APOGEE THERAPEUTICS®

APG808 Phase 1b interim results

MAY 12, 2025

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APG808 Phase 1b interim data met or exceeded trial objectives

GOAL

Confirm safety of APG808 as monotherapy in an **asthma patient population**

RESULT

Multiple doses of 600mg were **well-tolerated**

✓ ACHIEVED

GOAL

Demonstrate activity of APG808 via **maximal suppression of FeNO in line with standard of care** (~10-15 ppb change from baseline)

RESULT

Maximum FeNO reduction of 32 ppb (53% decrease from baseline)[1]

✓ EXCEEDED

GOAL

Show **durable suppression of FeNO supporting every 2-month dosing or less frequent**

RESULT

Sustained >30 ppb reduction from baseline through **week 12**

✓ ACHIEVED

NOTE: [1] Mean change from baseline in FeNO (ppb) and mean percent change from baseline FeNO, maximum mean reduction at D36. FeNO = fractional exhaled nitric oxide. Ppb = parts per billion. Data reported through week 12.

APG808 Phase 1b in mild-to-moderate asthma patients is fully enrolled with interim data for all patients

Design elements

Double-blind, placebo-controlled
two-dose regimen in patients with asthma

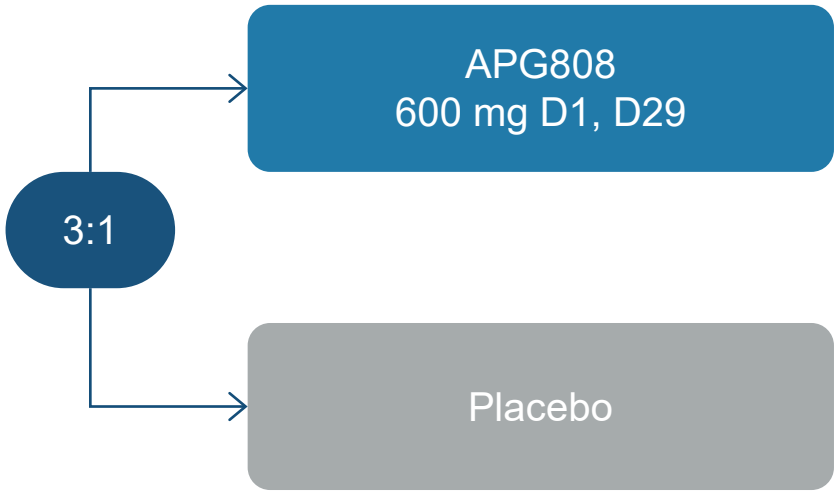
N = 22[1]

Key inclusion criteria:
- Mild-to-moderate asthma
- FeNO ≥25 ppb

Primary endpoint: safety

Additional endpoints: change in fractional exhaled nitric oxide (FeNO), PD

Schematic



NOTE: [1] 22 patients were included in the safety population (17 treatment, 5 placebo), 21 in the PD population (16 treatment, 5 placebo), and 20 in FeNO analysis population (15 treatment, 5 placebo). 1 patient was excluded from both PD and FeNO analysis populations after misdosing (received placebo at D1 and active dose D29) but included in the treatment safety population. 1 patient was excluded from FeNO analysis population due to FeNO falling below 25ppb at the baseline D1 measurement.

Baseline characteristics are in line with expectations

	Multiple Dose	
	Placebo D1, D29 N=5	**APG808** 600 mg D1, D29 N=17[1]
Age in years, mean (SD)	33.0 (12.6)	26.5 (6.7)
Female	40.0%	35.3%
White	100.0%	70.6%
Weight in kg, mean (SD)	73.7 (14.5)	75.8 (13.7)
Patients on daily ICS ± LABA (%)	60.0%	41.2%
Tobacco use[2]		
Never	40.0%	88.2%
Current	20.0%	0.0%
Former	40.0%	11.8%
FeNO in ppb, mean (SD)	47.6 (10.8)	52.6 (27.4)

Demographics were generally well-balanced across cohorts

NOTE: [1] APG808 safety population includes 1 patient who was misdosed (received placebo at D1 and active dose D29). [2] Tobacco use is inclusive of cigarettes, cigars, and smokeless tobacco or nicotine products.

