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Study No.: FFR101816		
Title: A Randomized, Double Blind, Placebo-Controlled, Single-Dose, Parallel-Group Study to Evaluate the Onset of Action of a Single Dose of Intranasal GW685698X Aqueous Nasal Spray 100mcg* in Adolescent and Adult Subjects (≥ 12 years of age) with Seasonal Allergic Rhinitis Exposed to Ragweed Pollen in an Allergen Challenge Chamber		
Rationale: Studies conducted to establish onset of action of an allergy product are performed either outdoors, usually in a park setting, or indoors in a special room designed to provide an atmosphere with uniform concentrations of naturally occurring allergen such as an allergen chamber. This study examined the onset of action of a GW685698X (hereafter referred to as fluticasone furoate) 100mcg* dose in the controlled setting of the allergen challenge chamber.		
Phase: III		
Study Period: 04Apr2005 to 30Jul2005		
Study Design: Allergen chamber, ragweed, onset of action		
Centres: 1 center (Atlanta, GA, USA.)		
Indication: Seasonal allergic rhinitis (SAR)		
Treatment: Single dose of either fluticasone furoate aqueous nasal spray 110mcg or vehicle placebo nasal spray *NOTE: GW685698X aqueous nasal spray 110mcg (actual); Drug content of Fluticasone Furoate Nasal Spray was approximated at 25mcg/spray in all Phase 3 clinical trial documentation pending confirmation from final batch and stability testing. Final testing and analyses determined one spray to contain 27.5mcg of fluticasone furoate, equating to 110mcg for the recommended adult dose of two sprays administered to each nostril.		
Objectives: The objective of this study was to evaluate the onset of action of fluticasone furoate 110mcg aqueous nasal spray compared to vehicle placebo nasal spray following a single dose in subjects ≥ 12 years of age with SAR exposed to controlled pollen concentrations in an allergen challenge chamber (ACC).		
Primary Outcome/Efficacy Variable: The primary efficacy measure was the mean change from baseline in subject-rated instantaneous total nasal symptom scores (iTNSS), assessed hourly during the 12-hour post-dose exposure period in the ACC. Onset of action was defined as the first time after the initiation of the treatment at which a statistically significant greater change in iTNSS was achieved for fluticasone furoate 110 mcg versus vehicle placebo and the treatment effect was sustained from this time point onward during the allergen chamber exposure.		
Secondary Outcome/Efficacy Variable(s): The secondary efficacy endpoint was the mean change from baseline in the individual instantaneous nasal symptom scores for rhinorrhea, nasal congestion, nasal itching and sneezing, as assessed hourly during the 12-hour, post-dose exposure period in the ACC.		
Statistical Methods: The primary analysis method was the comparison of treatment groups at each time point (active vs. placebo) using a repeated measures model with an unstructured covariance, adjusting for baseline TNSS, age, gender, session, treatment, time, and treatment by time interaction. Secondary efficacy measures for the individual nasal symptoms (rhinorrhea, nasal congestion, nasal itching, and sneezing) were analyzed similarly. The primary population was the Intent-to-Treat (ITT) Population, which was defined as all subjects who were randomized and received at least one dose of study drug. This population was the basis for all summaries, analyses, listings, and figures of demographic, efficacy, and safety. The proposed sample size provided 90% power to detect a difference of 0.75 between active and placebo at a 0.05 two-sided significance level for mean change from baseline iTNSS, assuming a standard deviation of 2.25.		
Study Population: Male and female subjects were eligible for participation in the study if they were ≥ 12 years of age and had been diagnosed as having seasonal allergic rhinitis as determined by a positive skin test to ragweed allergen and a moderate level of nasal symptoms (mean instantaneous total nasal symptom score [iTNSS] of ≥ 6 and a mean instantaneous nasal congestion scores of ≥ 2) during two priming visits.		
	Placebo	Fluticasone Furoate (FF) 110mcg
Number of Subjects:		
Planned,	190	190
Randomized, N	191	191
Completed, n (%)	190 (>99)	190 (>99)
Total Number Subjects Withdrawn, N (%)	1 (<1)	1 (<1)
Withdrawn due to Adverse Events n (%)	1 (<1)	1 (<1)

