

Study Finds Single Dose of Iomai Patch With Pandemic Flu Vaccine Achieves Protective Levels

- HHS Now Reviewing Data to Determine Next Steps in \$128 Million Contract -

GAITHERSBURG, Md., March 20 /PRNewswire-FirstCall/ -- Iomai Corporation (Nasdaq: [IOMI](#)) today announced positive interim results from the 500-subject Phase 1/2 trial of its immunostimulant adjuvant patch used with an injected vaccine for H5N1 influenza. The trial met a key endpoint, demonstrating a clinically relevant adjuvant effect when the Iomai patch was used with a single dose of the 45-microgram H5N1 vaccine. The trial found that a single 45-microgram dose of an H5N1 influenza vaccine, coupled with a single 50-microgram Iomai patch, was sufficient to provide an immune response considered protective in 73 percent of those tested, a statistically significant improvement over those who received the H5N1 influenza vaccine alone.

This is one of the first trials to demonstrate that a single dose of pandemic influenza vaccine may meet the level of protection suggested in U.S. Food and Drug Administration guidance, which recommends that a pandemic vaccine achieve immune response levels considered protective in 70 percent or more of vaccine recipients. The trial was conducted under a \$14.5 million contract with the U.S. Department of Health and Human Services (HHS) with the potential for an additional \$114 million in follow-on funding. Iomai has shared the data with HHS and is now working with them to determine the next steps.

The only FDA-approved vaccine in the United States for the avian influenza H5N1 virus requires two 90-microgram doses, administered 28 days apart, to achieve hemagglutinin inhibition (HI) titers equal to or greater than 40 in 44 percent of vaccinated individuals.

"During an influenza pandemic, public health officials will face two large hurdles. The first is the possibility of limited vaccine stocks. The second is the logistic difficulty of administering two vaccinations over a period of several weeks to all individuals in the face of a pandemic. This new research clearly indicates that a single dose of vaccine in combination with an Iomai patch could provide a significant level of protection, achieve protective levels more rapidly, and increase compliance," said Stanley C. Erck, President and Chief Executive Officer of Iomai. "This is a major breakthrough and could provide public health officials with an important solution for this looming problem."

The trial tested three different dose levels of Solvay Biologicals, B.V. (Netherlands) egg-derived H5N1 influenza vaccine, the adjuvant patch and placebo to determine which combinations would be most effective in a two-immunization regimen, administered 21 days apart. Data showed that 92 percent of the 50 subjects vaccinated a single time with the 45-microgram dose in combination with the Iomai patch had an immune response. Seventy-three percent of those subjects achieved an HI titer of greater than 40, which is considered protective, offering the potential to eliminate the need for a second vaccination. About 49 percent of those who

received the vaccine alone, without a patch, had an immune response considered protective after the first dose, and the 24 percentage point difference between the patch and no-patch groups was statistically significant ($p < 0.0001$). A second dose of both vaccine and patch further enhanced immunogenicity; 100 percent of subjects who received two 45-microgram doses of vaccine and two Iomai patches had a measurable immune response, and 94 percent of subjects had immune responses considered protective.

No treatment-related serious adverse events were reported.

With further testing, the patch has the potential to be used in conjunction with other injected pandemic influenza vaccines. It has been shown to be suitable for ambient temperature shipping and handling, and has at least a 2-year storage shelf life, making the product ideal for stockpiling and rapid distribution. The patch is easily applied and acts like an adhesive bandage placed at the site of the injection.

"This data also confirms our general approach of using an adjuvant patch to improve the immune response to injected vaccines and the ability of our adjuvant to safely and effectively stimulate robust immune responses via the skin," said Gregory Glenn, Iomai's Chief Scientific Officer. "We continue to explore ways to bring this approach to other applications in the high-value field of vaccine adjuvants."

ABOUT IOMAI CORPORATION

Iomai Corporation discovers and develops vaccines and immune system stimulants, delivered via a novel, needle-free technology called transcutaneous immunization (TCI). TCI, discovered by researchers at the Walter Reed Army Institute of Research, taps into the unique benefits of a major group of antigen-presenting cells found in the outer layers of the skin (Langerhans cells) to generate an enhanced immune response. Iomai is leveraging TCI to enhance the efficacy of existing vaccines, develop new vaccines that are viable only through transcutaneous administration and expand the global vaccine market. Iomai currently has four product candidates in development: three targeting influenza and pandemic flu and one to prevent travelers' diarrhea. For more information on Iomai, please visit <http://www.iomai.com>.

Some matters discussed in this press release constitute "forward-looking statements" that involve known and unknown risks and uncertainties that could cause actual results to differ materially from those expressed or implied by the forward-looking statements. Such forward-looking statements include statements about the ability of Iomai's adjuvant patch to provide protective immune responses with a single dose of pandemic flu vaccine; the significance of the results described in this press release to government health officials in addressing an outbreak of pandemic influenza; that Iomai's adjuvant patch may work with pandemic influenza vaccines from other manufacturers; that the characteristics of Iomai's adjuvant patch described in this press release would make the product ideal for stockpile and rapid distribution; and that the U.S. Department of Health and Human Services, or HHS, might consider these data sufficient for continuing the existing \$128 million government contract.

Applicable risks and uncertainties include, among others, that future clinical trials may not replicate results seen in the trial described in this press release; that HHS, as well as, the FDA or other regulatory authorities, may not concur with Iomai's analysis of the trial results described in this press release; that Iomai may not be able to enroll sufficient numbers of subjects in future clinical trials; that Iomai may be unable to obtain the regulatory approvals or financing necessary to conduct additional clinical trials, or to develop the product to a point where the adjuvant patch can be sold to the government for stockpiling for its pandemic influenza program; that competitors may develop products that are safer, more effective, or more convenient to use; future clinical results may not support regulatory approval to commercialize Iomai's adjuvant patch for pandemic influenza applications, which will depend on the outcome of additional clinical trials and analysis by regulatory authorities of data Iomai submits; that development costs may exceed expectations; that Iomai may fail to adequately protect its intellectual property or may be determined to infringe on the intellectual property of others; and the risks identified under the heading "Factors That May Impact Future Results" in Management's Discussion and Analysis of Financial Condition and Results of Operations in our Quarterly Report on Form 10-Q for the three months ended September 30, 2007, and filed with the Securities and Exchange Commission. Iomai cautions investors and others not to place undue reliance on the forward-looking statements contained in this press release. You are encouraged to read the Company's filings for a discussion of these and other risks and uncertainties which are filed with the U.S. Securities and Exchange Commission, available at <http://www.sec.gov>.

SOURCE Iomai Corporation
