Evaluation of Antibody Properties and Clinically Relevant Immunogenicity, Anaphylaxis, and Hypersensitivity Reactions in Two Phase III Trials of Tralokinumab in Severe, Uncontrolled Asthma

Drug Safety

Mats Carlsson,[1] Martin Braddock,[2] Yuling Li,[3] Jihong Wang,[3] Weichen Xu,[3] Nicholas White,[4] Ayman Megally,[5] Gillian Hunter,[6] Gene Colice[5]

[1]Patient Safety, Global Medicines Development, AstraZeneca, Pepparedsleden 1, Mölndal, SE-431 83, Sweden

[2]Global Medicines Development, AstraZeneca, Granta Park, Great Abington, Cambridge, CB21 6GH, United Kingdom

[3]Biopharmaceutical Development, MedImmune, One MedImmune Way, Gaithersburg, Maryland 20878, United States

[4]Clinical Pharmacology, Pharmacometrics and DMPK, MedImmune, Granta Park, Great Abington, Cambridge, CB21 6GH, United Kingdom

[5]Global Medicines Development, AstraZeneca, One MedImmune Way, Gaithersburg, Maryland 20878, United States

[6]Biometrics and Information Sciences, AstraZeneca, Granta Park, Great Abington, Cambridge, CB21 6GH, United Kingdom

Corresponding author: Mats Carlsson, Patient Safety, Global Medicines Development, AstraZeneca, Pepparedsleden 1, Mölndal, SE-431 83, Sweden.

Mats.Carlsson@astrazeneca.com

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Adverse events of hypersensitivity, anaphylactic reaction, and anaphylactic shock condition reported during the treatment period of STRATOS 1 and STRATOS 2 (safety analysis set)

STRATOS 1	Tralo Q2W (*N* = 398)	Tralo Q4W (*N* = 404)	Placebo (*N* = 400)
Participants with any relevant AE, *n* (%)	103 (25.9)	101 (25.0)	102 (25.5)
Most frequently reported relevant AEs (≥3 participants on tralokinumab), *n* (%)			
Asthma	47 (11.8)	48 (11.9)	51 (12.8)
Cough	12 (3.0)	13 (3.2)	12 (3.0)
Rhinitis allergic	10 (2.5)	15 (3.7)	14 (3.5)
Dyspnea	5 (1.3)	9 (2.2)	7 (1.8)
Rash	8 (2.0)	4 (1.0)	5 (1.3)
Injection site hypersensitivity	5 (1.3)	4 (1.0)	0
Pruritus	5 (1.3)	3 (0.7)	3 (0.8)
Urticaria	3 (0.8)	4 (1.0)	4 (1.0)
Erythema	5 (1.3)	1 (0.2)	0
Injection site rash	4 (1.0)	1 (0.2)	0
Conjunctivitis	2 (0.5)	2 (0.5)	3 (0.8)
Dermatitis contact	1 (0.3)	3 (0.7)	0
Injection site urticaria	3 (0.8)	1 (0.2)	1 (0.3)
Conjunctivitis allergic	2 (0.5)	1 (0.2)	1 (0.3)
Seasonal allergy	2 (0.5)	1 (0.2)	5 (1.3)
Wheezing	2 (0.5)	1 (0.2)	5 (1.3)
STRATOS 2	Tralo Q2W (*N* = 425)		Placebo (*N* = 422)
Participants with any relevant AE, *n* (%)	56 (13.2)		38 (9.0)
Most frequently reported relevant AEs (≥3 participants on tralokinumab), *n* (%)			
Asthma	14 (3.3)		16 (3.8)
Pruritus	6 (1.4)		2 (0.5)
Rash	5 (1.2)		0
Skin reaction	5 (1.2)		0
Erythema	3 (0.7)		0

AE adverse event, *Q2W* every 2 weeks, *Q4W* every 4 weeks, *tralo* tralokinumab