IN brief

India partners to fast track biotech

Wellcome Trust

S. Natesh at the launch of the DBT/ Wellcome Trust/India Fellowship Programme.

India is embarking on a series of foreign tie-ups to boost research and train manpower for its burgeoning biotech industry. The latest scheme, a £160 million jointly funded partnership over ten years between the London-based Wellcome Trust and India's Department of Biotechnology (DBT), is the latest example of the partnership model pursued by the Indian government to strengthen its biotech base. The joint program will provide 75 fellowships each year designed to attract the best Indian biomedical scientists working abroad. Last year, the Indian government and Stanford University, California, launched a five-year $4.8-million 'biodesign program' aimed at turning Indian doctors and engineers into medical device inventors and impelling India's biomedical technology industry, says Rajiv Doshi, the program's executive director at Stanford. Canada also pledged Ca$5 ($4.3) million for a fund to support plant biotech research, and another joint fund was set up with €3 ($4) million from the European Commission to support agricultural biotech research in April 2008. An Indo-Norwegian alliance has been launched to focus on vaccines, and a bioinformatics collaboration with Japan is on the cards. An $11.5 million Indo-Australian joint fund has been supporting public and private sector researchers since 2006 in the fields of stem cells, vaccines and transgenic crops. Academic scientists have benefited, but the fruits of these alliances have yet to flow to companies, says Prasanta Ghosh, former adviser to DBT and now managing director of New Delhi-based KEE GAD Biogen, a biopharma company. This is a wasted opportunity considering the expected growth in biotech activity. According to the London-based consultancy firm KPMG, biopharma already constitutes about 70% of the domestic biotech industry, and they predict biotech business will grow to $5 billion by 2010 from $2 billion last year. At present, Indian firms are only producing copies of established biologic drugs such as recombinant insulin, interferon alpha and erythropoietin and starting to move into monoclonal antibodies and recombinant vaccines. But a DBT five-year plan approved last year gives the highest priority to new biological entity discovery. The KMPG report says a few companies like Glenmark Pharmaceuticals are already breaking into the novel biologicals space. "In the past most of our programs were aimed at academic collaborations," says S. Natesh, head of DBT's international division. "Our new calls for proposals, hopefully, will bring in industrial collaboration." The Indian government also expects to expand opportunities for research and training once its $10 million regional biotech center being set up near New Delhi in partnership with UNESCO is ready. *–Killugudi Jayaraman*

Burroughs insists that providing wider access doesn't have to hurt trial enrollment, if patients are required to attempt to enroll in a trial before they can get the drug. The Access Act makes that provision.

Concerns over adverse events in cases of compassionate use may be overblown, notes Robert Temple, director of the office of medical policy in the FDA Center for Drug Evaluation and Research. "To the best of our knowledge that has never happened," he says. But he adds that FDA never intended that companies would be obliged to provide drugs to specific patients before approval.

Temple says the agency's key concern is maintaining clinical trial integrity. "There was always a perception that we were hostile to allowing access, but that's not true. As long as it doesn't interfere with drug development we are not against it," he says.

But Burroughs argues that the FDA's proposed regulations are "more public relations to show they are doing something about expanded access when it really does very little. They are just taking current FDA policy and putting it into regulation."

Most biotech companies are familiar with the traditional approach to expanded access and compassionate use. Osiris Therapeutics of Columbia, Maryland, for example, began a compassionate-use program for children several years ago, after it became clear that the company's mesenchymal stem cell therapy, Prochymal, was very effective for treating graft-versus-host disease (GVHD).

"It's a horrible disease and people suffer terribly," says Randy Mills, CEO of Osiris. The first child treated was an 8-month-old infant who had "peeled out of his skin and was shedding his intestinal lining," Mills says. The baby's condition was dire, but he recovered completely after five days on the therapy. Word spread quickly and Osiris eventually gave Prochymal to a dozen children on a compassionate-use basis, concurrently to running their trials.

Now, the company's two Prochymal phase 3 trials in GVHD are wrapping up, and Osiris will be providing the therapy via expanded access until it is approved, which should be sometime in the second half of 2009.

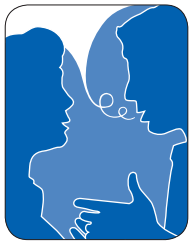
Kim McBride at Nationwide Children's Hospital treats many patients with rare genetic diseases and was recently involved in an expanded access program for BioMarin's (Novato, CA, USA) sapropterin dihydrochloride, or sapropterin, an investigational treatment for phenylketonuria. "Once it was clear people were getting better results with the drug, than just diet alone, we wanted to get this drug to children as quickly as possible," he says. Phenylketonuria is a rare genetic condition that can cause serious disability, including mental retardation.

McBride says that the most desperate patients, such as those with lysosomal storage diseases, "are ready to take greater risks, and giving those patients early access, through compassionate use, to investigational drugs gives us an early look at the drugs, too."

As this article went to press, PTC had succeeded in postponing the court's order until after the appeal. "But, they will be legally obliged to give him [Gunvalson] the drug, unless their appeal is successful," says Thompson. If the appeal fails, PTC's only recourse will be to try and get the Supreme Court to hear the case.

Malorye Allison *Acton, Massachusetts*

IN their words



"All we need is for you to just say 'yes' to save his life."

Andrew Baron pleads with Biogen Idec to give his father, Fred Baron, the Dallas trial lawyer who served as finance chairman for John Edward's presidential campaign, access to Tysabri. (*Bloomberg*, Oct. 16, 2008)

"This becomes more like a Wal-Mart than anything the industry has done before."

Neil MacAllister, head of consultantcy AVOS Life Sciences (Morrisville, NC), suggests outsourcing will become so integral to pharma companies they will resemble Wal-Mart, simply managing marketing, intellectual property and a network of suppliers. (*Pharmalot*, Sept. 8, 2008)

"In this business, bribery keeps everyone silent."

A dairy farmer from Shijiazhuang, China comments on the widespread bribing of milk testers by farmers and milk dealers, after tens of thousands of Chinese infants were sickened by milk formula tainted with melamine. (*New York Times*, Sept. 26, 2008)

"I wake up every day thinking about how to make beta cells."

Harvard researcher Doug Melton, whose two children have type 1 diabetes, on his quest to find ways of reprogramming differentiated cells into insulin-producing cells. (*Yahoo News*, Aug. 27, 2008)

"When one of the animals escaped on Home Office premises and mated by accident, the sow was killed under instructions from Defra and we are not allowed to do a post-mortem on the piglets to find out whether those piglets are transgenic."

Lord Robert Winston of London's Hammersmith Hospital on the UK regulations that are forcing his group to relocate their xenotransplantation work with transgenic pigs to Missouri. (*BBC Radio 4*, Sept. 8, 2008)