Multiple doses of APG808 were well-tolerated in mild-to-moderate asthma patients

n (%)	Multiple Dose Placebo D1, D29 N=5	Multiple Dose APG808 600 mg D1, D29 N=17
≥1 TEAE	5 (100.0%)	16 (94.1%)[1]
≥1 serious TEAE	0	0
≥1 Grade 3 TEAE	0	0
≥1 drug-related TEAE	2 (40.0%)	5 (29.4%)
≥1 drug-related serious TEAE	0	0
≥1 drug-related Grade 3 TEAE	0	0
Discontinued study due to TEAE	0	0

The safety profile is in line with expectations for therapies targeting IL-4Rα

NOTE: TEAE = Treatment-Emergent Adverse Event. [1] 1 patient was misdosed (received placebo on D1 and active dose on D29) but remains included in the APG808 safety population. This patient developed eczema before D29 (see detail on next page).

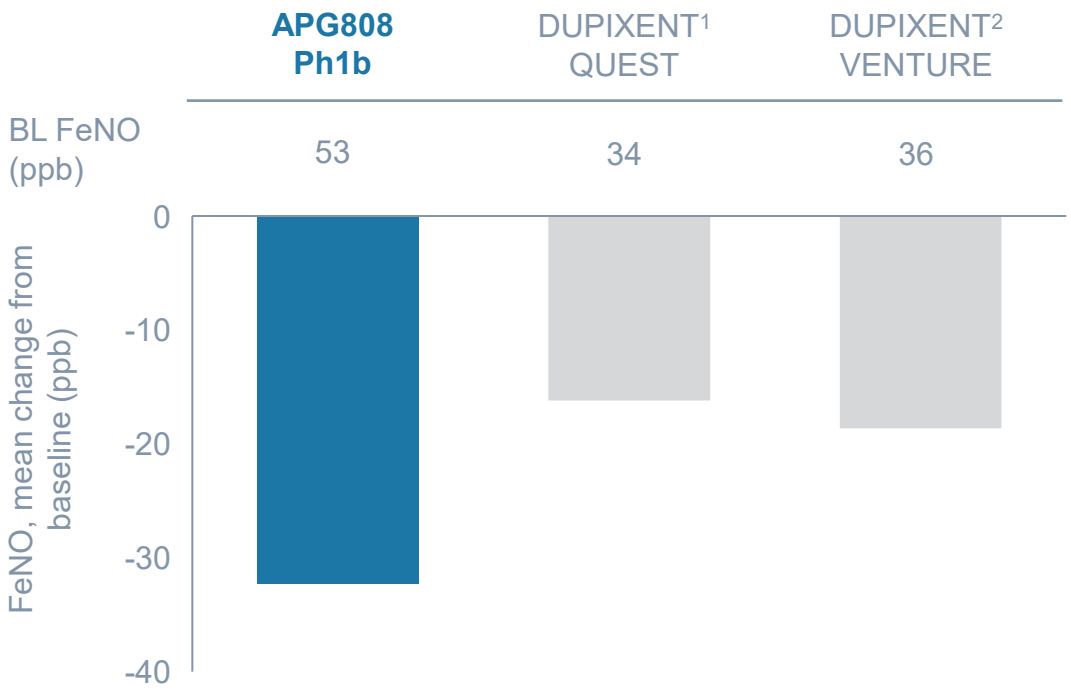
Multiple doses of APG808 were well-tolerated in mild-to-moderate asthma patients

