TIP Project Brief – 100002/11H001

Manufacturing
Production of Fully Deleted Helper-Virus Independent Adenoviral Vectors

Develop and optimize standardized manufacturing systems for a novel type of pharmaceutical-grade gene transfer vehicle for vaccination, gene therapy and tissue transplantation applications.

Sponsor: Isogenis, Inc.
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- Project Performance Period: 2/1/2011 - 1/31/2014
- Total project (est.): $5,511 K
- Requested TIP funds: $2,756 K

Since viruses are designed by nature to transport genetic material into an infected host cell, biotechnology researchers have developed various ways to adapt viruses as "vectors" to transfer genes for therapeutic purposes. Isogenis, Inc. has developed a versatile gene transfer vector based on the adenovirus, a family of common viruses. In this project Isogenis hopes to develop improved manufacturing technologies for commercial-scale production of modified versions of their adenovirus (Ad) vector, intended for a variety of medical uses, including vaccines, organ and tissue transplants, and gene therapy.

The Isogenis Ad vector is "fully deleted," meaning that it is essentially an empty icosahedral shell stripped of all the original virus genes. It is believed to be highly safe; it is not infectious and does not integrate into the target cell chromosomes. Isogenis is exploring the use of the Ad vector to create safe vaccines that can be developed rapidly for diseases ranging from influenza to dengue hemorrhagic fever. It also could be used to protect transplanted tissue from the body's immune system without the need for immune suppression drugs, and as a gene therapy vehicle to treat diseases such as hemophilia and cystic fibrosis.

Producing Isogenis's Ad vector is complicated because the deletion of all the Ad genes means that the biochemical "information" needed to assemble the vector, together with its biopharmaceutical payload, must be provided separately. Other "helper" viruses could be enlisted to do this, but the Food and Drug Administration has expressed concerns that this runs the risk of contaminating the final product. With TIP support, the company plans to develop and optimize standardized manufacturing systems for fully deleted, helper virus-independent Ad (fdhiAd) vectors that would enable mid- and large-sized batch manufacture of pharmaceutical-grade vectors for vaccination, gene therapy and tissue transplantation applications. If successful, the technology would provide valuable new capabilities to the nation's healthcare system. The vaccine applications alone would be important in combating emerging infectious threats and bioterrorism because the fdhiAd-based vaccines could be developed more quickly and at lower cost than traditional vaccines.

For project information:
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