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Transgene, NEC initiate trials with AI-Powered Cancer Vaccine

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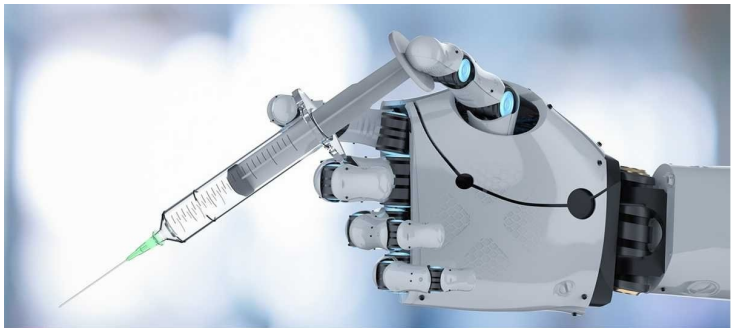
Novel immunotherapy using TG4050 moves therapeutic vaccination into the digital age to treat Ovarian and Head & Neck Cancers



French firm Transgene, a biotech company that designs and develops virus-based immunotherapies for the treatment of cancer, and Japan based NEC Corporation, a leader in IT and network technologies, have announced that the first patients have been enrolled in the first-in-human trials evaluating TG4050, a therapeutic vaccine based on the myvac technology and powered by NEC's cutting-edge AI capabilities. In these Phase 1 trials, TG4050 is being administered to patients with head and neck cancer who have a high risk of relapse after surgery and patients with ovarian cancer after surgery and adjuvant therapy.

Transgene's highly innovative myvac technology allows the generation of virus-based immunotherapy within a very short time frame while encoding patient-specific mutations identified and selected by NEC's Neoantigen Prediction System.

TG4050 has been designed to target up to 30 patient-specific neoantigens (cancer cell mutations). They are selected using NEC's Neoantigen Prediction System, an advanced AI technology that has already been applied in the field of oncology. The prediction system is based on more than two decades of expertise in AI and has been trained on proprietary immune data, allowing it to accurately prioritize and select the most immunogenic sequences.

Transgene uses its expertise in viral vectorization via myvac to incorporate the selected neoantigen sequences in the genome of the Modified Vaccinia virus Ankara (MVA) viral vector. The Company has also set up a unique in-house good manufacturing practice (GMP) unit dedicated to the manufacturing of the individualized batches of TG4050 needed for the clinical development of this novel therapeutic vaccine.

"As each patient's cancer is unique, we have developed a therapy that turns their solid tumor's genetic signature into a powerful highly specific anticancer weapon. TG4050 is based on an MVA viral vector that has proven biological activity and has the ability to elicit an immune response against tumor antigens. Our partnership with NEC ensures that TG4050 is benefitting from its world-leading expertise in artificial intelligence and its unique algorithm that is used to select up to 30 patient-specific antigens that allow this novel vaccine to induce a strong immune response. We are convinced that TG4050, which is at the crossroad of immunotherapy and big data sciences, will herald the start of a new era in the fight against cancer," explained Philippe Archinard, Chairman and Chief Executive Officer of Transgene.

"We are excited to enroll our first patients in these trials and see TG4050 advance to the clinic. This is another step closer towards the realization of AI-driven individualized immunotherapy for each patient. Our unique partnership with Transgene

enables us to leverage its significant clinical development know-how and proven viral vector delivery platform. We are hopeful that TG4050 will make a significant difference for patients throughout the world," commented Osamu Fujikawa, Senior Vice President, NEC Corporation.

A Phase 1 clinical trial of TG4050 is enrolling patients with ovarian cancer after surgery and first-line chemotherapy. This multi-centre, one-arm trial will recruit patients in the USA and in France. Endpoints of the trial include safety, feasibility and biological activity of the therapeutic vaccine. Dr. Matthew Block, MD, PhD, immunologist and medical oncologist at the Mayo Clinic, is conducting the trial in the USA; in France, the trial will be conducted by Dr. Martinez at Toulouse-Oncopole and by Pr. Le Tourneau at Institut Curie.

Another Phase 1 clinical trial of TG4050 is enrolling patients with newly diagnosed, locoregionally advanced, HPV negative, squamous cell carcinoma of the head and neck (SCCHN) that have received an adjuvant (first-line) therapy after surgery. This multi-center, open-label, randomized two arms trial will include patients in the UK and in France. Patients will receive either TG4050 monotherapy after completion of the adjuvant therapy or in combination with the standard of care at the time of recurrence. Endpoints of the trial include safety, feasibility and biological activity of the therapeutic vaccine. In France, the trial is being conducted by Pr. Delord at Toulouse-Oncopole and by Pr. Le Tourneau at Institut Curie; in the UK, the trial is coordinated by Pr. Ottensmeier from Southampton University.

Both studies are sponsored by Transgene and are co-financed by Transgene and NEC.