



## **Sosei Confirms the Safety of SD118 in Two Phase I Trials**

**Tokyo, Japan – 8 December 2008:** Sosei Group Corporation (“Sosei”; TSE Mothers Index: 4565), a biopharmaceutical company, today announces the successful results of two Phase I trials for its collaborative project on SD118, a compound in development for the treatment of neuropathic pain.

SD118 is being jointly developed with NeuroDiscovery Ltd (ASX Code: NDL) and its wholly owned subsidiary NeuroSolutions Ltd under a Collaboration Agreement concluded in June 2006. SD118 was previously under investigation in Japan for a different indication. Now, following animal model studies conducted in Sosei’s Drug Reprofitting Platform (DRP), it has demonstrated potential as a new oral neuropathic pain therapy.

The Phase I trials were both double-blind, placebo-controlled, dose escalation studies designed to evaluate the safety, tolerability and pharmacokinetics of SD118 administered in an oral formulation.

In the first trial, a single ascending dose (SAD) study conducted in 56 healthy male volunteers, no serious adverse events (SAEs) were reported in any of dose ranges including the highest dose used in the study. Notably, the plasma concentration of SD118 increased proportionately with administered doses of the drug across the entire dose range investigated. Consequently,, SD118 was considered to be safe and well tolerated in doses up to 2000mg..

In the second trial, a multiple ascending dose (MAD) study conducted in 36 healthy male volunteers, no SAEs were reported and SD118 was considered safe and well tolerated. At the maximum dose of 2,000mg BID, nervous system related adverse events were reported, paraesthesia by four subjects, and hypoaesthesia by one subject, but there were no concerns regarding clinical safety. In this study the pharmacokinetic profile also showed a plasma concentration increase in proportion to doses of SD118 from 100mg BID to 2,000mg BID.

Mr Shinichi Tamura, President & CEO of Sosei, said: "I am delighted that SD118 demonstrated a good safety profile, especially considering the wide range of doses tested. This project is now ready to move into the next step of development."

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## **Notes for Editors:**

### **About Neuropathic Pain**

Neuropathic pain is caused by a primary lesion or dysfunction in the nervous system and persists for months or years even after the initial damage had been healed. It can occur in a variety of traumatic diseases including spinal cord injury and nerve compression. Also, it is a common secondary symptom in diseases like diabetes, cancer and herpes zoster infection, and can occur after the use of cytotoxic drugs. The condition has a poor prognosis and is a significant cause of morbidity. The neuropathic pain market is forecast to reach US\$5.5 billion by 2010. Although there is no single definition of neuropathic pain, approximately 26 million patients worldwide suffer from some forms of the condition (Epicom, 2005). The management of neuropathic pain is still a major challenge to the pharmacotherapy due to its unresponsiveness to most of the pain-killers, anticonvulsants, antidepressants and in some cases, opioids.

### **Paraesthesia**

A transient sensation of numbness or tingling ["pins and needles"].

### **Hypoaesthesia**

A reduced sense of touch.

### **About Sosei**

Sosei Group is a leading international biopharmaceutical company with significant expertise in product discovery and development. It has established a reduced risk business model based primarily upon identifying new uses for established drugs and exploiting its unique position within Japanese, European and North American pharmaceutical markets by acquiring compounds from, and bringing compounds into, Japan.

For further information about Sosei, please visit [www.osei.com](http://www.osei.com)

### **About NeuroDiscovery**

NeuroDiscovery Ltd is an ASX listed speciality neuroscience services provider and drug development company which owns 100% of NeuroSolutions Ltd (ASX Code NDL).

### **About NeuroSolutions**

NeuroSolutions Limited is a profitable service company, which has applied its broad spectrum expertise and drug discovery platforms to become a leading provider of specialised electrophysiological assays to the biopharmaceutical industry. Electrophysiology is a specialised technique which is used to record electrical activity in membranes, cells or tissues. NeuroSolutions' current clients include many established pharmaceutical and biotechnology companies.

In parallel to running its service business, the Company is also exploiting its in-house technologies and expertise for its own internal R&D and has a mature pipeline of programmes underway for the treatment of pain.

During 2008, the Company reported success in a Phase II trial for NSL-101. The Company also successfully completed two Phase I trials for the development compound NSL-043/SD118, in partnership with Sosei Co. Ltd. Both of these trials reported a successful outcome, facilitating further development.