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“Next Generation” HIV/AIDS Treatments Featured in NAPWA and The AIDS Institute’s Community Forum at XVIII International AIDS Conference

Four Therapeutic Vaccines Show Efficacy; Other Leading Therapeutic HIV Vaccines, Anti-Immune Hyperactivation, and Immune-Based Therapies Hit Milestones

(Vienna, Austria 22 July 2010) New data presented by researchers at the XVIII International AIDS Conference this week shows significant momentum for the emerging field of therapeutic vaccines, immune hyperactivation, and other immune based therapies, according to officials from National Association of People with AIDS (NAPWA) and The AIDS Institute, two of the leading USA-based patient advocacy organizations. The data were presented at a special community forum, titled “Research Advances from Therapeutic Vaccines and Other Immune-Based Therapies.

“With proper funding, the innovative researchers at these companies will one day bring us better treatments that support or restore the immune systems of people living with HIV/AIDS,” said Stephen Bailous, Vice President Community Affairs, NAPWA.

Four therapeutic vaccines each showed new efficacy data at this conference:

- **FIT-06** from FIT Biotech and **DermaVir** from Genetic Immunity each showed significant reduction in viral load in treatment naïve patients in Phase 2 trials.
- Also in a Phase 2 trial, **AGS-004** from Argos Therapeutics showed large reductions in viral loads allowing extended ART holidays for treatment experienced patients.
- **Vacc-4x** from Bionor Immuno, which reported two years ago at the XVI International AIDS Conference in Mexico City that it allowed those with moderate viral loads to stay off treatment for an average of 31 months. High responder volunteers had a reduction in viral load by 0.5 lg. The Company today reports that these same individuals continue to show an immunologic response to the vaccine 7 years later, which is unprecedented.

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“These researchers are answering Dr. Fauci’s call for “good therapeutic vaccine candidates,” said Mr. Bailous, referring to Anthony Fauci, M.D., Director, National Institute of Allergy and Infectious Disease, who spoke at Tuesday’s plenary session of the XVIII International AIDS Conference in Vienna, where he called for “a good therapeutic vaccine” in order to preserve the immune function of people living with HIV.

The presentations at today’s Community Forum include:

Topically Applied DermaVir Safely Boosts HIV-specific Immune Response and Reduces Viral Load Within Six Months in Treatment-naïve Individuals: A Randomized, Double-Blinded, Placebo Controlled Phase II HIV Therapeutic Vaccine Study, Julianna Lisziewicz, PhD, CEO, Genetic Immunity

VS411 safely reduces both excessive immune system activation and HIV viral load within 28 days in treatment-naïve individuals: A Phase II HIV AV-HALT Anti-Immune Hyperactivation Study, Franco Lori, MD, CEO, ViroStatics

FIT-06 therapeutic DNA vaccine reduces viral load and increases CD4 cell count in two-year Phase II study, Mart Ustav, Ph.D., Senior VP and CSO, FIT Biotech

Vacc4x - a therapeutic HIV-1 vaccine based on modified peptides: Clinical trial results and update on clinical trial development, Maja Sommerfelt, PhD, Chief Scientific Officer Bionor Immuno

Clinical update on AGS-004: Overcoming the challenges to successful HIV Immunotherapy, Charles Nicolette, Ph.D., CSO and VP R&D, Argos Therapeutics

TBR-652, a potent dual chemokine receptor 5/chemokine receptor 2 (CCR5/CCR2) antagonist in phase 2 development for treatment of HIV infection, Richard Ogden PhD, Scientific Development Advisor, Tobira Therapeutics

Gene therapy-based cell therapy for HIV and therapeutic HIV vaccines, Riku Rautsola, Ph.D., CEO VirxSYS Corporation

Advanced development of dual acting pyrimidinediones (IQP-0410 and IQP-0528) as highly potent anti-HIV therapeutic drugs and topical microbicides, Daniel R. Caffoe, President and Chairman, ImQuest Life Sciences, Inc.

PEPTERON, A novel class of antiviral, Dr. Dorothy Bray, Ph.D., Consultant to Receptopharm Inc.

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National Association of People with AIDS and The AIDS Institute have joined to sponsor this important community forum to showcase efficacy data from leading therapeutic vaccines and other immune based therapies that could lead to next generation breakthrough treatments.

ABOUT NAPWA

Founded in 1983 as the first network of people living with HIV/AIDS (PLWHA), the National Association of People with AIDS (NAPWA) is the oldest national AIDS organization. NAPWA is the trusted independent voice for all people living with HIV/AIDS in the United States. By engaging in the aforementioned activities, NAPWA remains a strong voice in policy, capacity building, leadership development, and social networking. NAPWA is a 501(c) 3 non-profit organization based in Silver Spring, Maryland. For more information about NAPWA, please visit www.napwa.org.

ABOUT The AIDS Institute

The AIDS Institute is a U.S.-based national nonprofit agency that promotes action for social change through public policy research, advocacy and education.

