



## **Sosei Announces Completion of Phase III Trial for NorLevo®**

**Tokyo, Japan – 10 July 2008:** Sosei Group Corporation (“Sosei”; TSE Mothers Index: 4565), the biopharmaceutical company, today announced the completion of a Japanese Phase III clinical trial for the emergency contraceptive pill (ECP) SOH-075 (NorLevo®). Sosei acquired the exclusive distribution rights to the product in Japan from HRA Pharma.

The clinical study was designed to evaluate the safety and prevented pregnancy rate of SOH-075 in Japanese adult female subjects who require emergency contraception. No serious adverse events were reported during the study.

Further announcement will be made when all study results are fully analysed.

NorLevo® is an oral emergency contraceptive “morning after pill” which is used to prevent pregnancy after unprotected intercourse. NorLevo® contains only levonorgestrel as an active ingredient. The dosing is started within 72 hours after unprotected sexual intercourse. NorLevo® was first launched in Europe in 1999 and is currently approved in some 60 countries, the product being both well-tolerated and effective as an oral emergency contraceptive for post-coital use.

“We are delighted to announce the completion of Phase III trial of SOH-075, which will be the first ECP to be introduced into Japan. We believe that this product will meet one of the needs of Japanese women and that the trial will confirm that NorLevo® is as safe and effective in this population as has already been demonstrated in other countries” said Mr Shinichi Tamura, Chief Executive Officer of Sosei.

André Ulmann, CEO of HRA Pharma added: “We’re very proud of reaching this important milestone in Japan. We hope that, access to emergency contraception will benefit Japanese women and families by improving reproductive health.”

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## **Enquiries:**

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## **Editor's notes:**

### **levonorgestrel**

ECP is necessary for women who may be concerned about the possibility of an unwanted pregnancy following unprotected intercourse. Two large multinational studies, aiming to test a 12-24h regimen (Lancet, 1999) and a single administration (Lancet, 2002), both performed by the World Health Organisation (WHO) demonstrated that levonorgestrel mono therapy, such as NorLevo®, was well-tolerated and more effective than the Yuzpe method (ethinyl estradiol and levonorgestrel), a traditional emergency contraception method used since 1977. Levonorgestrel mono therapy for emergency contraception is listed as an essential drug by the WHO.

### **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 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 HRA Pharma**

HRA Pharma creates innovative medicines and products for women's and reproductive health, endocrine diseases, and cell-based therapies. The Company discovers, develops and markets its own products and licenses-in third party products as well. The company markets its products in more than 50 countries either through its own sales force or through a network of distributors and licensees.

For further information please visit the website at [www.hra-pharma.com](http://www.hra-pharma.com)