

## BUSINESS AND REGULATORY NEWS

**Cell Pathways to file NDA**

Cell Pathways (Horsham, PA) says it intends to file a new drug application with the FDA this summer following final positive data for exisulind, a pro-apoptotic compound for the treatment of adenomatous polyposis coli (APC). The target group of patients who formed 10–40 polyps per year—a 34-patient subgroup of the 65-patient trial—showed statistically significant (greater than 50%) reduction in new polyp formation when treated with exisulind as compared with placebo. The results contrast with disappointing preliminary analysis of phase III trial (*Nature Biotechnol*, 17, 220). However, in light of the relatively small number of patients who met inclusion criteria, the FDA has requested additional clinical data, which Cell Pathways says it will obtain from other ongoing APC trials.

**Cancer vaccine deal**

Seeking to develop a therapeutic against the effects of one of its own products, Japan Tobacco (Osaka) entered into a multiyear agreement in June with biotechnology firm Corixa Corp (Seattle, WA) for the development of therapeutic lung cancer vaccines. In exchange for over \$40 million in fees, funding, and milestone payments, Corixa will supply Japan Tobacco with lung cancer antigens, some of which will be formulated using its microsphere delivery system and adjuvant technologies. Japan Tobacco will receive exclusive rights in Japan and North America to resulting vaccine and antibody-based products for treating lung cancer and other solid tumors, as well as co-exclusive rights with Corixa partner Zambon Group SpA in China. With 500,000 new cases in the US, Europe, and Japan annually, lung cancer is the most common cancer in the world.

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**USDA bolsters biotech admin**

“With all that biotechnology has to offer, it is nothing if it’s not accepted,” said US Agriculture Secretary Dan Glickman during a policy address in July. In order to retain consumer trust in the US regulatory system, Glickman said the USDA will review its decade-old biotech approval process, aim to establish regional centers for the long-term evaluation of biotech products, and reinforce the independence of its regulatory and promotional/trade functions. He called for companies to monitor and disclose long-term effects of their products, and added that biotechnology should benefit farmers as well as consumers. “We must achieve a balance between fairness to farmers and corporate returns.” Glickman also hinted that voluntary labeling of GM foods might be introduced to help build consumer confidence. However, “it is imperative that such labeling does not undermine trade,” he said. Glickman, who partly blames the GM backlash in the EU on the lack of independent regulatory agencies there, was adamant that trade disputes should be based on sound science. “We will vigorously fight for our legitimate [trade] rights,” he warned.

**US study shows GM pros**

Some of the short-term advantages stemming from the use of the *Bt*-toxin gene were made clear in a 98-page study produced by the US National Center for Food and Agricultural Policy (Washington, DC) and published in mid-July. The study estimates that, in corn, the recombinant strains raised yields in the US by 47 million bushels on 4 million acres in 1997 (a year of high corn borer infestation) and by 60 million bushels on 14 million acres in 1998. Around 2 million fewer acres of corn were sprayed with insecticides as a result. For cotton, yields were up 85 million pounds and 5 million fewer acres were treated with insecticide.

**Infectech’s game plan**

World women’s chess champion, Hungarian-born Susan Polgar, is to join the scientific advisory board of Infectech (Sharon, PA), a biotechnology company developing rapid identification and typing tests for bacterial infections. Infectech’s president, Mitchell Felder, believes that applying the same kind of thinking that underpins chess can help entrepreneurial companies make the right connections between seemingly disparate concepts in medical technology.

**GM roundup**

□ In mid-July, The Genetic Engineering Network attacked and partly destroyed two stands of genetically modified poplar trees planted at the AstraZeneca agriculture research center near London. The Network’s anonymous statement released after its attack on the defenseless, immobile, life forms said that AstraZeneca was showing “contempt for our planet and the life it supports, including human life.” The trees have lowered levels of lignin and were being developed as part of an EU-funded research project to explore environmentally friendly sources of raw materials for paper and pulp production. According to AstraZeneca, English Nature (the UK government’s advisors on the environment) had written to the company three years ago telling it that there was negligible risk to native flora and fauna.

□ Thousands of people in Britain exposed themselves to the outdoor dangers of sunlight and non-GM crops in support of a call for a five-year moratorium on commercial planting of GM crops. While protestors consumed allegedly GM-free food and beverages at 50 sites around the UK, picnickers in Devauden (Scotland) had to face an additional hazard: the premiere of the anti-GM opera, “Soya Susie and the Gene Dictators.”

□ Japan’s Ministry of Agriculture, Forestry and Fisheries (Tokyo) has suspended safety trials of crops into which the gene for the *Bt* insecticidal protein has been inserted until it has formulated guidelines to indicate how pollen toxicity should be assessed. The short-term moratorium does not affect imports of GM corn into Japan from the US.

□ The environmental protest group Greenpeace has threatened to sue the EU unless the EC withdraws marketing authorizations it has already granted for *Bt*-maize developed by Monsanto and Novartis.

□ UK parliamentarian Alan Simpson is proposing that company directors should be personally liable for any damage caused by the supply of GM crops to the environment. The MP for Nottingham South is sponsoring the GM Food and Producer Liability Bill, a private measure that stands no chance of becoming law. Simpson contrasted the warnings about risks to human health displayed on pesticides that can be bought in garden supply shops with the absence of such warnings on plants that produce their own lepidopteran-specific toxins.