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Key Development Advances from Therapeutic Vaccines, Immune Hyperactivation and Immune based Therapies

Immunacia's ViroStatics small molecule program has been successful in significantly reducing the amount of circulating HIV as well as the state of excessive immune system activation now seen as driving HIV progression. The Company is developing both two-drug combinations and single drugs that accomplish two goals. The first is the reduction of circulating virus, something that the nearly 30 approved HIV/AIDS medications also do. What is exceptional about the Immunacia approach is that these novel products are designed to also reduce the inappropriately elevated level of immune system activation that is now recognized as the driver behind the loss of CD4+ T cells and the onset of AIDS. This second mechanism is so unique that drugs that can effectively accomplish both goals are now known as a new class – the *AV-HALTs* (Antiviral-HyperActivation Limiting Therapeutics). Immunacia will be presenting Phase II data at the XVIII International AIDS Conference in which the four key markers of the immune hyperactivation seen throughout HIV infection were significantly reduced in antiretroviral-naïve individuals after only 28 days of treatment with VS411, the first agent to demonstrate true AV-HALT activity in HIV/AIDS.

Immunacia's Genetic Immunity a Hungarian/US company has successfully concluded a Phase II clinical trial with DermaVir nanomedicine as a therapeutic vaccine for HIV/AIDS. Data from the randomized, double-blind, placebo-controlled study presented at the XVIII International AIDS Conference demonstrates DermaVir's ability to reduce circulating HIV virus by 70% at six months following only four three-hour skin applications of the vaccine in antiretroviral-naïve individuals. Designed as a synthetic "pathogen," DermaVir is applied to the skin where it is captured by activated Langerhans cells that directly transport the nanoparticles to the lymph nodes where they mature into dendritic cells carrying the DermaVir pDNA encoding for expression of structural (gag, pol, env) and regulatory (tat, rev, vpr, vpu) proteins. The HIV genes have been altered to ensure the proteins they produce form safe and highly immunogenic, complex HIV

virus-like-particles (VLP+) to accomplish the long-sought goal of using HIV itself to generate a targeted and long-lived cellular immune response.

FIT-06 is a DNA-based therapeutic HIV vaccine developed by **FIT Biotech**. It is based on FIT Biotech's novel, proprietary GTU® technology. As described in a poster presented at the International AIDS Conference in Vienna on July 19, 2010, FIT-06 showed long-term reductions in viral load (approximately 0.5 log) and statistically significant CD4 cell count increases in HIV-infected, treatment-naïve patients. The effect lasted longer than two years in the absence of any anti-retroviral therapy. The results are an early indication that patients could potentially benefit from FIT-06 in the future by virtue of possible delayed initiation of antiretroviral therapy, longer drug holidays and a lower lifetime drug burden leading to lower side effects associated with antiretroviral therapy.

FIT Biotech (www.fitbiotech.com) is an innovative medical biotechnology company based in Tampere, Finland and Tartu, Estonia. FIT Biotech is developing and commercialising its proprietary Gene Transport Unit (GTU®) technology including FIT-06 for HIV/AIDS. Other GTU product applications include novel DNA vaccination and immuno- and gene therapies for other infectious diseases including neglected and emerging diseases with high unmet medical need.

AGS-004 is a product of **Argos'** proprietary Arcelis™ technology for personalizing RNA-loaded dendritic cell (DC) immunotherapies for HIV, as well as other infectious diseases and cancer. To address the challenge of the unique genetic profile of each patient's disease and the genetic mutations of that disease, Argos loads the patient's DCs with a sample of messenger RNA isolated from their disease. Through this process, DCs can potentially prime immune responses to the entire antigenic repertoire, resulting in an immunotherapy that is customized to the patient's specific disease.

Argos recently reported data from a Phase 2a trial, demonstrating viral load control in the absence of antiretroviral therapy and robust immune responses to a diverse set of HIV antigens. This month Argos initiated a randomized, placebo-controlled Phase 2b trial to confirm the efficacy of AGS-004 in the absence of antiretroviral therapy. The majority of the costs of the Phase 2b trial will be funded by the National Institutes of Health, as part of a \$21 million contract that Argos was awarded in 2006.

Vacc-4x is an peptide-based HIV immunotherapy vaccine under development by the Norwegian company **Bionor Immuno**. It is made from peptides up to 27 amino acids long that are modified from highly conserved domains of HIV p24. To date, Vacc-4x has been given to 140 patients and has been shown to be safe in uneventful clinical trials. The vaccine is easy to mass produce because the peptides are short to medium length. Today at the AIDS 2010 conference in Vienna, company researchers present a poster titled "Longterm proliferative CD4+ and CD8+ T cell memory detected 7 years after intradermal immunizations against short HIV Gag p24-like peptides targeting dendritic cells."

