University nonprofit poised to bridge 'Valley of Death' and spur drug development

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With the "Valley of Death" looming as an increasingly serious obstacle to introducing better ways of preventing, diagnosing and treating diseases, a noted scientist today described a new approach for moving promising discoveries out of laboratories and into the hands of patients and physicians. He spoke at the 246th National Meeting & Exposition of the American Chemical Society, the world's largest scientific society, being held here this week.

Dennis Liotta, Ph.D., cited widespread concern that innovative scientific discoveries, especially those resulting from billions of dollars in government investment in research, are withering on the vine rather than being translated into breakthrough new treatments.

"The Valley of Death is the place where potential new drugs all too often go to die," said Liotta. "In drug development parlance, the Valley of Death refers to the obstacles that are keeping innovative medical research discoveries from becoming new drugs. Potential new drugs never even make it to clinical trials. We think we have an approach to bridge the valley."

Liotta has been involved in moving 10 drugs into the hands of patients as medications approved by the U.S. Food and Drug Administration. Among them is the HIV drug Emtriva®, which was co-invented by Liotta, Raymond Schinazi and Woo-Baeg Choi and approved by the U.S. Food and Drug Administration in 2003. Emtriva is now used in more than 90 percent of all HIV combination therapies prescribed around the

world. In 2005, Emory University, where the drug was developed, sold its royalty interest in Emtriva for $540 million to Gilead Sciences Inc.

The chances of a promising new discovery actually becoming a new drug always have been razor-slim, Liotta said. Hundreds of such discoveries happen each year, but only a handful of truly new medicines reach the market. Others are "me-too" drugs, similar to drugs approved in the past but in forms that have longer-lasting effects or with other minor improvements. But circumstances are making the Valley of Death even more hazardous, further reducing the movement of new compounds from lab to real-world remedies.

"Big pharmaceutical companies are cutting back on the kind of research and development activity needed to introduce truly new drugs," Liotta said. "Research universities are the logical institutions to step in and complement the work in private industry. Dozens of universities have such programs, but with a focus that makes it difficult for them to move a potential new drug forward to the point of clinical trials."

To fill that gap, Emory used $30 million from the royalty sale of Emtriva to form two nonprofits: Drug Innovation Ventures at Emory (DRIVE) and the Emory Institute for Drug Development (EIDD). DRIVE's goal is to invest in discoveries with the potential to become new drugs. In effect, DRIVE is the "industrial partner" of the EIDD, organized as a virtual drug development company with a highly experienced management team. As a nonprofit, DRIVE can license attractive development opportunities from Emory or elsewhere on commercially favorable terms.

"With either its own seed capital or external funds, DRIVE then can use EIDD or external vendors to move these opportunities quickly and efficiently down the development continuum to meet the critical need for new therapeutic agents to treat infectious diseases," Liotta said.

The EIDD-DRIVE combo currently is doing that for promising compounds for dengue fever and hepatitis C that have reached the "drug-lead" stage, said Liotta. Those are chemical compounds that show promising signs of treating diseases, but need further modifications in their molecular architecture.

Liotta's talk was part of the "Entrepreneurial Skills Interactive Symposium," which included four other presentations on the ups and downs of commercializing academic research.

More information: Abstract

DRIVE: An innovative, nonprofit drug discovery company

The Emory Institute for Drug Development (EIDD) was founded in 2009 to discover therapeutic agents to treat infectious diseases, particularly viral diseases. The EIDD has the personnel, laboratory space and equipment necessary to conduct the key preclinical activities required to bring a drug into clinical development. DRIVE, the "industrial partner" of the EIDD, is organized as a virtual drug development company with a highly experienced management team. As a 501(c) (3) entity, it will be able to in-license attractive development opportunities from Emory or elsewhere on commercially favorable terms. Then, either by using its own seed capital or by raising external funds, it can utilize the EIDD and/or external vendors to move these opportunities quickly and efficiently down the development continuum to meet the critical need for new therapeutic agents to treat emerging infectious disease. DRIVE has been designed to be a self-sustaining entity, i.e., the company can reinvest its earnings from outlicensing or sale of assets in new development opportunities as they emerge.