These results are supplied for informational purposes only.
Prescribing decisions should be made based on the approved package insert in the country of prescription.

Sponsor: Sanofi **Drug substance:** SAR439794	**Study Identifiers:** U1111-1200-1824, IND 016878, NCT03463135 **Study code:** TDR14287
Title of the study: A randomized, multicenter, 3-arm, double-blind, placebo-controlled study to assess the safety, tolerability, and pharmacodynamics of repeated sublingual daily administration of SAR439794 in peanut allergic adult and adolescent patients	
Study centers: Multicenter study involving 14 investigational sites in the USA	
Study period: Date first participant enrolled: 07/May/2018 Date last participant completed: 26/Mar/2019 Completion date of long-term safety follow-up period: 10/Mar/2020 Study Status: Completed	
Phase of development: 1	
Objectives: • The primary objective was to assess tolerability and safety of SAR439794 after repeated sublingual (SL) daily administration in peanut allergic adult and adolescent patients. • The secondary objective was to assess pharmacodynamics (PD) of SAR439794 after repeated SL daily administration in peanut allergic adult and adolescent patients.	
Methodology: A randomized, multicenter, 3-arm, double-blind, placebo-controlled study in peanut allergic adult and adolescent patients with repeated SL daily administrations of either: • SAR439794 (peanut extract SL immunotherapy [SLIT PE] adjuvanted with Glucopyranosyl Lipid A [GLA]), or • Placebo GLA with SLIT PE, or • Matching placebo GLA with placebo SLIT PE. SAR439794 was administered SL once a day as a combination of a fixed GLA dose (GLA or placebo GLA) and an escalating SLIT PE dose or placebo SLIT PE dose. During the 6-week dose-escalation phase, gradual dose escalation of SLIT PE or placebo SLIT PE was performed during clinic visits on Day 1, Day 15, Day 29, and Day 43. If the patient experienced subjective symptoms and discomfort during any of the dose-escalation days, or for convenience reasons, dose escalation may have been spread over 2 consecutive days instead of within a single day (ie, Day 1 and Day 2; Day 15 and Day 16; etc). On dose-escalation days, dose escalation was performed according to the symptoms and/or signs of an objective allergic reaction scoring system. After the dose-escalation phase, the SLIT PE or placebo SLIT PE dose was maintained for 6 additional weeks from Day 44 (or Day 45 if escalation was spread over 2 days) until Day 85 (dose-maintenance phase). A post-treatment follow-up was performed from Day 85 to Day 99 (end-of-study [EOS] visit). A long-term safety follow-up was performed by phone call at Week 26 and Week 52 after the last investigational medicinal product (IMP) dose.	

Number of participants:	
	Planned: 44
	Randomized: 27 (5:5:1 for SLIT PE with GLA: SLIT PE with placebo GLA: placebo SLIT PE with placebo GLA) at the time of project discontinuation as per strategic portfolio decision.
	Treated: 27
Evaluated:	
	Safety: 27
	Pharmacodynamics: 26

Diagnosis and criteria for inclusion: Male or female patients, between 18 and 55 years of age, inclusive, and male or female adolescents 12 to 17 years of age, inclusive (adolescent patients were to be enrolled after 20 adults had completed the 6-week dose-escalation phase with acceptable safety and tolerability). All adult patients (adolescents were not enrolled) had a physician-diagnosed peanut allergy OR convincing history of objective clinical symptoms consistent with immediate hypersensitivity within 4 hours following known ingestion of peanuts or peanut-containing food AND met the following combined criteria:

- Peanut-specific immunoglobulin (Ig)-E (P-sIgE) >5 kUA/L and AraH2-specific IgE (AraH2-IgE) >2 kUA/L,
- Skin Prick Test (SPT) to peanut allergen ≥5 mm compared to saline control.

