

## Indo-US collaboration on herbal drugs

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A four-day scientific event, "Indo-US Symposium on Scientific Approaches to Quality, Safety and Efficacy Assessment of Ayurvedic and Botanical Products" was organized by Regional Research Laboratory, Jammu, a constituent research Institute of CSIR in collaboration with National Center for Natural Products Research, University of Mississippi, USA, in Delhi.

In his inaugural address, Dr Mashelkar mentioned that drug discovery using modern science is very expensive and time consuming and there is need to develop safe and affordable drugs. Since herbal drugs are widely acceptable, CSIR is deeply involved in the development of herbal drugs in collaboration with ayurvedic establishments. In this context, the collaboration between India and the US will be highly beneficial and this is the need of time looking into requirements of mankind globally. He was hopeful that the use of good practices, modern technologies, ayurvedic concept and collaborative efforts will lead us to development of the products that will be available in the market.

Prof. Larry A Walker, director, National Center for Natural Products Research (NCNPR), University of Mississippi, USA expressed his interest and that of his Institute in the area of natural products chemistry and herbal drugs and hoped that Indo-US collaboration have great potential. Dr Ikhlas A Khan, director, FDA Program, NCNPR, University of Mississippi, USA mentioned that collective efforts of the Indian and the US academicians, industries and government agencies will be of great interest in the area of developing herbal drugs.

Dr GN Qazi, director, Regional Research laboratory, Jammu presented a note about the CSIR's capabilities, contributions

and public private partnership in the area of herbals. He mentioned that Indian system of medicine has stood the test of the time and has potential to meet the need of the global market. To achieve the objective, there is need to include modern scientific approach and technologies for standardization of herbal drugs to meet the quality, safety and therapeutics. The approach is also essential for regulatory compliance in force from time to time and all such related issues will be discussed in the present symposium.

Dr Somesh Sharma, chief scientific officer, Nicholas Piramal, Mumbai discussed the possibilities to develop therapeutics based on plants. He explained the advantages of using plant extracts in terms of modern science taking an example of arthritis. He also mentioned that due care of quality, efficacy and safety should be taken.

During this four-day event, distinguished speakers addressed the contemporary issues on the quality, safety, efficacy of ayurvedic and botanical products. A gathering of 100 researchers were present that included eminent national and international scientists and experts from industry, R&D institutions, academia, non-profit institutions, regulatory authorities and centers of excellence within India and abroad.

### **Agami to provide access to Indian firms**

Agami, a Chicago-based contract research organization (CRO), will provide the US companies access to multiple labs, manufacturing facilities, and CROs through a network of "preferred partners" in India. Agami provides drug discovery and development services for the biopharmaceutical industry.

Agami has screened over 100 companies in India and prepared a list of preferred providers for the US companies based on their ability to generate data acceptable to the US FDA and European regulatory authorities. The data generated by these companies have been used by sponsors for receiving approvals from the US FDA and European authorities.

"We have selected our partners based on their ability to provide services of very high quality at affordable costs with long-term commitments. We not only provide the best of the services available from India for contract research but also take away the hassles and confusion North Americans sometimes face in dealing owing to socio-cultural and time differences," said Dinesh Jain, founder and CEO, Agami.

### **17 organizations call for ban on GE rice**

A coalition of 17 organizations from across Asia have issued a World Food Day statement calling for a global ban on the introduction of genetically engineered (GE) rice.

"Rice is the world's most important staple food crop and we simply cannot allow a small number of biotech companies and GE scientists to determine the future of rice development," said Varoonvarn Svangsopakul of Greenpeace Southeast Asia. "GE rice is not a solution to world hunger. It poses unacceptable risks to health and the environment, as well as people's livelihoods."

"GE rice poses threats to the center of origin and diversity of rice in Asia, as well as the cultural diversity of rice-growing communities across the region. The introduction of GE rice is contradictory to the theme of this year's World Food Day celebration," said Dr Suman Sahai from Gene Campaign, India.

