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<b>Study No.:</b> SAS110101
<b>Title:</b> Clinical Assessment of GW815SF (SLM/FP) HFA MDI in Paediatric Patients With Bronchial Asthma – A Long Term (24-Week) Study
<b>Rationale:</b> To evaluate the safety and efficacy of two inhalations of GW815SF (salmeterol [SLM]/fluticasone propionate [FP]) HFA MDI 25/50mcg twice daily in paediatric subjects with bronchial asthma.
<b>Phase:</b> III
<b>Study Period:</b> 30 March 2007 – 24 November 2007
<b>Study Design:</b> A multicentre, non-comparative, open-label, long-term study
<b>Centres:</b> A total of 3 medical institutions in Japan At all centres, subjects entered the treatment period.
<b>Indication:</b> Paediatric Asthma
<b>Treatment:</b> During the 2-week run-in period, subjects who met the eligibility criteria for entry in the run-in period continued to take the antiasthma medication containing inhaled corticosteroid [ICS; fluticasone propionate (FP) 100-200g/ day or equivalent] which had been started before the run-in period. During the 24-week treatment period, subjects who met the eligibility criteria for entry in the treatment period discontinued the ICS and took two inhalations of GW815SF HFA MDI 25/50mcg twice daily.
<b>Objectives:</b> To evaluate the safety and efficacy of two inhalations of GW815SF (SLM/FP) HFA MDI 25/50mcg twice daily in paediatric subjects with bronchial asthma.
<b>Primary Outcome/Efficacy Variable:</b> The primary objective of the study was the assessment of adverse events (AEs).
<b>Secondary Outcome/Efficacy Variables:</b> Morning Peak Expiratory Flow (PEF), percent predicted morning PEF, evening PEF, circadian variation in PEF, percentage of subjects with symptom-free nights and days, percentage of subjects with rescue medication-free nights and days
<b>Statistical Methods:</b> The target sample size for analysis was set at 30 subjects completing 24 weeks of treatment based on the feasibility of study. Assuming a 15% attrition due to withdrawal or dropout during the treatment period, the target number for enrolment was set at 35. No sample size estimation based on efficacy endpoints was performed because the primary objective of the study was to assess the safety of two inhalations of GW815SF HFA MDI 25/50mcg twice daily in paediatric subjects with bronchial asthma based on the AE profile of the product in long-term use. No statistical hypothesis testing was performed. For all the endpoints, descriptive statistics were calculated. Efficacy analyses were performed on the Full Analysis Set (FAS) population, defined as all subjects who entered the treatment period, excluding all those who received no dose of the study medication (for treatment period) or who had no post-baseline efficacy data. Safety analyses were performed on the Safety Population (SP), defined as all subjects who entered the treatment period and received at least one dose of the study medication.
<b>Study Population:</b> Main Inclusion Criteria: Paediatric outpatients, $\geq 5$ and $\leq 14$ years of age, with bronchial asthma who have received ICS (FP 100-200g/ day or equivalent) for at least 4 weeks prior to the start of run-in period (Visit 1); who are suitable, in the investigator's/subinvestigator's judgment, for treatment by two inhalations of GW815SF HFA MDI 25/50mcg twice daily; and who are able to make entries in the asthma diary and to use a peak flow meter in a correct manner in the investigator's/subinvestigator's judgment. Main Exclusion Criteria: Subjects who were admitted to the hospital due to asthma exacerbation within 8 weeks prior to Visit 1; who used systemic steroid within 4 weeks prior to Visit 1; who

received antibacterials or antivirals for treatment of upper or lower respiratory tract infection within 2 weeks prior to Visit 1; who have a past or current history of a disease or require medical or other treatments, that may affect the safety of subjects or the efficacy or safety evaluation of the study medication; who were admitted to the hospital due to asthma exacerbation during the run-in period; who have upper or lower respiratory tract infection during the 2 weeks just before the start of study treatment (Visit 2); or who used prohibited drugs during the 2 weeks just before Visit 2.

	<b>SFC 100/200mcg/day</b>
<b>Number of Subjects:</b>	
Planned, N	35
Entered, N	40
Completed, n (%)	40 (100)
Total Number Subjects Withdrawn, N (%)	0
Withdrawn due to Adverse Events n (%)	0
Withdrawn due to Lack of Efficacy n (%)	0
Withdrawn for other reasons n (%)	0
<b>Demographics</b>	
N (FAS)	40
Females: Males	16: 24
Mean Age, years (SD)	8.7 (2.50)
Race, n (%), duplicate counting allowed	
Asian – Japanese Heritage	40 (100)
White -Arabic/North African Heritage	1 (2.50)
<b>Efficacy Results (FAS Population):</b>	
	<b>SFC 100/200mcg/day (N=40)</b>
<b>Morning PEF (L/min)</b>	
Baseline, mean (SD)	223.7 (73.78)
Change from baseline during Weeks 1-24 (SD)	32.9 (34.48)
<b>Percent Predicted Morning PEF (%)</b>	
Baseline, mean (SD)	84.04 (16.734)
Change from baseline during Weeks 1-24 (SD)	12.50 (11.294)
<b>Evening PEF (L/min)</b>	
Baseline, mean (SD)	230.2 (75.86)
Change from baseline during Weeks 1-24 (SD)	31.2 (29.28)
<b>Circadian Variation in PEF (%)</b>	
Baseline, mean (SD)	7.43 (3.299)
Change from baseline during Weeks 1-24 (SD)	-1.62 (3.583)
<b>Percentage of Subjects with Symptom-Free Nights and Days (%)</b>	
Baseline, Subjects n/N (%)	29/40 (72.5)
Week 24, Subjects n/N (%)	31/32 (96.9)
<b>Percentage of Subjects with Rescue Medication-Free Nights and Days (%)</b>	
Baseline, Subjects n/N (%)	33/40 (82.5)
Week 24, Subjects n/N (%)	32/32 (100)
<b>Safety Results (Safety Population):</b> On-Therapy Adverse events (AEs) and serious adverse events (SAEs) were defined as those occurring during the treatment period.	
	<b>SFC 100/200mcg/day (N=40)</b>
<b>Most Frequent Adverse Events – On-Therapy</b>	<b>n (%)</b>
Subjects with any AE(s), n(%)	39 (97.5)
The most frequent 10 events	
Laryngopharyngitis	8 (20.0)
Bronchitis	8 (20.0)
Nasopharyngitis	8 (20.0)

Asthma	8 (20.0)
Pharyngitis	6 (15.0)
Pyrexia	5 (12.5)
Otitis media	4 (10.0)
Pharyngotonsillitis	3 (7.5)
Laryngotracheo bronchitis	3 (7.5)
Molluscum contagiosum	3 (7.5)
Stomatitis	3 (7.5)
<b>Serious Adverse Events - On-Therapy</b>	
<b>n (%) [n considered by the investigator to be related to study medication]</b>	
	<b>SFC 100/200mcg/day (N=40)</b>
Subjects with non-fatal SAEs, n (%)	1 (2.5)
	<b>n (%) [related]</b>
Asthma	1 (2.5) [0]
Subjects with fatal SAEs, n (%)	0

**Conclusion:**

- Long-term (24-week) use of two inhalations of GW815SF (SLM/FP) HFA MDI 25/50mcg twice daily (100/200mcg/day) was well tolerated in paediatric subjects, 5 to 14 years of age, with moderate persistent or severe persistent bronchial asthma.
- Improvements were persistent in lung function (PEF) through the treatment period and observed in asthma symptoms and the use of rescue medication.

**Publications:** No Publication

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