



## **Sosei Announces Letter of Intent with Shin Nippon Biomedical Laboratories, and Project Finance**

- *Sosei and SNBL have executed a Letter of Intent to negotiate the terms for co-development of pharmaceutical products*
- *Sosei has decided to finance the initial period expenses for the SNBL and G2B Pharma co-development project of a nasally-delivered adrenaline (epinephrine) formulation for treating anaphylaxis*
- *Sosei will receive a portion of future G2B revenues, as well as the first negotiation rights for the future investments and the right to negotiate the licensing of worldwide development and commercialization rights for this project*

**Tokyo, Japan – 13 August 2014:** Sosei Group Corporation (“Sosei”; TSE Mothers Index: 4565) is pleased to announced that it has executed a non-binding letter of intent (“LOI”) with Shin Nippon Biomedical Laboratories, Ltd. (“SNBL”, Chairman and CEO Ryoichi Nagata, Tokyo, Japan) to negotiate the terms for co-development of pharmaceutical products based on SNBL’s nasal delivery technology platform<sup>1</sup>.

As a part of its translational research business<sup>2</sup>, SNBL conducts research and development of nasal formulations, based on its novel nasal delivery technology, and out-licenses its platform technology to multiple pharmaceutical companies. Part of Sosei’s pipeline strategy has been drug reprofiling<sup>3</sup>, an approach that enables identifying new uses for existing drugs (either halted or marketed), and as a part of its reprofiling strategy Sosei utilizes APNT<sup>4</sup> (a core technology platform for nanonizing insoluble solutions) for research and development.

Sosei and SNBL will enter the negotiations for co-development that would make the maximum use of Sosei’s expertise in reprofiling and formulation development, with SNBL’s expertise in nasal delivery technology and development know-how.

In addition, prior to executing the LOI, a joint project for development and commercialization of nasally-delivered adrenaline (epinephrine) formulation for treating anaphylaxis has been initiated.

SNBL and G2B Pharma Inc. (“G2B”, Chairman and CEO, Nigel Ten Fleming, San Francisco, USA) have decided to jointly develop nasally-delivered adrenaline (epinephrine) formulation for treating anaphylaxis. Sosei has recognized that the project has the potential to fulfill clinically unmet medical needs, and has decided to finance the initial period expenses for this project. At the same time, SNBL has provided a licensing option for its nasal platform technology to G2B. In return for financing the project, Sosei will receive a part of future G2B revenue, as well as the first negotiation right for the future investments and the right to negotiate the licensing of worldwide development and commercialization rights for this project.

Sosei and SNBL tie-up will not be limited to this project only. Both parties will enter the negotiations for future wide spectrum collaboration that would make a maximum use of both sides’ know-how and technologies.

**Enquiries:**

Sosei Group Corporation  
Tokyo Office  
Milica STOJKOVIC,  
Investor Relations  
+81-(0)3-5210-3399  
mstojkovic@sosei.com

London Office  
Kathryn LYDON, PA to CEO & Corporate  
Communication  
+44-(0)20-7691-0983  
klydon@sosei.com

**About Sosei**

Sosei is an international biopharmaceutical company anchored in Japan with a global reach. It practises a reduced risk business model by acquiring compounds from, and bringing compounds into, Japan through exploitation of its unique position within global markets.

For further information about Sosei, please visit [www.sosei.com](http://www.sosei.com).

**About Shin Nippon Biomedical Laboratories**

For more than 55 years, SNBL has been a leader in helping biopharmaceutical companies generate high quality data with the exceptional precision needed to rapidly advance new medical therapies and innovations that improve patients' lives. SNBL's business consists of contract research in preclinical studies, clinical pharmacology studies, pharmacokinetics/bioanalysis, and clinical studies, as well as SMO business. In the recent years, SNBL is aggressively expanding the Translational Research business.

For further information about SNBL, please visit [www.snbl.com](http://www.snbl.com).

**About G2B Pharma**

G2B Pharma Inc. is a specialty pharmaceutical company, focused on the reformulation of off-patent drugs. G2B's mission is to take drugs that have recently come off patent and reformulate them into a different dosage form that may achieve clinically significant benefits.

For further information about G2B, please visit [www.g2bpharma.com](http://www.g2bpharma.com).

**About Anaphylaxis**

Anaphylaxis is a systemic and life-threatening allergic reaction characterized by anaphylactic shock associated with a decrease in blood pressure and deterioration in consciousness. Especially anaphylactic shocks triggered by food allergies in babies and school children represent a serious social issue. The prevalence of food allergies is estimated at 1-2 % in Japan and 3-4% in the US<sup>1</sup> and has been increasing in the recent years. At present, when a baby or a child experiences anaphylactic shock at home or school, guardian or a teacher needs to administer an adrenaline injection within 30 minutes from the anaphylactic reaction. However, a person without medical background may feel confusion, fear and reluctance to give an injection, and the psychological burden may prevent providing the necessary medical attention, sometimes causing fatal consequences. G2B is focused on the development of a needle-free alternative for epinephrine using the nasal delivery route, and has partnered in this effort with SNBL. The data from animal studies have shown that SNBL's nasal delivery platform together with G2B's adrenaline formulation demonstrates rapid and high absorption, and that has a potential to become a novel anaphylaxis treatment.

## Notes

- <sup>1</sup> Nasal Delivery Technology - SNBL has discovered and developed an innovative nasal delivery technology, consisting of a muco-adhesive powder drug carrier designed for enhanced drug absorption and nasal delivery devices. The technology, now protected by international patent, is a versatile platform technology that can be applied to a broad range of drugs. Safety and efficacy of the technology have been proven in a number of clinical studies. For more information please visit [www.snbl-nds.co.jp](http://www.snbl-nds.co.jp)
- <sup>2</sup> Translational research - translates the findings of basic research into clinical applications quickly and efficiently, in order to bring new drugs to those in need as early as possible. SNBL utilizes its pre-clinical and clinical development facilities to develop value-adding technologies and provides them to the pharmaceutical and medical industry.
- <sup>3</sup> Drug reprofiling – one of Sosei's development strategies that is based upon identifying new uses for existing drugs (either halted or marketed), or drug templates for which clinical development has been undertaken and the safety profile in humans confirmed.
- <sup>4</sup> APNT – (Activus Pure Nanoparticle Technology) unlike other nano-particle processing technologies, keeps compounds virtually free from contamination. At the same time, it can yield pharmaceutical ingredients with particle sizes ranging from 50 to 300nm levels. Thus, APNT enables the development of injections, ophthalmic solutions and inhalations with poorly soluble compounds where high purity is required.

## References

- \* Reference: Clinical Research Center for Allergy and Rheumatology, National Hospital Organization Sagamihara National Hospital, "Guideline for Care of Food Allergy 2011"

## Forward-looking statements

*This press release contains forward-looking statements, including statements about the discovery, development and commercialisation of products. Various risks may cause Sosei's actual results to differ materially from those expressed or implied by the forward-looking statements, including: adverse results in clinical development programmes; failure to obtain patent protection for inventions; commercial limitations imposed by patents owned or controlled by third parties; dependence upon strategic alliance partners to develop and commercialise products and services; difficulties or delays in obtaining regulatory approvals to market products and services resulting from development efforts; the requirement for substantial funding to conduct research and development and to expand commercialisation activities; and product initiatives by competitors. As a result of these factors, prospective investors are cautioned not to rely on any forward-looking statements. We disclaim any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.*