In addition, the inclusion criteria specific to the study were high-sensitivity C-reactive protein (hs-CRP), fibrinogen, and neutrophil count were to be within laboratory normal range unless the Investigator considered an abnormality to be clinically irrelevant, ability to perform spirometry based on the American Thoracic Society guidelines, and the patient had to be trained on the proper use of an injectable epinephrine device and was able to use it.

Study products

Investigational medicinal product(s): SAR439794 (SLIT PE adjuvanted with GLA), or matching placebo GLA, matching placebo SLIT PE

Formulation:

- GLA: amber glass vials containing 800 µL of GLA colloidal aqueous dispersion at a concentration of 100 µg/mL or 800 µL of matching placebo GLA colloidal aqueous dispersion.
- SLIT PE: amber glass vials containing 3 mL of solution at a concentration of 0.2 mg/mL, 1.6 mg/mL, or 6.4 mg/mL SLIT PE, or 3 mL of matching placebo SLIT PE solution.

Drop dispensers of 50 or 100 µL (delivered per dose/drop) were mounted on vials depending on the required dose to be administered.

Route(s) of administration: SL

Dose regimen: Once-daily, Day 1 to Day 85.

Fixed dose of 20 µg GLA (or placebo GLA) was to be administered once-daily SL first, followed approximately 1 minute later by SL administration of varying doses of SLIT PE (or placebo SLIT PE). Doses of SLIT PE (or placebo SLIT PE) were planned to start at 10 µg, and over a 6-week period escalate to 5120 µg, where they would be maintained for a 6-week maintenance phase. On dose-escalation days, SLIT PE or placebo SLIT PE were administered in escalating doses according to the dosing schedule: Day 1: 10 to 320 µg; Day 15: 320 to 1280 µg; Day 29: 1280 to 2560 µg; and Day 43: 2560 to 5120 µg.

Non investigational medicinal product(s): Antihistamines could be used on SLIT PE (or placebo SLIT PE) dose-escalation days at the Investigator's discretion. In addition, over-the-counter antihistamines were allowed if needed for patients' use during at-home self-administration periods.

Duration of treatment: 85 days; once-daily SL doses

Duration of observation: Core study duration (approximately 18 weeks) including screening (Days -28 to -7), a treatment period of 85 days, post-treatment follow-up from Day 85 to Day 99, and an EOS visit on Day 99.

Long-term safety follow-up was conducted by 2 phone calls at Week 26 and Week 52 after the last IMP dose; therefore, total participation was approximately 70 weeks.

Criteria for evaluation:

Safety:

Adverse events (AEs) spontaneously reported by the patient or observed or solicited by the Investigator (including serious adverse events (SAEs), adverse events of special interest (AESI), AEs leading to treatment discontinuation, and deaths); physical examination and body weight; clinical laboratory evaluations (hematology, biochemistry, and urinalysis [including hs-CRP, fibrinogen and absolute neutrophils count]); vital signs assessments (heart rate, respiratory rate, systolic and diastolic blood pressure, and oral body temperature).

Pharmacodynamics:

Blood samples were assessed for serum concentrations of total peanut-specific serum immunoglobulins G (P-sIgG), P-sIgG4, P-sIgG1, total immunoglobulins E (IgE), P-sIgE, and AraH2-IgE. The following PD endpoints were assessed in patients administered with GLA + SLIT PE versus placebo GLA + SLIT PE:

- The primary PD endpoint was the changes from baseline to Day 85 in peanut-specific serum IgG levels (total P-sIgG, P-sIgG4, and P-sIgG1).
- The secondary PD endpoints were changes from baseline to Day 57 in peanut-specific serum IgG levels (total P-sIgG, P-sIgG4, and P-sIgG1); changes from baseline to Day 57 and Day 85 in P-sIgE, AraH2-IgE, total IgE; and relative changes from baseline in SPT to peanut allergen at Day 85. Another secondary endpoint was the maximum SLIT PE dose reached by patients.

In addition, blood was collected for banking and further exploratory assessments to demonstrate an improved immune modulatory effect towards desensitization of GLA + SLIT PE versus placebo GLA + SLIT PE.