Withdrawn due to Lack of Efficacy n (%)	0	0	
Withdrawn for other reasons n (%)	0	0	
Demographics	Placebo	FF 110mcg	
N (ITT)	191	191	
Females: Males	137:54	130:61	
Mean Age, years (SD)	33.7 (12.5)	33.1 (12.5)	
White, n (%)	33 (17)	42 (22)	
Black	157 (82)	147 (77)	
Other	1 (<1)	2 (1)	
Primary Efficacy Results			
	Placebo (N =191)	FF 110mcg (N =191)	p-value
Baseline Mean (SE)	8.8 (0.11)	8.8 (0.11)	
1 Hour Post-Dose, LS Mean Change (SE)	-1.89 (0.18)	-1.98 (0.17)	0.695
LS Mean Difference, 95% CI	-0.091 (-0.55, 0.36)		
2 Hours Post-Dose, LS Mean Change (SE)	-2.42 (0.19)	-2.46 (0.19)	0.879
LS Mean Difference	-0.038 (-0.53, 0.46)		
3 Hours Post-Dose, LS Mean Change (SE)	-2.71 (0.20)	-2.86 (0.19)	0.556
LS Mean Difference, 95% CI	-0.154 (-0.67, 0.36)		
4 Hours Post-Dose, LS Mean Change (SE)	-2.98 (0.20)	-3.20 (0.20)	0.431
LS Mean Difference	-0.216 (-0.76, 0.32)		
5 Hours Post-Dose, LS Mean Change (SE)	-3.16 (0.21)	-3.41 (0.21)	0.386
LS Mean Difference, 95% CI	-0.243 (-0.79, 0.31)		
6 Hours Post-Dose, LS Mean Change (SE)	-3.09 (0.21)	-3.48 (0.21)	0.167
LS Mean Difference	-0.399 (-0.97, 0.17)		
7 Hours Post-Dose, LS Mean Change (SE)	-3.53 (0.21)	-3.61 (0.21)	0.775
LS Mean Difference, 95% CI	-0.082 (-0.64, 0.48)		
8 Hours Post-Dose, LS Mean Change (SE)	-3.60 (0.22)	-3.71 (0.21)	0.688
LS Mean Difference	-0.117 (-0.69, 0.46)		
9 Hours Post-Dose, LS Mean Change (SE)	-3.70 (0.22)	-3.90 (0.22)	0.500
LS Mean Difference, 95% CI	-0.200 (-0.78, 0.38)		
10 Hours Post-Dose, LS Mean Change (SE)	-3.61 (0.22)	-3.88 (0.22)	0.356
LS Mean Difference	-0.273 (-0.85, 0.31)		
11 Hours Post-Dose, LS Mean Change (SE)	-3.73 (0.22)	-3.90 (0.22)	0.552
LS Mean Difference, 95% CI	-0.178 (-0.76, 0.41)		
12 Hours Post-Dose, LS Mean Change (SE)	-3.73 (0.22)	-3.98 (0.22)	0.399
LS Mean Difference	-0.254 (-0.85, 0.34)		

Secondary Outcome Variable(s):

At baseline, the mean scores for rhinorrhea, nasal congestion, nasal itching, and sneezing were similar between placebo and fluticasone furoate. The LS mean change from baseline was greater (more negative) with fluticasone furoate 110mcg compared with placebo at all 12 time points for rhinorrhea, 10 time points for nasal congestion, 7 time points for nasal itching, and three time points for sneezing.

Safety Results: All Adverse Events (AEs) related to study participation were collected from Visit 1 through the follow-up phone call. Adverse events during the treatment period include those with a date of onset from the date and time of treatment initiation, through the entire day following study treatment termination.

	Placebo (N=191)	FF 110mcg (N=191)
Most Frequent Adverse Events – On-Therapy		
Subjects with any AE(s), n (%)	12 (6%)	9 (5%)
Headache	1 (<1%)	5 (3%)
Pharyngolaryngeal pain	1 (<1%)	1 (<1%)
Serious Adverse Events - On-Therapy		
Subjects with non-fatal SAEs, n (%)	0	0
Subjects with fatal SAEs, n (%)	0	0

Conclusion:

Based on the protocol definition of onset of action, fluticasone furoate 110mcg given as a single dose did not achieve an onset of action during the 12-hour allergen exposure period.

The AE profile with fluticasone furoate 110mcg did not differ notably in comparison to vehicle placebo. No safety concerns were raised in this study following single-dose treatment with fluticasone furoate 110mcg.

Publications: No Publication

Date updated: 6-Mar-2008