AE occurring in ≥5% of total population[1] n (%)	Multiple Dose	
	Placebo D1, D29 N=5	**APG808** 600 mg D1, D29 N=17
Headache	2 (40.0%)	8 (47.1%)
Injection site erythema	0 (0.0%)	3 (17.6%)
Upper respiratory tract infection	1 (20.0%)	2 (11.8%)
Eczema	1 (16.7%)[2]	1 (6.3%)
Injection site bruising	0 (0.0%)	2 (11.8%)
Injection site pain	1 (20.0%)	1 (5.9%)
Nausea	0 (0.0%)	2 (11.8%)

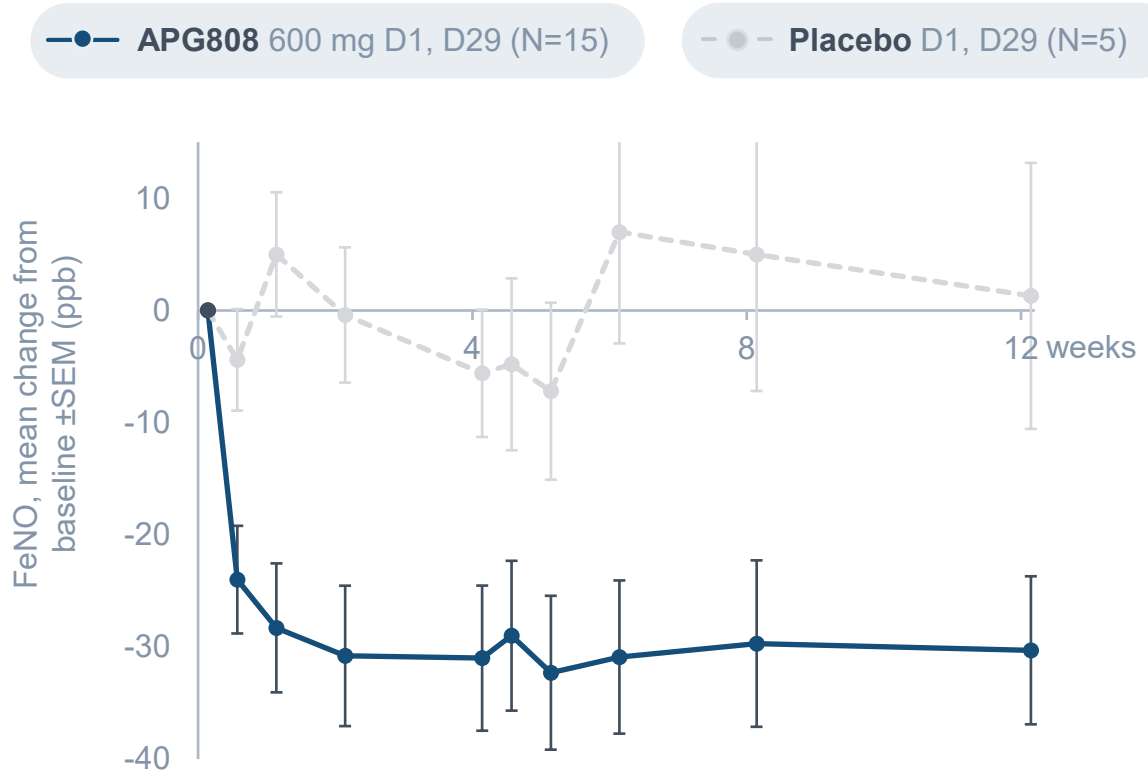
NOTE: [1] Inclusive of AEs detected in ≥5% of total population (≥2 patients). [2] 1 patient was misdosed (received placebo at D1 and active dose D29) but remains included in the APG808 safety population. This patient developed a case of eczema before D29. Therefore, the eczema case is included in the placebo column of this safety table. For the eczema row N = 6 for placebo and N=16 for APG808 group.