Pharmacogenomics:

Samples were collected to assess possible relationship between genes and response to treatment with SAR439794, how the body processes SAR439794 and possible side effects to SAR439794. Genes that could potentially be studied included those for the toll-like receptor (TLR) 4 and additional genes that are part of the TLR4 signaling pathway.

Pharmacodynamics sampling times and bioanalytical methods:

Blood samples for PD assessments were collected at T0 on Day 1, Day 57, and Day 85. Serum concentrations of P-sIgG4, total P-sIgG, total IgE, P-sIgE, and AraH2-IgE were assessed in different assays using a fluorescence enzyme immunoassay on the ImmunoCAP platform. P-sIgG1 was assessed in an enzyme-linked immunosorbent assay.

The SPT was performed at screening and on Day 85.

BAT was performed in a centralized laboratory (Viracor) on blood collected within 48 hours.

Optional blood sample for pharmacogenomics assessment was collected at T0 on Day 1.

Statistical methods:

Safety:

The safety analyses were conducted on the safety population and were based on the reported AEs and other safety information such as clinical laboratory data, vital signs, and physical examination. Adverse events were coded using the Medical Dictionary for Regulatory Activities (Version 22.1), and treatment-emergent AEs (TEAEs) were summarized (number and percent) by primary system-organ-class (SOC), preferred term (PT), and treatment group. Potentially clinically significant abnormalities (PCSAs) for vital signs and clinical laboratory parameters were listed, flagged, and summarized for each treatment group. Raw data and changes from baseline for some relevant parameters (vital signs and specific clinical laboratory parameters) were summarized using descriptive statistics and summary plots.

Pharmacodynamics:

Due to project discontinuation resulting in a small sample size, only standard descriptive analyses on raw data (including arithmetic mean, standard deviation [SD], standard error of mean [SEM], median, minimum, maximum, including geometric mean), changes from baseline, relative changes from baseline, and fold-changes from baseline were performed on total P sIgG, P sIgG4, and P-sIgG1 at Day 57 and Day 85 for the 3 treatment groups (placebo GLA + placebo SLIT PE, GLA + SLIT PE, and placebo GLA + SLIT PE).

For the secondary endpoints (P-sIgE, AraH2-IgE, total IgE, SPT), descriptive statistics of raw data, changes from baseline (except SPT), and relative changes from baseline were provided by treatment group and time point. Time profile plots (except SPT) of raw data (mean ± 90% confidence intervals [CIs]), and changes from baseline (median) were also provided. One curve per treatment group. Similarly, for exploratory endpoints (EC50 parameter on BAT), descriptive statistics and time profile plots of raw data, changes from baseline, and relative changes from baseline were provided by treatment group and time point. Box plots (representing mean, median, minimum, 25th, 75th quartile, and maximum) of individual %CD63+ BAT activated by the different allergen concentrations were provided for each time point and treatment group. Descriptive statistics of the maximum SLIT PE dose reached by patients were provided for the 2 treatment groups and day.

Following database lock, it was decided to also summarize the PD variables for only the patients who completed the study (Completers population).

Summary

To facilitate the reading, placebo GLA/placebo SLIT PE group will be reported as “placebo”, placebo GLA/SLIT PE group as “SLIT” and GLA/SLIT PE will be reported as “GLA/SLIT”.

This study was originally designed to include a total number of 44 patients (20 SLIT; 20 GLA/SLIT; 4 placebos) and was discontinued early as per a strategic portfolio decision.

A total of 27 peanut allergic adult patients were included in the study. Of these, 20 patients completed the study and received approximately 12 weeks daily SL administration of IMPs, with 2 of 2 patients (100%) in the placebo group, 11 of 13 patients (84.6%) in the SLIT group, and 7 of 12 patients (58.3%) in the GLA/SLIT group.

Two patients in the SLIT group (1 for TEAE, 1 for patient’s withdrawal) and 5 patients in the GLA/SLIT group (3 for TEAE, 2 for patient’s withdrawal) discontinued treatment prematurely.

