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IMMUNOXYL PROVES EFFECTIVE IN AIDS TRIAL

Zodiac Capital Limited (NSX:ZOD) – Sydney Australia 14 May 2009 - advises that the results of highly promising findings from a clinical trial of Immunoxel, (one of the key products of its pending joint venture with Stirling Products Limited - ASX:STI) in AIDS patients has been published in the May 2009 issue of peer-reviewed "The Open Virology Journal" published by Bentham Science Publishers (Nikolaeva et al., "Effect of immunomodulating adjuvant Dzherelo (Immunoxel) in HIV infected patients receiving standard antiretroviral therapy". *Open Virol J* 2009;3;31-36; a full copy of the paper is freely available online at <http://www.bentham-open.org>).

Since the introduction of modern antiretroviral therapy (ART), there has been a dramatic decrease in HIV-related morbidity and mortality. Suppressing HIV replication by ART can result in elevation of the CD4+ T-cell counts and consequently restoration of normal immunity. However, the degree of immune restoration that can be achieved with ART is often incomplete and can be poorest in those patients who have low CD4+ counts. Currently available immunotherapeutic options for AIDS patients are practically non-existent and largely unsuccessful. Novel approaches are urgently needed to enhance the immune function.

To address this unmet need, Ukrainian doctors led by Professor Lyudmila Nikolaeva, M.D., head of the Regional AIDS Center, in Kharkov, Ukraine, using Immunoxel in a clinical trial, have developed a highly successful method of enhancing the outcome of antiviral therapy, which at the same time helps to restore normal immunity.

Immunoxel was evaluated in an expanded, matched-case comparative clinical trial involving HIV infected patients in the advanced disease stage. The control group of twenty AIDS patients received standard anti-retroviral therapy (ART) consisting of Zidovudine (AZT), Lamivudine (3TC), and Efavirenz (EFV). The immune intervention group of twenty HIV patients received 50 drops of Immunoxel twice per day in addition to the ART treatment.

At the end of study the total CD3 T-lymphocytes increased slightly in ART recipients ($P=0.06$), whereas among those who received Immunoxel they rose significantly ($P=0.03$). The population of CD4 T-cells had expanded by a half in ART recipients ($P=0.002$), whereas in Immunoxel treated patients they almost doubled (from 184 to 356; $P=0.004$). The accrual in absolute and relative number of CD8+ lymphocytes in ART and Immunoxel recipients was not significant.

The CD4/CD8 ratio in Immunoxel recipients increased from 1.495 to 1.940 ($P=0.03$), but in the control group on antiviral drugs alone, the increase was not significant ($P=0.14$).

Immunoxel also produced changes in distinct immune cell populations that were not seen previously in any reported immunotherapy trials. For example, no changes in CD20+ B-lymphocytes were seen among ART recipients, but in the Immunoxel patients this cell population declined to normal levels from 509 to 333 ($P=0.00008$). Similarly, the effect of ART on activated CD3+ HLA-DR+ T-cells was

negligible (from 209 to 264 cells; $P=0.02$), but among those who received Immunoxel this cell population increased by 216% (from 161 to 348; $P=0.0007$). ART did not affect the proportion of CD3-CD16+CD56+ natural killer (NK) cells, but administration of Immunoxel raised NK cells by 52.7% ($P=0.0001$).

In addition to this impressive effect on various immune cell populations, Immunoxel demonstrated a significant impact on viral load reduction. While about three-quarters of patients on ART displayed a decrease in viral load ($P=0.008$), almost every patient (95%) on Immunoxel had a decrease in their viral burden ($P=0.001$). Thus, Immunoxel clearly demonstrated a favourable effect on the immune status and viral load when given as an immunomodulating adjunct to ART.

"In earlier published clinical trials oral immunomodulator Immunoxel has been shown to be very safe and effective as an adjunct immunotherapy in tuberculosis patients, including MDR and XDR-TB. Similar benefits were observed in patients with TB who were also infected with HIV" said Mr. Volodymyr Pylypchuk, scientific director of Ekomed LLC, the product licensor. "We now have shown that our product is an excellent and safe immunotherapeutic adjuvant not only to TB therapy but also to AIDS drugs. The increase in CD4 counts was two-fold higher among those who have had the combination of Immunoxel and ART. Other important populations of immune cells were also favourably affected by Immunoxel. What is remarkable is that patients who were in the immune intervention arm showed the decrease in viral load at much higher proportion than among those who received ART alone. Immunoxel could become an indispensable tool in AIDS therapy, especially when all other options have been exhausted."

"Our findings indicate that the improved immune function is closely associated with the inhibitory adjunct effect of Immunoxel on viral load," said Professor Lyudmila Nikolaeva, M.D., head of the Regional AIDS Center, in Kharkov, Ukraine, who is the lead author on the study.

Zodiac Capital and Stirling Products, Managing Director Mr. Peter Boonen, added: "It should be understood that Immunoxel is not a drug but a patented natural botanical immunomodulator which has been shown in all trials conducted and published to date to regulate or normalise ("tune") the immune system far more effectively and powerfully than other products.

Immunomodulators are substances that correct imbalanced immune systems or strengthen weakened immune systems. They do this through their unique ability to stimulate the body's natural and adaptive defences, including cytokines resulting in the body being more able to help itself. Most importantly, in the case of many conditions that are treated with antibiotics, antiviral drugs or chemotherapy, they provide for these treatments - when used in conjunction with an immunomodulator such as Immunoxel - to be far more effective than the prescription medicines alone.

In the case of Immunoxel this has to date been convincingly established in all clinical trials reported, without any side or adverse effects, ranging from treatment of XDR-TB with or without HIV co-infection, seasonal influenza, including H1N1, and hepatitis as reported in earlier press releases."

Immunoxel is one of 26 phytopharmaceutical (botanical) products being commercialised globally under a Zodiac Capital Limited License Agreement that, subject to shareholder approval at a meeting scheduled for 29 May 2009, the Company has agreed to joint venture with Zodiac Capital Limited as has previously been advised to the market.



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