

IN brief

Cuba's first GM corn

Cuba will be planting its first genetically modified (GM) corn to help reduce its dependence on costly food imports. The Cuban Center for Genetic Engineering and Biotechnology (CIGB) of Havana will begin the experimental plantation of 125 acres with the GM corn, provisionally called FR-Bt1. This corn is currently undergoing regulatory approval for its environmental release. "Cuban rules are very strict... but in Cuba there is a political will for employing the technology," explains Carlos Borroto, deputy director of the state-run center, and head of the Cuban National Program of Agricultural Biotechnology. The FR-Bt1, whose technical details cannot be revealed due to confidentiality clauses in the registration process, is aimed at animal feed and will be used exclusively in Cuba. The GM crop is engineered to resist the country's main pest: the lepidopteron *Spodoptera frugiperda*. The FR-Bt1 corn was developed by a large CIGB team, led by Camilo Ayra, in collaboration with other research bodies. The entire project was financed with public funds from the Cuban Council of State. "Because the corn has shown an elevated level of multiplication, some 2.5 acres could produce enough seeds to plant 300 acres," says Borroto. Although the use of GM organisms is debated in Cuba, public perception is mostly positive because these developments do not seek commercial gain but the nation's food sufficiency. The outcome of these field trials is expected for April 2009. *—Veronica Guerrero*

EU pushes advanced therapies

This month, the EU Committee for Advanced Therapies (CAT) will be holding its first workshop to discuss the implementation of a new legislation designed to harmonize gene therapies, cell therapies and tissue-engineered products within Europe. The lack of EU-wide regulatory frameworks for such novel therapies has, in the past, hampered the biotech industry's growth and hindered patient access. The recently passed EU Advanced Therapies Regulation lays down rules on the authorization, supervision and pharmacovigilance of newly emerging therapies. The committee, which is responsible for preparing draft opinions on quality, safety and efficacy of advanced therapies for final approval by the Committee for Medicinal Products for Human Use (CHMP), is part of the European Medicines Agency (EMA). It includes representatives from CHMP, member states, clinicians and patient organizations. The regulation outlines a centralized marketing authorization procedure and special incentives for small and medium-sized enterprises (SMEs). Christiane Abouzeid, of the BioIndustry Association, believes that the CAT will help small companies by providing expert advice on complex products. An industry spokesperson notes that incentives for companies and investors within the new Advanced Therapies Regulation will more than offset any short term "pain" while procedures are set up. *—Susan Aldridge*

FDA holds court on *post hoc* data linking KRAS status to drug response

In mid-December, Amgen of Thousand Oaks, California, and its competitor ImClone Systems of New York jointly went in front of the US Food and Drug Administration (FDA) Oncologic Drug Advisory Committee (ODAC) to request permission to shrink the market for their products on the basis of genetic stratification of their target patient populations. Both argued, on the basis of retrospective analyses correlating mutation status with therapeutic response, that their respective anti-epidermal growth factor receptor (EGFR) monoclonal antibodies Vectibix (panitumumab) and Erbitux

(cetuximab) for advanced colorectal cancer should be relabeled for use in only the 60% of individuals whose tumors harbor the wild-type KRAS gene. While the FDA continues to gather opinions and debate internally its criteria for biomarker validation, thus far the agency continues to be reluctant to consider retrospective data, even if such data indicate that a group of patients could be spared futile therapy.

Post hoc re-evaluation of clinical data runs counter to conventional statistical practice at the FDA. According to the agency's standard line of thinking, biomarker and therapeutic

should be developed in parallel and end-points designed prospectively in order for the validity of a hypothesis (and a related null hypothesis) to be tested. For its part, the FDA acknowledges that the science of drug development tied to prognostic indicators is moving at break-neck speed and that new developments may provide reasons for re-evaluating its stance—for example, in situations where patients could be spared futile treatment on the basis



ImClone and Amgen were hoping to include label warnings about KRAS mutations on their products to assist physicians in making treatment decisions for their patients.

SELECTED research collaborations

Partner 1	Partner 2	\$ (millions)
Archemix (Cambridge, Massachusetts)	GlaxoSmithKline (GSK, London)	1,420
Dynavax (Berkeley, California)	GlaxoSmithKline (London)	810
Apitope (Bristol, UK)	Merck Serono (Geneva)	€154
BRAIN (Zwingenberg, Germany)	Genencor/Danisco (Palo Alto, California)	*

*Terms not disclosed.

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