During the 1-year long-term safety follow-up period, which was ongoing at the time of the previous CSR, 17 of 20 patients who completed the study were contactable for the scheduled phone calls at Weeks 26 and 52. Following 3 attempts of contact, 3 of 20 patients were not contactable during the long-term safety follow-up period.

Population characteristics:

The mean age for all patients was 25.0 years (min:max of 18 to 39 years). Twenty patients (74.1%) were male and 7 patients (25.9%) were female.

Other population characteristics did not show any relevant differences between the SLIT and GLA/SLIT groups.

Two, 13, and 11 patients from the placebo, SLIT, and GLA/SLIT groups, respectively, were included in the PD population and 2, 11, and 7 patients, respectively, completed the study and were classified as Completers.

Safety results:

Treatment-emergent AEs were experienced by 2 (100%), 13 (100%), and 11 (91.7%) peanut allergic patients in the placebo, SLIT, and GLA/SLIT groups, respectively.

Overall, 13 TEAEs (grade 1) were reported in the placebo group, 454 TEAEs (including 18 grade 2) were reported in the SLIT group, and 159 TEAEs (including 13 grade 2) were reported in the GLA/SLIT group.

There were no deaths and no severe TEAEs experienced during the study. Three patients experienced 4 treatment-emergent SAEs, although none led to treatment discontinuation. Four patients experienced TEAEs that led to treatment discontinuation.

Three patients experienced SAEs:

- In the SLIT group, one patient reported chest discomfort (chest constriction) and dysphagia (hard to swallow) on Day 52. The patient administered epinephrine, which per protocol qualified the AEs to be considered serious irrespective of the AE grade. The SAEs were considered to be of grade 1 intensity and related to the IMP by the Principal Investigator (PI). The SAEs resolved after 30 minutes and the patient completed the study.
- In the GLA/SLIT group, one patient had an SAE of food allergy (allergic reaction to peanuts) on Day 22 following ingestion of a peanut-containing food. The patient received diphenhydramine hydrochloride, prednisone, epinephrine, and cetirizine hydrochloride for the SAE. The SAE was considered to be of grade 1 intensity and not related to the IMPs by the PI. The patient received epinephrine, which per protocol qualified the AE to be considered serious irrespective of its grade. The IMPs were interrupted for a day and were restarted after the SAE was resolved. The patient later withdrew himself from the study.
- In the GLA/SLIT group, one patient had an SAE of anaphylactic reaction immediately following IMP intake on Day 6. This event occurred after the patient reintroduced the IMPs following 2 days of non-compliance at the beginning of the studied immunotherapy. The SAE was considered to be an AESI of grade 2 intensity and was considered related to the IMPs by the PI. The SAE resolved within 1 hour. Discontinuation of treatment occurred on Day 8 due to other TEAEs of urticaria, oral pruritus, diarrhea, glossodynia, and nausea, which began soon after the SAE on Day 6. These TEAEs were all recorded to be recovered/resolved.

In addition to the patient in the GLA/SLIT group that was discontinued due to TEAEs of urticaria, oral pruritus, diarrhea, glossodynia, and nausea, there were 2 other patients in the GLA/SLIT group and 1 patient in the SLIT group who had TEAEs which led to permanent discontinuation of treatment (4 patients in total; 1 in the SLIT group and 3 in the GLA/SLIT group):

- In the GLA/SLIT group, one patient had TEAEs of headache and fatigue that began on Day 2 and which led to treatment discontinuation on Day 13. The TEAEs were considered by the PI to be of Grade 1 and 2 intensity, respectively, not serious or AESIs, and related to the IMPs.
- In the GLA/SLIT group, one patient had TEAEs of throat irritation, mouth swelling, oral pruritus, hypoesthesia oral, cough, and enlarged uvula, beginning from Days 3 to 7, and which led to treatment discontinuation on Day 7. The TEAEs were non-serious AESIs (except cough), of grade 1/2 intensity, related to the IMPs.

