NOTHING PARTICULARLY NOVEL

EUROPE'S FIRST GENE THERAPY

MILAN, Italy—The first human gene-therapy trial in Europe took place on March 9 at the Instituto San Raffaele (Milan, Italy). A group of scientists led by Claudio Bordignon and Fulvio Mavilio used retroviral-vector-mediated gene transfer to introduce a normal adenosine deaminase (ADA) gene into the peripheral blood lymphocytes (PBLs) of a five-year-old boy affected by the ADA-deficient variant of severe combined immunodeficiency. The cells were then restored to the boy. There was nothing particularly novel about the technical approach used—it closely mirrors the ADA-gene-therapy methods which W. French Anderson of the Molecular Hematology Branch of the National Institutes of Health's Heart, Lung, and Blood Institute (Bethesda, MD) used in September of 1990 and January 1991. This first European protocol, moreover, is likely to be followed shortly by other trials in the Netherlands and the U.K.

Gene therapy is increasing in Europe. An Italian gene-therapy trial is likely to be followed shortly by other trials in the Netherlands and the U.K.

The next stage in the Italian work will be to transfer the normal ADA gene into the same patient's bone marrow (BM) cells. So investigators can recognize the relative contribution of BM cells and PBLs in long-term reconstruction of the patient's immune system, the Italian group has used two different gene-transfer vectors. The one for transfer into PBLs is DCA, which was developed at Memorial Sloan Kettering Cancer Center (New York). For transfer into BM cells, the Milan researchers developed a modified version of DCA, DCAm.

There has been some concern in Europe about regulatory authority expertise in gene therapy. The Italian gene-transfer protocol, however, was approved by the Instituto San Raffaele ethics committee last December. At around the same time, the Italian National Bioethical Committee (Rome)—an advisory rather than a statutory organization—also came out with support for the protocol.

Somatic gene-therapy activity is increasing in Europe. Dinko Valerio of the Netherlands Organization for Applied Research (Delft), who has previously been involved in ADA-deficiency gene-therapy trials in the U.S., hopes to begin a similar treatment (using the BM-cell route) in the Netherlands in the near future. He is currently awaiting the decision of the ethics committee of the Dutch National Health Council (The Hague). In January, in the U.K., the Department of Health (London) gave a clear statement that it saw no serious ethical objections to somatic gene therapy. The cystic-fibrosis research group led by Robert Williamson at St. Mary's Hospital (London) is expected to be among the first in the U.K. to embark upon gene therapy.

—Angiola Bono