Dupilumab for Treatment of **Bullous Pemphigoid**: **LIBERTY-BP ADEPT** Trial Results

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LB1136

BP

Conclusion

Dupilumab showed significant benefits across multiple disease aspects of BP, including achieving sustained remission while off OCS, reducing disease activity and itch, and reducing rescue medication use and cumulative OCS exposure, as well as improving QoL

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Objective

To report the efficacy and safety of dupilumab in adult patients with moderate-to-severe BP: results from the LIBERTY-BP ADEPT phase 2/3 clinical trial

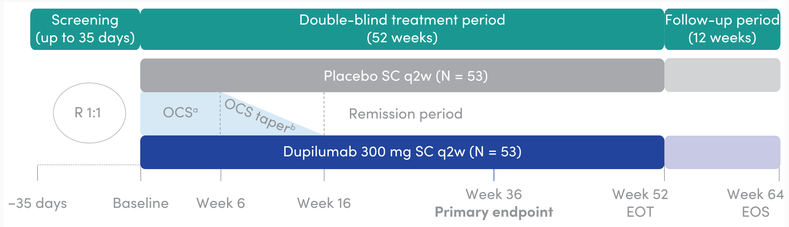
Background

- BP is a life-threatening, chronic, autoimmune, subepidermal blistering skin disease that predominantly affects the elderly[1,2]
- Currently, there are no approved targeted therapies for BP in the USA or Europe. Topical and/or systemic corticosteroids along with immunosuppressants are the mainstay of treatment; however, they are accompanied by side effects and risk-benefit considerations especially in the elderly population[1,3]
- Type 2 inflammation plays a critical role in BP pathogenesis[4,5]
- Dupilumab blocks the shared receptor component for IL-4 and IL-13, key drivers of type 2 inflammation[4,5]

Methods

- LIBERTY-BP ADEPT (NCT04206553) is a global, randomized, double-blind, placebo-controlled, parallel-group study

Study design



Primary endpoint:

- Proportion of patients achieving sustained remission at Week 36, defined as meeting all **3** following criteria:
  1. Achievement of complete remission[c] and off OCS no later than Week 16
  2. Absence of need for rescue therapy[d] during the 36-week treatment period
  3. Absence of disease relapse[e] after completion of OCS taper (no later than Week 16) to Week 36

Secondary endpoints:

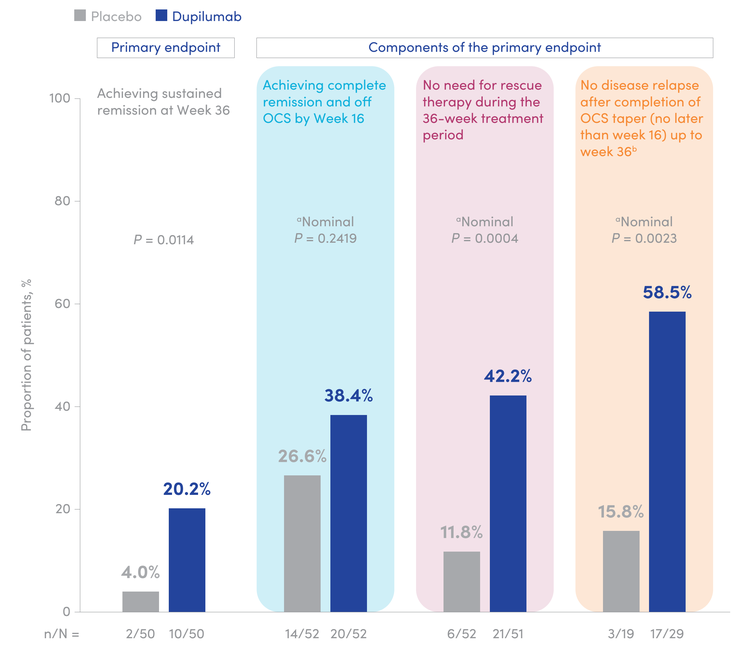
- Total cumulative OCS dose over the 36-week treatment period
- Proportion of patients achieving ≥90% reduction in BPDAI[f] activity score from baseline at Week 36
- Proportion of patients achieving ≥4-point reduction in PP-NRS[g] from baseline at Week 36
- Change in ABQoL[h] score from baseline to Week 36
- Time to first use of rescue medication up to Week 36

[a]Patients were initiated on a standard-of-care regimen of OCS (prednisone or prednisolone: 0.5 mg/kg for moderate BP and 0.75 mg/kg for severe BP) on Day 1. [b]OCS taper was initiated by Week 4–6 and OCS were tapered as long as disease control (new lesions cease to form and existing lesions begin to heal) was maintained with the objective to taper off OCS no later than Week 16. [c]Complete remission was defined as absence of new lesions and epithelialization of old lesions. [d]Rescue therapy included increase of OCS dose during the taper, reinitiation of OCS after completion of the OCS taper, or initiation of any BP-directed therapy. [e]Relapse was defined as the appearance of ≥3 new lesions a month (blisters, eczematous lesions, or urticarial plaques) or ≥1 large (>10 cm diameter) eczematous lesion or urticarial plaque that did not heal within 1 week. [f]BPDAI range 0–360, covering a range of cutaneous and mucosal BP lesions; higher scores indicate greater disease activity. [g]PP-NRS range 0–10, measuring the intensity of itching; higher scores indicate more severe pruritus. [h]ABQoL score range 0–51, assessing disease-specific quality of life in autoimmune blistering diseases; higher scores indicate poorer quality of life.

