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ImmunoVaccine Technologies and FIT Biotech enter partnership on DNA-based vaccine

by Marie Daghlian, Assistant Editor

ImmunoVaccine Technologies (IVT) is partnering with FIT Biotech to advance the development of a therapeutic HIV vaccine, which will be a combination of FIT Biotech's DNA plasmid therapeutic HIV vaccine MultiHIV with IVT's DepoVax vaccine delivery system. The companies will collaborate on pre-clinical studies in animal models, examining the novel vaccine's capabilities of inducing cell-mediated and humoral immunity against HIV virus.

Although the agreement between the two companies is just a research partnership at present, it could move in several different directions based on

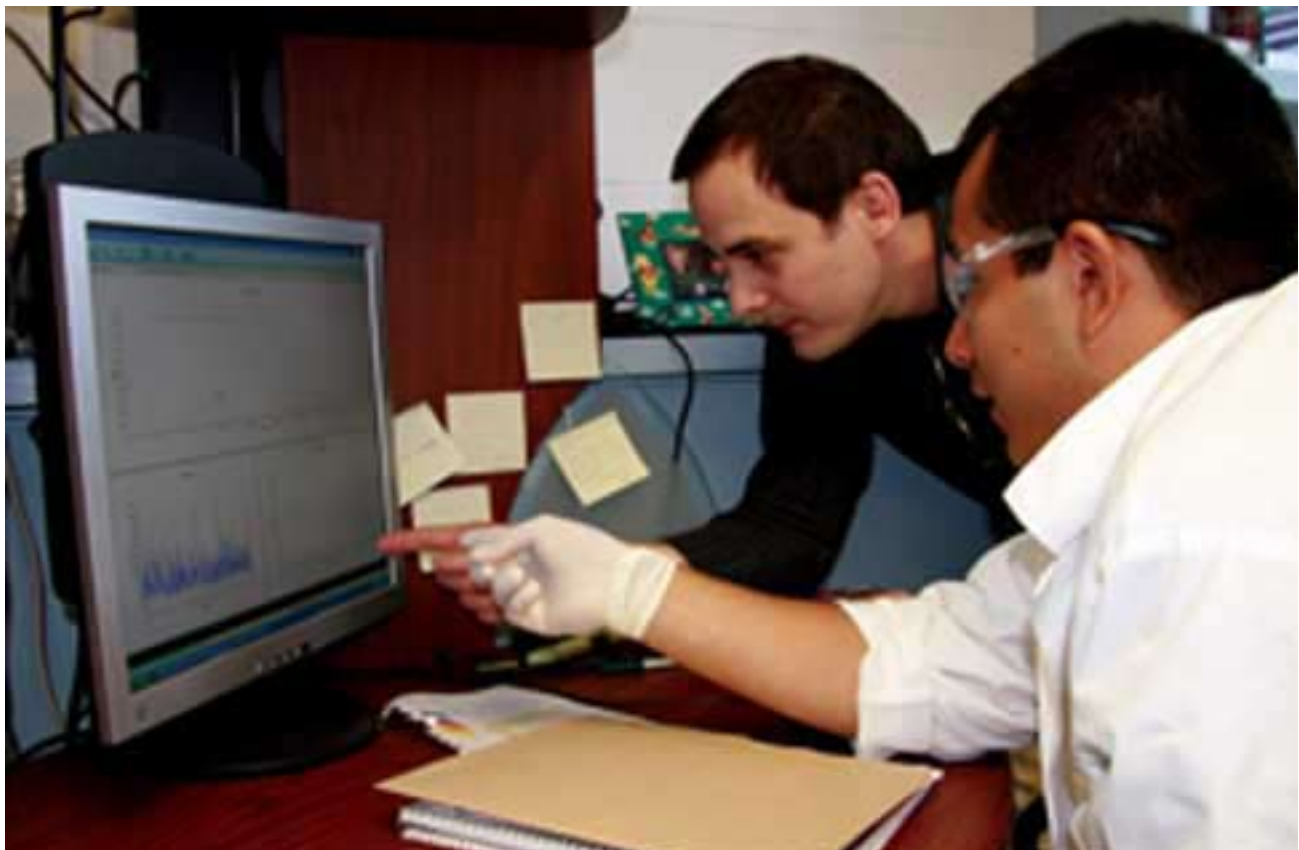
the results of the animal trials. "Based on the results of those trials we will see how to develop it further, either as a partnership or whether we in-license their antigen or they in-license our delivery technology, we will see," said Dr. Marc Mansour, vice president of R&D at Halifax, Nova Scotia-based IVT.

According to Dr. Mansour, the company's proprietary delivery system makes it possible for a vaccine to stimulate an effective immune response in the individual with a single dose, eliminating the need for a series of shots and boosters.

"By testing DepoVax in combination with GTU MultiHIV plasmid, we are working towards developing a superior vaccine candidate for therapeutic use against HIV and AIDS," said Kalevi Reijonen, President and CEO at FIT Biotech.

