Good news for Amylin

Amylin Pharmaceuticals (San Diego, CA) announced that its lead diabetes drug candidate helped control blood sugar levels in a phase III trial, prompting a 56% (\$1.4062) surge in share price at the end of August. In the one-year study, patients with type II diabetes were treated with pramlintide, a synthetic amylin analog, in addition to their usual diabetes treatment (insulin and oral hypoglycemic agents). For the 656 patients receiving 120 µg twice a day, there was a 0.7% reduction in glycated hemoglobin (HbA1c) at both six months and a year, compared to 0.3% and 0.1%, respectively, for the control group. In addition, patients receiving pramlintide lost 3.1 lb (1.4 kg) after a year compared to a gain of 1.5 lb (0.7 kg) in the control group. The results are good news for Amylin, which has suffered a series of setbacks, including the failure of three out of four previous trials, and the loss of its development partner: After investing \$160 million in the drug, Johnson & Johnson (New Brunswick, NJ) pulled out of joint development in March 1998, causing a 50% plummet in Amylin stock price (Nat. Biotechnol. 16, 317, 1998). Amylin is now likely to look for a new partner to bring the drug to market. Results from a phase III trial of pramlintide in type I diabetes is expected before year's end.

Bexxar rejected for now

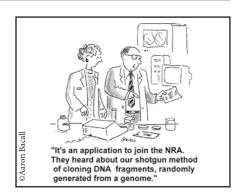
The era of the monoclonal antibody is clearly still not with us. At the end of August, the FDA turned down application for approval of Bexxar, a monoclonal antibody linked to a radioisotope for the treatment of low-grade B-cell non-Hodgkin's lymphoma. The FDA is not seeking new clinical trial data, but it does want the Biologics License Application (BLA) submission reanalyzed and reformatted. Nevertheless, shares of Coulter Pharmaceuticals (Palo Alto, CA), which is developing the drug in conjunction with SmithKline Beecham, dropped 31% the day following the announcement, closing at \$23.50. Since Coulter's product portfolio is relatively small, its future is linked to Bexxar, its most advanced candidate (Nat. Biotechnol. 16, 1000, 1998). By the end of this month the company plans to submit the amended BLA, which will take six months to priority review. In the meantime, Coulter's rival, Idec Pharmaceuticals (San Diego, CA), saw its share price drop 23% (to \$105.44) after announcing that the third quarter sales of Rituxan-a naked monoclonal for treatment of non-Hodgkin's lymphoma—are unlikely to reach the high end of its \$70-\$80 million target.

GFP: Kacs and dogs

In some organisms at least, recombinant DNA is still an art. That is certainly the case for Eduardo Kac, a transgenic artist based in Chicago who described two pieces of his transgenic art at the Life Sciences symposium organized at the recent Ars Electronica festival in Linz, Austria.

His installation, Genesis, says Kac, explores the relationship between biology, belief systems, IT, dialogical interactions, ethics, and the Internet. Genesis uses Escherichia coli to transmute the words of the god of the Christians and the Jews. Kac first created the "genesis gene" by translating the biblical quotation "Let man have dominion over the fish of the sea, and over the fowl of the air, and over every living thing that moves upon the earth" first into Morse code and thence into DNA code. Through transformation he produced blue E. coli contain ing both the "genesis gene" and a gene for enhanced cyan fluorescent protein. Internet observers (www.ekac.org) can interact with the installation by turning on and off a mutagenic UV radiation source that illuminates a mixed culture of the "genesis strain" with yellow E. coli (gene for enhanced yellow fluorescent protein and no "genesis gene").

Kac's other transgenic installation is GFP-K9, a dog transformed to express the gene for green fluorescent protein in its coat. Kac believes that the creation of transgenic companion animals will challenge people to reassess their views of transgenics in general. At present, he says, transgenics are stigmatized by their being—in the main—laboratory variants. GFP-K9, Kac points out, is a work in progress pending advances such as the transformation of canine cells through microinjection and the completion of the dog genome project (in order to locate coat coloration genes).



Blow for UK biotech

The Wellcome Trust's (London) mighty genomics wagon came off the rails slightly when plans for a £100 million biotechnology park in the UK were thwarted by local planning authorities. Wellcome wanted to expand its Genome Campus in Hinxton (near Cambridge) to provide facilities for firms that might commercialize the exploitation of raw data being generated at the Sanger Center for gene sequencing and processed by the European Bioinformatics Institute. The plan was expected to create 1,000 jobs and many start-up companies, but the UK secretary of state for the Department of the Environment, Transport and Regions rejected the proposal amid local concerns about the effects an expansion—about 40,000 square meters would have on the surrounding countryside. The decision starkly contradicts sentiment at the UK Department of Trade and Industry, which recently emphasized the importance of promoting biotechnology "clusters" for development of the industry (Nat. Biotechnol. 17, 520, 1999). Rumors that the Wellcome Trust is now looking to locate abroad have not been confirmed.

Novartis to de-merge ag biz?

Novartis (Basel, Switzerland) will neither confirm nor deny it is looking to spin off its ag business. Although such a concept is conceivable, it is pure speculation at the moment, according to Novartis CEO Daniel Vasella. Half-year financial results for the division were disappointing (down 10%), but "at present a spin-off does not make sense," says Rolf Furter, analyst at Bank J. Vontobel (Zürich, Switzerland), who recently published the study Agri Business 1999. The ag market as a whole (crop protection 64%, animal health 23%, and seeds 13%) grows very slowly and is already more consolidated than the pharmaceutical market. Moreover, acceptance of GM food in Europe is likely to be low for several years. But, Furter says, "You do not dispose of the division in times when the agri market is difficult." In addition, only Monsanto and DuPont have larger seed businesses than Novartis, making it very difficult to find a buyer for Novartis. "Monsanto and DuPont could not acquire Novartis' agri business because a merger would dominate local markets and specific crops," explains Furter. But he says that if Novartis were to become involved in M&A activity, the most likely candidates are German partners such (Leverkusen) or (Ludwigshafen), which currently lack seed investments.