



## **Sosei Announces Completion of Phase I Trial for NorLevo<sup>®</sup>**

**Tokyo, Japan – 13 August 2007:** Sosei Group Corporation (“Sosei”; TSE Mothers Index: 4565), the biopharmaceutical company, today announced the completion of a Japanese Phase I clinical trial for the emergency contraceptive pill (ECP) SOH-075 (NorLevo<sup>®</sup>). Sosei acquired the exclusive distribution rights to the product in Japan from HRA Pharma.

The clinical study was a randomised, double blind, placebo-controlled trial designed to evaluate the safety and pharmacokinetics of SOH-075 in healthy Japanese adult female volunteers. A total of 33 subjects in three cohorts were enrolled at a single study centre. The trial achieved all of its primary and secondary endpoints.

NorLevo<sup>®</sup> is an oral emergency contraceptive “morning after pill” which is used to prevent pregnancy after unprotected intercourse. NorLevo<sup>®</sup> contains only levonorgestrel as an active ingredient. The dosing is started within 72 hours after unprotected sexual intercourse. Since it inhibits pregnancy before the implantation of the egg, it is not a controversial pregnancy termination pill, but a helpful opportunity for post-coital contraception. NorLevo<sup>®</sup> has been approved in 65 countries and is both well-tolerated and effective as an oral emergency contraceptive for post-coital use.

“We are delighted to complete our Phase I study of SOH-075, which is the only ECP under development in Japan. We will do our best to provide this product, which is widely used elsewhere in the world, to women in Japan” said Mr Shinichi Tamura, Chief Executive Officer of Sosei.

André Ulmann, CEO of HRA Pharma added: “This Phase I result provides further validation of NorLevo<sup>®</sup> as an ECP. We are delighted to see our product progress further towards commercialisation in Japan.”

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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. As a result of a large multinational study in 1998, the World Health Organisation (WHO) demonstrated that levonorgestrel mono therapy, such as NorLevo<sup>®</sup>, 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 is a private pharmaceutical company that creates and markets innovative medicines and products for women's and reproductive health, hormonal cancer treatments and cell-based therapies.

Its first product, NorLevo<sup>®</sup> emergency contraception, was launched in France in 1999 and has been approved in 65 countries. The company has four other marketed products and a strong R&D pipeline. Its products are marketed through global marketing partners and through its own sales organisation in France and parts of Europe.

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