

Media Release

ICAV/CITAV Receives Second Round Of Funding From Public Health Agency Of Canada

September 25th, 2009

Peterborough, ON, Canada - Dean Del Mastro MP (Peterborough) announced today that the International Consortium on Anti-Virals/Consortium International sur les Thérapies Antivirales will receive \$2 million over the next two years to continue their pioneering work on accelerating the discovery and development of novel anti-viral therapies. These funds are being provided from the Public Health Agency of Canada's Pandemic Preparedness and Response Fund.

Dr. Jeremy Carver, Co-Founder and CEO of ICAV/CITAV stated: "People who become seriously ill from H1N1 infection generally do so because they have failed to mount an adequate immune response. From the outset of this pandemic, ICAV has been working with its participating scientists to find a treatment for the seriously ill and save lives."

Earlier this year ICAV announced an initiative to develop truly human monoclonal antibodies (tHuMAbs) directed against the pandemic H1N1. "These tHuMAbs promise an effective treatment for the seriously ill from H1N1 infection because they provide the patient with the antibodies that their body should have generated. The identification of the tHuMAbs approach to pandemic preparedness is an example of the contribution ICAV made with PHAC's initial \$2 million funding, granted in 2007," added Dr. Carver.

"We look forward to being able to continue our work of identifying and advancing the most innovative anti-viral strategies, where-ever in the world they may have been discovered with this new PHAC funding," said Dr. Michel Chrétien, Co-Founder of ICAV-CITAV responsible for International Partnerships.

Trent's President, Steven Franklin said: "I am pleased that PHAC has extended ICAV's funding for another two years. With this funding Trent's global image will continue to be strengthened through ICAV's International Symposia and the engagement of Trent Faculty and students in its humanitarian mission."

ICAV/CITAV holds International Symposia around the world as a means of identifying promising new approaches to anti-viral therapy and communicating with its participants. ICAV/CITAV will be reporting on its progress with the tHuMAbs Program at its 8th International Symposium being held in Corsica October 2nd to the 6th, 2009.

Headquartered at Trent University in Peterborough, ICAV/CITAV is an institutional innovation - a not-for-profit drug development and discovery company - dedicated to the discovery and development of anti-viral therapies for neglected and emerging diseases. Through the international collaboration of scientists, government and industry, ICAV's goal is to deliver at least one novel drug to market every five years that is affordable, effective, and globally accessible to all patients in need. Specifically, ICAV: fills the gap between academic research and clinical development; accelerates development of drugs for neglected and emerging viral diseases; and ensures global access to novel therapies at affordable prices.

About Trent University:

One of Canada's top universities, Trent University is renowned for striking a unique balance between outstanding teaching and leading-edge research. The University is consistently recognized nationally for faculty who maintain a high level of innovative research activity and a deep commitment to the individual student. Distinguished by excellence in the humanities, social sciences and natural sciences and increasingly popular professional and graduate programs, Trent is dedicated to providing its students with an exceptional world view, producing graduates who are ready to succeed and make a difference in the world.

About the Greater Peterborough Innovation Cluster:

The Greater Peterborough Innovation Cluster is a not-for-profit corporation with a mission to facilitate and advance life sciences, environmental, DNA and other innovative research in the Peterborough region. Its goal is to help promote and sustain a strong local knowledge-based economy.

For more information please contact

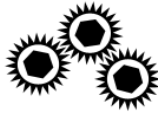
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BACKGROUND FOR MEDIA

1 INTERNATIONAL CONSORTIUM ON ANTI-VIRALS (ICAV)/CONSORTIUM INTERNATIONAL SUR LES THÉRAPIES ANTI- VIRALES (CITAV)

1.1 *Mandate*

ICAV/CITAV was launched in 2004 and incorporated in January 2006 as a Canadian company without share capital. ICAV is an institutional innovation that solves the challenge of rapidly transforming world-class research into low-cost, anti-viral drugs with high-impact, global health results.

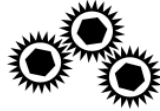
ICAV's business model addresses the commercialization and anti-viral "gaps" through innovative access to potential drug candidates and a novel business strategy. ICAV harvests promising drug candidates from a worldwide network of academic scientists, assesses them and incorporates the most promising ones into its drug development pipeline.

ICAV rapidly and cost effectively moves drug candidates through preclinical development, adding value for future licensees while leveraging existing resources and avoiding excessive administrative and infrastructure costs. By advancing drug candidates to the clinical-trials stage, ICAV will be supplying the industry with the late stage products that they desperately need. In this way, ICAV's public-private approach mitigates much of the risk of drug development and encourages the realization of therapies for diseases that would otherwise be "neglected".

ICAV's global network of scientists acts as a forum for the pooling of resources and creates avenues for multi-country funding of discovery research. This innovative approach allows ICAV to leverage billions of dollars of research grants, infrastructure and salaries paid for by public institutions around the world. Such networking also provides efficiencies by exploiting the specializations of different laboratories.

1.2 *Results from Phase I Funding of the ICAV Pandemic Preparedness Program*

Initial Funding - The Public Health Agency of Canada granted ICAV \$2 million in March 2007 to initiate its drug research and development activities. A key purpose of the grant was to provide initial funds to allow ICAV, as part of Canada's Pandemic Preparedness Strategy, to assemble a



prioritized list of potential therapies that could be deployed in a pandemic situation as an alternative to Tamiflu® or Relenza®.

