Table 14.2.2.1.1 Comparison of number of vulvovaginitis episodes between treatments in patients with prevailing mycotic or bacterial etiology (PPS)

		IMUNOR N = 49	PLACEBO N = 19	Comparison
Number of vulvovaginitis episodes	0 episodes	27 (55.1%)	4 (21.1%)	
	1 episode	11 (22.4%)	5 (26.3%)	
	2 episodes	8 (16.3%)	6 (31.6%)	
	3 episodes	1 (2.0%)	2 (10.5%)	
	4 episodes	1 (2.0%)	2 (10.5%)	
	6 episodes	1 (2.0%)		
Comparison of number of vulvovaginitis episodes	Mean episode count	0.82	1.63	
	Ratio of mean episode counts (95% CI)			0.500 (0.280, 0.892)
	p-value			0.0190

% = Percentage of subjects out of N; CI = Confidence inetrval; N = Total number of subjects in the treatment arm; PPS = Per Protocol Set.
Mean episode estimates, ratio of mean episode counts with corresponding confidence interval and p-value were obtained from negative binomial regression model with number of episodes as dependent variable and treatment group as independent variable.

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Table 14.2.2.1.2 Comparison of number of vulvovaginitis episodes between treatments in patients with prevailing mycotic or bacterial etiology (FAS)

		IMUNOR N = 62	PLACEBO N = 27	Comparison
Number of vulvovaginitis episodes	0 episodes	32 (51.6%)	6 (22.2%)	
	1 episode	16 (25.8%)	8 (29.6%)	
	2 episodes	10 (16.1%)	7 (25.9%)	
	3 episodes	1 (1.6%)	2 (7.4%)	
	4 episodes	2 (3.2%)	4 (14.8%)	
	6 episodes	1 (1.6%)		
Comparison of number of vulvovaginitis episodes	Mean episode count	0.85	1.63	
	Ratio of mean episode counts (95% CI)			0.525 (0.323, 0.851)
	p-value			0.0090

% = Percentage of subjects out of N; CI = Confidence inetrval; FAS = Full Analysis Set; N = Total number of subjects in the treatment arm..
Mean episode estimates, ratio of mean episode counts with corresponding confidence interval and p-value were obtained from negative binomial regression model with number of episodes as dependent variable and treatment group as independent variable.

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