APG808 rapidly and durably suppressed FeNO through week 12

Maximum FeNO change from baseline



FeNO change from baseline

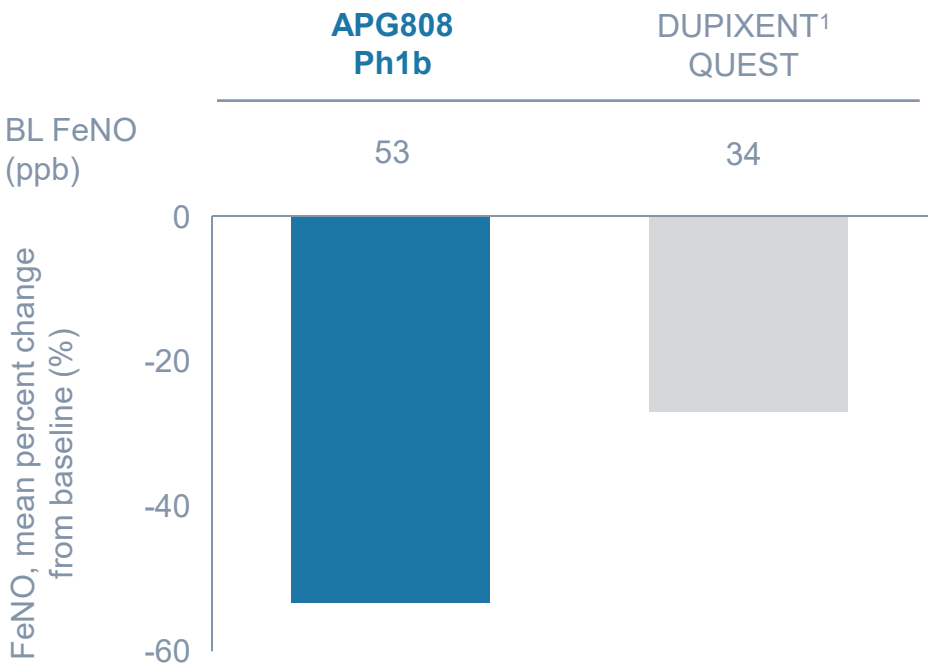


APG808 showed greater mean FeNO reduction relative to DUPIXENT

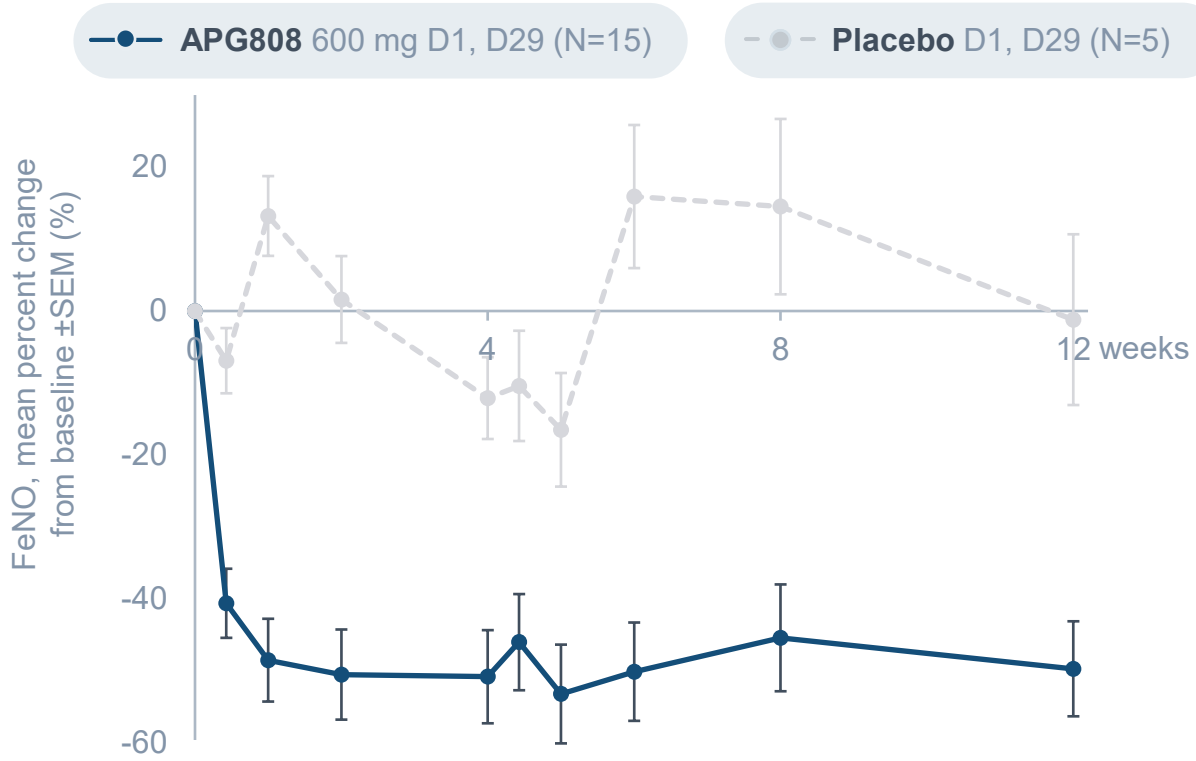
NOTE: 2 patients were excluded from FeNO analysis population. 1 patient was misdosed (received placebo at D1 and active dose D29). 1 patient had FeNO below 25ppb at the baseline D1 measurement. Data are derived from different clinical trials conducted at different times, with differences in trial design and patient populations. As a