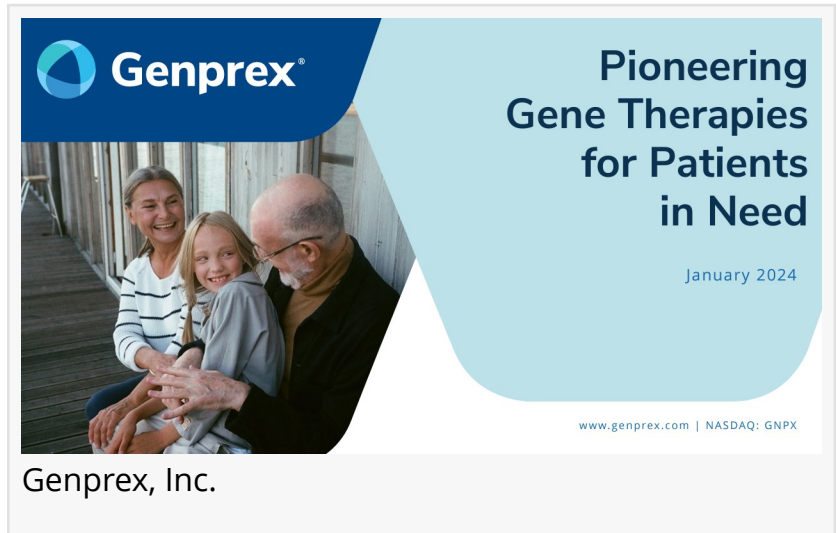


# Clinical Trials Commenced for Immunogene Therapy: Advancing Small Cell Lung Cancer Treatment : Genprex; NASDAQ: GNPX

*GNPX in combination with Genentech's Tecentriq® to treat patients with extensive-stage small cell lung cancer. Genentech became a member of the Roche Group*

AUSTIN, TEXAS, UNITED STATES , May 14, 2024 /EINPresswire.com/ -- Clinical Trials Commenced for Promising Acclaim-3 Reqorsa® Immunogene Therapy in Combination with Tecentriq® to Treat Small Cell Lung Cancer: Genprex, [Inc. \(NASDAQ: GNPX\)](https://www.genprex.com)



Genprex, Inc.

GNPX in combination with Genentech's Tecentriq® to treat patients with extensive-stage small cell lung cancer. Genentech became a member of the Roche Group in March of 2009.



We are excited to take this next step in our fight against lung cancers as we work to advance an innovative therapy that we believe provides hope to patients suffering with ES-SCLC"

*Ryan Confer, President and Chief Executive Officer at Genprex*

For more information on \$GNPX visit: [www.genprex.com](https://www.genprex.com) and <https://compasslivemedia.com/gnpx/>

Gene Therapy Focused on Life-Changing Developments for Cancer and Diabetes.

Working With World-Class Institutions and Collaborators to Provide Novel Treatment Approaches.

New Top Company Officers Appointed with High

Qualifications and Experience.

First Patient Dosed in Acclaim-3 Clinical Study of Reqorsa® Immunogene Therapy in Combination

with Tecentriq® to Treat Small Cell Lung Cancer

Expects to Initiate the Phase 2 Expansion Study in the Second Half of 2024.

Acclaim-3 Study Supported by FDA Orphan Drug and Fast Track Designations.

High Profile Presentations at May 2024 Investor and Industry Conferences.

Compelling Data Validates the Potential of Reqorsa® Immunogene Therapy and the Oncoprex® Delivery System as Innovative Cancer Treatments.

Genprex, Inc. ([Nasdaq: GNPX](#)) is a clinical-stage gene therapy company focused on developing life-changing therapies for patients with cancer and diabetes. GNPX technologies are designed to administer disease-fighting genes to provide new therapies for large patient populations with cancer and diabetes who currently have limited treatment options. GNPX works with world-class institutions and collaborators to develop drug candidates to further its pipeline of gene therapies in order to provide novel treatment approaches. The GNPX oncology program utilizes its systemic, non-viral Oncoprex® Delivery System

which encapsulates the gene-expressing plasmids using lipid-based nanoparticles in a lipoplex form. The resultant product is administered intravenously, where it is taken up by tumor cells that then express tumor suppressor proteins that were deficient in the tumor.

