A clinical study to assess the efficacy and safety of MP-AzeFlu (a fixed dose combination of Azelastine Hydrochloride and Fluticasone Propionate) nasal spray in comparison to commercially available azelastine hydrochloride and fluticasone propionate nasal sprays in Chinese volunteers with allergic rhinitis

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Running Title:
Efficacy and safety of MP-AzeFlu in Chinese volunteers

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Sup. Table 1 : Analysis of 12-hour rTNSS in AM and PM – ITT

Variable Time Point	Treatment	N	Mean (S.D)	Source	p-Value	Difference, 95% CI
rTNSS (AM) Baseline	MP-AzeFlu	300	8.69(1.63)	Treatment	0.9231	
	Aze	298	8.64(1.72)			
	Flu	299	8.69(1.80)			
Day 2 to Day 7 Change from Baseline of rTNSS (AM)	MP-AzeFlu	300	-2.77(2.67)			
	Aze	298	-1.61(2.52)	MP-AzeFlu vs Aze	<0.0001	-1.90 (-1.09, -0.50)
	Flu	298	-2.30(2.78)	MP-AzeFlu vs Flu	0.0008	-2.19, (-0.80, -0.21)
Day 2 to Day 14 Change from Baseline of rTNSS (AM)	MP-AzeFlu	300	-3.74(2.95)			
	Aze	298	-2.26 (2.89)	MP-AzeFlu vs Aze	<0.0001	-2.69(-1.22, -0.65)
	Flu	299	-3.45 (3.19)	MP-AzeFlu vs Flu	0.0042	-3.21(-0.70, -0.13)
rTNSS (PM) Baseline	MP-AzeFlu	300	8.52 (1.80)	Treatment	0.9869	
	Aze	298	8.49 (1.83)			
	Flu	299	8.51 (1.86)			
Day 2 to Day 7 Change from Baseline of rTNSS (PM)	MP-AzeFlu	300	-3.01 (2.79)			
	Aze	298	-1.74 (2.77)	MP-AzeFlu vs Aze	<0.0001	-1.96(-1.37, -0.73)
	Flu	298	-2.51 (2.80)	MP-AzeFlu vs Flu	<0.0001	-2.35(-0.98, -0.33)
Day 2 to Day 14 Change from Baseline of rTNSS (PM)	MP-AzeFlu	300	-3.86 (3.05)			
	Aze	298	-2.35 (3.07)	MP-AzeFlu vs Aze	<0.0001	-2.66(-1.48, -0.86)
	Flu	299	-3.56 (3.14)	MP-AzeFlu vs Flu	0.0006	-3.28(-0.86, -0.24)

Sup. Table 2: LS Mean change from baseline in rTNSS (AM + PM) scores during second day, first week and entire treatment period with MP-AzeFlu vs AZE vs Flu

Variable Time Point	Treatment	LSM	SEM	Source	p-Value	Treatment Difference (95% CI)
Day 2	MP-AzeFlu	-3.5072	0.2241			
	Aze	-2.0904	0.2262	MP-AzeFlu vs Aze	<0.0001	-1.4167 (-2.0261, -0.8074)
	Flu	-2.1972	0.2251	MP-AzeFlu vs Flu	<0.0001	-1.3100 (-1.9187, -0.7012)
Day 2 to Day 7 Change from Baseline (AM+PM)	MP-AzeFlu	-5.6819	0.2251			
	Aze	-3.9476	0.2267	MP-AzeFlu vs Aze	<0.0001	-1.7343 (-2.3216, -1.1471)
	Flu	-4.5106	0.2261	MP-AzeFlu vs Flu	<0.0001	-1.1713 (-1.7585, -0.5841)
Day 2 to Day 14 Change from Baseline (AM+PM)	MP-AzeFlu	-7.4275	0.2230			
	Aze	-5.4666	0.2245	MP-AzeFlu vs Aze	<0.0001	-1.9608 (-2.5270, -1.3947)
	Flu	-6.4468	0.2239	MP-AzeFlu vs Flu	0.0007	-0.9807 (-1.5467, -0.4147)

Sup. Table 3: LS Mean change from baseline in rTOSS (AM + PM) scores during second day, first week and entire treatment period with MP-AzeFlu vs AZE vs Flu

Variable Time Point	Treatment	LSM	SEM	Source	p-Value	Treatment Difference (95% CI)
Day 2	MP-AzeFlu	-1.3265	0.1534			
	Aze	-0.9148	0.1544	MP-AzeFlu vs Aze	0.0527	-0.4116 (-0.8281, 0.0048)
	Flu	-0.6784	0.1546	MP-AzeFlu vs Flu	0.0024	-0.6480 (-1.0651, -0.2309)
Day 2 to Day 7 Change from Baseline (AM+PM)	MP-AzeFlu	-2.4339	0.1481			
	Aze	-1.9322	0.1493	MP-AzeFlu vs Aze	0.0121	-0.5017 (-0.8932, -0.1103)
	Flu	-1.7599	0.1489	MP-AzeFlu vs Flu	0.0008	-0.6741 (-1.0656, -0.2826)
Day 2 to Day 14 Change from Baseline (AM+PM)	MP-AzeFlu	-3.2573	0.1470			
	Aze	-2.7204	0.1481	MP-AzeFlu vs Aze	0.0056	-0.5534 (-0.9160, -0.1578)
	Flu	-2.7039	0.1478	MP-AzeFlu vs Flu	0.0043	-0.5534 (-0.9326, -0.1743)

Sup. Table 4: Frequent TEAEs by preferred term in any treatment group (≥1%)

Preferred Term	MP-AzeFlu N= 301 n %	AZE N= 298 n %	FLU N= 299 n %
Dysgeusia	13 (4.3)	7 (2.3)	1 (0.3)
Epistaxis	4 (1.3)	14 (4.7)	5 (1.7)
Nasal dryness	3 (1.0)	0 (0.0)	2 (0.7)
Headache	3 (1.0)	3 (1.0)	2 (0.7)
Somnolence	2 (0.7)	5 (1.7)	1 (0.3)
Fatigue	2 (0.7)	3 (1.0)	2 (0.7)
Application site reaction	2 (0.7)	3 (1.0)	0 (0.0)
Nasal mucosal erosion	0 (0.0)	3 (1.0)	2 (0.7)
Dizziness	0 (0.0)	3 (1.0)	0 (0.0)