Bionor Immuno (OSLO:BIONOR) is an innovative biotech company developing pharmaceutical-grade peptide vaccines that stimulate cell-mediated immunity using T-cell stimulation. Bionor Immuno carefully designs synthetic peptides from non-mutating parts of the virus with improved immunogenicity, resulting in improved efficacy and safety profiles. HIV is the first disease targeted, with the most advanced vaccine candidate about to finish clinical phase IIb. However, Bionor Immuno's platform technology is broadly applicable, and the company has vaccine candidates also for chronic infections such as Hepatitis C (HCV), Human Papilloma Virus (HPV) and Influenza. Bionor Immuno is a wholly owned subsidiary of Bionor Pharma ASA, listed on the Oslo Stock Exchange under the ticker symbol "BIONOR". More information is available at www.bionorpharma.com.

Tobira's lead compound, TBR-652, is a dual-action CCR5/CCR2 antagonist showing great promise to address the unmet therapeutic needs of people with HIV. It's the only developmental agent currently being investigated to determine both its anti-viral and anti-inflammatory effects. In its short-term proof of concept study, TBR-652 showed potent viral suppression (mean nadir response up to $-1.8 \log_{10}$) and potent CCR2 inhibition, as well as excellent safety and tolerability. Importantly, TBR-652 provides the potential for once-daily dosing, without the need for a boosting agent, and has the necessary attributes to form one-pill, once-a-day fixed dose combinations, key for simplified dosing and administration.

As HIV is increasingly understood as a chronic inflammatory disease associated with potential poor long-term health implications for patients, new treatment strategies are being explored. There is a need to reduce the use of older drugs with safety concerns and provide long-term health benefits for an aging patient population. One intriguing approach is to develop therapeutic agents that provide full virologic suppression and down-regulate chronic immune activation. TBR-652's promising attributes are well-aligned with this approach and may provide a high-potential therapeutic advance to lead the new frontier of HIV medical management in the future. The company's Phase 2b study is expected to begin in early 2011, and will include various sub-studies designed to evaluate the compound's immunologic, cardiovascular and metabolic endpoints.

VIRxSYS Corporation is developing *Lexgenleucel-T*, an investigational gene-modified cellular therapy product (autologous VRX496™ transduced CD4⁺ T cells), for the treatment of HIV. This is a novel cell and gene therapy product using autologous human CD4⁺ T lymphocytes purified from peripheral blood mononuclear cells collected from HIV-infected subjects during an outpatient leukapheresis procedure. The purified CD4⁺ T cells are modified by ex vivo transduction with VRX496™ antisense RNA, then expanded and reinfused into the patient. The Company has conducted a Phase 1 clinical trial followed by three Phase 2 trials evaluating the safety and tolerability of *Lexgenleucel-T* in 65 HIV positive subjects, including 48 who had failed drug regimens and had limited treatment options remaining. Infusions of the product have been well tolerated. In Phase 1, three of the five subjects experienced significant

reductions in HIV viral load and stabilization or slight increases in CD4⁺ T cell counts. Preliminary Phase 2 data suggest a stabilization of the CD4 compartment and a rendering the subjects' HIV replication deficient. Planning is in progress for an additional Phase 2 study supported by the NIAID/NIH AIDS Clinical Trial Group (ACTG) (Protocol A5291), expected to commence in 2011. This novel therapy consisting of a long RNA antisense forces the evolution of the virus into extinction, providing a unique mechanism of action.

VIRxSYS is developing a therapeutic and prophylactic HIV lentiviral based vaccine, VRX1273, with antigens gag, pol and rev. Non-human primate prophylaxis studies have demonstrated safety and strong cytotoxic T lymphocyte (CTL) responses and SIV (Simian Immunodeficiency Virus) control. VIRxSYS intends for VRX1273 initially to be a therapeutic vaccine. Additional therapeutic strategies would follow, including in treatment naïve patients to delay the initiation of chemical therapies. VRX1273 could have a prophylactic application, either stand alone or in conjunction with other therapies. Human vaccination with VRX1273 could induce high frequencies of polyfunctional anti-HIV CD8 and CD4 T lymphocytes, a prerequisite for sparing the highly toxic and costly NRTIs currently used in combination HIV therapies.

Receptopharm's lead antiviral product, Pepton, is a novel therapeutic inhibitor of HIV replication. Unlike current antiretroviral drugs, it works by stimulating the immune system to resist infection. Exposing immune cells to Pepton causes a burst in the production of antiviral cytokines including gamma interferon, a major inhibitor of viral replication in the human body. Pepton has recently been shown to inhibit many drug resistant strains of HIV, an emerging problem for current HIV therapies. It has completed human safety trials, demonstrating no toxicity and was readily tolerated. The Company currently is developing plans to move Pepton into Phase 2 studies in subjects with HIV.

ReceptoPharm, a subsidiary of NutraPharma Corp (US), is an innovative biopharmaceutical drug discovery company developing proprietary therapeutic protein products primarily for the prevention and treatment of viral, autoimmune and neurological diseases in humans, including Pain, Multiple Sclerosis (MS), and Human Immunodeficiency Virus (HIV).