

FOR IMMEDIATE RELEASE

ZODIAC ADVISES OF MAJOR NEW TB THERAPY

Sydney NSW, March, 2009 -- Zodiac Capital Limited (NSX: ZOD) presents the following information for Immunoxel, one of the key products of its Zocap Pharma Joint Venture.

In over 600 clinical trial patients Immunoxel has demonstrated that it represents a major breakthrough TB therapy as a powerful immunomodulator for the treatment of TB, multidrug resistant TB (MDR-TB), extensively drug resistant TB (XDR-TB) as well as in all cases of HIV co-infection. Immunoxel:

- improves clinical symptoms and produces higher and far quicker cure rates than in TB patients on anti-tuberculosis therapy (ATT) alone
- achieves faster and superior rate of mycobacterial clearance
- reduces HIV burden
- accelerates clearance of pulmonary lesions
- decreases inflammation markers
- decreases liver damage
- improves haematology – increased haemoglobin levels and CD4 counts
- significantly improves quality of life through achieving weight gain, reduced fever, improved respiratory function and physical fitness

In a recent trial 66 patients were followed for 3 months and then assessed for sputum smear clearance rate, radiological findings and liver damage markers such as bilirubin, ALT, cholinesterase, gamma-glutamyl transpeptidase and thymol turbidity test. At the 3rd month follow-up 27 out of 33 (81.8%) of patients on Immunoxel+ATT had negative sputum smear compared to only 7 out of 33 patients (21.2%) on ATT alone. Complete healing of pulmonary infiltrations and cavities in 12 (36.4%) patients was observed in the Immunoxel group and in only one patient (3%) in the ATT group. Additionally, in liver function tests Immunoxel was found to be safe and improved or reversed the side effect liver damage caused by ATT use.

Clinical improvements: The improvement of baseline clinical symptoms such as night sweats, dyspnoea, nausea, fatigue and general malaise was observed within 2-3 weeks. By 8-10 weeks increase in body weight, disappearance of fever and weakness were clearly established. The improvement in quality of life signs among patients on ATT was less common and usually correlated with other endpoints.

Sputum smear conversion: At the end of 2nd month follow-up 21 of 33 patients (63.6%) on Immunoxel (Dzherelo) had negative sputum smear conversion, whereas only 6 patients (18.2%) on ATT had converted. The difference by Fisher's exact two-way test was highly significant ($p = 0.0002$). Further discrepancy was observed at the end of 3rd month. Negative smear test has been found in additional 6 patients on Immunoxel (Dzherelo)

whereas only one individual converted in ATT arm, bringing the total to 81.8% and 21.2% ($p = 0.000001$).

Radiological findings: Administration of Immunoxel (Dzherelo) was characterized by remarkable clinical response as judged by treating physicians. In the ATT group these improvements were seldom observed. Chest X-ray analysis confirmed these subjective impressions. The healing of pulmonary lesions and cavities was seen in 12 (36.4%) patients in Immunoxel (Dzherelo) group while only one patient (3%) treated with TB drugs had shown resolution by third month ($p = 0.0008$).

Liver function test: Since TB chemotherapy causes hepatotoxicity we compared liver function markers in 2 groups of patients. The levels of ALT appeared slightly to increase above normal in Immunoxel (Dzherelo) group ($p = 0.09$) while they had almost doubled in ATT group ($p < 0.0001$). The levels of total bilirubin descended to normal in Immunoxel (Dzherelo) recipients but increased in patients treated with chemotherapy alone. The activity of cholinesterase deteriorated in ATT group but improved in immune intervention group. Levels of gamma-glutamyl transpeptidase were not much affected by either of treatment modalities. Thymol turbidity test appeared to show twice-higher inflammation process in ATT but no differences were seen in Immunoxel (Dzherelo) recipients.

The results indicate that when Immunoxel (Dzherelo) is combined with ATT significant clinical, microbiological and radiological improvements are produced. Immunoxel (Dzherelo) was found to be safe and has improved or even reversed liver damage produced by ATT. These findings support earlier clinical investigations of Dzherelo by other investigators (Melnik *et al.*, 1999; Chechitany *et al.*, 2007; Prihoda *et al.*, 2007, 2008; Nikolaeva *et al.*, 2008a, b; Zaitzeva *et al.*, 2008).

Another trial in TB and TB/HIV co-infection patients demonstrated:

- The average duration of therapy was only 16.2 ± 5.2 weeks (range 10.6 - 30.3; median 16)
- The mean time to bacterial clearance was 4.4 ± 1.8 weeks (range 1.3 - 8.9, median 4.3)
- All patients (95%), except one gained weight, ranging between 3 -17 kg with average 8.7 kg ($P=0.000009$)
- The liver function tests revealed that the level of total bilirubin had decreased from 15.5 to 11.6 $\mu\text{mol/L}$ ($P=0.009$). Alanine transaminase (ALT) declined from elevated 53.1 IU/L to normal 30.4 IU/L level ($P=0.001$)
- Haemoglobin levels increased from 103.2 to 117.3 g/L ($P=0.00005$)
- Inflammation-associated, elevated leukocyte counts returned back to normal from 8.9 to 6.9×10^9 cells/L ($P=0.003$)

In the past 40 years there has been no new significant drug development for the treatment of TB and especially its MDR-TB and XDR-TB strains. Immunoxel in all of its 10 trials to date in over 600 patients has demonstrated that it effectively and safely can dramatically improve current clinical practice therapies.

To date all trial work and patient has been carried out in the Ukraine where Immunoxel (Dzherelo) was first approved by the Ministry of Health as an immunomodulating supplement for TB treatment in 1999 and in 2006, Immunoxel (Dzherelo) was declared a functional food – a superior category of herbal supplement which can carry medical claims substantiated by clinical evidence.

Despite having received clinical trial funding support from the French MAPI Research Trust and support from the Bill and Melinda Gates Foundation providing for presentation at last year's Keystone Symposia at Banff in Canada, Immunoxel has had very little exposure to the western pharmaceutical industry.

As Immunoxel is a fully developed product with extensive human use and clinical data to support both its safety and extraordinary effectiveness in TB treatment, the Joint Venture is now progressing to actively introduce Immunoxel to the global markets.

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