New Data Demonstrate SMARTube Technology May Provide Basis for Creation of an Index to Estimate the Rate of Spread of HIV in High-Risk Populations

ORLANDO and REHOVOT, Israel, March 25 <u>PRNewswire</u>/ -- New data presented at the Center for Disease Control (CDC)-sponsored 2010 HIV Diagnostics Conference suggests that an assay based on SMARTube™ technology may prove useful in developing a standardized measure for estimating what proportion of those infected with HIV have become recently infected.

These results indicate that using the SMARTube technology, developed by SMART Biotech, Ltd., physicians can create a "stimulation index," which can be used as a biomarker based on the ratio of stimulated (following pretreatment with SMARTube technology) to unstimulated antibodies, which can be measured by a conventional blood diagnostic assay. This index can be used to help public health officials have a more accurate picture of HIV infection in high-risk populations in order to take appropriate treatment and preventative measures.

"These results are significant in that they suggest that in addition to fact that the SMARTube technology can aid physicians in diagnosing infections such as HIV even before the current standard serology allows, there is an additional potential benefit to using the SMARTube process," said Tamar Jehuda-Cohen, one of the key investigators of the study and chief technology officer of SMART Biotech. "This study demonstrates that SMARTube may be effective in providing valuable information about the rate of recent HIV infection in any given patient population. Just as important as it is that SMARTube enables detection of HIV antibodies in those who are still in the seronegative window period; enabling an estimate of incidence (rate of new infections) within a population, is an additional tool which could aid public health officials in efforts to curtail the HIV epidemic."

The study utilized blood samples that had been tested after being treated using the SMARTube process (termed SMARTplasma), and the level of HIV antibodies was compared to that of the antibodies in the regular, non-stimulated, plasma, to determine the Stimulation Index (SI). A mathematical modeling of the data, done by Reshma Kassangee, and Alex Welte, Ph.D., both from the University of the Witwatersrand, South Africa, indicated a very low rate of "false recent" as well as an initial ruff estimation of the duration of the "recent" stage of seropositivity. Both these parameters are critical for any incidence assay to be effective. Thus, this mathematical analysis of the data demonstrated that by using the SMARTube technology, epidemiologists and public health professionals could potentially create an index that could determine with statistical significance the incidence of HIV infection in a given population.

About SMART Biotech and SMARTube Technology

Established in 2004, Israel-based SMART Biotech Ltd. develops, manufactures and markets a unique family of products called SMARTube[™]. The SMARTube family is based on Stimmunology, the only technology in the world specifically designed to potentially solve the major diagnostic problem of the "window period" in the diagnosis of HIV, HCV and other infectious diseases.

SMARTube technology enables the diagnosis of HIV, or the detection of HIV antibodies in the weeks and months between initial infection and current serological diagnosis, during which time, infected individuals are misdiagnosed potentially enabling further spread of these infections. The company aims to use its technology to save lives, reduce individual suffering and help the healthcare system to save money. Applications of the technology include potentially preventing of mother-to-child transmission, focusing prevention programs, reducing the need for repeated testing and enabling a more confirmed diagnosis, among others.

SMARTube has been tested in controlled clinical trials with the number of patients/individuals tested summing up to over 10,000 in total. Trials and testing have been conducted by various government agencies, blood banks, reference laboratories and other institutions in several countries around the world including Israel, Mexico, South Africa, Kenya, China, and Romania resulting in its registration in the EU (CE Mark), Israel, Russia, South Africa, Nigeria, Romania, Hungary, and Turkey.

SMARTube is a trademark of SMART Biotech.

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