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Ichor Medical Systems and the TriGrid Delivery System

Company Background

Ichor Medical Systems, a privately-held biotech company founded in San Diego in 1994, is developing products based on the in vivo application of electroporation to enhance intracellular delivery of DNA drugs encoding therapeutic proteins or antigens for vaccines. Ichor's proprietary TriGrid™ Delivery System (TriGrid) is the first and only integrated and fully automated system for electroporation-mediated DNA administration.

TriGrid is currently being used on three continents in collaborations with some of the world's leading research organizations and medical centers working on a wide range of pre-clinical and clinical studies for treatments of cancer, HIV, viral hepatitis, bio-defense indications, and avian flu.

Staff and Facilities

Ichor's 25 employees form a multi-disciplinary research and development team comprised primarily of biological scientists, engineers and technicians. It occupies a 6,500-square-foot corporate headquarters in the Sorrento Mesa area, in the heart of San Diego's thriving biotechnology cluster.

Electroporation Technology

Electroporation is a process that employs a brief electrical pulse to create temporary pathways through cell membranes. Pores temporarily appear in the membrane as a result of electroporation to create an opening for surrounding agents to enter the cell. It has been used in research laboratories for some 20 years. Studies show that electroporation can increase uptake of agents by up to 1,000-fold compared to other methods of delivery. However, the clinical use of multi-step electroporation procedures established in the research environment are likely to be highly error-prone and variable, and thus expected to cast doubts on study results in patients. Realizing this, the Ichor team worked for more than ten years to develop and perfect its proprietary TriGrid system, which offers a new level of precision to help fulfill the promise of DNA-based vaccines and gene therapies for use in oncology, infectious diseases and autoimmune diseases.



Ichor's Breakthrough TriGrid Delivery System

TriGrid is the first and only fully integrated and automated clinical electroporation system with reproducible administration at the push of a button – a powerful technology for delivering DNA encoding vaccines and other gene-based therapies to endogenously produce protein from the patient's own muscle.

TriGrid provides several significant advancements over multi-step manual electroporation systems, where DNA is injected at a marked site and the operator implants electrodes manually in the second step. Results using the old approaches are based substantially on the skill of the technician, and subject to considerable patient and operator variability. Patients also prefer TriGrid because they never see the needles or suffer from poor manual insertions.

Ichor's technologically superior push-button electroporation system virtually eliminates operator error and ensures the safe, effective and reproducible administration of DNA from one patient to another with minimal operator training. This system allows the site of DNA injection, placement of electrodes, rate of DNA administration and timing of electrical pulse application to be consistent among different operators and patients. As a result, Ichor's TriGrid enables the clinical application of electroporation in a manner capable of supporting development and commercialization of DNA-based products.

As Ichor's competitors evaluate their devices' low efficiency and inconsistent results, it is likely that they will logically move into Ichor's space and attempt to develop an integrated, automated single-step electroporation device. Throughout the development of the TriGrid, Ichor has been aware of this threat and the company remains confident that its patent portfolio will exclude its competitors from commercialization of such a device.

Ichor has an excellent patent position and a far superior electroporation technology than its competitors, with significant opportunities to be an enabling technology in the emerging DNA Vaccine market and a disruptive platform in the growing \$40 billion therapeutic protein markets.

Expert Overview

The greatest initial potential for Ichor's TriGrid lies in the consistent delivery of DNA vaccines, according to Dr. David Ho, M.D., CEO of the Aaron Diamond AIDS Research Center (ADARC). He believes that electroporation helps revive DNA vaccine strategies. It increases the transfection efficiency – the ability to have DNA vaccines enter through cellular walls – by up to a thousand-fold. Additionally, using TriGrid, DNA vaccines can be given repeatedly without safety or toxicity issues, are cheap to manufacture and can show improved results with reproducible transfection using the Ichor device, Dr. Ho said. ADARC is using TriGrid in its extensive work in HIV research for both preventative and therapeutic applications.



Dr. Ho said TriGrid can provide significant advantages in preparing for an avian flu pandemic, a global problem that many nations are struggling with presently. The danger is the growing prevalence of the flu in the bird populations and the possibility that it could jump species to humans. In the event of pandemic flu, a nation with limited vaccine manufacturing capacity could use TriGrid to significantly increase the potency of that vaccine in a consistent manner, which means a smaller amount of vaccine would be necessary and thus allow effective treatment of more people, Dr. Ho said.

For therapeutic proteins, Dr. John Laszlo, M.D., chairman of the Ichor Scientific Advisory Board and former National Vice President of research for the American Cancer Society, cited the ability of the patient to become the ‘factory’ for whatever product they need, whether for prophylactic or therapeutic uses. For efficiency and patient comfort, instead of having to give repeated injections of a recombinant protein, clinicians can use TriGrid to effectively deliver DNA encoding that protein and let the patient’s own muscle manufacture the protein, Laszlo said, making life simpler for the patient, reducing costs and ensuring compliance.

Dr. Jeffrey Weber M.D., Ph.D., Director, Donald A. Adam Comprehensive Melanoma Research Center, H. Lee Moffitt Cancer Center, Tampa, and also member of the Ichor Scientific Advisory Board, believes the next big areas for use of TriGrid will be in oncology. He cited successful animal research with melanoma and the recent launch of human testing. Ichor is currently pursuing trials in treating melanoma under an investigational new drug application (IND) with Memorial Sloan Kettering Cancer Center.

How the TriGrid Delivery System Works

Ichor’s TriGrid Delivery System is a small hand-held device that contains a syringe needle and four electrodes recessed in the main shaft. Operation of the device is simple. The clinician holds the TriGrid applicator against the patient’s upper arm and presses a button. The device then deploys the needle and electrodes at a fixed depth and location and delivers the DNA drug and the electrical field to each patient in a consistent manner.

The electrodes are arranged in a diamond shape around the central syringe needle. This co-localization of the syringe needle (used to deliver the DNA) and the four electrodes (used to deliver the electroporation) is critical to drug efficiency. The needle and four electrodes enter a space in the muscle tissue that is smaller than one cubic centimeter. For the DNA to be most effectively transferred into the cells, the electrical field must be consistently applied to the small area around the DNA.

Before TriGrid, clinicians were limited to use of a two-step process, first injecting the drug or vaccine with a needle and then inserting visible electrodes. Between step one (the needle) and step two (the electrodes), it is common for patients to move, flex or unflex their muscles, or change position. Even the slightest variation in placement location or angle of the electrodes relative to the DNA can cause a significant loss of delivery efficiency, resulting in reduced or absent drug effectiveness. In addition, the time between steps can vary between different operators, further increasing the likelihood of variability



in response. The TriGrid integrated, automated one-step DNA delivery process using electroporation minimizes human error and increases patient comfort and confidence in the results.

Financial Information

Initial funding for Ichor has come from Bob Bernard, CEO, and a small group of private investors. The company is currently pursuing additional financing opportunities to pursue the development of DNA vaccines, expand its manufacturing and marketing capabilities, and increase the number of collaborations with leading research institutions and pharmaceutical companies around the world.

For additional information, see www.ichorms.com.

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