Controversial AIDS drug for US market

Berkeley, California

ETHIGEN Corporation of Los Angeles will market AL-721, a controversial lipid mixture reputed to have anti-AIDS action, as an over-the-counter nutritional supplement in US pharmacies and health food stores, beginning in April. The price will be \$250-\$300 for a month's supply.

Clinical benefits of AL-721, which is made from egg-yolks, have yet to be shown in controlled trials, but reports of its anti-viral properties resulted in a clamour from AIDS patients to make it available. Ethigen vice president Robert Weingarten said the company decided to begin sales now rather than wait for results of controlled trials in AIDS patients, due to increasing demand and a proliferation of 'copycat' compounds.

AL-721 was developed in the early 1980s by Meir Shinitzky at the Weizmann Institute in Israel, as a possible treatment for alcohol withdrawal and age-associated memory loss. It has not been proved effective for either condition, but a limited human trial suggested that it may improve immune function, spurring Ethigen, originally called Praxis Pharmaceuticals, to obtain the licence to produce it. Ethigen angered Weizmann officials by using the institute's name in promoting the unproved treatment.

AL-721 is Ethigen's first product, and the company's stock has ridden a roller coaster of publicity over the compound. Priced at \$1.25 per share when Praxis went public in January 1985, it jumped to \$4 per share that November, after publication in the *New England Journal of Medicine* of results from Robert Gallo's laboratory at the National Institutes of Health suggesting that the compound inhibited viral replication. In early 1987, an 8-patient, uncontrolled clinical trial in New York showed what Weingarten called "promising but inconclusive" reduction of virus in blood of some HIV (human immunodeficiency virus) patients with lymphadenopathy, boosting the company's stock to an all-time high of \$11 per share. Currently priced at about \$1.50 per share, the stock showed only a "muted response" to the recent marketing decision, said Weingarten.

AL-721 has been shown to scavenge excess cholesterol from cell membranes and from the AIDS virus envelope. Company scientists speculate that such a change could alter the configuration of surface proteins, preventing the virus from binding to cells. The company says it has found that the imitation compounds

New US-Japan science agreement reached

■ Cooperation to be expanded

■ Compromise on security issues

Washington

US AND Japanese negotiators at last concurred "in substance" last Thursday on the terms of a new science and technology cooperation agreement. It took eight rounds of talks, held alternately in Tokyo and Washington, to reach this point and neither side could manage a smile.

The agreement will be officially signed by US President Ronald Reagan and Japanese Prime Minister Noboru Takeshita at a time yet to be decided, but perhaps at the June economic summit in Toronto. Before then, legal details of the agreement will be worked out. The present bilateral science and technology agreement, which would have expired last Thursday, will be extended by three months to allow the finishing touches to be put to the new agreement.

Under the current agreement, 48 cooperative projects have been carried out in the fields of space, health, energy and environmental research. Included in the diverse areas studied are joint projects on Halley's comet, X-ray astronomy, typhoons, alcoholism and insect pest management.

The new agreement will not significantly affect projects already under way. But it will set much clearer terms for an expected major expansion of joint research by the two nations and provide a new management structure to make expansion possible. It is hoped that the number of US scientists working in Japan will rise as cooperation increases.

Although details of the new agreement remain secret, a major compromise ap-

pears to have been made on research that may affect national security. The Japanese government carries out only a little defence research, most of it at a Technical Research and Development Institute which employs just 1,200 scientists. Elsewhere in Japan, even in government laboratories, there is a strong tradition of open access to research results which Japanese researchers are anxious to maintain.

Early demands from US negotiators would have required a change in Japanese law to increase government control over joint research deemed by the United States to affect national security. Research related to the Strategic Defense Initiative would have been an obvious candidate for increased security.

The final agreement does contain a security agreement to prevent militarily-useful information from reaching other countries. But it does not require a change in Japanese law to enforce and is apparently worded in a way unlikely to outrage Japan's opposition parties.

Debate over how intellectual property rights from joint research are to be apportioned also appears to have ended in compromise. Instead of the new set of general rules that the US side is thought to have been seeking, rights will be given on a 'case-by-case' basis, according to the contributions made by each side. Although that is an advance from the current agreement, which provides no specific guidelines, it falls far short of a US view that all joint research conducted within the United States would be US property.

Alun Anderson

on the market lack the proper lipid ratio to produce the membrane effects seen with AL-721.

Despite doubts on the part of many AIDS researchers about the plausibility of the proposed action of AL-721, the National Institute of Allergy and Infectious Diseases (NIAID) has begun toxicity trials, due as much to pressure from AIDS sufferers as to any belief in its promise as a treatment. "It's not an obvious candidate to be a major breakthrough", said Dale Spriggs, of the AIDS treatment branch of NIAID.

Ethigen says it will comply with US Food and Drug Administration (FDA) guidelines, which allow a product to be marketed as a nutritional supplement only

if it is produced from substances recognized as safe, and the producer makes no claims of therapeutic effects. The FDA is currently investigating an Indiana company for marketing a compound similar to AL-721 as an AIDS treatment. Because of AL-721's widespread reputation, Ethigen is seeking advice from regulatory lawyers on whether it should make a specific disclaimer for AIDS.

AL-721 is currently available by prescription in Britain for patients with AIDS or AIDS-related conditions. It is classified as a "special" pharmaceutical, said Weingarten, which means it has not completed testing but has a high safety profile and some indication of possible efficacy.

Marcia Barinaga