Viral Genetics Updates HIV/AIDS and Drug Resistant Cancer Research Programs

SOURCE: Viral Genetics, Inc.

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Business Wire
SAN MARINO, Calif., June 14, 2011 /PRNewswire/ — Viral Genetics, Inc. (Pinksheets:VRAL.pk – News) continues to make the transition to a clinical-stage company. The Company's two lead pharmaceutical programs — APi1177 for HIV/AIDS, and various Metabolic Disruption (MDT) compounds for drug-resistant cancers — are being advanced towards clinical development under sponsor- or investigator-initiated Investigational New Drug (IND) pathways. An IND application is the submission that a company provides to the FDA requesting permission to conduct clinical trials on humans. Each program is continuing as detailed below.

HIV/AIDS — APi1177 Pre-IND
The Company recently communicated with the United States Food and Drug Administration (FDA) through submission of a pre-IND package for APi1177. As a result of this dialogue, the Company is focused on a three-step plan leading towards filing a full IND and clinical trials in the US.

Step one of the plan is securing a manufacturer to supply APi1177 in sufficient quantity and meeting established quality standards throughout the remainder of the development and clinical trial process. Up until this point the Company's manufacturer has produced "research grade" drug which has been sufficient for early preclinical studies conducted to date, but all drug used going forward must be produced in compliance with Good Laboratory Practice (GLP) and Good Manufacturing Practice (GMP) standards. A suitable manufacturer has been identified and they are now working with the Company's research-grade manufacturer to reproduce the product used in earlier-stage studies.

Upon completion of this, step two of the development plan is to move forward with a limited number of relatively-brief laboratory studies designed to establish any "in vitro" antiviral efficacy for APi1177 as well as to highlight any potential issues relating to interaction with existing HIV antiviral drugs. While "efficacy" results may be achieved in certain assays during this stage — that is, reducing the amount of HIV virus (viral load) or blocking reproduction of the virus — this batch of in vitro studies is primarily geared towards meeting FDA guidelines that have been designed specifically for the anti-retroviral drugs commonly used to treat HIV/AIDS.

Step three of the IND plan is to complete standard animal safety, pharmacology, and toxicology studies designed to highlight any safety or toxicity issues. The Company has identified a potential laboratory partner to complete these animal studies. The Company's strategy is to submit the IND after completion of step one or two, but prior to step three, on the basis that step three would be completed as a condition to moving ahead in humans. Conditional on availability of funding, the Company believes it will be able to submit an IND application for APi1177 in 3-6 months.

MDT Cancer Study — Scott and White Hospital
The clinical trial protocol for this study, which is being funded by a grant of $1.5 million to the hospital, is now being prepared for review by the Institutional Review Board (IRB) of Scott and White Hospital located in Temple, Texas and affiliated with Texas A&M University Health Sciences Center. The review is the final step prior to submission of the Investigator IND (I-IND) to the FDA. IRB review is primarily focused on establishing, monitoring and reviewing the treatment of research subjects in experiments, ensuring certain ethical standards are maintained.

The enrollment and treatment phase of the study can commence following IRB and FDA approval of the protocol. While the Company had earlier indicated that patient enrollment and treatment was expected to start in the spring, the final protocol for the clinical trial was delayed due to the addition of new types of cancers to be studied as well as difficulty in obtaining a non-MDT compound being used in one arm of the study for one type of cancer. The amended protocol is now being finalized by the investigators, and may be modified again in the future although we do not anticipate any significant additional delays.

While the central aim of the study is to determine efficacy of our MDT compounds in certain patients in certain cancers, and we are involved in reviewing the study's design, the study itself is being conducted and controlled by the hospital investigators. IRB review is expected to be completed between June and July 2011 and the Company expects the I-IND to be submitted shortly thereafter.

About Viral Genetics, Inc.
San Marino, California-based Viral Genetics discovers drug therapies from two platform technologies based on over 60 patents: Metabolic Disruption (MDT) and Targeted Peptides (TPT). Founded in 1994, the biotech company is researching treatments for HIV/AIDS, Lyme Disease, Strep, Staph and drug resistant cancer. A majority-owned subsidiary, VG Energy (www.vgenergy.net), is dedicated to exploring biofuel and agricultural applications for the MDT platform. For more information, visit www.viralgenetics.com.

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