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Presentation at session 1.1: Scientific Basis and Emerging Technologies for Antibodies

Stimmunology and the SMARTube™ HIV&HCV - a novel technology for stimulating antibody production in-vitro – leading to the detection of new, early, and unique antibodies.

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Both HIV and HCV are chronic infections which have a long serological window period (WP) between the time of infection and seroconversion. It has been shown that the WP can be attributed to the fact that the initial humoral immune response against the virus is suppressed by the virus, and thus the infected person remains seronegative and thus undiagnosed for weeks and months following the initial infection date.

A novel technology has been developed, Stimmunology, which overcomes the *in-vivo* immune suppression and peripheral tolerance by cell activation *in-vitro*. This technology, embodied in the SMARTube, leads to B-cell differentiation into plasma cells, and to the production of HIV and/or HCV antibodies in a short incubation step of a 1ml whole blood sample. Following the SMARTube pre-treatment step, antibodies can be detected in the SMART-plasma not only from all seropositive samples but also from those infected yet seronegative individuals in the WP – leading to their proper diagnosis.

A study was conducted to look at the antibodies' antigenic profile in both plasma samples from seropositive individuals and SAMRT-plasma from seronegative ones, with the goal of possible expression of "suppressed" and unexpressed antibodies through the Stimmunology process.

It was found that there are new and unique antibodies in the SMART-plasma, directed at different proteins of the virus. These antibodies, some of which are not present even after seroconversion, could hold a key for retrieving information regarding the initial, potentially protective, immune response against the virus, a response which did not come to fruition in the body. We believe that these unique antibodies could provide information which could offer not only a tool for better and earlier diagnosis, but also for drug and vaccine developments.

Dr. Tamar Jehuda-Cohen has been a lecturer in the academia in the fields of Biology, Immunology, Diagnostics, and Bioethics for the last 14 years. During her Post-Doctoral work at Emory University, at Prof. A. Ansari's laboratory, she studied the humoral immune response against HIV using the SIV monkey model of AIDS. Since then she has been involved in studies concerned with early detection of HIV infection and understanding the initial host (immune response) – viral (HIV) relationship. Based on those studies she has developed means to overcome the viral immune suppression so as to enable the detection of those who are infected yet are in the seronegative window period and thus missed by the current diagnostic antibody assays.

Dr. Jehuda-Cohen is the developer of the Stimmunology technology and its embodiment in the SMARTube. Since 2004 she is serving as the CTO of SMART-Biotech Ltd., a company which is dedicated to the development, production and marketing of the SMARTube family of products in the infectious diseases arena.

Dr. Tamar Jehuda-Cohen holds a position of an adjunct senior lecturer at the Department of Biomedical Engineering in the Technion, Israel Institute of Technology. She has published over 30 articles in peer reviewed journals, and has presented in over 100 conferences, in some as an invited speaker. During the years of Stimmunology and SMARTube products' development, publications were suppressed, to be renewed in early 2009. Dr. Tamar Jehuda-Cohen studies the early immune recognition of viruses such as HIV and HCV and how uncovering or unmasking it can be harnessed for both: better, earlier, and more confirmed diagnosis, and for the design and study of new vaccines and therapeutics for those infections, and others.

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