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## LB16. Phase 3 Trial of Baloxavir Marboxil in High Risk Influenza Patients (CAPSTONE-2 Study)

**Session:** Oral Abstract Session: Late Breaker Oral Abstracts: Influenza and Vaccines
*Saturday, October 6, 2018: 10:50 AM*
*Room: S 152-154*

**Background**: Baloxavir marboxil (BXM), an oral selective cap-dependent endonuclease inhibitor, is effective and safe for treating acute influenza in otherwise healthy patients (pts).

**Method**: We conducted an international, randomized, double-blind, placebo (PLC)- and oseltamivir (Os) -controlled treatment study in patients at higher risk (HR) of influenza complications. Inclusion criteria included age ≥12 yrs, fever + influenza symptoms of ≤48 hrs duration, and presence of at least 1 HR factor adapted from CDC criteria. Pts were randomized (1:1:1) to a single oral dose of BXM (40/80 mg for BW </≥80 kg), PLC, or 75 mg Os BID for 5 d. The primary endpoint was time to improvement of influenza symptoms (TTIIS) in those with RT-PCR confirmed influenza (ITTI population). Secondary endpoints included infectious virus detection in serial nasopharyngeal swabs, prescription of antibiotics, and influenza-related complications.

**Result**: Among 2184 randomized pts, 1163(53%) comprised the ITTI population (47.9% A/H3N2, 6.9% A/H1N1, 41.6% B). The most common risk factors were asthma or chronic lung disease(39.2%) and age ≥65 years (27.4%).TTIIS was significantly shorter in BXM than PLC (median 73.2hr vs 102.3hr, p<0.0001) and numerically shorter than Os (81.0 hr, p=0.8347). TTIIS in BXM pts with A/H3N2 virus (median: 75.4 hr) was significantly shorter than in PLC (100.4 hr; P =0.0141) and was significantly shorter in pts with influenza B (74.6 hr) than in either PLC (100.6 hr; P =0.0138) or Os (101.6 hr; P =0.0251). Median time to cessation of viral shedding in BXM pts was 48 hr, significantly less than 96 hours in both PLC and Os pts. Systemic antibiotic use and influenza-related complications were significantly fewer in BXM (3.4% and 2.8%, resp.) than PLC (7.5% and 10.4%; P=0.0112, and P<0.0001). The incidence of any (25.1-29.7%) or serious adverse events (0.7-1.2%) did not differ significantly across the groups.

**Conclusion**: BXM was well-tolerated and associated with faster recovery and reduced risk of complications in HR influenza patients compared to PLC. It proved superior to Os in shortening the duration of virus replication and in resolving influenza B illness. Oral BXM is a promising treatment option for pts with risk factors for influenza complications.

**Michael G. Ison, MD MS, FIDSA**[1], Simon Portsmouth, MD[2], Yuki Yoshida, MS[3], Takao Shishido, PhD[3], Frederick Hayden, MD[4] and Takeki Uehara, PhD[3], (1)Northwestern University, Chicago, IL, (2)Shionogi Inc., Florham Park, NJ, (3)Shionogi & Co., Ltd., Osaka, Japan, (4)Medicine, University of Virginia, Charlottesville, VA

**Disclosures:**

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**S. Portsmouth**, Shionogi Inc: Employee , Salary .

**Y. Yoshida**, Shionogi & Co., Ltd.: Employee , Salary .

**T. Shishido**, Shionogi & Co., Ltd.: Employee , Salary .

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**T. Uehara**, Shionogi & Co., Ltd.: Employee , Salary .

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