Tralokinumab for the treatment of severe, uncontrolled asthma: the ATMOSPHERE clinical development program

**TROPOS: OCS-sparing study**

**Participant Population**

Participants with asthma who require treatment with maintenance OCS in addition to ICS plus LABA

- ≥80% <90%
- 12–75 years of age
- Pre-BD FEV1 <80% predicted (<90% in adolescents) at enrollment
- OCS for 6 months before visit 1 and stable OCS dose ≥ 7.5 – ≤ 30 mg (prednisone or equivalent) daily for ≥1 month before enrollment

**Primary Objective**

Assess the effect of tralokinumab on reducing the oral OCS dosage

**Study Design and Treatment**

<table>
<thead>
<tr>
<th>Phase</th>
<th>Period</th>
<th>Treatment/Placebo</th>
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</thead>
<tbody>
<tr>
<td>Phase I</td>
<td>Enrollment/run-in (2 weeks)</td>
<td>1207 participants were randomized at 198 sites</td>
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<tr>
<td>Phase II</td>
<td>OCS optimization (8 weeks)</td>
<td>140 participants were randomized at 44 sites</td>
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<td>40-week treatment period</td>
<td>Reduction phase (20 weeks)</td>
<td>52-week treatment period</td>
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<tr>
<td>STRATOS 1:</td>
<td>Tralokinumab 300 mg Q2W SC</td>
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<td>STRATOS 2:</td>
<td>Placebo Q2W SC</td>
<td>Placebo Q2W SC</td>
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**Primary Outcome Measure**

Change in number of AEs and SAEs up to week 52

**Glossary**

- AAER: annualized asthma exacerbation rate
- ADQI: asthma disease questionnaire
- AEs: adverse events
- BDP: beclomethasone dipropionate
- BHR: bronchial hyperresponsiveness
- BHR test: methacholine challenge test
- BD: bronchodilator
- BDQSR: bronchodilator drug questionnaires survey of respiratory symptoms
- BiP: bronchial provocation concentration causing a 20% fall in baseline FEV1
- BiP 80%: bronchial provocation concentration causing an 80% fall in baseline FEV1
- BV: beclomethasone
- CAF: terbutaline
- COLD: chronic obstructive lung disease
- COPD: chronic obstructive pulmonary disease
- CVT: cardiovascular
- DHEA: dehydroepiandrosterone
- DHEAS: dehydroepiandrosterone sulfate
- DQI: disease questionnaire index
- EOM: eosinophils
- EPOC: exercise-induced pulmonary orchestra
- FOB: forced oscillation technique
- FOS: forced oscillations technique
- FVC: forced vital capacity
- FVDC: forced vital capacity depression
- FEV1: forced expiratory volume in 1 second
- FEV1/FVC: forced expiratory volume in 1 second/forced vital capacity
- FEV1/FVC%: forced expiratory volume in 1 second/forced vital capacity percentage
- FEV1% pred: FEV1 as percentage of predicted
- FEV1/FEV2: forced expiratory volume in 2 seconds
- FEF25–75: forced expiratory flow at 25–75% of the FVC
- FEF50: forced expiratory flow at 50% of the FVC
- FEF75: forced expiratory flow at 75% of the FVC
- FEO: fractional exhaled NO
- FEX: fractional exhaled nitric oxide
- FIC: forearm ischemic challenge
- FOS: forced oscillation
- FVC: forced vital capacity
- GPR: generalized pitting edema
- GTE: general thyroid evaluation
- HbA1c: glycosylated Hb
- HbA1c: glycosylated hemoglobin
- HDL: high-density lipoprotein
- ICS: inhaled corticosteroid
- IL-13: interleukin-13
- LABA: long-acting β2-agonists
- LFT: liver function test
- MELD: model for end-stage liver disease
- MPA: aminoglycosides
- MPA: aminoglycoside
- MPA: aminoglycoside
- mAb: monoclonal antibody
- NO: nitric oxide
- NSAID: nonsteroidal anti-inflammatory drug
- O2: oxygen
- OCS: oral corticosteroid
- OTC: over-the-counter
- PAO2: partial pressure of arterial oxygen
- PEAK: peak expiratory flow
- PEFR: peak expiratory flow rate
- PEF: peak expiratory flow
- PI: percent improvement
- PIR: peak inspiratory pressure
- PFT: pulmonary function test
- PTT: partial pressure of arterial carbon dioxide
- Q: quality
- RRT: respiratory rate
- SA: severe asthma
- SABA: short-acting β2-agonist
- SADS: severe asthma disease severity
- SAI: severe asthma index
- SCD: severe clinical deterioration
- SCL: severe clinical limitation
- SCORT: severe clinical rating of asthma
- SOT: severe clinical outcome
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- SPP: severe persistent pulmonary hypertension of the newborn
- SPT: skin prick test
- SPRINT: severe persistent airflow limitation
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