New single-dose influenza drug appears safe and effective

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An analysis of phase 2 and phase 3 clinical trials shows that a single injected dose of the neuraminidase inhibitor (NAI) peramivir is safe and effective at alleviating influenza symptoms, including fever and viral shedding, when administered within 48 hours of the onset of symptoms. Researchers report their findings today at the 54th Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC), an infectious diseases meeting of the American Society for Microbiology (ASM).

"Based on clinical data, peramivir is the first neuraminidase inhibitor (NAI) that has shown to be safe and effective as a single-dose therapy for patients with acute, uncomplicated influenza. According to a retrospective combined analysis of two clinical studies, a single dose of peramivir, administered intramuscularly (IM), alleviated flu symptoms, including fever, significantly faster than the studies' placebo arms," says presenting author Rich Whitley of the University of Alabama at Birmingham.

In two placebo-controlled studies (one Phase II and one Phase III), involving a combined 427 adults, a single dose of peramivir was given as an injection within 48 hours of the onset of flu-like symptoms. Study participants recorded their temperature and the severity of seven flu symptoms using a four-point scale for 14 days. Peramivir was found to be generally safe and well tolerated and effectively reduced the duration of symptoms in peramivir-treated patients.

Compared to patients who received placebo, peramivir reduced median time to alleviation of symptoms by 22 hours, time to resolution of fever by 24 hours and the amount of nasal viral shedding over the first two days following treatment.

Influenza is a major public health problem. According to the Centers for Disease Control and Prevention, it is responsible for over 200,000 hospitalizations and 36,000 deaths annually in the United States. Vaccines can be effective in preventing influenza, but changing viral strains make vaccine formulation a challenge, and it is difficult to ensure broad populations are appropriately inoculated. Therefore, the CDC recommend antiviral treatment as soon as possible for any patient with confirmed or suspected influenza who is hospitalized, has severe, complicated or progressive illness or is at higher risk for complications. The two currently available NAIs—oral oseltamivir and inhaled zanamivir—are both administered twice daily for five days. At present, no single-dose or parenteral agent for treatment of influenza is available in the United States.

Peramivir has been approved in Japan and Korea since 2010, and it is estimated that 1 million Japanese patients have received drug post-approval. To date, more than 2,700 subjects have been treated with peramivir in 27 clinical trials. If approved by the FDA, peramivir would be the only single-dose and injection treatment for influenza in the U.S., and would be the first new NAI approved in more than a decade.

Provided by American Society for Microbiology