Generex Announces Collaboration with Shenzhen BioScien Pharmaceuticals to Develop and Commercialize the AE37 Immunotherapeutic Vaccine for the Treatment of Prostate Cancer in China

Generex to receive a $700,000 USD up-front license fee; deal includes milestone payments and royalties

MIRAMAR, Florida, December 7, 2017 (BUSINESS WIRE) – Generex Biotechnology Corporation (OTCQB:GNBT) (http://www.otcmarkets.com/stock/GNBT/quote) (www.generex.com) today announced that its wholly-owned subsidiary, Antigen Express, Inc. (www.antigenexpress.com), has entered into a License and Research Agreement with Shenzhen BioScien Pharmaceuticals Co. Ltd. www.BioScien.cn to develop and commercialize the Antigen Express AE37 immunotherapeutic vaccine for prostate cancer in the People's Republic of China (including Taiwan, Hong Kong, and Macau).

A previously completed Phase I study of the vaccine conducted by Antigen Express in patients with prostate cancer demonstrated robust, long-term, and specific activation of cancer-fighting T cells in immunized patients.

Shenzhen BioScien will pay Generex a non-refundable, up-front license fee of $700,000 USD. Under the Agreement, Shenzhen BioScien will also make milestone payments to Generex of $1,000,000 USD each upon completion of the Phase II and Phase III clinical studies of the vaccine as well as a milestone payment of $2,000,000 USD upon regulatory approval of the vaccine in the territory. Generex will also receive a 10% royalty on net sales of the product.

Under the Agreement, Shenzhen BioScien has responsibility for paying for and conducting the clinical trials, securing Chinese regulatory approvals, and the manufacturing, marketing, distribution, and sale of the product. The clinical trials will be designed and conducted so as to meet the regulatory requirements of the U.S. Food and Drug Administration and the European Medicines Agency and Antigen Express will have free access to all data for support of global regulatory filings and further development and commercialization initiatives outside the licensed territories.

The AE37 vaccine is designed using a proprietary technology platform that ensures a more robust and long-lasting immune response than would be possible otherwise. In addition to the Phase I prostate study, the clinical activity of AE37 has been demonstrated in a controlled, randomized Phase II study in 300 breast cancer patients. Based on encouraging efficacy data from that study, the Company has entered into an agreement with Merck (d.b.a. as Merck Sharp

& Dohme outside the United States and Canada) to evaluate Antigen's AE37 cancer vaccine in combination with Merck's anti-PD-1 (programmed death receptor-1) therapy, KEYTRUDA® (pembrolizumab), in patients with metastatic triple-negative breast cancer.

"We are delighted that Shenzhen BioScien will continue development of AE37 for prostate cancer," said Joe Moscato, President & Chief Executive Officer of Generex. "AE37 is the lead compound being developed using our Antigen Express technology platform. The clinical studies conducted to date establish the wide applicability of AE37 and its underlying Ii-Key technology. This license, together with the Merck collaboration, highlights the value of the core assets of Generex as we reinvigorate those assets in the wake of our recently completed reorganization."

"The AE37 cancer vaccine has shown impressive results in clinical trials," said Dr. Yinke Yang, Chief Executive Officer of Shenzhen BioScien. "We are pleased to be able to include this in our innovative pipeline of novel therapeutics."

Cautionary Note Regarding Forward-Looking Statements

This release and oral statements made from time to time by Generex representatives in respect of the same subject matter may contain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These statements can be identified by introductory words such as "expects," "plan," "believes," "will," "achieve," "anticipate," "would," "should," "subject to" or words of similar meaning, and by the fact that they do not relate strictly to historical or current facts. Forward-looking statements frequently are used in discussing potential product applications, potential collaborations, product development activities, clinical studies, regulatory submissions and approvals, and similar operating matters. Many factors may cause actual results to differ from forward-looking statements, including inaccurate assumptions and a broad variety of risks and uncertainties, some of which are known and others of which are not. Known risks and uncertainties include those identified from time to time in the reports filed by Generex with the Securities and Exchange Commission, which should be considered together with any forward-looking statement. No forward-looking statement is a guarantee of future results or events, and one should avoid placing undue reliance on such statements. Generex undertakes no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise. Generex claims the protection of the safe harbor for forward-looking statements that is contained in the Private Securities Litigation Reform Act.

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