



Sosei Announces Approval to Start AD 923 Phase III Studies in Europe

Tokyo, Japan – 28 November 2007: Sosei Group Corporation (“Sosei”; TSE Mothers Index: 4565), a biopharmaceutical company, today announces that it has received approval from the UK Medicines and Healthcare products Regulatory Agency (MHRA) for the Phase III clinical trial programme for its fentanyl sublingual spray (AD 923), an opioid analgesic for the treatment of cancer breakthrough pain.

The clinical trial authorisation (CTA) covers two multi-centre pivotal Phase III efficacy studies followed by an open label safety study. Patient enrolment in the UK is expected to commence before the end of the year and will be the subject of a separate announcement. Applications have been made in other European countries and further patient recruitment will be initiated as soon as approval is received from the relevant local regulatory body.

This first CTA in a major European country will also trigger the receipt of a project milestone payment under the AD 923 Licence Agreement signed with Mundipharma in June 2006.

Mr Shinichi Tamura, President & CEO of Sosei, said: "Receipt of our first Phase III CTA represents an important milestone in the evolution of Sosei and the continuing progress of the AD 923 development programme. We look forward to enlisting our first patients in the trial".

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Notes for Editors:

About Sosei

Sosei Group Corporation is a leading international biopharmaceutical company with significant expertise in product discovery and development. It has established a reduced risk business model 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

About AD 923

AD 923 is an optimised, sublingual formulation of the strong opioid analgesic fentanyl. It has been specifically designed to provide rapid onset of analgesia in a device that is easy to use by either the patient or their care giver. An additional benefit is the lockout system that prevents inadvertent overdosing. Sosei has concluded a range of studies that confirm the potential of this novel product.

In June 2006, Sosei entered into an agreement with Mundipharma International Corporation Limited for the development and commercialisation of AD 923 in Europe and other international markets, excluding North America and Japan. Sosei is currently evaluating its commercialisation options for the un-partnered territories.

About Cancer Breakthrough Pain

Cancer breakthrough pain is characterised by temporary exacerbations of moderate to severe pain in cancer patients that “breakthrough” their around-the-clock opioid treatments. Each episode may be spontaneous or incidental to an activity. It is estimated that the condition is prevalent in approximately 60% of cancer pain patients across Europe, the US and Japan, representing a total population size of 2.3 million. Most current treatments for cancer breakthrough pain are considered sub-optimal. The market seeks products which have a rapid onset of action and are easy to use. The current worldwide market for cancer breakthrough pain drug treatment is estimated to be worth \$1.5bn and represents a growing market opportunity.