- In the SLIT group, one patient had TEAEs of swollen tongue and tongue pruritus that began on Day 18, and which led to treatment discontinuation on Day 18. The TEAEs were considered by the PI to be of grade 2 and 1 intensity, respectively, not serious, and related to the IMP.

The most commonly experienced TEAEs by SOC were gastrointestinal disorders, with 5 TEAEs experienced by 1 patient in the placebo group, 254 TEAEs experienced by 12 patients in the SLIT group, and 79 TEAEs experienced by 11 patients in the GLA/SLIT group.

Overall, the most commonly experienced TEAE by PT was throat irritation (respiratory, thoracic, and mediastinal disorders SOC), with 1 TEAE experienced by 1 patient in the placebo group, 151 TEAEs experienced by 7 patients in the SLIT group, and 51 TEAEs experienced by 6 patients in the GLA/SLIT group. The next most commonly experienced TEAE by PT was tongue pruritus (gastrointestinal disorders SOC), with 0 TEAEs experienced by patients in the placebo group, 137 TEAEs experienced by 7 patients in the SLIT group, and 11 TEAEs experienced by 2 patients in the GLA/SLIT group. Other TEAEs experienced by ≥4 patients in a treatment group was oral pruritus (62 TEAEs), nausea (23 TEAEs), lip swelling (16 TEAEs), paresthesia oral (14 TEAEs), dyspepsia (13 TEAEs), abdominal pain (11 TEAEs), cough (11 TEAEs), accidental overdose (9 TEAEs), and nasopharyngitis (4 TEAEs). All other TEAEs were experienced by <4 patients per treatment group.

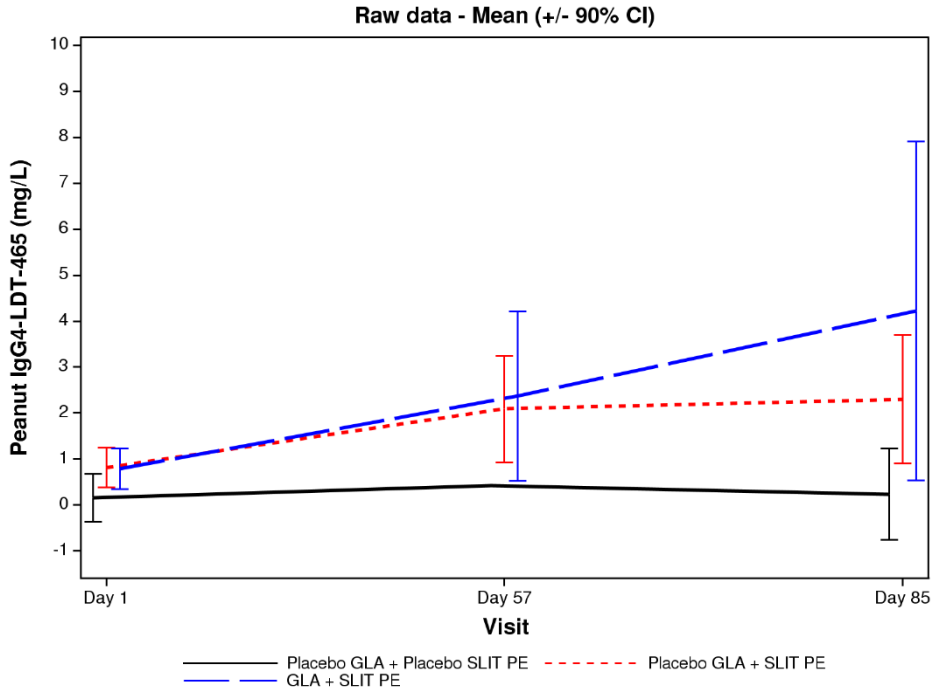
The majority of TEAEs experienced during the study were considered by the Investigator to be of grade 1 (mild) intensity. All 13 TEAEs in the placebo group were considered to be grade 1 (mild), 18 of 454 TEAEs in the SLIT group were considered to be grade 2 (moderate), and 13 of the 159 TEAEs in the GLA/SLIT group were considered to be grade 2 (moderate). No severe TEAEs (grade 3) were reported.

