# Genprex Receives U.S. FDA Fast Track Designation for Gene Therapy that Targets Lung Cancer

*January 21, 2020*

*Lung cancer is the world's leading cause of cancer deaths*

AUSTIN, Texas & CAMBRIDGE, Mass.— (Jan. 21, 2020) — Genprex, Inc.("Genprex" or the "Company") (NASDAQ: GNPX), a clinical-stage gene therapy company utilizing a unique, non-viral proprietary platform designed to deliver tumor suppressor genes to cancer cells, today announced that the U.S Food and Drug Administration (FDA) has granted Fast Track Designation for Genprex's Oncoprex™ immunogene therapy in combination with EGFR inhibitor osimertinib (AstraZeneca's Tagrisso®, which had worldwide sales in 2018 of $1.86 billion, $2.31 billion in the first 9 months of 2019 and is currently AstraZeneca's highest grossing product) for the treatment of non-small cell lung cancer (NSCLC) patients with EFGR mutations that progressed after treatment with osimertinib alone. Oncoprex is comprised of the TUSC2 (Tumor Suppressor Candidate 2) gene complexed with a lipid nanoparticle. TUSC2 is the active agent in Oncoprex.

Genprex has treated more than 50 lung cancer patients with Oncoprex in Phase I and II clinical trials.  The company believes the data from these trials are encouraging as to both safety and efficacy.

> Varner, Chairman and Chief Executive Officer of Genprex.“In addition to potentially facilitating and expediting our pathway to approval, we believe that this FDA designation validates our plan to commercialize Oncoprex immunogene therapy in combination with EGFR inhibitors for the treatment of lung cancer. We hope that Fast Track Designation helps us bring our gene therapy to patients more rapidly and that our unique gene therapy platform is more widely recognized for its potential in cancer treatment.”

FDA may award Fast Track Designation if it determines that a drug demonstrates the potential to address unmet medical needs for a serious or life-threatening disease or condition.This provision is intended to facilitate development and expedite review of drugs to treat serious and life-threatening conditions so that an approved product can reach the market expeditiously.

Fast Track drug candidates must show advantages over available therapies, such as superior effectiveness, avoiding serious side effects, improving diagnosis and outcome, decreasing significant toxicity, and the ability to address public health needs.

Fast Track Designation recipients may also be eligible for accelerated approval or rolling review of the recipient’s Biologics License Application (BLA). In addition, Fast Track product candidates could be eligible for priority review if supported by clinical data at the time of BLA submission.

The initial disease indication for Oncoprex is NSCLC. Lung cancer isthe world’s leading cause of cancer death, taking more lives each year than colon, breast and prostate cancers combined. Each year, there are more than 2 million new lung cancer cases and 1.7 million deaths from lung cancer worldwide. In the United States, there are more than 228,000 new cases of lung cancer and more than 142,000 deaths from lung cancer each year. NSCLC represents 84 percent of all lung cancers, and the five-year relative survival rate for metastatic lung cancer is less than 5 percent.

Genprex is preparing to initiate a Phase I/II clinical trial evaluating Oncoprex in combination with osimertinib, as well as a new Phase I clinical trial evaluating Oncoprex in combination with a checkpoint inhibitor.For more information on the U.S. FDA’s Fast Track Designation, please visit the FDA’s Fast Track webpage.

**About Genprex, Inc.**

Genprex, Inc. is a clinical-stage gene therapy company developing potentially life-changing technologies for cancer patients based upon a unique proprietary technology platform.

administered intravenously and taken up by tumor cells where they express proteins that are missing or found in low quantities. The company's lead product candidate, Oncoprex™ immunogene therapy for non-small cell lung cancer (NSCLC), has a multimodal mechanism of action whereby it has been shown to interrupt cell signaling pathways that cause replication and proliferation of cancer cells, re-establish pathways for apoptosis, or programmed cell death, in cancer cells, and modulate the immune response against cancer cells. Oncoprex has also been shown to block mechanisms that create drug resistance. For more information, please visit the company's web site at www.genprex.com or follow Genprex on Twitter, Facebook and LinkedIn.

**Forward-Looking Statements**

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, 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 effects of Oncoprex, or Oncoprex in combination with immunotherapies, and Oncoprex combined with immunotherapies and chemotherapies, on cancer, as well as the potential benefits of Fast Track Designation to us. Risks that contribute to the uncertain nature of the forward-looking statements include risks relating to the presence and level of the effects of Oncoprex, alone and in combination with immunotherapies and chemotherapies, on cancer, the safety and effectiveness of Oncoprex, alone and in combination with immunotherapies and chemotherapies, as well as the timing and success of our clinical trials and planned clinical trials of Oncoprex™ and our other potential product candidates. Other risks and uncertainties associated with Genprex and its lead product candidate Oncoprex are described more fully under the caption "Risk Factors" and elsewhere in our 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. We undertake no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

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