

CHRONICLE

SMITHKLINE-DAMON LINK ON T-PA; OTA STUDY

t-PA update. Damon Biotech (Needham Heights, MA) has filled in its tissue-plasminogen activator (t-PA) dance card with an agreement with SmithKline Beckman Corp. (Philadelphia, PA) for the manufacture and development of this much-touted blood-clot dissolver. Damon will manufacture the t-PA for SmithKline clinical trials and worldwide marketing—except in Japan where Yamanouchi Pharmaceutical (Tokyo) will commercialize the mouse myeloma cell-line-derived substance.

SmithKline has been developing CHO-derived t-PA in collaboration with Biogen (Cambridge, MA) since 1984 and plans to begin U.S. clinical trials in the near future. The Damon accord gives SmithKline access to Damon's production system and its unique form of t-PA, and it would skirt any possible patent difficulties with CHO-derived product.

In the meantime, all of biotechnology awaits U.S. Food and Drug Administration approval of Genentech's (South San Francisco, CA) t-PA. Although Wall Street's pundits had been expecting approval in June or July (see "Picking biotech stock winners gets trickier," in this issue), the drug will be reviewed by FDA's cardio-renal advisory panel on May 28–29, pushing back the probable approval date until July or August (in the opinion of Kidder, Peabody analyst Peter Drake) or maybe the fourth quarter of this year (according to Prudential-Bache vice president Linda Miller).

Cell line ownership. *New Developments in Biotechnology: Ownership of Human Tissues and Cells*, a recent study from the U.S. Office of Technology Assessment (OTA), lays out several options for Congress in considering this complicated issue. Concerning the commercialization of human biological materials, Congress could mandate compensation of donors or it could enact a statute prohibiting the buying and selling of human tissues. Moreover, Congress could amend patent law, extending it to provide compensation to donors, or could enact statutes to mandate sharing of profits with research subjects or patients whose cells are used in developing a commercial product. Alternatively, laws might be enacted indicating that cells are in "the public

domain" unless formally registered as otherwise. Copies of the report, stock number 052-003-01060-7, are available from the U.S. Government Printing Office, Superintendent of Documents, Washington, D.C. 20402.

Agricultural advances. Commercialization of agricultural biotechnology is heating up with new research advances, products, and field trials. Here are a few examples:

- Integrated Genetics (Framingham, MA) and Granada R&D Ventures (Houston, TX) received Food and Drug Administration approval to commence field trials of their bovine follicle stimulating hormone (bFSH). Essential in regulating reproduction in cows, bFSH will be used in embryo transfer.

- International Minerals & Chemicals Corp. (Northbrook, IL) plans to spend \$50 million on the construction of a facility to produce porcine somatotropin. This growth hormone could help produce leaner pork with lower feed costs.

- Synbiotics Corp. (San Diego, CA) introduced two new monoclonal antibody-based tests: KoliChek™ to detect bovine scours, and EstruChek™ to pinpoint estrus in cows.

- Advanced Genetic Sciences (Oakland, CA) selected Brentwood, CA, as the site for its controversial field test of its "Frostban" bacteria engineered to prevent frost damage to crops. The U.S. Environmental Protection Agency has already approved the trials, but state go-ahead is also needed.

- Calgene (Davis, CA) achieved expression of a recombinant marker gene under the regulation of a seed-specific transcription initiation signal in genetically engineered rapeseed plants. The firm plans to apply this technology to the control of a gene it has already cloned: the gene coding for acyl carrier protein, which is critical to plant fatty-acid synthesis.

- BioTechnica International (Cambridge, MA) established a new subsidiary, BioTechnica Agriculture (Overland Park, KS) to develop and commercialize microbial and plant products for improving crops. Charles Baker, who has been president of Rohm and Haas Seeds, will lead the new operation.

Changes at the top. Genex Corp. (Gaithersburg, MD) gained a presi-

dent, while Applied Biosystems (Foster City, CA) lost its chairman. Genex, which has been struggling since 1985 when G.D. Searle opted against buying its phenylalanine, recruited Gary E. Frashier as president and chief executive officer. The former chief executive officer of Continental Water Systems Corp. (San Antonio, TX) reports that he will solidify Genex around its antibody technology and bioadhesives. At Applied Biosystems, the sudden resignation of founder Sam Eletr—reportedly for health reasons—combined with soft overseas orders for its gene machines, caused the stock to plummet 30 percent.

Recombinant factor VIII. Baxter Travenol Laboratories' (Deerfield, IL) Hyland Therapeutics unit has begun the first human clinical trials on genetically engineered factor VIII. Developed by Genetics Institute (Cambridge, MA), the clotting factor has been difficult to produce because of its large size and delicate structure. Separately, Genetics Institute paid \$15.3 million for a 139,000-square-foot facility in Andover, MA, and announced that it will invest an additional \$20 million to equip the plant for process development and clinical production.

New agreements:

- Repligen Corp. (Cambridge, MA) and Centocor (Malvern, PA) restructured their AIDS vaccine agreement: Repligen obtained \$2.9 million in cash and rights to the vaccine; Centocor received 1.2 million shares of Repligen stock representing 17 percent of its outstanding equity.

- Millipore Corp. (Bedford, MA) acquired an equity interest in Protein Databases Inc. (PDI, Huntington, NY). Also, PDI announced that James Watson, director of the Cold Spring Harbor Laboratory, has joined the firm's board of advisors.

- Eastman Kodak (Rochester, NY) acquired a 16-percent equity interest in Genencor (South San Francisco, CA), a firm owned by Genentech, Staley Continental, and Corning Glass Works that focuses on industrial biotechnology products. Also, Kodak announced plans to sell its 2.3-percent stake in ICN Pharmaceuticals (Costa Mesa, CA) and much of its 9-percent interest in ICN's partly owned Viratek subsidiary