There was no relevant difference between the placebo, SLIT, and GLA/SLIT groups in occurrence of any PCSAs for biochemistry and hematology parameters, or vital signs, with the exception of eosinophils. Of note, in the SLIT group, 5 of 12 patients reached the PCSA threshold (>upper limit of normal [ULN] of 0.5 Giga/L or >ULN [if ULN ≥0.5 Giga/L]) with a normal baseline value during the TEAE period (all recovered before or at the EOS). No eosinophils PCSAs with a normal baseline value during the TEAE period were recorded in the placebo or GLA/SLIT groups.

During the long-term safety follow-up, 1 patient (placebo) experienced a post-treatment AE of food allergy and 1 patient (GLA/SLIT group) experienced post-treatment AEs of pharyngitis streptococcal and cough. None of the post-treatment AEs were considered to be related to the IMP, serious, or AESIs. The grade 1 post-treatment AE of food allergy occurred on Day 132 (approximately Week 19) and resolved after 30 minutes without any corrective treatment/therapy. The grade 2 post-treatment AEs of pharyngitis streptococcal and cough occurred on Day 256 (approximately Week 37), with pharyngitis streptococcal resolving after 13 days and cough resolving after 10 days. The patient received lidocaine and cephalexin for pharyngitis streptococcal and benzonatate for cough.

Pharmacodynamic results:

- The primary PD endpoint was changes from baseline to Day 85 in P-sIgGs levels (total P-sIgG, P-sIgG4, and P-sIgG1) for the PD population:
  - **For the SLIT group (n=13)**, mean (SD) P-sIgG4 increased from 0.81 (0.88) mg/L at baseline to 2.30 (2.55) mg/L at Day 85 (mean [SD] fold-change from baseline of 4.34 [4.14]). Median P-sIgG4 increased from 0.56 mg/L at baseline to 1.17 mg/L at Day 85 (median [min-max] fold-change from baseline of 3.30 [1.0-15.6]).
  - **For the GLA/SLIT group (n=11)**, mean (SD) P-sIgG4 increased from 0.79 (0.81) mg/L at baseline to 4.22 (5.03) mg/L at Day 85 (mean [SD] fold-change from baseline of 6.00 [7.05]). Median P-sIgG4 increased from 0.46 mg/L at baseline to 2.07 mg/L at Day 85 (median [min-max] fold-change from baseline of 4.15 [1.3-21.2]).
  - The placebo group (n=2) showed minimum change from baseline to Day 85 for P-sIgG4 in mean and median values (mean and median values of 0.16 mg/L at baseline to 0.23 mg/L at Day 85).
  - Changes from baseline to Day 85 for total P-sIgG and P-sIgG1 were not markedly different between SLIT PE and GLA/SLIT groups.



Note: Baseline is defined as the D1 T0H assessment value.
LLOQ values are replaced by LLOQ/2, ULOQ values are replaced by ULOQ
PGM=PRODOPS/SAR439794/TDR14287/CSR/REPORT/PGM/pd_ipdsum_pd_g.sas OUT=REPORT/OUTPUT/pd_ipdsum_pd_g_ORT18363_i.rtf (14APR2020 - 8:47)

As illustrated in the graph above, even if the P-sIgG4 levels were not different between the SLIT and GLA/SLIT groups at Day 57, a numerical difference in mean P-sIgG4 between the SLIT and GLA/SLIT groups was evident at Day 85. The fold-difference in mean fold-changes from baseline in the SLIT and GLA/SLIT groups was 1.38 (4.34 for the SLIT group and 6.00 for the GLA/SLIT group).