The development of an HIV vaccine is complicated

Dr. Marc Mansour (left) discusses DepoVax's safety profile with research associate Antar Fuentes-Ortega



by the ability of the virus to mutate rapidly. FIT Biotech, based in Tampere, Finland and Tartu, Estonia has designed a synthetic DNA plasmid, known as GTU MultiHIV that covers the antigenic variability within HIV strains. GTU MultiHIV and is comprised of the multi-epitope/multivalent HIV antigens. As FIT Biotech's lead vaccine candidate, GTU MultiHIV has the potential to trigger an immune response that slows the progression of HIV in infected individuals.

According to the company, the GTU technology can result in plasmid expression that is up to 100 times stronger than using conventional plasmids. FIT has already completed proof-of-concept Phase II trials of an early version of MultiHIV and is planning to submit an IND to the FDA to conduct its first U.S. trial.

The DepoVax platform uses liposomes to encapsulate a target antigen, like GTU MultiHIV, and adjuvant. DepoVax also relies on a hydrophobic carrier to create a depot effect that significantly enhances vaccine induced cell-mediated and humoral immunity. IVT's pre-clinical research has shown that DepoVax effectively delivers DNA plasmids into draining lymph nodes with as little as one dose.

"DepoVax will act as a vector to deliver FIT Biotech's GTU MultiHIV DNA vaccine and our goal is to develop a more sophisticated and efficient HIV vaccine candidate," commented Dr. Marc Mansour, Vice President R&D at IVT.

Both FIT's GTU technology and IVT's DepoVax delivery system have broad applications and can be used to develop vaccines against many different types of targets. FIT is currently developing vaccines against melanoma, diabetes, and hepatitis C, for example, all using GTU technology. IVT's first in-house immunotherapeutic is a cancer vaccine targeting prostate, breast, and ovarian tumors that

will be going to the clinic in early 2010.

Privately-held ImmunoVaccine Technologies has an interesting history. The company was started in 2000 to commercialize vaccine delivery technology that originated at Dalhousie University in Halifax. According to Dr. Mansour, the technology was originally developed for an immuno-contraceptive vaccine for control of the seal population. "The problem with seals is that you can't capture them again to deliver a booster immunization," said Dr. Mansour. "So this had to be a vaccine that would be effective with a single dose. That is how the concept was born."

The Dalhousie University researchers used liposomes to encapsulate the antigen that was combined with an oil depot. "This created a vaccine with long lasting immune responses because of combination of things," continued Dr. Mansour. "For one thing, it was a depot formulation which meant that when you injected it, it remained at the site of vaccination so it would be exposed to the immune system for a longer period of time than normal vaccines would be. But it also used liposomes to deliver the payload more efficiently to the immune system. And it also had some immune activators to make sure that the immune response was properly generated. The combination of all these things resulted in very strong immune responses that could be achieved with a single dose."

Although the vaccine developed at Dalhousie wasn't commercially viable, the technology could enhance any vaccine. IVT was founded with the idea to develop the technology for other types of vaccines and it started with developing animal health vaccines. In January 2008, IVT licensed its technology for the development of livestock vaccines to Pfizer Animal Health for undisclosed fees, milestones, and royalty payments.

Today, the company no longer works on animal

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Web site: www.canadianbiotechnews.com

Subscription Enquiries: pwinter@b-c.com

EDITORIAL

Editor-in-Chief:

Peter Winter (pwinter@b-c.com)

Assistant Editor: Marie Daghlian (mdaghlian@b-c.com)

Advertising

Advertising Director:

Leslie Errington (lerrington@b-c.com)

Production

Creative Director: Shawna Kirby (skirby@b-c.com)

health vaccines except to license the technology to others. It has shifted its focus entirely on human health vaccines, with a cancer immunotherapeutic vaccine as its lead candidate.

The DepoVax technology has broad application, not only for cancer but also for infectious disease vaccines. IVT has done studies with hepatitis B and has been able to show that it can reduce the number of doses required from a Hep B vaccine from three doses down to one dose. IVT has also done some work with pandemic influenza, a vaccine for which requires two doses. "They're all two dose vaccines which means, in the case of a pandemic, you need to immunize people and then you have to ask them to come back in a month for a second shot before the vaccine is effective," says Dr. Mansour. "So we saw the value there and we tried combining a pandemic influenza antigen for target in our technology and we were able to show that we were able to get strong immune responses in as little as two weeks after a single immunization."

IVT scientist Genevieve Weir examines a tumor slide



Although IVT has been able to show efficacy in proof of concept studies in the infectious disease arena, being a small company, they are focused on the cancer vaccine to bring it into the clinic as quickly as possible to show the safety and efficacy of the platform in humans. At the same time, they are continually looking at partnerships and collaborations to work on infectious disease applications because the technology is very broad. This has resulted in a number of recent collaborations, including one with the NIH for malaria and HIV vaccines, another with the La Jolla Institute for Allergy and Immunology in San Diego that is looking at influenza and arenavirus vaccines, and a collaboration with the Department of Defense in Canada looking at enhancing an anthrax vaccine because anthrax vaccines require six doses at present. FIT Biotech is the latest example where IVT is collaborating to enhance their DNA based HIV vaccine.

