

Nano Science, Technology and Industry Scoreboard

Genprex Pairs Gene Therapy Delivery Tech with Keytruda in Lung Cancer Trial

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Genprex has begun testing a drug candidate based on its systemic gene therapy delivery platform in combination with Merck's Keytruda. The phase 1/2 clinical trial marks the start of Genprex's effort to determine whether a delivery system based on opposing electrical charges can help improve the efficacy of the checkpoint inhibitor in patients with late-stage non-small cell lung cancer (NSCLC).

The investigational candidate, <u>Regorsa</u>, consists of the tumor suppressor gene TUSC2 encapsulated in a positively charged lipid nanoparticle. Because cancer cells generally have a negative electrical charge, <u>Genprex</u> thinks intravenously administered nanoparticles will specifically target the tumor, leading to the expression of the TUSC2 gene and a range of anti-cancer effects.

Genprex wants to find out whether those effects can enhance Keytruda. The phase 1/2 clinical trial is focused on NSCLC patients who progress after treatment with Merck's checkpoint inhibitor. If Genprex is right, Reqorsa could give those patients a new option by modulating the immune system.

The first part of the phase 1/2 clinical trial will enroll up to 30 patients for dose escalation. Once it has found the maximum tolerated dose of the combination, Genprex plans to enroll around 126 patients to receive either the Reqorsa-Keytruda combination or docetaxel and/or ramucirumab. The phase 2 part of the trial will assess progression-free survival in the two cohorts.

Genprex is aiming to complete the phase 1 part of the trial by the first quarter of 2023. An interim analysis of the efficacy data will happen after 50 events. Genprex expects its existing cash and marketable securities to fund its operation into 2024.