The GNPX lead product candidate, Reqorsa® Immunogene Therapy (quaratusugene ozeplasmid), is being evaluated in three clinical trials as a treatment for NSCLC and SCLC. Each of the GNPX



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Genprex, Inc. NASDAQ: GNPX



Cancer Gene Therapy: NASDAQ: GNPX

three lung cancer clinical programs has received a Fast Track Designation from the FDA for the treatment of that patient population, and the GNPX SCLC program has received an FDA Orphan Drug Designation.

The GNPX diabetes gene therapy approach is comprised of a novel infusion process that uses an AAV vector to deliver Pdx1 and MafA genes directly to the pancreas. In models of Type 1 diabetes, GPX-002 transforms alpha cells in the pancreas into functional beta-like cells, which can produce insulin but may be distinct

enough from beta cells to evade the body's immune system. In a similar approach, GPX-002 for Type 2 diabetes, where autoimmunity is not at play, is believed to rejuvenate and replenish exhausted beta cells.



GNPX Doses First Patient in Acclaim-3 Clinical Study of Reqorsa® Immunogene Therapy in Combination with Tecentriq® to Treat Small Cell Lung Cancer

On May 14th GNPX announced that the first patient has been enrolled and dosed in the Company's Phase 1 dose escalation portion of the Acclaim-3 clinical study of Reqorsa® (quaratusugene ozeplasmid) Immunogene Therapy in combination with Genentech's Tecentriq® to treat patients with extensive-stage small cell lung cancer (ES-SCLC).

Genentech became a member of the Roche Group in March of 2009. As part of their merger agreement, Roche and Genentech combined their pharmaceutical operations in the United States. Genentech's South San Francisco campus serves as the headquarters for Roche pharmaceutical operations in the United States.

"We are excited to take this next step in our fight against lung cancers as we work to advance an innovative therapy that we believe provides hope to patients suffering with ES-SCLC, an especially aggressive form of lung cancer that has extremely limited treatment options," said Ryan Confer, President and Chief Executive Officer at Genprex. "With a median progression free survival (PFS) of 5.2 months, ES-SCLC has a particularly poor prognosis. Additionally, patients receiving Tecentriq as maintenance therapy have a median PFS of 2.6 months after the start of maintenance therapy. With such limited benefit from current treatments, we believe the combination of REQORSA and Tecentriq can provide a promising new therapeutic option for the treatment of small cell lung cancer."

"The Phase 1 dose escalation portion of the Acclaim-3 study is expected to determine the maximum tolerated dose for the Phase 2 expansion study," stated Mark Berger, M.D., Chief Medical Officer of Genprex. "The favorable results from our Phase 1 Acclaim-1 study in non-small cell lung cancer (NSCLC) enabled us to shorten the Phase 1 portion of Acclaim-3. This should allow us to complete the Phase 1 portion of the study during the second half of 2024 and to advance more quickly into the Phase 2 expansion portion of Acclaim-3 in the second half of 2024. We look forward to providing study updates as we advance this potentially life-saving therapy to benefit patients battling ES-SCLC."

Genprex has a novel cancer treatment platform that re-expresses tumor suppressor genes in cancers. Tumor suppressor genes are often deleted or inactivated early in the process of cancer development. REQORSA contains a plasmid that expresses TUSC2, a tumor suppressor gene protein. Nearly 100% of SCLCs have reduced or no TUSC2 protein expression, and 41% completely lack TUSC2 protein expression. Nonclinical studies in mice support the hypothesis that re-expressing the TUSC2 protein may lead to improved clinical efficacy in combination with Tecentriq.

#### Appointment of Jose A. Moreno Toscano as Chairman of the Board of Directors

On May 13th GNPX announced that the Board of Directors has appointed Jose A. Moreno Toscano as non-executive Chairman of the Board following the passing of the Company's co-founder and previous Chairman Rodney Varner.

Prior to his appointment as Chairman, Mr. Moreno Toscano has served on the GNPX Board of Directors since March 2020. Since April 2018, Mr. Moreno Toscano has been Chief Executive Officer of LFB USA Inc, the US subsidiary of LFB Group, a global integrated biopharmaceutical company, and he has more than 20 years of experience in the pharmaceutical and biotechnology industries, building, developing and transforming organizations. Mr. Moreno Toscano has a successful track record of identifying and capitalizing on opportunities to drive exponential revenue growth and market expansion, revitalizing underperforming operations and establishing foundations for successful start-up operations. His experience includes strategic planning, corporate restructuring, business development, M&A, investor relations and general management.

