IN brief

GM bananas

Uganda has launched field trials of its own genetically modified (GM) bananas in an effort to counter a disease that is devastating plantations in the Great Lakes region of Africa. The GM bananas are genetically engineered to resist the *Xanthomonas musacearum* or BXW, a wilt-causing bacterium that destroys the entire plant. Scientists at the National Banana Research Program in Kampala, led by Wilberforce Tushemereirwe, obtained three banana varieties resistant to BXW by transferring two different sweet pepper (*Capsicum annuum*) genes into bananas—one encoding the hypersensitivity response–assisting protein and another the plant ferredoxin like protein. Results from the field tests, carried out at the National Agricultural Research Laboratories Institute in Kawanda, are expected by the end of 2011. "The next step is a multilocation field trial that will take a further two years," says Leena Tripathi, a biotechnologist from the International Institute of Tropical Agriculture in Nairobi, Kenya, also involved in the project. Support comes from the Gatsby Charitable Foundation, African Agricultural Technology Foundation and USAID. The transgene patent holder, Taiwan's Academia Sinica based in Taipei, issued a royalty-free license for commercial production in sub-Saharan Africa. "Crop scientists in the country are making significant progress for both GM banana and drought-tolerant maize. Parliament should now pass the biosafety law needed to permit an eventual release of these improved varieties to farmers," says Robert Paarlberg, a policy analyst at Wellesley College, Massachusetts. *Anna Meldolesi*

IN their words

"Zombie products are never very much fun." Bank Vontobel AG analyst Andrew Weiss comments on Novartis' plans to resurrect a cyclooxygenase 2 inhibitor Prexige (lumiracoxib) banned four years ago. (*Bloomberg*, 5 April 2011)

"There has been a fundamental shift in healthcare industries. Investors no longer place any meaningful value on the pipeline....The stocks are now mostly owned by the likes of people who would own utilities." Bain & Co.'s Tim van Biesen on investors' tendency to shun biopharma's long timelines, as Amgen finally bows to investor demands and agrees to pay dividends for the first time. (*FierceBiotech*, 18 April 2011)

"We were shocked to find out that the FDA is often one of the greatest impediments to job creation." US Rep. Darrell Issa, speaking at a recent public forum, takes aim at regulators for holding back the growth of the biotech and pharma industries. (*The San Diego Union-Tribune*, 22 April 2011)

compliance is a voluntary one, and many domestic vaccine makers are likely to remain reluctant to collect and report side effects of their vaccines. "The Chinese watchdog should increase regulation and education to improve general industry awareness," the insider says.

Liu of Sinovac adds that most Chinese vaccine makers are not familiar with international vaccine purchasers. "It is a long road to sell Chinese vaccines in the global market, despite our lower prices," he says.

Vaccines made in China are indeed cheap. For example, the combined measles, mumps and rubella vaccine is priced by China's National Development and Reform Commission at 20.8 yuan ($3.20) per dose—one-fifth of the price approved by the US Centers for Disease Control and Prevention. Most of these low-cost vaccines are made by the China National Biotec Group, headquartered in Beijing, for the domestic market. But meeting international standards will likely require more expensive materials than those currently employed by manufacturers, says WanTai's Qiu.

To supply vaccines through the United Nations agencies, vaccine makers must now abide by China's new version of good manufacturing practice (GMP), which was released in late February. The new GMP stipulates stricter requirements on sanitation, production process and standardization, in line with requirements adopted by the US, EU and WHO. Most of China's nearly 5,000 pharmas have been asked to pass the new GMP approval in three years and vaccine makers must pass in five years or lose their drug production licenses.

For Western pharma, China's new status presents an interesting prospect. On the one hand, an opportunity exists for technology transfer agreements and partnerships to help Chinese manufacturers maintain compliance with the SFDA. On the other hand, China could gain significant market share in developed nations where vaccine companies, such as Merck of Whitehouse Station, New Jersey, GlaxoSmithKline of London, Pfizer of New York, Novartis of Basel, and Sanofi of Paris currently have a stranglehold, with combined vaccine sales of about $20 billion in 2010.

When contacted by *Nature Biotechnology*, executives at multinational vaccine makers were reluctant to speculate on how WHO approval might influence the business strategy of China's 36 vaccine manufacturing firms going forward. But in the short term, Chinese manufacturers are likely to seek help from foreign firms in improving their operations, particularly as the government begins to open its doors to multinational corporations.

Geneva's International Federation of Pharmaceutical Manufacturers and Associations says the SFDA has "lowered the barriers to entry," allowing foreign investments, buyouts and partnerships in an effort to improve the country's capabilities. To Western pharmaceutical firms, China's domestic vaccine market is an attractive prospect. Novartis, for example, laid down $125 million in March to pick up an 85% stake in Bio-Pharmaceutical, located in Zhejiang, Tianyuan. This vaccine maker produces seasonal inactivated flu vaccines, inactivated bivalent hemorrhagic fever with renal syndrome virus vaccine with alum adjuvant, inactivated Japanese encephalitis virus vaccine and a quadrivalent polysaccharide-based vaccine covering the other four pathogenic meningococcal serogroups, A, C, Y and W-135.

"This is a very positive signal for other foreign companies and investors who wish to follow," says Feng Li, senior vice president of Advanced Pharmaceuticals, a technology transfer consulting firm based in Raleigh, North Carolina, and Shanghai. "There might be an opportunity for them to get their foot in the Chinese market."

GlaxoSmithKline and Merck each believe there is a place for Chinese manufacturers beyond the domestic market in emerging nations, such as Brazil, India, Mexico, Russia and Turkey. Two years ago, GlaxoSmithKline joined with Chinese companies Shenzhen Neptunus and Walvax Biotech to manufacture influenza vaccines and pediatric vaccines, whereas Merck signed a deal in 2010 with Sinopharm Group and its affiliates to work on human papilloma virus and other vaccines. "We believe that great science knows no borders," says Mark Feinberg, vice president of medical affairs and policy at Merck, "and we are impressed with the strong scientific capabilities that are abundant in China."

Chinese manufacturers may help improve access to vaccines in developed nations. WHO prequalification acts as a quality assurance watchdog for low-income countries that lack their own regulatory process. Sabine Haubenreisser, of the European Medicines Agency in London, says, "influenza vaccine supply during the H1N1 pandemic was a bottleneck. China could potentially facilitate supply for global demand in a pandemic."

China's first export is likely to be a vaccine against Japanese encephalitis virus, a virus for which there are currently no WHO-prequalified vaccines, although there are marketed ones made by The Research Foundation for Microbial Diseases of Osaka University (BIKEN) and Vienna-based Intercell, and distributed by Sanofi and Novartis. China expects to have a WHO prequalified vaccine for this disease within one to two years.

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