



## **Sosei Announces Start of AD 923 Phase III Studies in Europe**

**Tokyo, Japan – 12 February 2008:** Sosei Group Corporation (“Sosei”; TSE Mothers Index: 4565), a biopharmaceutical company, today announces that it has commenced Phase III studies for its fentanyl sublingual spray (AD 923), an opioid analgesic for the treatment of cancer breakthrough pain.

The trial is a multi-centre, randomised, double-blind, double-dummy, crossover study to evaluate the safety and efficacy of AD 923 against an active comparator (morphine sulphate immediate release (MSIR)) for the treatment of breakthrough pain in patients with malignancies. The primary endpoint is the well established summary of pain intensity difference (SPID) measure over the first 30 minutes from initial dosing.

Overall, the European Phase III programme will involve some 300 patients in two studies, involving an active comparator, across 10 European countries. These will then be followed by a single combined open label study to assess the long term effectiveness, safety and tolerability of AD 923.

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.

Mr Shinichi Tamura, President & CEO of Sosei, said: "I am delighted that we are able to announce the start of Phase III studies. AD 923 has been optimised to meet the well recognised need for a safe and effective method of delivering fentanyl for the rapid relief of breakthrough pain in malignant and also non-malignant conditions"

### **Sosei Group Corporation**

Ichiban-cho FS Bldg., 8 Ichiban-cho, Chiyoda-ku, Tokyo 102-0082 Japan  
Hiroki MAEKAWA, Representative Executive Officer,  
E-mail: [hmaekawa@sosei.com](mailto:hmaekawa@sosei.com) Tel: +81 3 5210 3399 Fax: +81 3 5210 3291

### **Sosei R&D Ltd.**

Chesterford Research Park, Saffron Walden, CB10 1XL England  
John DAFFURN, EVP Corporate Development,  
E-mail: [daffurnj@sosei.com](mailto:daffurnj@sosei.com) Tel: +44 1799 532 350 Fax: +44 1799 532 351

### **The Trout Group**

Seth Lewis  
Brandon Lewis

Tel: +1 617 583 1308  
Tel: +1 646 378 2915

## **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](http://www.sosei.com)

### **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. The recent European Pain in Cancer Survey (EPIC) results reveal that cancer related pain is widespread in Europe, with one in two (56%) cancer patients enduring moderate to severe pain (n=5,084). The second, detailed phase of the survey reveals that cancer breakthrough pain or inadequate pain relief is a common problem for many patients – 63% of patients in Europe prescribed analgesia, report that they are affected by breakthrough pain (n=441). It also highlights that breakthrough pain can be a frequent occurrence – 26% experiencing it at least once a day (n=279). For further information please visit [www.epicsurvey.com](http://www.epicsurvey.com)

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.