Fralex Therapeutics purchased by Baylis Medical

Toronto - Fralex Therapeutics Inc., a medical technology company has been purchased by Baylis Medical Company Inc., a developer, manufacturer and supplier of high-technology medical devices for chronic pain management, interventional cardiology and radiology products. The sale was effected by way of a court approved plan of arrangement involving Fralex, Attwell Capital Inc. (formerly 2201761 Ontario Inc.) and Baylis. Under the terms of the arrangement, Baylis acquired all of the issued and outstanding shares of Fralex and its current business of developing Complex Neural Pulse (CNP) in exchange for \$900,000. Attwell acquired Fralex's non-CNP related assets, including all its cash, and assumed all liabilities of Fralex. Further, each holder of Fralex common shares exchanged each Fralex common share held by them for one common share of Attwell and cash consideration of \$0.0001. Attwell expects that its common shares will commence listing on NEX board of the TSXV, under the symbol "AT.H", on June 3, at which time Fralex common shares will be delisted from the NEX. Attwell continues to review investment opportunities with distribution of the remaining cash continuing to be an option. A final decision is expected prior to the end of this year.

Oncothyreon closes registered direct financing

Seattle - Oncothyreon Inc. has closed its previously announced sale of 3,878,993 shares of its common stock and warrants to purchase 2,909,244 shares of its common stock for gross proceeds of approximately \$11.1 million. Oncothyreon sold the shares and warrants for \$2.85 per unit (each unit consisting of one share and a warrant to purchase 0.75 shares of common stock). The exercise price of the warrants is \$3.92 per share. The warrants will be exercisable at any time on or after the six-month anniversary and on or prior to the fifth anniversary of the closing of the transaction on May 26, 2009. Oncothyreon plans to use the proceeds from this financing for general corporate purposes. Boenning & Scattergood, Inc. acted as exclusive placement agent in the transaction.

Oncolytics Biotech first quarter results

Calgary - Oncolytics Biotech Inc. reported its financial results for the three-month period ending March 31, 2009. "The first quarter was highlighted by the announcement of very positive results in several of our combination REOLYSIN® clinical trials," said Dr. Brad Thompson, President and CEO of Oncolytics. "We continue to report clinical benefit in the majority of patients treated with Reolysin in combination with chemotherapy or radiation, paving the way for our pivotal program to begin this year."

Subsequent to the end of the first quarter of 2009, on April 9, 2009, the company completed the acquisition of an inactive private company (PrivateCo). The net cash available from PrivateCo, at the time of closing, was \$2.13 million and they issued 1,875,121 common shares in our capital based on the previously determined exchange ratio of \$1.69. The company estimated at the beginning of 2009 that the cash requirements to fund the base level of activity for the year would be approximately \$11,000,000. Their net loss for the first quarter of 2009 was \$3,957,646 with cash and short-term investments totaling \$9,292,081

In other news, Oncolytics also announced that it has successfully completed patient enrolment in its multi-centre Phase II clinical trial to evaluate the intravenous administration of Reolysin® in patients with various sarcomas that have metastasized to the

lung. 52 patients have been enrolled in the trial.

The primary endpoint of the trial was met in late 2008 where at least three out of 52 patients had to experience stabilization of disease or better for more than six months. Of the 33 patients evaluable at that time, five had experienced stable disease for periods greater than six months, including one patient who had maintained stable disease for more than 16 months.

Medicago 1Q results

Quebec City - For the first quarter ending March 31, 2009, Medicago Inc. (TSX-V: MDG) announced its operational and financial results. Consolidated loss was \$2,625,000 or \$0.03 per basic and diluted share, compared to a loss of \$326,000 or (\$0.01) per basic and diluted share in the same period in 2008. There were no revenues in the first quarter of 2009 compared to \$1,665,000 in the first quarter of 2008. This decrease is due to revenues generated by two agreements signed with Philip Morris Int'l. (PMI).

Revenues were offset by \$196,000, representing the value of the 2,000,000 common share purchase warrants granted to PMI upon the execution of the non-exclusive licensing agreement in February 2008. R&D expenses totaled \$1,397,000 in the first quarter compared to \$1,101,000 in 2008. As at March 31, 2009, the company had consolidated assets of \$18.7 million, including cash, cash equivalents and short-term investments of \$11.8 million, compared to consolidated assets of \$20.6 million, including cash and cash equivalents of \$14.0 million as at December 31, 2008.

"During the quarter, we focused on moving our lead H5N1 VLP vaccine candidate into final preclinical studies in preparation for a CTA-filing this summer," said Andy Sheldon, President and CEO of Medicago. "In parallel with the development of our lead candidate, we initiated work on a VLP vaccine candidate against the new strain of influenza, A (H1N1) that recently surfaced in North America. We successfully expressed a H1 VLP antigen within 14 days of receiving the genetic sequence of the new virus. This rapid timeline establishes the capability of our proprietary vaccine manufacturing technology in plants and our ability to potentially be a first responder solution in the event of a pandemic. Results from a first animal study to confirm the immunogenic potential of this new candidate are expected in June 2009," concluded Mr. Sheldon.

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