result, cross-trial comparisons cannot be made, and no head-to-head clinical trials have been conducted. DUPIXENT data is from the 300mg Q2W dose in two Ph3 studies. APG808 is an investigational drug and has not been approved by the FDA as safe and effective. BL = baseline.
SOURCE: [1] Castro M, et al. NEJM 2018. [2] Rabe KF et al. NEJM, 2018.

APG808 rapidly and durably suppressed FeNO through week 12

Maximum percent FeNO change from baseline



FeNO percent change from baseline



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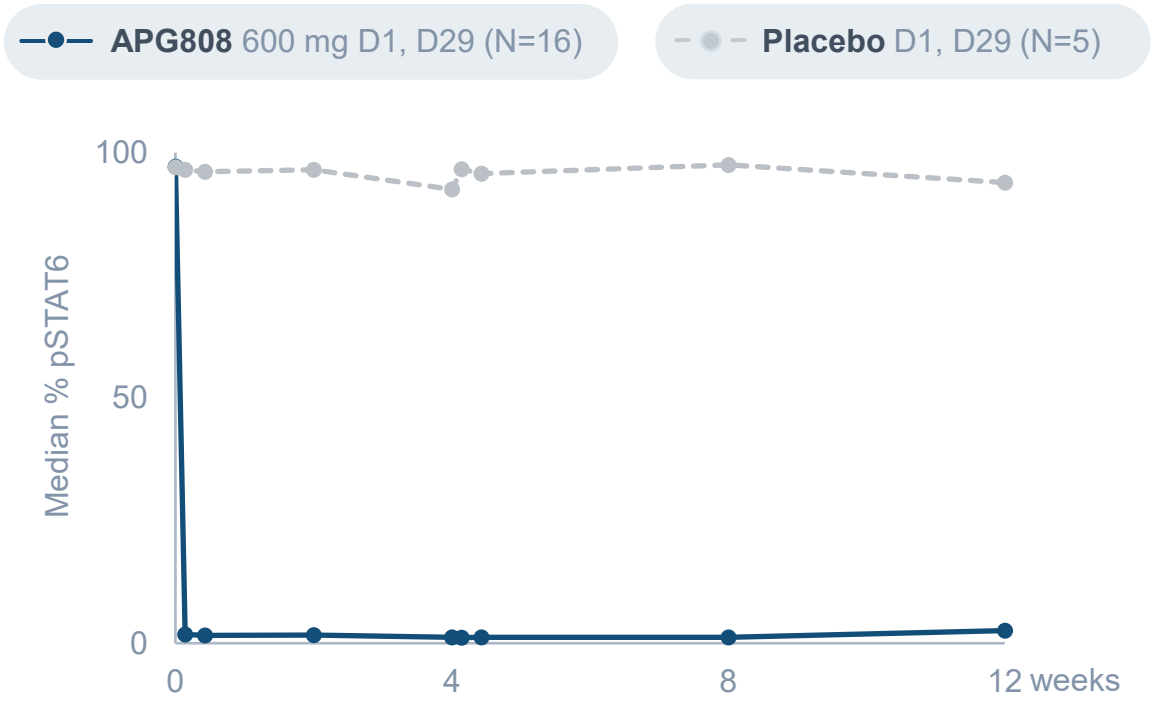
SOURCE: [1] Castro M, et al. NEJM 2018.

