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Australia, Thailand to participate in NIH-sponsored trials

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Singapore: Three clinical trials that seek to find more effective treatments for influenza are enrolling volunteers with influenza at the National Institutes of Health's Clinical Center in Bethesda in the US and at several dozen other sites, both domestic and international. Researchers are based in 36 sites, including Australia and Thailand in Asia Pacific apart from Argentina and Mexico.

One study examines whether treatment with a licensed influenza drug, oseltamivir, reduces the time that infected people continue to produce virus in the upper airway. The second trial tests whether a combination of three licensed flu antiviral drugs works better than oseltamivir alone in people with influenza who have chronic health conditions, such as heart or lung disease, that put them at greater risk of severe illness.

The third tests whether treatment with plasma enriched with anti-influenza antibodies improves the condition of hospitalized influenza patients compared to standard antiviral treatment alone.

"This year's flu season came earlier than usual and has been particularly hard on the elderly," said Dr Anthony S Fauci, director of the National Institute of Allergy and Infectious diseases, part of the NIH. "Despite our best efforts to prevent influenza through vaccination, people still get sick every year with the flu. At best, influenza infection is a miserable experience. At worst, it can be a deadly one. We need better ways to treat people with influenza, which kills thousands of people in the US each year, and clinical research supported by NIAID helps to address that need."

The studies are sponsored by the NIAID Influenza Research Collaboration, a clinical research network funded by the NIAID Division of Clinical Research (DCR). Activities of the collaboration are coordinated under the leadership of Dr Richard Davey, deputy clinical director, NIAID DCR, and Dr John Beigel, medical affairs scientist on contract with NIAID.

Although oseltamivir has been approved for use in the US since 1999, no studies have shown conclusively whether the drug

significantly reduces the amount of virus produced (shed) by an infected person. Reduced shedding would likely lessen the chances of an infected person passing the virus to others. The oseltamivir trial will enroll a total of approximately 560 people at 31 locations in the US, Argentina and Thailand.

The trial comparing oral oseltamivir alone to treatment with oseltamivir plus two other licensed antiviral drugs is enrolling a total of up to 720 adults at sites in the US, Argentina, Australia, Mexico and Thailand.

The third trial is enrolling children as well as adults, including pregnant women, hospitalized with severe influenza. This trial aims to enroll a total of approximately 100 people at approximately 20 sites in the US. All participants will receive standard drug treatment for influenza, and half will also receive two infusions of plasma enriched with antibodies against the virus. Antibodies are infection-fighting proteins produced by the immune system. The antibodies used in the trial are derived from blood donated by volunteers who were recently vaccinated against flu or are recovered from a recent bout of flu.

"Anecdotal evidence suggests that the addition of plasma with high levels of antibody against the virus may confer additional benefit over drug treatment alone. This trial will be one of the first to examine that possibility in a scientifically rigorous fashion," said Dr Davey. "The outcome of this trial may provide valuable data on how best to treat patients hospitalized with severe influenza."