Mr. Moreno Toscano's appointment follows the recent appointment of Ryan Confer to serve as GNPX President and Chief Executive Officer. Mr. Confer was also appointed to the GNPX Board of Directors.

#### Presentations at May 2024 Investor and Industry Conferences

For the month of May, GNPX announced participation in the following investor and industry conferences:

Event: Sidoti Microcap Conference

Conference Dates: May 8-9, 2024

Presentation Date: Wednesday, May 8, 2024

Presentation Time: 3:15 p.m. ET

Venue: Virtual

GNPX Presenter: Ryan Confer, Genprex's  
Chief Financial Officer

Presentation link: <https://bit.ly/3UITsgl>

An archive of the presentation will be available in the Investor Relations section of the GNPX website.

Event: American Society of Gene & Cell Therapy Annual Meeting

Dates: May 7-11, 2024

Location: Baltimore Convention Center

GNPX Participant: Thomas Gallagher, Senior Vice President of Intellectual Property and Licensing.

Positive Preclinical Data on GNPX Reqorsa<sup>®</sup> and NPRL2 Gene Therapy Utilizing Non-Viral Oncoprex<sup>®</sup> Delivery System for the Treatment of Lung Cancers

On April 9th GNPX announced that its research collaborators presented positive preclinical data for Reqorsa<sup>®</sup> Immunogene Therapy (quaratusugene ozeplasmid) and NPRL2 gene therapy, which both utilize the Company's non-viral Oncoprex<sup>®</sup> Delivery System for the treatment of lung cancer. These studies were presented at the 2024 American Association for Cancer Research (AACR) Annual Meeting, held April 5-10, 2024 in San Diego, California.

In the first GNPX poster, entitled "Quaratusugene ozeplasmid mediated TUSC2 upregulation in EML4-ALK bearing Non-Small Cell Lung Carcinoma can induce cellular apoptosis," researchers reported that REQORSA induced apoptosis in alectinib resistant EML4-ALK positive non-small cell lung cancer (NSCLC) cell lines. Alectinib is an ALK-inhibitor commonly used to treat patients with ALK rearrangements such as EML4-ALK positive NSCLCs. This research suggests that REQORSA may be an effective treatment in patients progressing on alectinib.

The second GNPX poster, entitled, "Mechanism of NPRL2 gene therapy induced anti-tumor immunity in KRAS/STK11mt aPD1 resistant metastatic NSCLC" detailed a humanized mouse

model study in which the researchers investigated the anti-tumor immune responses to NPRL2 gene therapy in pembrolizumab resistant KRAS/STK11mt NSCLC. In the study, lung metastases in humanized mice were treated through I.V. injection of NPRL2 nanoparticles, made with the ONCOPREX Delivery System, with or without pembrolizumab. The study found that the NPRL2 treatment by itself led to a marked decrease in the size of lung metastases but pembrolizumab had no effect. Additionally, a greater anti-tumor effect was seen in humanized compared to non-humanized mice, demonstrating that immune cells play a role in the effects of the NPRL2 nanoparticle therapy. Study findings suggest that NPRL2 gene therapy induces anti-tumor activity against KRAS/STK11mt tumors through dendritic cell-mediated antigen presentation and cytotoxic immune cell activation. The Company believes this data could support the potential for a new drug candidate in its pipeline, and it also provides further evidence for the Company's belief that the ONCOPREX Delivery System has the ability to be successful using genes other than the TUSC2 gene the Company is already using in clinical trials with REQORSA.

In the GNPX third poster, entitled, "Tumor Suppressor Gene TUSC2 suppresses energy metabolism in lung cancer cells with opposite effects in normal bronchial epithelial cells" researchers reported that TUSC2-deficient cancer cells consistently exhibited decreased glycolytic rates and mitochondrial ATP production, leaving these cells without enough energy to support their vital functions. By comparison, when Beas2B, a normal human bronchial epithelial cell line with normal levels of TUSC2, was transfected with a TUSC2 containing plasmid, the glycolytic rate and mitochondrial metabolism was increased. This suggests the mechanism by which REQORSA treatment affects immune and other non-cancerous cells that leads to increased immune response against tumors. The study further suggested that REQORSA may play an important role as a cancer treatment to target and disrupt the metabolism of cancer cells, leading to a decrease in the rate of glycolysis.

These AACR posters have been made available on the GNPX website at [www.genprex.com](http://www.genprex.com).

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Disclosure listed on the CorporateAds website

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