Results

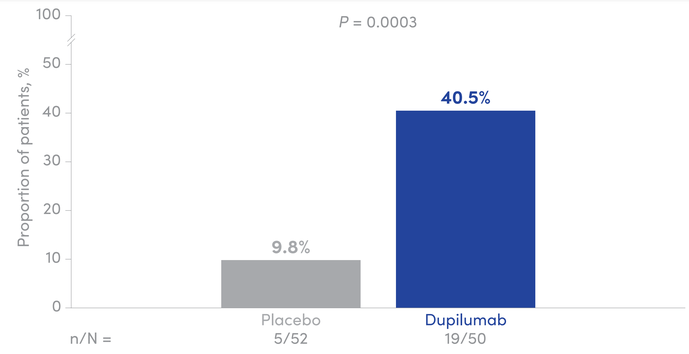
- Baseline demographics and disease characteristics were generally well balanced between treatment arms

A significantly higher proportion of dupilumab-treated patients achieved sustained BP disease remission at Week 36



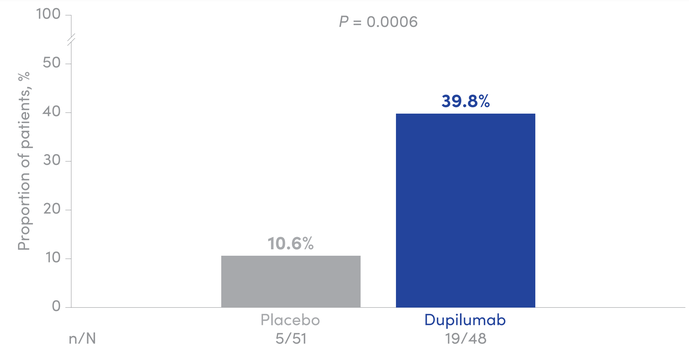
N = number of patients with observed data for the endpoint; n = number of patients with observed responder status for the endpoint. Multiple imputation was used for patients without observed data.
[c]Components of sustained disease remission were prespecified for analysis in the statistical analysis plan. They were not prespecified for inclusion in the statistical hierarchy and are therefore nominal.
[b]The disease relapse component was only evaluated among patients who completed the OCS taper by Week 16.

Significantly more dupilumab-treated patients achieved ≥90% improvement in BPDAI activity score at Week 36 compared with those receiving placebo



These proportions account for multiple imputation. N = number of patients with observed data for the endpoint; n = number of patients with observed responder status for the endpoint.

Significantly more dupilumab-treated patients achieved ≥4-point improvement in PP-NRS at Week 36 compared with those receiving placebo

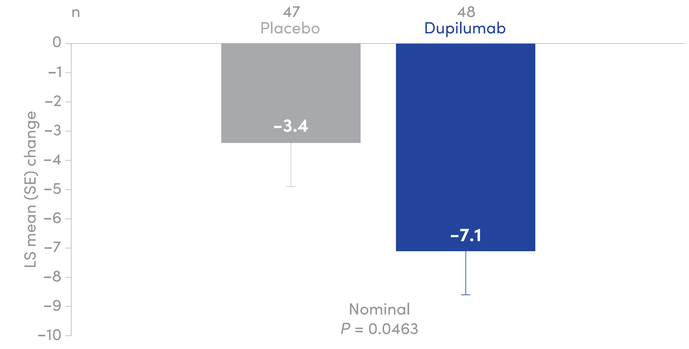


These proportions account for multiple imputation. N = number of patients with observed data for the endpoint; n = number of patients with observed responder status for the endpoint.

Dupilumab-treated patients had a significantly lower cumulative OCS dose over 36 weeks compared with those receiving placebo

	Cumulative OCS dose LS mean (SE), mg	LS mean difference vs placebo (95% CI), mg	*P* value
Dupilumab N = 53	5,646 (566.0)	−1,678 (−3,108, −248)	0.0220
Placebo N = 53	7,324 (588.8)		

Improvements in ABQoL score favored dupilumab over placebo at Week 36



At baseline, ABQoL mean (SD) was 21.7 (9.1) for placebo and 22.9 (9.8) for dupilumab. At Week 36, LS mean difference in change from baseline vs placebo (95% CI) was −3.70 (−7.346, −0.061). n = number of patients with observed or imputed data.

- Dupilumab-treated patients had a 54% lower risk of rescue medication use over 36 weeks compared with those on placebo (*P* = 0.0016)
- Overall safety was consistent with the known dupilumab safety profile
  - For more information on the results, please scan the QR code

ABQoL, Autoimmune Bullous Disease Quality of Life; BP, bullous pemphigoid; BPDAI, bullous pemphigoid disease area index; CI, confidence interval; EOS, end of study; EOT, end of treatment; IL, interleukin; LS, least squares; OCS, oral corticosteroid(s); PP-NRS, Peak Pruritus Numerical Rating Scale; q2w, every 2 weeks; QoL, quality of life; R, randomization; SC, subcutaneous; SD, standard deviation; SE, standard error.

References: 1. Werth VP, et al. J Eur Acad Dermatol Venereol. 2025;39:290-300. 2. Rhyou HI, et al. Allergy Asthma Clin Immunol. 2021;17:117. 3. Akbariallabad H, et al. Nat Rev Dis Primers. 2025;11:12. 4. Zhang L, et al. Front Immunol. 2023;14:1115083. 5. Werth VP, et al. Adv Ther. 2024;41:4418-32.

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