

761. Clinical and Virologic Outcomes with Peramivir Therapy in Hospitalized Adults with Influenza B: Sub-Group Analysis of a Phase 2 Trial

•**Session:** Abstracts: Virology: Influenza
 Friday, October 22, 2010

Background:

The investigational neuraminidase inhibitor (NAI) peramivir is more potent *in vitro* against influenza B than oseltamivir. Possible clinical correlates were analyzed in a completed, multinational study comparing both NAIs (BCX1812-201).

Methods:

Subjects received 5 days therapy with IV peramivir QD, (400 mg or 200 mg), or PO oseltamivir 75 mg BID. An exploratory primary endpoint (time to clinical stability, TTCS) was based on normalization of vital signs and O₂ saturation. Nasal swabs were collected twice daily, while hospitalized and cultured on MDCK cells with susceptibility by MUNANA.. A *post-hoc* analysis for influenza B combined subjects randomized to peramivir vs. oseltamivir.

Results:

Influenza B was confirmed by PCR in 32 subjects among a total study population of 137 subjects

Endpoint	Peramivir	Osetamivir	P value
	n=21	n=11	
	[median (95% CI)]		
TTCS (hr)	31.0 (21.2, 48.4)*	41.8 (28.1, 68.0)*	0.38
Time to Normal Temperature (hr)	24.3 (13.1, 47.7)	35.5 (12.1, 48.5)	0.78
Time to Return to Usual Activities (TTRUA; days)	6.4 (3.5, NA)	10.0 (2.7, NA)	0.95
All AEs	14 (67%)	4 (36%)	
Grade 3/4 AEs	3 (14%)	1 (9%)	
SAEs	2 (10%)	0	
	(unrelated to treatment)		
Deaths	0	0	

*Data on TTCS are based on 17 peramivir- and 10 oseltamivir-treated subjects clinically unstable at baseline.

Change from baseline in viral titers (log₁₀ TCID₅₀/mL):

Hours after initiation of treatment	Peramivir	Osetamivir	Difference between Peramivir and Osetamivir	P value
	n=21	n=11		
	Mean (SD)	Mean (SD)		
12	-1.3 (1.35)	-0.9 (1.24)	0.4	0.49
24	-2.1 (0.99)	-1.6 (1.11)	0.5	0.36
36	-2.8 (1.07)	-1.7 (1.38)	1.1	0.03
48	-2.9 (0.76)	-2.2 (2.05)	0.7	0.14

Conclusion:

In a sub-group analysis, peramivir appeared clinically and virologically better than oseltamivir in treatment of adults hospitalized with influenza B. These preliminary findings may reflect superior *in vitro* antiviral activity of peramivir against influenza B.

•**Subject Category:** V. Virology including clinical and basic studies of viral infections, including hepatitis

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•**Disclosures:**

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