reinfused into patients, who then receive low doses of IL-2 to keep the cells activated. AIS is conducting two 20-patient phase-II trials in AIDS patients with Kaposi's sarcoma, with the protocols calling for five one-month cycles of cell removal, treatment, and reinfusion.

• For kidney-cancer therapy, AIS's Cellector uses anti-CD8 MAbs to recover tumor infiltrating lymphocytes (TILs) from surgically removed tumors. The TILs are activated with IL-2, multiplied 100 fold, and then reinfused into patients. Presently, AIS is conducting a phase-I trial involving 14 kidney-cancer patients.

• In gene therapy, AIS will use a Cellector containing anti-CD34 MAbs to isolate stem cells for gene insertion, as well as the human adeno-associated virus (AAV) to introduce genes into these stem cells. AAV, which is present in 90 percent of people yet isn't associated with any disease, integrates with human DNA at sites that don't disrupt normal chromosome function. AIS has also made a $1.5 million equity investment in Genetix Pharmaceuticals (New York), a gene-therapy company developing multiple-drug-resistance technology to enable stem cells to survive chemotherapy. For its part, RPR is making a major investment in gene therapy, with as many as 100 researchers expected to work in the area.

The Food and Drug Administration (FDA, Bethesda, MD) will likely regulate AIS' Cellector as either a device or a biological therapy, depending on its application. In bone-marrow transplants, the Cellector acts as a device, since it simply harvests cells. Yet in AIDS therapy, kidney-cancer therapy, and gene therapy, the Cellector acts as a biological therapy, because the harvested cells are further manipulated. FDA has already granted the Cellector 510(k) marketing approval for cell separation without therapeutic-use claims. AIS is awaiting 510(k) marketing approval for the Cellector for T-cell depletion.

RPR will likely prove a good partner for AIS. RPR—which racked up sales of $4.1 billion last year and spent over $500 million on research and development—is rapidly expanding its presence in biotechnology. One example is its Bioavenir partnership with the French government, which will invest $150 million over the next five years in French biotech firms and academic research centers. RPR, moreover, is putting little pressure on AIS, as it doesn't expect AIS, a loser of $15.4 million last year on revenues of $1.5 million, to break even until 1997.

—B.J. Spalding

National body will spur vaccine development

WASHINGTON, D.C.—The federal government should create a national vaccine authority (NVA) to "encourage the development, production, and procurement of new and improved vaccines of limited commercial potential but of high public need." So states an Institute of Medicine (IOM, Washington, DC) committee in a recent report entitled "The Children's Vaccine Initiative: Achieving the Vision."

The IOM committee argues that an NVA would cost from $30 million to $75 million to establish and could bring together elements of the public and private sectors, including many small biotechnology companies. Working in cooperation, these players could "make a major contribution toward disease eradication," says IOM committee chairman, Jay Sanford, dean emeritus of the Uniformed Services University of Health Sciences (Bethesda, MD).

Early last year, several federal agencies requested that the IOM committee identify the major economic and policy factors now retarding the development of vaccines in the U.S. The committee was also asked what steps are needed to achieve the major goals of the Children's Vaccine Initiative as outlined in 1990 during a world summit held in New York.

According to Sanford, those goals, which are "within our grasp," include "new and improved vaccines that could be given in fewer doses, contain multiple antigens, be heat stable, be effective when given at an earlier age, include protection against other diseases, and be affordable." Such vaccines are needed not only in developing countries but also "within our own inner cities and for other disadvantaged segments of the U.S. population," Sanford notes.

The members of the IOM committee, however, soon realized that "fragmentation" is the "overwhelming problem" now faced by the system of public vaccine development, says Sanford. He adds that even though the U.S. government invests well over $230 million annually in vaccine research and development (R&D), this effort carries only "limited attention or planning."

The IOM committee concludes that a new federal entity, an NVA, is needed to overcome these obstacles. Start-up costs for the NVA would range from $30 million, if it were created from existing federal facilities, to $75 million, if a free-standing federal organization were built and staffed. Annual operating costs would range from $55 million to $75 million. These cost estimates need to be weighed against savings that would be realized by preventing diseases. "Eliminating smallpox in the world saved the U.S. an estimated $120 million annually," Sanford says.

The NVA would bring other economic benefits, particularly to the biotechnology industry. For example, the committee recommends that a pilot production facility be made available for the purpose of making adequate supplies of candidate vaccines needed for clinical trials. Such a facility would spare small companies from having to make heavy investments in production facilities before an experimental vaccine has been proved safe and effective.

Moreover, the NVA could also benefit biotechnology companies by providing a "stable source of revenue" in the form of grant or contract support for them to do vaccine R&D and thus "keep the lights on and the rent paid," says committee member David Mowery of the University of California at Berkeley.

—Jeffrey L. Fox

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