

Theraclone has flu therapy ready for human trials

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Valerie Bauman
Staff Writer
[Email](#)

Seattle-based Theraclone Sciences Inc. announced Sept. 21 that its research into influenza-fighting antibodies is entering the next, critical phase: human clinical trials.

Theraclone's new kind of flu therapy would treat the illness, instead of focusing on preventing it, as current vaccines do.

And it could treat multiple mutations of the virus, instead of having to be adapted each year to new strains.

"We hope this is the one that can be used every season and potentially for a pandemic," said Dr. **Leni Ramos**, Theraclone's chief medical officer. "The reason old vaccines don't work is because they mutate."

Theraclone identified an antibody in people who successfully recovered from influenza, and were able to use that antibody to design antibody flu treatments.

The research news follows a Sept. 8 announcement that Theraclone received a \$10.6 million extension to its Series B financing, from previous investors **ARCH Venture Partners**, Canaan Partners, **MPM Capital**, Healthcare Ventures, **Alexandria Real Estate Equities**, Amgen Ventures and Japan-based Zenyaku Kogyo.

The financing supports the company's technology platform for rapid screening and identification of rare, potent and therapeutically relevant antibodies, and was used in Theraclone's development of the new influenza A antibody therapy, known as TCN-032.

Kristine Swiderek, Theraclone's vice president of research, said the treatment works because antibodies recognize pathogens – viruses or bacteria for example – by binding to parts of the pathogen protein called epitopes.

Vaccines also target epitope regions, but must be adapted for each mutation of the flu, which changes every year. The new antibody therapy would be closer to a universal solution because it targets a specific epitope that doesn't change from one mutation to the next.

Essentially, each influenza strain is like a different locked room within a large house. Vaccines are the keys that can separately unlock individual doors, but Ramos and her research team anticipate their antibody therapy will act as a single master skeleton key for the whole house of influenza A virus mutations.

The Phase 1 clinical trial of TCN-032 will be a randomized, double-blind dose-escalation trial in 40 healthy adult volunteers. Results are expected in the first half of 2012.