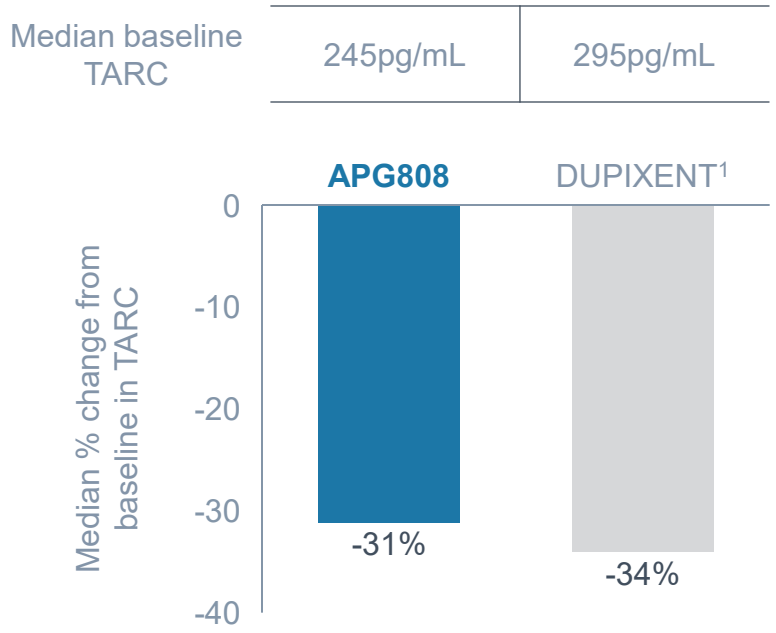
APG808 rapidly and durably suppressed pSTAT6 and showed changes in TARC similar to DUPIXENT

Median % pSTAT6



APG808 shows near-complete pSTAT6 inhibition for ~3 months

Median % change from baseline in TARC at 12 weeks



APG808 TARC suppression was similar to DUPIXENT

NOTE: 1 patient was excluded from PD analysis population due to misdosing (received placebo at D1 and active dose D29). TARC data from different clinical trials conducted at different points in time, with differences in trial design, dosing regimen and patient populations. DUPIXENT data is from a Phase 3 study of moderate-to-severe asthma patients receiving DUPIXENT 300mg Q2W. Cross-trial comparisons cannot be made, and no head-to-head clinical trials have been conducted. APG808 is an investigational drug and has not been approved by the FDA as safe and effective.
SOURCE: [1] Castro M, et al. NEJM 2018. pSTAT6 measured using flow cytometry of whole blood samples stimulated with 10 ng/mL IL-13 (approximately 100 times the level of IL-13 present in the sputum of severe asthma patients). APG808 data at 12 weeks, the longest available follow up. Similar results were obtained for pSTAT6 measured following stimulation with IL-4.


Apogee /ˈapəjē/ noun
The highest point in the development of something; a climax or culmination