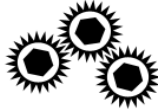
Development Opportunities - From March 2007 to the current date, ICAV through its International Symposia, assembled dossiers on over 20 Development Opportunities and submitted these to an evaluation by ICAV's expert consultants – a process termed the “Initial Review of Opportunities” (IRO) process. The five candidates with the greatest prospects to advance to clinical development were identified.

Conclusion from Phase I Funding - ICAV0003, the fully human monoclonal antibody (tHumAbs) technology to identify antibodies from blood samples from individuals infected with various influenza viruses (including H1N1) – represents its most significant advance not only in scientific development as a potential anti-viral therapeutic and prophylactic, but also as a "third leg" in Canada's Pandemic Preparedness Strategy, complementing both anti-viral therapeutics as well as anti-viral vaccines as a tool to combat influenza.

The three legs to the pandemic preparedness stool				
	Protective	Therapeutic	Strengths	Weaknesses
Vaccines	✓	X	Low-cost hence wide population coverage possible	Time-lag for production and for the development of protective immunity Cannot address needs of seriously ill
Anti-virals	✓	✓	More expensive than vaccines but both protective and therapeutic	prone to emergence of resistance
tHuMAbs	✓	✓	Most expensive but immediately and highly effective; less prone to emergence of resistance	Expensive - so only limited initially to ICU patients

1.3 Public Health Threats and Opportunities

The major public health threat from influenza arises from the potential that a new viral strain will become **both** virulent (high fatality rate such as the avian H5N1) and have the ability to spread rapidly and uncontrollably from human-to-human (high transmissibility such as the current pandemic H1N1).



Protection from infection by influenza – The single most useful tool available to protect a population from the emergence of a new and highly virulent influenza strain is vaccination. However, as is being confirmed with the current pandemic, preparing and deploying vaccines against new influenza viruses is a lengthy process creating what has been termed the “vaccine gap”

Therapy for infected individuals - Vaccines are deployed to protect populations from infection and cannot help those already infected and seriously ill. This “therapeutic gap” is being filled at present by the anti-virals, Tamiflu and Relenza. The antiviral Tamiflu also has some utility as a prophylactic against influenza and because of its broad specificity it can be stock-piled in anticipation of a pandemic. Although clinical trials have demonstrated that direct prophylaxis (protection from infection on exposure to an infected individual) is only about 30% effective, a more important effect is on the viral load of a treated infected individual. It has been estimated that the probability of transmission to immediate contacts is reduced by 65%. As a result, Tamiflu can partially fill the therapeutic gap but with the emergence of anti-viral resistant strains the therapeutic gap will become even wider.

The truly human monoclonal antibodies are a possible solution to fill these “gaps”.

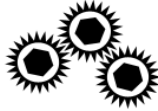
The third Leg – ICAV’s “truly human” monoclonal antibodies (tHumAbs) to H1N1 [swine] influenza, that are both neutralizing and sterilizing, are a unique tool to fill the “therapeutic and vaccine gaps” and address a potential Canadian public health threat. These antibodies have the singular feature of conveying immediate immune protection to recipients that can last months after administration. Furthermore, tHuMAbs will be of value in treating the severely ill. Quantities of monoclonal antibodies can also be stockpiled in anticipation of an eventual further viral outbreak.

ICAV, in collaboration with scientists and physicians across Canada and the US, is currently generating such “truly human” monoclonal antibodies from Ontario patients infected with the H1N1 [swine] flu virus and planning for their GMP production.

2 PHASE II OF THE ICAV PANDEMIC PREPAREDNESS PROJECT

2.1 Principal Partners

Participating Scientists - ICAV’s principal partners are its 250 participating scientists from 25 countries. Key collaborators for the development of tHuMAbs have been Drs. Schrader (UBC) and Rini (Toronto). Dr. Nancy Cox (USCDC, Atlanta) provided the cDNA, ICAV has worked closely



with OAHPP to date on the collection of blood samples for use in the discovery of antibodies and their development in the tHuMAbs platform. Under the direction of Dr. Donald Low (who is also a member of the ICAV Scientific Advisory Board), other OAHPP collaborators include Dr. Vanessa Allen, Dr. Allison McGeer and Jonathon Gubbay. Going forward in the Phase II project OAHPP will continue to collect blood samples, provide sample characterization data, supply killed virus for scientific evaluation, perform in vitro infection assays and participate in providing other support for the therapeutic use and deployment of tHuMAbs.

2.2 Objectives

New funding by PHAC in the amount of \$2 million for Phase II of the ICAV Pandemic Preparedness Project will advance new anti-viral development and accelerate the delivery of ICAV's therapies for public health purposes.

The specific objectives of Phase II are:

1. Pre-clinical development of the truly human monoclonal antibody (tHuMAbs) platform identified in Phase I;
2. Dissemination of the results with tHuMAbs and identification of additional novel influenza-therapeutic “Development Opportunities” from its international network through international symposia;
3. Evaluation and prioritization of new anti-influenza Development Opportunities;
4. Identification of additional outside sources of funds to ensure sustainability.