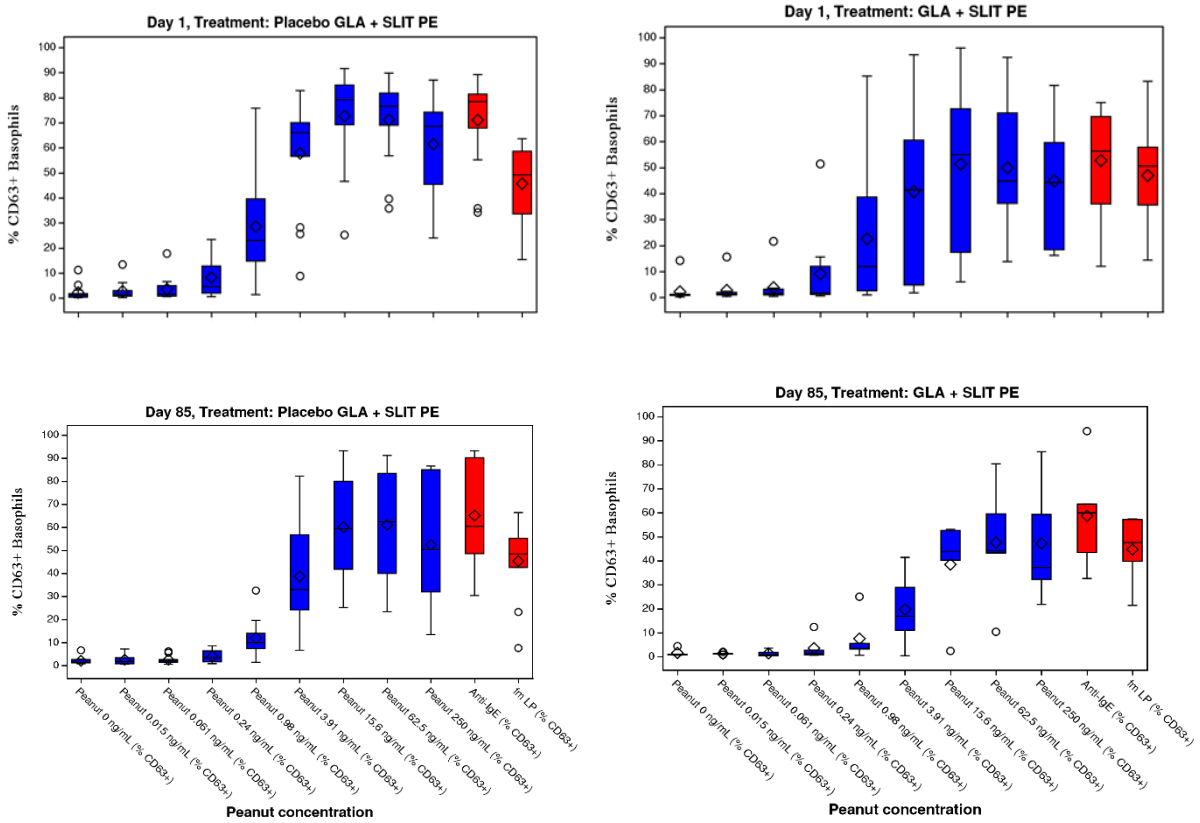
The results of the primary PD variables for the Completers population (including only patients who completed the study) were identical to the results of the primary PD variables for the PD population because the numbers of patients who completed the study and had data available at Day 85 in the Completers population were the same as the number of patients that had data available at Day 85 in the PD population.

