

Iomai Vaccine For Travelers' Diarrhea Blunts Severity Of Disease In Clinical Study

06 Mar 2007

Iomai Corporation (Nasdaq: IOMI) today announced the publication of results from its double-blind challenge study of its vaccine patch for travelers' diarrhea. The clinical study found that volunteers who received the vaccine before being exposed to high levels of enterotoxigenic E. coli (ETEC) bacteria had less severe diarrhea and were significantly less likely to require intravenous fluids than patients who were not vaccinated. The results were published online in advance of print publication in the journal *Vaccine*.

"These compelling results suggest that Iomai's patch-based, needle-free ETEC vaccine mitigates the severity of this common bacterial illness, which could help travelers avoid a debilitating illness during a vacation," said Dr. Gregory Glenn, Iomai's founder and chief scientific officer. "We are continuing to study the vaccine and plan to launch a Phase 3 trial of the vaccine in the next year."

Though ETEC is the most common cause of travelers' diarrhea, which sickens between 20 and 50 percent of international travelers to areas where the bacteria is endemic, no ETEC vaccine is available in the United States. The existing strategy for avoiding travelers' diarrhea -- prophylactic antibiotics -- raises concerns about antibiotic resistance.

The study, lead by Dr. Robin McKenzie, an assistant professor of medicine at The Johns Hopkins University School of Medicine, enrolled 27 patients who received three doses of the Iomai ETEC vaccine and 20 patients who received a placebo. Those volunteers were then given a dose of E. coli larger than would be expected under natural conditions and monitored closely to assess stool frequency, weight, and antibiotic and intravenous fluid use.

Similar numbers in both vaccine and control groups met the definition of moderate to severe illness, but patients who received the vaccine had significantly fewer loose stools ($p=0.04$) and lower mean weights of the loose stools ($p<0.05$). In addition, volunteers who did not receive the vaccine became ill more quickly and were more likely to require intravenous fluids, with 40 percent of the control group receiving fluids compared with only 14 percent of the vaccine group ($p=0.03$). "The in-patient challenge study is an extreme test of the travelers' patch vaccine. We expect that the protective effects will be amplified in the field, where the disease is debilitating but not as severe as we saw in this challenge study," said Dr. Glenn.

Members of the vaccine group also saw increases in two antibodies, IgA and IgG, associated with protection against enterotoxigenic E. coli. After three doses, all patients had a four-fold increase in serum IgG and 97 percent had a four-fold increase in IgA.

Company researchers also published a study demonstrating improved immunogenicity of the ETEC vaccine with the use of a simple skin preparation that disrupts the top layer of skin cells, a technique that is now a standard part of Iomai's vaccination process. That research has been published online by the journal *Infection & Immunity*. It will appear in print in the May 2007 issue.

Iomai's vaccine uses the company's transcutaneous immunization (TCI) technology, which allows the vaccine to be delivered to the immune system via a simple patch affixed to the skin.

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 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 E. coli-related 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 ETEC vaccine to mitigate the severity of ETEC or otherwise avoid traveler's diarrhea, the expectation that the protective effects shown in this trial would be amplified in the field or Iomai's ability to launch a Phase 3 trial in the next year. Applicable risks and uncertainties include, among others, that results in the trials described in this press release may not provide the needed information necessary to conduct future Phase 2 and Phase 3 trials, that Iomai may not be able to enroll sufficient numbers of patients in these and future clinical trials; that future clinical trials may not replicate results seen in the trials described in this press release; that Iomai may be unable to obtain the regulatory approvals necessary to conduct additional clinical trials or to market any product candidates for travelers' diarrhea; 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 "Risk Factors" in the Company's Quarterly Report on Form 10-Q for the three months ended September 30, 2006 and its Annual Report on Form 10-K for the year ended December 31, 2005 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>.

These statements speak only as of the date of this document, and IOMAI undertakes no obligation to update or revise the statements.

Iomai Corporation
<http://www.iomai.com>

Article URL: <http://www.medicalnewstoday.com/medicalnews.php?newsid=64525>

Save time! Get the latest medical news headlines for your specialist area, in a weekly newsletter e-mail. See <http://www.medicalnewstoday.com/newsletters.php> for details.

Send your press releases to pressrelease@medicalnewstoday.com