Dupilumab sustains efficacy in patients with moderate-to-severe type 2 asthma regardless of ICS dose

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Abstract

Background: Dupilumab, a human monoclonal antibody, blocks the shared receptor component for interleukins 4/13, key and central drivers of type 2 inflammation. The LIBERTY ASTHMA TRAVERSE (NCT02134028) open-label extension study demonstrated the long-term safety and efficacy of dupilumab in patients [?]12 years who had participated in a previous dupilumab asthma study. The safety profile was consistent with that observed in the parent studies. **Methods:** This analysis includes patients from phase 2b (NCT01854047) or phase 3 (QUEST; NCT02414854) studies receiving high- or medium-dose inhaled corticosteroids (ICS) at parent study baseline (PSBL) and enrolled in TRAVERSE. We analyzed unadjusted annualized severe exacerbation rates, change from PSBL in pre-bronchodilator (pre-BD) FEV $_1$ (L), asthma control (5-item asthma control questionnaire), and type 2 biomarkers in patients with type 2 asthma at baseline (blood eosinophils [?]150 cells/μL or fractional exhaled nitric oxide [FeNO] [?]25 ppb), and subgroups defined by baseline blood eosinophils or FeNO. **Results:** Of patients with type 2 asthma (n=1,666) in this analysis, 891 (53.5%) were receiving high-dose ICS at PSBL. In this subgroup, unadjusted exacerbation rates for dupilumab vs placebo were 0.517 vs. 1.883 (phase 2b) and 0.571 vs. 1.300 (QUEST) over 52 weeks of the parent study, and remained low throughout TRAVERSE (0.313–0.494). Improvements in pre-BD FEV $_1$ from PSBL were sustained throughout TRAVERSE. Similar clinical efficacy was observed among patients receiving medium-dose ICS at PSBL and biomarker subgroups. **Conclusions:** Dupilumab showed sustained efficacy for up to 3 years in patients with uncontrolled, moderate-to-severe type 2 asthma on high- or medium-dose ICS.

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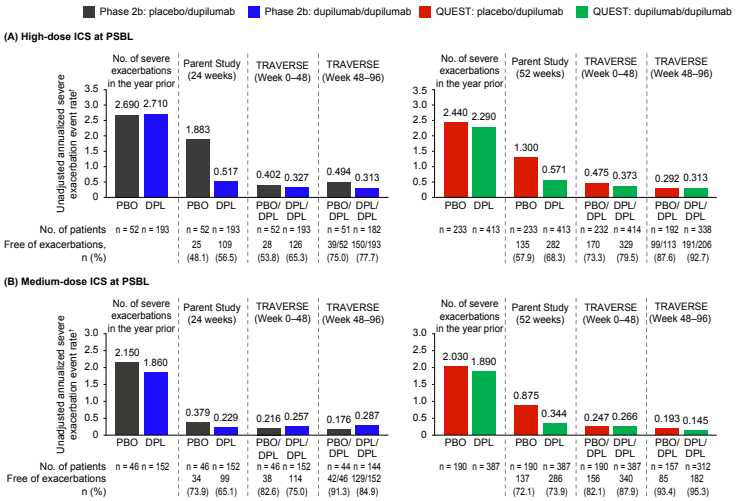
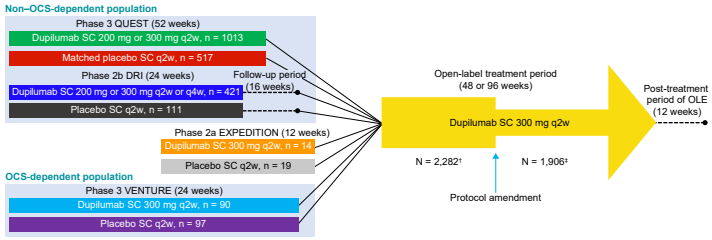
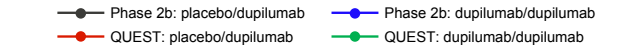
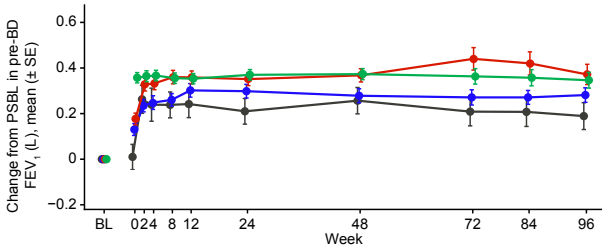




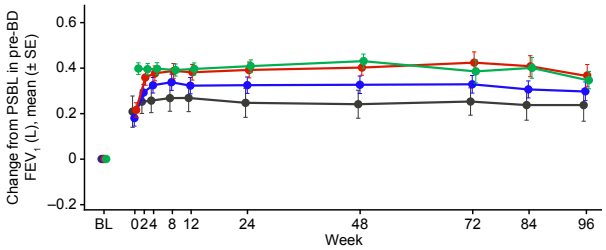


(A) High-dose ICS at PSBL



Number of patients											
Phase 2b PBO/DPL	52	52	50	52	51	52	52	50	49	49	49
Phase 2b DPL/DPL	193	193	190	190	189	188	186	184	175	175	177
QUEST PBO/DPL	232	232	224	227	222	225	227	223	103	102	102
QUEST DPL/DPL	414	413	395	396	390	399	389	381	188	185	187

(B) Medium-dose ICS at PSBL



Number of patients											
Phase 2b PBO/DPL	46	46	46	46	46	46	45	43	44	42	42
Phase 2b DPL/DPL	152	152	149	152	148	151	148	143	139	137	138
QUEST PBO/DPL	190	189	184	186	172	182	182	177	83	81	82
QUEST DPL/DPL	387	385	378	376	367	370	375	364	173	174	175