- Changes from baseline to Day 85 in P-sIgE and AraH2-IgE levels were part of the secondary PD endpoints for the PD population:
  - **For the SLIT group**, mean (SD) P-sIgE and AraH2-IgE increased from 55.42 (37.91) kU/L at baseline to 74.71 (35.66) kU/L at Day 85 and from 35.22 (29.70) kU/L at baseline to 72.74 (39.13) kU/L at Day 85, respectively. Median P-sIgE and AraH2-IgE markedly increased from 54.20 kU/L at baseline to 100.00 kU/L (assay maximal value) at Day 85 and from 30.95 kU/L at baseline to 90.20 kU/L at Day 85, respectively.
  - **For the GLA/SLIT group**, mean (SD) P-sIgE and AraH2-IgE decreased from 41.79 (39.02) kU/L at baseline to 36.57 (31.05) kU/L at Day 85 and from 26.74 (30.89) kU/L at baseline to 21.64 (27.65) kU/L at Day 85, respectively. Median P-sIgE and AraH2-IgE slightly increased from 24.10 kU/L at baseline to 29.20 kU/L at Day 85, and from 10.40 kU/L at baseline to 11.21 kU/L at Day 85, respectively.
  - The placebo group (n=2) showed virtually no change from baseline to Day 85 in P-sIgE (66.00 kU/l to 64.30 kU/L

for both mean and median, respectively) and in AraH2-IgE (62.75 kU/L to 60.90 kU/L for both mean and median, respectively).

- Activated basophils (CD63+) were quantified in relation to peanut solution concentrations ex vivo and EC50s were derived for each treatment group as part of the exploratory PD endpoints for the PD population. An increase in EC50 is associated to a decrease in sensitization to peanut.
  - **For SLIT group**, mean (SD) EC50 increased from 2.43 (2.86) ng/mL at baseline to 3.75 (2.90) ng/mL at Day 85 (mean absolute change from baseline of 1.58 ng/mL).
  - **For GLA/SLIT group**, mean (SD) EC50 increased from 7.56 (11.94) ng/mL at baseline to 20.97 (33.41) ng/mL at Day 85 (mean absolute change from baseline of 6.26 ng/mL).
  - Mean EC50 was virtually stable with 1.05 ng/mL at baseline and 0.46 ng/mL at Day 85 in the placebo group (n=2).

Basophils activation (%CD63+) versus peanut solution concentrations at baseline (Day 1) and Week 12 (Day 85) are displayed below for both SLIT and GLA/SLIT groups:



Note: Baseline is defined as the D1 T0H assessment value.
LLOQ values are replaced by LLOQ/2, ULOQ values are replaced by ULOQ
Horizontal line denotes mean value. Diamond denotes median value. Circle denotes outlier value.

- Absolute and percent changes from baseline to Day 85 in SPT were part of the secondary PD endpoints for the PD population:
  - **For the SLIT group** (n=10 at Day 85), mean (SD) SPT decreased from 15.058 (4.713) mm at baseline to 10.800 (3.817) mm at Day 85 yielding a mean (SD) relative change from baseline of -17.52% (28.26%).
  - **For the GLA/SLIT group** (n=7 at Day 85), mean (SD) SPT slightly decreased from 13.609 (3.685) mm at baseline to 11.714 (3.604) mm at Day 85 yielding a mean (SD) relative change from baseline of -4.57% (38.14%).
  - In the placebo group (n=2), mean (SD) SPT slightly increased from 10.000 (4.243) mm at baseline to 12.000 (6.364) mm at Day 85 yielding a mean (SD) relative change from baseline of 17.03% (13.99%).
- Maximum SLIT peanut dose reached by patients administered with SLIT or GLA/SLIT for the safety population:
  - Among the 11 (84.6%) patients who completed the treatment period in the SLIT group, 9 (69.2%) patients were receiving 5120 µg SLIT PE and 2 (15.4%) patients were receiving 2560 µg SLIT PE at the end of the maintenance phase. All of the 7 (58.3%) patients who completed the treatment period in the GLA/SLIT group were receiving 5120 µg SLIT PE at the end of the maintenance phase, although 1 patient did not receive a dose on Day 85.

The changes from baseline results of the secondary and exploratory PD endpoints for the Completers population were identical to the results for the PD population because the number of patients who completed the study and had data available at Days 57 and 85 in the Completers population was the same as the number of patients that had data available at Days 57 and 85 in the PD population.

Issue date: 30-Apr-2021