



8TH ANNUAL BIODEFENSE VACCINES & THERAPEUTICS

June 14-17, 2010 | Almas Temple Club | Washington DC

Pre-Conference Symposium
Monday, June 14, 2010

Developments in Biodefense Technology Platforms *A Briefing from Leading Biodefense Researchers*

Technology platform projects are intended to impact multiple medical countermeasures (MCM) products. This symposium will provide an overview of several kinds of technology platform projects being developed in biodefense and how these innovations are/can be used to address threats from emerging infectious diseases.

Monday, June 14, 2010

8:00 – 9:00 Registration and Networking Breakfast

9:00 – 9:15 Welcome and Comments by the Co-Chairs

Michael Callahan, M.D., DTM&H, Program Manager, Defense Science Office, Defense Advanced Research Projects Agency

Michael Kurilla, M.D., Ph.D., Director, Office of BioDefense Research Affairs, and Associate Director for BioDefense Product Development, DMID, National Institute of Allergy and Infectious Diseases (NIAID), NIH

9:15 – 9:45 **Non-Chemical Adjuvants for Enhanced Safety and Efficacy**
Boston BioCom LLC, in collaboration with Massachusetts General Hospital, is developing a unique approach to enhancing immune responses through the use of non-destructive laser irradiation. Brief illumination of the skin with specific parameters of laser energy result in non-destructive tissue stress that concentrates activated

antigen-presenting cells at the site of illumination, resulting in significantly increased systemic immune response to intradermally-delivered antigens without the need for chemical or biological adjuvants. This approach also has promise as a direct immunotherapy through the stimulation of local innate immune responses.

Jeffrey Gelfand, M.D., FACP, *Professor of Medicine*, Harvard Medical School and *Chief Scientific Officer*, Boston BioCom LLC

9:45 – 10:30

A Broad-Spectrum Host-Based Antiviral Drug Platform for Biodefense and Emerging Viral Diseases

Unither Virology is developing a host-based platform of iminosugar compounds which shows promise for developing broad spectrum antiviral drugs with potential to treat viruses from at least 9 families. The iminosugars inhibit processing of viral glycoproteins and impair viral assembly, secretion and infectivity. In vitro, compounds from the platform have shown activity against 9 of 10 virus families tested, including arena, bunya, filo, flavi, orthomyxo, pox, toga, retro and hepadnaviruses. In vivo, compounds have been tested so far against filo, flavi and orthomyxoviruses and have shown protection against each of these families. Candidate compounds from the platform are safe and are orally bioavailable. Thus, drugs based on this platform could provide important biodefense countermeasures against known, emerging, and artificial virus threats.

Urban Ramstedt, Ph.D., *Chief Scientist*, Unither Virology

10:30 – 11:15

Morning Networking Break

11:15 – 11:45

Accelerated Manufacturing of MCMs to Counter Emerging and Human Evolved Threat Agents

The Texas A&M University System, together with its commercial and academic partners, has initiated two large-scale biopharmaceutical manufacturing research, development, and production facilities to demonstrate the concepts of “flexible-by-design” and “real-time surge” required for future biosecurity. The first project emphasizes multi-technology and multi-product capabilities, and utilizes modular, mobile clean rooms in an expandable facility architecture. The second project will demonstrate proof of concept for rapid, massive scale up (billion dose per year capacity) of sub-unit vaccines using a plant based protein production system. Both facilities are embedded in an academic R&D ecosystem committed to co-development of

validated animal models and the training of students to support US strategic workforce needs

Brett Giroir, M.D., *Vice Chancellor for Research*, The Texas A&M University System and *Adjunct Professor*, The Bush School of Government and Public Service

11:45 – 1:00

Group Luncheon

1:00 – 1:30

Broad Spectrum Antiviral

Zirus is a biotechnology company with a proprietary platform of over 1000 human host targets (discovered with gene trap and siRNA genome screening) that are essential for viral replication and not essential for host cell survival. Hundreds of the Zirus targets can block several distinct virus families and the company is rapidly and cost effectively discovering repurposed drugs and preclinical small molecule antagonists to its platform to develop near term broad spectrum antiviral drugs for pandemic influenza and bioterror threats.

David Perryman, *President & CEO*, Zirus

1:30 – 2:00

Broad Spectrum Vaccine Concept

The threat of attack by bacterial bio-warfare agents has increased as a consequence of the development and ease of genetic manipulation of such agents, potentially rendering them impervious to standard treatments. The recent negative Congressional evaluation of our readiness to protect the war fighter and the general population against such agents has magnified the significance of this threat. Vaccines both prophylactic and therapeutic are required to provide protection and an effective response to such attacks. Syntiron™ has unique vaccine technology which, by preventing the iron intake by bacteria can render them non-pathogenic and is potentially impervious to genetic engineering. Syntiron's technology provides a unique, validated platform for the development a series of both prophylactic and therapeutic vaccines against bacterial bio-warfare agents.

R.H. Joseph Shaw, Ph.D., *CEO & Chairperson*, Syntiron LLC

2:00 – 2:30

Left of Disease: Technologies to Counter Infectious Diseases Prior to Illness

COL Geoffrey Ling, MD, Ph.D., *Program Manager*, *Defense Science Office*, Defense Advanced Research Projects Agency

2:30 – 3:00 Afternoon Networking Break

3:00 – 3:30

Phosphatidylserine-Targeting Broad Spectrum Antibodies for the Treatment of Hemorrhagic Fever Virus Infections

Peregrine Pharmaceuticals Inc. and its academic collaborators are developing broad spectrum anti-viral agents. These anti-viral monoclonal antibodies target anionic phospholipids such as phosphatidylserine (PS) which become exposed on the surface of virus-infected cells and egressed virions. The antibodies exert their anti-viral effect via clearance of circulating virus and destruction of virus-infected cells by antibody-dependent cell-mediated cytotoxicity. We present data supporting the use of PS-targeting antibodies against members of three major hemorrhagic fever virus families including Pichinde virus and Junin virus (Arenaviridae), Punta Toro virus (a model for Rift Valley fever virus, Bunyaviridae family) and yellow fever virus (Flaviviridae).

Melina Soares, Ph.D., *Assistant Professor*, University of Texas Southwestern Medical Center at Dallas

3:30 – 4:00

Plant Based Systems for Rapid Production of Vaccine and Monoclonal Antibody Medical Countermeasures

KBP operates a cGMP compliant bioprocessing facility dedicated to the creation and execution of commercial scale processes for production of pharmaceuticals from plants. Working with collaborators Mapp Biopharmaceutical and CBR International, KBP has developed plant growth, extraction and downstream purification processes inside a Quality Assurance framework to speed process development and the creation of scalable, cGMP compliant manufacturing processes. The creation and implementation of these systems compliments the inherent speed in which plant based systems express and accumulate recombinant proteins, and utilizes an integrated platform ideally suited for the rapid production of vaccines and monoclonal antibodies (with mammalian glycoforms) for use as medical counter measures.

Hugh Haydon, *Chairman*, Kentucky Bioprocessing LLC
Jeanne Novak, Ph.D., *President*, CBR INTERNATIONAL

4:00

Symposium Adjourns