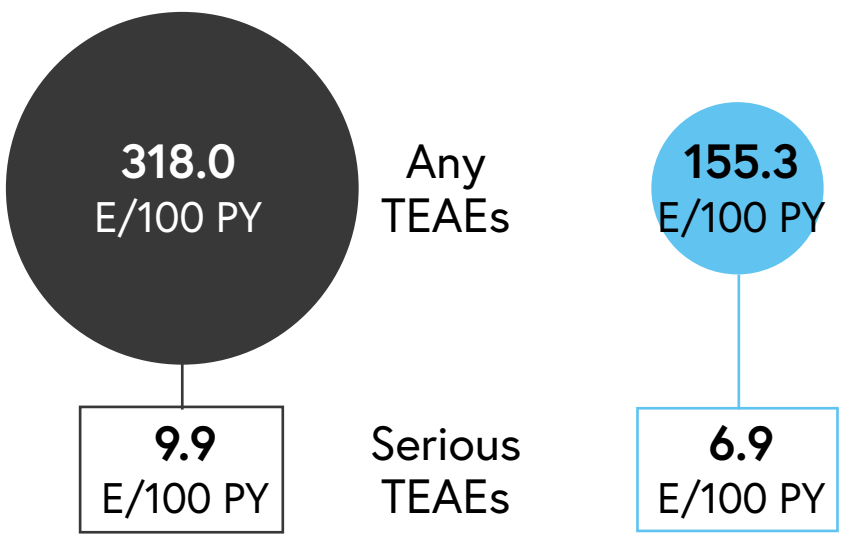
96.8% ≥4-point improvement in DLQI

70.8% PASI 90 and DLQI 0/1

Data presented is modified for the non-responder imputation statistical method, where non-response was cited only for treatment discontinuation due to psoriasis worsening, and using a mixed-effect model for missing data in patients without treatment issues.

SAFETY

Base (16 weeks) N = 1,306 | **LIMMitless** (≤304 weeks) N = 897

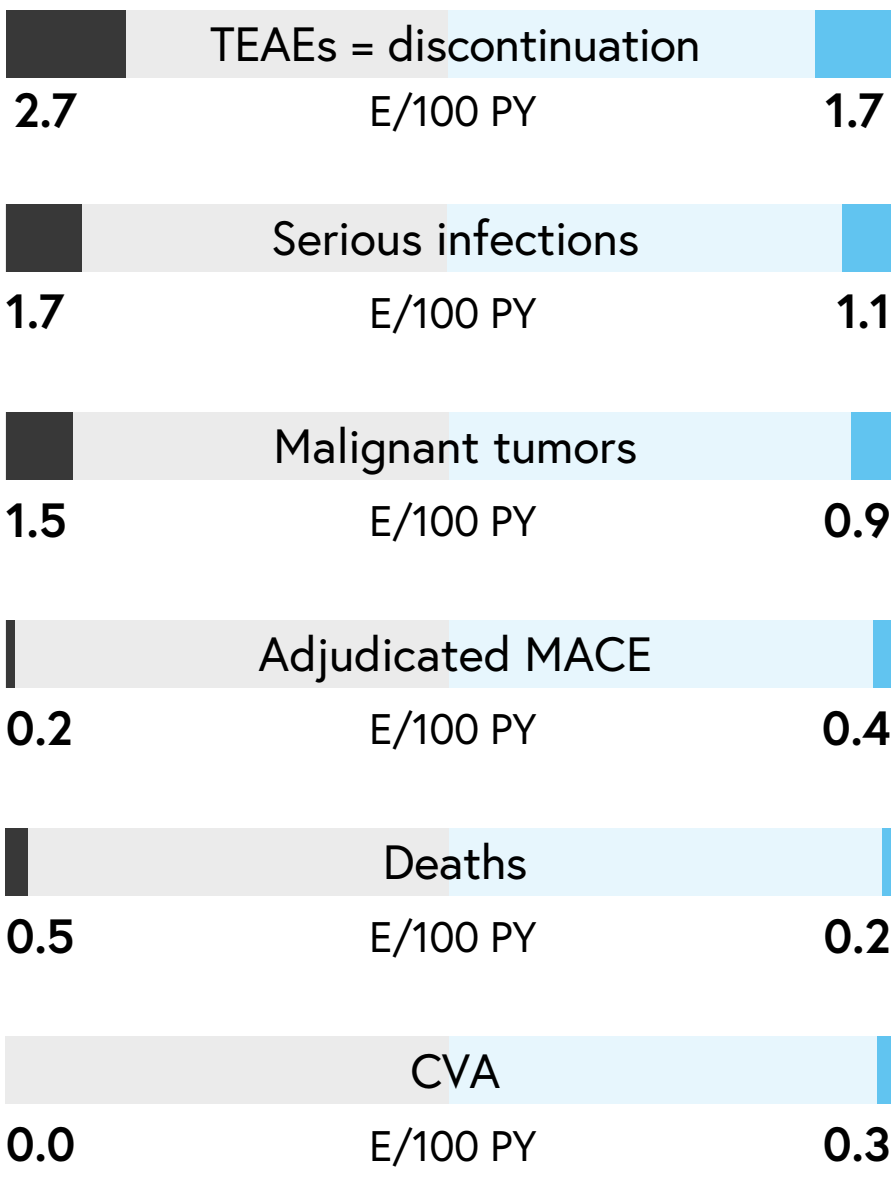


Most common TEAEs (any grade)

13.7 E/100 PY	Nasopharyngitis
8.0 E/100 PY	URTI
4.3 E/100 PY	Arthralgia

Most common serious AE

0.2 E/100 PY	Osteoarthritis



Risankizumab shows durable efficacy and was well tolerated for up to 5 years of treatment in patients with moderate-to-severe plaque psoriasis.

Abbreviations: AE, adverse event; CVA, cerebrovascular accident; DLQI, Dermatology Life Quality Index; E/100 PY, events/100 patient-years; MACE, major adverse cardiac event; PASI, Psoriasis Area and Severity Index; TEAE, treatment-emergent adverse event; URTI, upper respiratory tract infection sPGA, static Physician's Global Assessment.

Papp KA, et al. *J Am Acad Dermatol*. 2023;89(6):1149-1158.

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