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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, 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 for a wide range of pre-clinical and clinical studies for potential treatments of cancer, viral hepatitis, multiple sclerosis, diabetes, and cardiovascular disease. Ichor technology is also being used to develop vaccines for the prevention/treatment of HIV/AIDS, influenza, hospital acquired infections, and numerous diseases that are considered to be high priorities for U.S. biodefense initiatives.

Staff and Facilities

Ichor's 25 employees form a multi-disciplinary research and development team comprised primarily of scientists, engineers and technicians. It currently 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 enables efficient intracellular delivery of drugs, This technology can dramatically enhance the effectiveness of drugs that achieve their function on the inside of cells, but, due to their large size or composition, are not taken up efficiently by the cells on their own. Treatments based on DNA or other nucleic acids are among the most promising of this type of agent. These "DNA drugs" are unique in their ability to provide sustained production of the proteins encoded in the DNA from the patients' own cells. As a result, this class of agents holds tremendous promise in the development of novel therapies to both treat and prevent a variety of infectious diseases, cancers, and autoimmune disorders.

Electroporation-based delivery is achieved by first distributing the drug within the target tissue. A series of brief electrical pulses are then applied through electrodes contacting the target tissue. These electrical pulses temporarily disrupt cell membranes in the vicinity of the electrodes. This allows the locally distributed drug to enter the cell more efficiently than would be possible otherwise. Studies show that this process can increase uptake of agents by up to 1,000 times compared to other methods of delivery.

Although electroporation has been used in research laboratories for over 20 years, the development of new clinical products based on this technology has been hampered by the absence of devices and procedures suitable for use in humans. Recognizing this tremendous untapped potential, Ichor was founded to create new products, systems and platforms capable of supporting the development of novel drug and biologic products delivered by electroporation. The efforts of the Ichor team have culminated in the global launch of the company's TriGrid, which enables delivery with an unequalled level of safety, effectiveness, and consistency. The expectation is that this may fulfill the potential of DNA-based vaccines and therapies for use in oncology, infectious diseases, and autoimmune diseases in the very near future.

Ichor's Breakthrough TriGrid Delivery System

TriGrid is the first and only integrated, fully automated clinical electroporation system capable of providing effective and reproducible administration at the push of a button. This makes the TriGrid a powerful technology for delivering DNA-based vaccines and therapies to endogenously produce protein from the patient's own tissue.

By integrating the means for agent administration and electroporation application into a single, automated device, TriGrid addresses the shortcomings of other electroporation systems. Specifically, TriGrid allows the site of DNA injection, placement of electrodes, rate of DNA administration and timing of electrical pulse application to be easily performed in a consistent fashion across all operators and patients. In contrast, other electroporation technologies rely on multi-step application procedures under manual control. Results using such approaches are based substantially on the skill of the clinician, and subject to considerable variability from patient to patient and operator to operator. For these systems, the inability to consistently deliver a given drug product across its target patient population is likely to represent a substantial hurdle for clinical and commercial acceptance where consistency, safety and dependability are key.

Ichor's advanced, push-button electroporation system minimizes operator error and ensures the safe, effective and reproducible administration of DNA from one patient to another with minimal operator training. 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.

In addition to achieving effective and consistent delivery with its technology and design, Ichor made patient acceptance a key consideration. Importantly, with the TriGrid integrated device, the entire delivery procedure is completed within 5-10 seconds. In contrast, some competing systems can require two to three minutes or more for the operator to complete the manual, multi-step process. Patients also

prefer TriGrid because the injection needle and electrodes are recessed within the device and never visible. In contrast, some electroporation technologies use fixed, visible electrodes that can create anxiety for the patient and can be difficult to insert correctly.

As Ichor's competitors evaluate their devices' low efficiency, inconsistent results and consider patient acceptability, 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 next generation devices incorporating an integrated and automated approach.

Given the promising results obtained with the TriGrid's electroporation based delivery, the company's superior technology, and an excellent patent position, Ichor is well positioned 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

According to Dr. David Ho, CEO of the Aaron Diamond AIDS Research Center (ADARC), the greatest initial potential for Ichor's TriGrid lies in the consistent delivery of DNA vaccines. He believes that electroporation will help revive the promise of DNA vaccines. Although DNA vaccines have exhibited tremendous promise in animal studies, clinical trials in humans have been disappointing due to low and inconsistent immune responses. By increasing vaccine delivery by up to a thousand-fold, TriGrid is well positioned to achieve target levels of immune response. Additionally, using TriGrid, DNA vaccines can be given repeatedly without safety or toxicity issues, are cheap to manufacture and can show consistent enhancement in immune responses, Dr. Ho said. ADARC is using TriGrid in its extensive work in HIV research for both preventative and therapeutic applications.

Dr. Ho also indicated that TriGrid can provide significant advantages in preparing for an avian influenza pandemic, a global problem that many nations are struggling with currently The danger is the growing prevalence of the influenza virus in bird populations and the possibility that mutations in the virus could allow it to be transmissible from human to human. In the event of an influenza pandemic, 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 disease prevention in more people, Dr. Ho said.

For delivery of 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 it is for prophylactic or therapeutic uses. For efficiency and patient comfort, instead of having to give frequent 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., Chief, Division of Medical Oncology Keck/USC School of Medicine, and also a member of the Ichor Scientific Advisory Board, believes that use of TriGrid has significant potential in the field of 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 recessed electrodes. Operation of the device is simple. The clinician holds the TriGrid applicator against the patient's 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 safely and consistently.

The electrodes are arranged in a diamond shape around the central syringe needle in order to encompass the tissue in which the drug is administered. 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, so co-localization of the syringe needle (used to deliver the DNA) and the four electrodes (used to deliver the electroporation) is critical to effective drug delivery.

With some electroporation technologies, clinicians are limited to the multi-step, manual process: first injecting the agent and then inserting fixed, visible electrodes. Between step one (the drug administration) 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 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 among different operators, further increasing the likelihood of variability in response. The TriGrid integrated, automated one-step DNA delivery process using electroporation minimizes human error while enhancing patient acceptance.

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 in order 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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