



**FOR IMMEDIATE RELEASE**

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Contact:  
Erin Koch  
Gable PR  
619-261-0762 (cell)  
erin@gablepr.com

**FDA Approves Phase I Clinical Trial Using Ichor's TriGrid System  
And DNA Vaccine for Melanoma Developed at Sloan-Kettering**

*Electroporation Seen as Powerful Addition  
To Human Trials, Future Commercial Applications*

SAN DIEGO – Ichor Medical Systems announced today it has received FDA approval to conduct a Phase I clinical trial of a melanoma vaccine to be administered to patients utilizing a novel delivery technology.

The vaccine, which was developed by Memorial Sloan-Kettering Cancer Center scientists, consists of DNA encoding a form of the tyrosinase protein. This protein is found broadly in melanoma cells and is a promising target for immunotherapy. The vaccine will be administered with the Ichor TriGrid™ Delivery System (TriGrid), which uses electroporation to increase the intracellular delivery of the DNA vaccine to the cells at the site of administration. By “teaching” the body’s own immune or disease-fighting system to target melanoma cells which contain the tyrosinase protein, the vaccine has the potential to alter the course of the disease.

The TriGrid, a small hand-held device used to apply the entire administration procedure, is the first fully automated one-step method for electroporation based DNA delivery. The integrated design of electrodes and DNA injection needle in the TriGrid yields consistent placement of electroporation pulses where DNA is administered in the target tissue. The automated one-step push-of-a-button process controls the rate of DNA injection and the time interval between injection and electroporation application. Taken together, these features of the TriGrid system minimize human error and deliver DNA to each patient in a consistent manner – a requirement in clinical trials and eventual commercialization. Studies show that TriGrid electroporation can increase uptake of agents by 10, 100 or even 1,000 times compared to other methods of delivery.

MSKCC has started enrolling patients with stage IIB to IV malignant melanoma for the two-year period.

"We are seeing the emergence of immunotherapy as an important component of cancer treatment through the application of new technologies," said Dr. Alan N. Houghton, a member of the melanoma/sarcoma service and head of the melanoma disease management team at Memorial Sloan-Kettering. "DNA cancer vaccines offer a new approach to immunotherapy, but we need to improve the efficiency of vaccine delivery. We are hopeful that Ichor's TriGrid will help fulfill that potential."

Dr. John Laszlo, chairman of Ichor's scientific advisory board and former national vice president of the American Cancer Society, said everyone involved is excited about the launch of Phase I clinical trials on the melanoma vaccine developed by Dr. Houghton and his team at Memorial Sloan-Kettering Cancer Center.

"Dr. Houghton has been a pioneer in developing cancer vaccines and there is no better place to begin an evaluation of the TriGrid than with this distinguished group of investigators at Memorial," said Laszlo. "Our new TriGrid DNA vaccine delivery system has shown tremendous promise in terms of preclinical testing for efficacy and practicality; hopefully it will address the shortcomings of conventional methods for DNA vaccine delivery and help us take an important step forward in the field of melanoma therapy."

"Since advanced melanoma is life threatening, and current therapies are neither highly effective nor free of side effects, we are pleased the TriGrid platform has been selected by Memorial Sloan-Kettering Cancer Center physicians to advance possible treatment of this disease," said Bob Bernard, CEO of Ichor.

Bernard said DNA vaccines hold promise for the prevention and treatment of many diseases. In addition to MSKCC, Ichor and its other research partners are using TriGrid in a wide range of pre-clinical and clinical studies for potential treatments of MS, atherosclerosis, HIV, Hepatitis B, Avian Flu and vaccine research for countering bio defense threats.

### ***About Ichor Medical Systems:***

Ichor Medical Systems, a privately-held biotech company, 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. 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 safe, effective and reproducible clinical application of electroporation in a manner capable of supporting development and commercialization of DNA-based products. The Ichor system is currently being used on three continents in a wide range of pre-clinical and clinical studies for potential treatments of melanoma, MS, atherosclerosis, HIV, Hepatitis B, and Avian Flu. For further information, visit [www.ichorms.com](http://www.ichorms.com).

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For additional inquiries, please contact:

***Ichor Medical Systems – 858-550-2022***

May de las Alas  
mdelasalas@ichorms.com  
Direct: 858-550-2022

***Gable PR – 877-251-3888***

Erin Koch  
erin@gablepr.com  
Cell: 619-261-0762

Tom Gable  
tom@gablepr.com  
Cell: 619-251-3881

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