Genprex Provides Clinical and Corporate Update for Third Quarter 2018

November 20, 2018

AUSTIN, Texas--(BUSINESS WIRE)--Nov. 20, 2018-- Genprex, Inc. (NASDAQ:GNPX), a clinical stage gene therapy company developing a new approach to treating cancer based upon a novel proprietary technology platform, today announced a clinical and corporate update, and the filing of quarterly results for the third quarter ended September 30, 2018 on Form 10-Q with the Securities and Exchange Commission.

Rodney Varner, Chairman and CEO, remarked, “Over the past quarter, we have taken steps to advance our clinical development activities. We extended our ability to strengthen our patent protection for our TUSC2 gene platform, expanded our collaborations and augmented our team. Most notably, we added Jan Stevens, RN, whose expertise in clinical operations will be invaluable as we look to expand our Phase I/II clinical study evaluating Oncoprextm in combination with Tarceva® for treatment of Stage IV or recurrent non-small cell lung cancer (NSCLC).”

Julien L. Pham, MD, MPH, President and Chief Operating Officer, stated, “We are confident in our choice of Aldevron as a plasmid manufacturing partner and look forward to working with them to continue our clinical trials of our immunogene therapy Oncoprex™ for the treatment on non-small cell lung cancer.”

Clinical Development and Corporate Update

- Entered into amendments with The University of Texas MD Anderson Cancer Center (MD Anderson) to extend the terms of two option agreements between Genprex and MD Anderson pertaining the use of TUSC2, the active agent in Genprex’s lead product candidate Oncoprex, in combination with immunotherapies and the development and the use of biomarkers to predict patient response to TUSC2 therapy.
- Entered into an agreement with Aldevron, a leading contract manufacturing organization, to supply TUSC2 (Tumor Suppressor Candidate 2) plasmid DNA for use in Genprex’s clinical development program evaluating Oncoprex for the treatment of NSCLC.
- Entered into agreements with additional contract manufacturing organizations to assist with manufacturing scale-up and transfer of manufacturing processes from manufacturing facilities of the University of Texas MD Anderson Cancer Center to commercial facilities.
- Appointed Jan Stevens, RN as Vice President of Clinical Operations in October 2018. Ms. Stevens joined the Company’s Cambridge office to lead clinical operations and support corporate development efforts, focusing on expanding research and clinical development opportunities, including the expansion of Genprex’s Oncoprex + Tarceva combination trial across multiple US sites.

Third Quarter 2018 Financial Update

Genprex’s research and development expense was $489,689 for the three months ended September 30, 2018 as compared to $55,517 for the three months ended September 30, 2017. The increase in the current year period was driven entirely by increased R&D and commercialization activities associated with the development of our drug candidate and the progression of our Phase I/II clinical trial at MD Anderson.

Genprex had a cash position of $10.3 million as of September 30, 2018.

Forward Looking Statements

Statements contained in this press release that are not statements of historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Because these statements are subject to risks and uncertainties, the actual results may differ materially from those expressed or implied by such forward-looking statements. Such statements include, but are not limited to, statements regarding the effect of TUSC2 on cancer, either alone or in combination with other drugs, the effect of methods for predicting patients’ response to therapy, the products and services we expect to receive from Aldevron and contract manufacturing organizations and the effect of those products and services on the development of Oncoprex™, statements about Genprex’s business plans, statements about the timing and success of the Company’s existing and planned clinical trials, statements about the development of the Company’s current and potential future product candidates and statements about the Company’s plans to seek regulatory approval of its product candidates. Risks that contribute to the uncertain nature of the forward-looking statements include: the presence and level of TUSC2’s effect on cancer; the ability of Aldevron and contract manufacturing organizations to provide products and services to the Company and the Company’s ability to utilize those products and services; the ability of the products and services of Aldevron and contract manufacturing organizations to influence the development of Oncoprex™; the effect on cancer of combining TUSC2 with immunotherapies, EGFR inhibitors, or other drugs; whether or not Genprex will be able to negotiate and execute final technology license agreements under the extended options with MD Anderson; the nature and scope of protection ultimately provided under any of the licensed patents and patent applications should such technology license agreements be executed; the timing, success and cost of the Company’s clinical trials and planned clinical trials of TUSC2 and Oncoprex and other potential product candidates; the timing and success of obtaining FDA approval of Oncoprex and the Company’s other potential product candidates; the success, cost and timing of the Company’s product candidate development activities; the Company’s ability to execute on its strategy; regulatory developments in the United States and foreign countries; and the Company’s estimates regarding expenses, future revenue and capital requirements. These and other risks and uncertainties are described more fully under the caption "Risk Factors" and elsewhere in Genprex’s filings and reports with the United States Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made. Genprex does not undertake any obligation to update these statements to reflect any events that occur or facts that exist after the date on which the statements were made.

About Genprex, Inc.
Genprex, Inc. is a clinical stage gene therapy company developing a new approach to treating cancer, based upon a novel proprietary technology platform, including Genprex's initial product candidate, Oncoprex™ immunogene therapy for non-small cell lung cancer (NSCLC). Genprex's platform technologies are designed to administer cancer fighting genes by encapsulating them into nanoscale hollow spheres called nanovesicles, which are then administered intravenously and taken up by tumor cells where they express proteins that are missing or found in low quantities. Oncoprex has a multimodal mechanism of action whereby it interrupts cell signaling pathways that cause replication and proliferation of cancer cells, re-establishes pathways for apoptosis, or programmed cell death, in cancer cells, and modulates the immune response against cancer cells. Oncoprex has also been shown to block mechanisms that create drug resistance. Visit the company's web site at www.genprex.com or follow Genprex on Twitter at https://twitter.com/genprex and Facebook at https://www.facebook.com/genprexinc/.

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