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Company Announcement **“Unexpected” Efficacy of *Ropren*[®] in Treating Severe Alcoholism**

The Directors of Solagran Limited are pleased to provide a summary of the results of the *Ropren*[®] clinical trials conducted at the Skvortsova-Stepanova psychiatric hospital in 2006-07 with serious and critically ill, drug addicted chronic alcoholics. These very challenging trials constitute a key element in Solagran’s ongoing research effort in both Australia and Russia to demonstrate the multi-faceted nature of *Ropren*[®] and specifically its efficacy in the prevention and treatment of a range of neurodegenerative disorders.

The company has been in possession of these results for some time. A short statement pointing to the significance of the findings was provided to shareholders at the 2006 AGM. A further update was provided at the EGM held in September 2007 by Dr Nina Golovkina, the Head of the Department of Psychosomatic Illnesses at the Skvortsova-Stepanova hospital. However the release of any written information relating to the results was embargoed by the Board while intellectual property arising from these and other related trials was secured. IP protection was achieved in January this year with the granting of patents for the use of *Ropren*[®] and its active ingredient *Bioeffective*[®] *R* in the treatment of memory decline and dementia (including Alzheimer’s disease), and for the use of *Ropren*[®] in the treatment of conditions arising from long term addiction to both alcohol and drugs.

The Trial

The trial set out to determine the safety and efficacy of *Ropren*[®] in the treatment of chronic alcoholism and related disorders. It was conducted in conjunction with a detoxification therapy.

90 patients were involved in the trial. 60 were in the experimental group and 30 in the control group. Each trial participant was recruited through the hospital’s emergency department, having been brought in by ambulance. All 90 patients in the trial had been diagnosed with second stage chronic alcoholism.

Patients in the control group were treated in accordance with international standards and were administered nootropics, cerebroprotectors, B group vitamins and anti-depressant tranquilisers (benzodiazepine). A minimal therapeutic dose of neuroleptics was also administered.

Where necessary, some patients in the experimental group that received *Ropren*[®] were also given minimal doses of neuroleptics and anti-depressant tranquilisers. Nootropics, cerebroprotectors and B group vitamins were not administered.

Ropren[®] was administered at the dose of 8 drops, 3 times per day for 1 month.

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Summary of Results

The trial clearly demonstrated the clinical efficacy of *Ropren*[®] in treating second stage chronic alcoholism and its related psychosomatic and neurological disorders – tested using standard international scales. This was supported by pre and post treatment clinical data including blood and urine tests, blood biochemical analyses and EEG readings.

Distinct, rapid and statistically significant positive changes were evident in patients with psychosomatic, neurological and functional pathologies of the central and peripheral nervous systems. These changes included:

- Regression of the symptoms of alcohol abstinence syndromeⁱ by Day 5-7 compared with Day 14-21 in the control groupⁱⁱ
- Improvement in neurological status in 81.4% of the patients with severe localised cerebral damage compared with only 36.7% in the control group. Improvement was evident by Day 15 in the experimental group but not until Day 21-30 in the control group
- Rapid and very obvious regression of the symptoms of polyneuropathy of the limbs by Day 10-15, compared with Day 21-30 for the control group. After *Ropren*[®] treatment was completed, the severity of polyneuropathy continued to reduce progressively. 76.6% of patients experienced a transformation from a severe and very evident condition, to a much more moderate form. 10% experienced a full recovery
- Marked improvement in the functioning of the liver, pancreas and kidneys, leading to rapid regression of alcohol abstinence syndrome, and significant improvement of the patients' overall condition. This was accompanied by normalisation of blood sugar and total cholesterol levels compared with the control group, as well as improvement in the functional condition of the kidneys. These improvements with *Ropren*[®] treatment were registered in patients who were also suffering from chronic viral hepatitis (B & C) and type 2 diabetes
- Improvement in 80% of the patients suffering from psychosomatic conditions including depression. The anti-depressive effect of *Ropren*[®] was evident by Day 15-20 of the treatment. In the control group, 44.8% of patients were still suffering from the same level of depression at the end of the trial as was evident at the beginning
- Improvement in cognitive function by Day 10-14, as measured through stability, reduction in exhaustion and ability to concentrate, compared with Day 21-30 for the control
- Significant positive changes in EEG data in 66% of patients. A further 23.5% experienced positive changes of a more moderate nature. EEG improvement was expressed in the form of stronger alpha-rhythm, reduction in irritability symptoms and processes of agitation (especially in frontal areas) and disappearance or reduction in symptoms of vascular instability. The spectrum of these changes had a modulating nature tending towards the norm. In the control group, 76.5% had no significant changes

Ropren[®] was well tolerated by the patients and was considered safe. During the treatment, there were no side effects registered, no allergic reactions, and no worsening of the condition in any patient from the experimental group.

The relative impact of *Ropren*[®] treatment compared with the control group increased with the time the patient had been suffering from chronic alcoholism. Efficacy of the standard treatment is reduced in patients suffering from alcoholism for more than 10 years. This was shown not to be the case with *Ropren*[®] treatment.

Two thirds of the patients had been prescribed pharmaceuticals from the phenothiazine group (drugs which have hepatotoxic activity) as well as having severe virally induced liver damage (hepatitis B and C). Despite this, patients treated with *Ropren*[®] had positive changes to blood biochemical parameters.

Excellent results were obtained with *Ropren*[®] in patients suffering from both chronic alcoholism and drug addiction. In the experimental group, alcohol abstinence syndrome began to come under control from Day 3-6. In patients that did not receive *Ropren*[®], it did not begin to come under control until Day 21. This result was underpinned by strong EEG data.

The researchers concluded that:

Ropren[®] treatment resulted in a much faster regression in psychological disorders and neurological abnormalities, together with biochemical and pathology indices, which allows its inclusion into the practice of treatment of exogenous alcoholic, drug and other toxic psychoses and thereby reduce the economic cost of treatment.

Commercial Implications

Ropren[®] is currently registered as a pharmaceutical in Russia on the basis of its liver regenerating properties. It is indicated "*in cases of diseases of the hepatobiliary system, fat and protein dystrophy, chronic hepatitis A, B and C, and different types of liver damage related to toxic poisoning, drug substances and alcohol; as well as partial hepatic resection during the post surgical period*".

While its registered applications cover a wide range of liver related illnesses for which there are few satisfactory existing treatments, *Ropren*[®]'s demonstrated potential to now deal with the many conditions associated with chronic alcoholism – and particularly those of a psychosomatic and neurological nature – should have a positive impact on both the rate and the level of market penetration when it is released.

The Board believes these trials results are particularly significant. They were seminal in the award of two patents earlier this year.

The Board also considers the timing of this announcement to be very helpful for the company with the imminent award of a manufacturing licence in Russia. This licence will enable Solagran to begin distributing *Ropren*[®] to hospitals and pharmacies in Moscow and St Petersburg.



Peter Stedwell
Company Secretary
On behalf of the Board of Directors of Solagran Limited

ⁱ Abstinence syndrome is a series of physiological and psychological changes undergone by people who have become physically dependent on a drug. Generally the effects are observed in an opposite direction from those produced by the drug. For example, the withdrawal syndrome for barbiturates consists of insomnia, restlessness, tremulousness, hallucinations, and in extreme cases, potentially fatal convulsions. With alcohol, the symptoms include craving, agitation and depression amongst many others. Onset time and severity of the syndrome depends on the rate at which the drug disappears from the body.

ⁱⁱ There were 3 cases of patients (2 men and 1 woman) who abstained from alcohol consumption for more than one month after the conclusion of *Ropren*[®] treatment