

## **Generex Biotechnology Provides Update on NuGenerex Immuno-Oncology**

- Update on AE37 Clinical Trial
- NuGenerex Immuno-Oncology Spin Out and Stock Dividend

MIRAMAR, FL, January 4, 2019 Generex Biotechnology Corporation (OTCQB:GNBT) is pleased to provide an update on operational and strategic developments at NuGenerex Immuno-Oncology (previously Antigen Express), a wholly-owned subsidiary.

The protocol for the Phase II clinical trial of pembrolizumab (Keytruda®) in combination with the AE37 Peptide Vaccine in patients with metastatic triple negative breast cancer is under review at the Institutional Review Board (IRB) with oversight of this NSABP Foundation managed study. Site selection has begun, and study drugs are being packaged for shipment to study sites.

“With the initiation of the AE37/PD-1 Inhibitor combination trial and the advancement of the company’s clinical development partnership with Shenzhen BioScien for AE37 in prostate cancer, we have validated the li-Key technology, as a viable immunotherapy platform,” said Richard Purcell, SVP of R&D at Generex. “The li-Key can activate a CD-4 T-cell immune response against any peptide to which it is linked. Given the advances in immunotherapy in the last couple of years, and the potential combinations with checkpoint inhibitors like pembrolizumab, NuGenerex Immuno-Oncology is positioned, with years of clinical experience in immunotherapy of cancer, to explore a range of opportunities for the li-Key technology in personalized medicine using tumor-associated antigens and neo-antigens for tumor-specific cancer therapy. To that end, Generex has initiated partnering discussions with synergistic companies to explore co-development and collaborative R&D opportunities for immunotherapeutic product development.”

### **NuGenerex Immuno-Oncology Spin-Out & Stock Dividend**

Generex President & Chief Executive Officer Joe Moscato stated, “NuGenerex Immuno-Oncology is being established to not only to advance the NuGenerex Immuno-Oncology core technology, but also to expand the Company’s portfolio in the field of immunotherapy and personalized medicine through partnerships and acquisitions. As part of our strategy, we are exploring opportunities to spin-out NuGenerex Immuno-Oncology as a separate DTC-eligible SEC registered company. Mr. Moscato stated that following the spin-out, NuGenerex Immuno-Oncology is expected to seek to list its common stock on a national stock exchange. “The spin-out of NuGenerex Immuno-Oncology into a separate, publicly

traded entity has been the focus of the Generex strategic development plan in cancer drug development," Mr. Moscato indicated. "The li-Key technology has been underappreciated for too long, as we have advanced the immunotherapy field with the largest breast cancer vaccine study ever conducted, and now the results of that trial have led to an exciting combination Phase II trial with AE37 plus Ketruda® in triple negative breast cancer. We believe this spin-out will help to unlock the true value of the li-Key technology for our stockholders as it creates a pure play in immunotherapy, which will foster investment and collaboration."

The spin-out will be accomplished by the issuance of one or more dividends of NuGenerex Immuno-Oncology stock to Generex stockholders. The record dates in respect of such dividends are yet to be determined and will be announced in due course. The stock dividends will enable Generex stockholders to directly participate in the promising future of NuGenerex Immuno-Oncology as well as create a large shareholder base with the potential for substantial liquidity on an immediate basis. That liquidity will be further enhanced should NuGenerex Immuno-Oncology be successful in attaining a national stock exchange listing, and should provide NuGenerex Immuno-Oncology with ready access to the capital markets to finance its on-going clinical and regulatory initiatives.

Following the issuance of stock dividends, Generex expects to retain a controlling interest in NuGenerex Immuno-Oncology, but the exact proportion of the shares to be held by Generex has not yet been determined.

Subject to market conditions and the satisfaction of regulatory requirements, it is expected that the NuGenerex Immuno-Oncology spin-out will occur sometime following the upcoming Annual Meeting of the Generex stockholders. Generex has formed a committee to seek qualified professionals to populate NuGenerex Immuno-Oncology's Board of Directors, Scientific Advisory Board, and executive management team. Further announcements in respect of the status of the spin-out are expected to be made over the course of the coming months.

### **About Generex Biotechnology Corporation**

Generex is a strategic, diversified healthcare holdings company with offerings in a variety of services, diagnostics, medical devices, and pharmaceutical development. The Company's direct-to-patient services support its strategy of all-inclusive access to doctors, diagnostics, therapeutics, and additional health-related services to greatly improve the patient experience in receiving care. On the provider side, Generex's management services remove administrative burdens in multiple provider settings, including private practice and hospital, allowing doctors to devote more time to patient care. Revenue from the Company's subsidiaries will support clinical advancement of its wholly owned therapeutic products with a focus in immunotherapeutics based on stimulating critical members of the immune

response, known as T helper cells, and its proprietary buccal administration of insulin.

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