

## NEWS RELEASE

### SOSEI CO. LTD

#### ***SOT-107 GRANTED ORPHAN DESIGNATION IN JAPAN***

*Tokyo/London, 14<sup>th</sup> February, 2005* - Sosei Co. Ltd., (4565, Tokyo Stock Exchange MOTHERS Index) announced today that SOT-107 has been granted orphan drug status for the treatment of glioma (type of brain tumour) by the MHLW (Ministry of Health, Labour and Welfare) in Japan. SOT-107, licensed from Xenova Group plc (NASDAQ: XNVA; London Stock Exchange: XEN), is being developed by the company initially for the recurrent form of this brain tumour. The medical need for improved treatment of this disease is very high as survival rates for patients suffering glioma are low.

Orphan drug designation will facilitate Sosei's initiation of clinical trials and provide a fast track approval process by the MHLW once trials have been completed and a dossier seeking marketing approval has been filed.

Mr. Shinichi Tamura, President & CEO of Sosei, commented: "This orphan drug status is a significant step for the development and commercialisation of SOT-107 in Japan and we will do our best to bring this product to patients as soon as possible. Sosei will continue its diligent efforts to develop drugs to satisfy the unmet needs of the market"

Mr. David Oxlade, Chief Executive Officer of Xenova said: "We welcome the decision to grant orphan drug designation to TransMID™ in Japan. Glioblastoma multiforme is an indication that is very poorly served by current treatments. The positive response from the MHLW in Japan, following that from the FDA and the EMEA, underlines the potential for TransMID™ in the worldwide market for brain tumour treatment."

The company in-licensed the rights for SOT-107, in Japan and Taiwan, from KS Biomedix Holdings plc. (now Xenova Group plc.) in November 2002. SOT-107 is a novel product, developed as TransMID™ in the EU/US. It is based on the transferrin-mediated delivery of a modified diphtheria toxin, which is capable of selectively killing cancer cells. A completed Phase II study conducted in a number of leading centres in the USA showed highly promising clinical response rates and an improvement in median survival times in patients with recurrent brain tumour from a historical average of 26 weeks up to 37 weeks. The FDA granted TransMID™ Fast Track status in August 2001 and Orphan Drug Status for the treatment of malignant tumours of the central nervous system in December 2001 and the European Medicines Agency's ("EMEA") Committee

for Orphan Medicinal Products granted Orphan designation for the treatment of glioma in March 2002. Phase III clinical trials started in the US and the EU in May 2004.

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Notes for editors:

**\*Orphan designation in Japan**

There are few incentives for industry to undertake the research, development and marketing of drugs for small patient populations. The orphan drugs system is intended to encourage the pharmaceutical industry to undertake the work on these drugs for the treatment of rare diseases.

MHLW designates a drug as an orphan drug according to the following criteria.

- 1) Patient population less than 50,000
- 2) No alternative drugs are available or much higher efficacy or safety compared to existing drugs
- 3) Theoretical basis for the application and a feasible plan to develop

Orphan designated drugs may receive the following support measures from the government.

- a) Grant money up to a half of the development study costs
- b) Tax deduction
- c) Free advice for studies for IND/NDA
- d) Prioritized examination for NDA
- e) Extended re-examination period up to 10 years (period when generics cannot appear)

**\*TransMID™:**

TransMID™ is a treatment initially being developed for glioblastoma multiforme (a type of brain cancer), a disease for which improved treatment is essential, as there remains a poor prognosis for patients. TransMID™ is a modified diphtheria toxin conjugated to transferrin. When TransMID™ binds to transferrin receptors expressed on the surface of glioma cells, the diphtheria toxin gains entry to the cell. Once inside the cell, the diphtheria toxin interferes with protein synthesis and ultimately kills the cell. Transferrin receptors are particularly prevalent on rapidly dividing cells, and the high level of transferrin receptor expression on glioma cells relative to normal brain tissue makes transferrin an appropriate targeting mechanism for the diseased cells.

TransMID™ is pumped directly into the brain tumour using CED (Convection Enhanced Delivery - licensed from the National Institutes of Health, Bethesda, Maryland, USA). CED enhances the distribution of TransMID™ through the tumour mass and produces high local concentrations of drug. This also has the benefit of circumventing the usual obstacles present in

drug delivery to the brain caused by the blood-brain barrier.

Phase I and Phase II clinical trials for TransMID™ have been successfully completed in patients suffering from inoperable, recurrent high grade gliomas who have failed to respond to other forms of treatment. A Phase I dose-escalating study was performed at the National Institutes of Health in the US and was followed by a Phase II multi-centre study at nine premier US medical centres.

In a Phase II study, 50% or greater reduction in tumour volume was noted in 35% of evaluable patients, with a corresponding increase in life expectancy in those patients that did respond. Median survival time for patients receiving TransMID™ was approximately 37 weeks. This compares to the historic average life expectancy of approximately 26 weeks for patients with this condition being treated with best standard of care.

TransMID™ is currently licensed to Nycomed Denmark A/S in Europe, Sosei Co Ltd in Japan, Medison Pharma Ltd in Israel and Ranbaxy Laboratories Limited in India. The rights to TransMID™ in North America have been retained by Xenova Group plc.

#### **About Sosei Co. Ltd.**

Sosei Co. Ltd. founded in 1990 by Shinichi Tamura, the ex-CEO of Genentech Japan, is a leading Japanese biopharmaceutical company with significant expertise in drug development. It enriches its core product pipeline by in-licensing compounds from Western and Japanese companies, by its distinctive Drug Reprofiling Platform® (DRP®) and through new molecular entity (NME) research programmes in collaboration with biopharmaceutical companies and universities both in Japan and the West. Sosei is also developing its own sales and marketing organization in Japan. The company is capitalising on its extensive global network established over the past 10 years in its successful technology transfer business. For further information about Sosei, please visit [www.sosei.com](http://www.sosei.com).

#### **About Xenova Group plc.**

Xenova Group plc is a UK-based biopharmaceutical company focused on the development of novel drugs to treat cancer and addiction with a secondary focus in immunotherapy. The Company has a broad pipeline of products in clinical development, including three cancer programmes: its lead product TransMID™, for the treatment of glioblastoma multiforme, is in Phase III trials, and its novel DNA targeting agents and XR303 are both in Phase I for cancer indications. Xenova is also developing two therapeutic vaccines for cocaine and nicotine addiction, which are in Phase II and Phase I trials respectively. Quoted on the London Stock Exchange (XEN) and on NASDAQ (XNVA), Xenova employs approximately 75 people in the UK and North America

(Reuters XEN.L; Bloomberg XEN LN). For more information on Xenova, visit the company's website at [www.xenova.com](http://www.xenova.com).

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