Sosei Announces Successful Completion of AD 923 Pharmacokinetic Study in the USA

Tokyo, Japan – **22 May 2007**: Sosei Group Corporation ("Sosei"; TSE Mothers Index: 4565), a biopharmaceutical company, today announces the successful completion of a study of its fentanyl sublingual spray (AD 923), an opioid analgesic for the treatment of cancer breakthrough pain.

This was a pharmacokinetic Phase I single centre, open-label, single dose, cross-over, randomised study of AD 923 versus Actiq® (oral transmucosal fentanyl citrate lozenge) and versus fentanyl citrate injection. The study was conducted in healthy human volunteers, under an IND in the United States. All of the primary and secondary objectives of the study were achieved.

The more rapid absorption of fentanyl from AD 923 compared with Actiq® was statistically significant, with substantial plasma exposure seen within 10 minutes. The median Tmax (time to maximum plasma concentration) for AD 923 was 40 minutes compared with 120 minutes for Actiq®. In addition, the higher absolute bioavailability of AD 923 compared with Actiq® was also statistically significant. Both formulations were well tolerated with no significant safety issues identified.

Sosei has reached agreement with EU regulatory authorities to move AD 923 directly into Phase III trials and plan to file a CTA (clinical trial application) in the second half of 2007. Following the outcome of this pharmacokinetic study the company will continue its discussions with the FDA regarding the detailed requirements for the Phase III programme in the USA.

Mr Shinichi Tamura, President & CEO of Sosei, said: "These data demonstrate that AD 923 has the potential to provide significantly faster onset of analgesia compared with existing therapy. Additionally, the higher absolute bioavailability indicates more predictable pain relief across the patient population. These factors together with the ease of administration will provide an optimised product with a rapid onset of action, which is generally recognised as being the most important attribute in the treatment of cancer breakthrough pain. We now look forward to moving this product into Phase III studies."

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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.sosei.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.