"Dr Sahai said that recent evidence of serious health damage from the rat feeding studies on Bt corn, leaked from Monsanto's laboratories and older studies on GM potatoes and tomatoes all point to the fact that GM foods are highly unsafe and pose a danger to human health. Introducing GM rice in India which is the cradle of rice, the land from where rice originated and in other countries of Asia, is a reckless and irresponsible act. Dr Sahai who joined representatives of 10 other Asian countries in Bangkok said that the Indian government must scrap the work on GM rice and GM foods".

"The real way forward for sustainable agriculture and solution for hunger is through the protection and use of biodiversity rather than genetic engineering, and the promotion of ecological agriculture based on the traditional knowledge of farming communities," said Paul Borja, SEARICE, based in the Philippines.

"Bangladesh farmers have a long tradition of maintaining local rice diversity and they are resisting Syngenta's move to introduce Golden Rice," said Palash Baral, from UBINIG Bangladesh. "With breeding and growing local rice varieties, Thailand farmers are able to enjoy nutritious food and stabilize their income," said Supanee Taneewut, RRAFA, Thailand.

Following a two-day meeting outside Bangkok, representatives from 10 rice growing countries wearing traditional dresses delivered the GE-Free Rice Declaration to the FAO headquarters in Bangkok, along with a collection of rice varieties as a demonstration of the importance of maintaining rice diversity. In the declaration, the group called for a ban on the

development and cultivation of GE rice, and called upon the FAO to cease support for GE crops, and to instead support the development of sustainable, ecologically sound farming systems.

### **India, Netherlands in biotech pact**

India and the Netherlands have signed a MoU for co-operation in biotech to find solutions to problems in agricultural and health areas. The MoU was signed between the Department of Biotechnology (DBT) and Netherlands' institutes of higher education. According to Laurens Jan Brinkhorst, deputy prime minister and minister of economic affairs, Netherlands specific areas for joint activities would be identified in the next three months. "While DBT would contribute Rs 7 crore, Netherlands' institutes of higher education would contribute Rs 10 crore in the beginning," informed Kapil Sibal, the science and technology minister. The first round of project proposals, selected on the basis of recommendations of a joint action committee, would be implemented by March 31, 2006.

"The Aim is to use science for societal development and find solutions to agricultural and health problems. For example, Netherlands has technology to grow plants in salinated soil which could be useful for India," Sibal said. Similarly projects to grow plants in conditions of biotic and abiotic stress would also be taken up, he said. The intellectual property generated by the joint research would be shared, said Dr MK Bhan, secretary, DBT.

### **Nobel Prize for discovering stomach inflammation bacterium**

Two Australian scientists who upset medical dogma by discovering a bacterium that causes stomach inflammation, ulcers and cancer, won the 2005 Nobel Prize for Physiology or Medicine recently. The winners were Dr Barry J Marshall, 54, a gastroenterologist from the University of Western Australia in Nedlands, and Dr J Robin Warren, 68, a retired pathologist from the Royal Perth Hospital. They won the Nobel Prize for medicine for their discovery of the bacterium *Helicobacter pylori*. The findings by the Australians in the early 1980s went so against medical thinking, which held that psychological stress caused stomach and duodenal ulcers, that it took many more years for an entrenched medical profession to accept it.

In its citation, the Nobel committee from the Karolinska Institute in Stockholm said that Dr Marshall and Dr Warren "made an irrefutable case that the bacterium *Helicobacter pylori*" causes ulcers and other diseases."It is now firmly established that *H. pylori* causes more than 90 percent of duodenal ulcers and up to 80 percent of gastric ulcers," the Nobel committee said.

In the early 1980s, Dr Warren noted the bacterium in the lower part of the stomach in about half of the patients who had biopsies. He made a crucial observation that signs of inflammation were always present in the surface lining of the stomach near where he observed the bacterium. Dr Marshall joined Dr Warren in studying biopsies from a series of patients. After several attempts, Dr Marshall succeeded in growing a bacterium that was unknown then; he named it *Campylobacter pyloridis*, believing that it was a member of the *Campylobacter* family. (It was later found to be a member of the *Helicobacter* family and renamed *H. pylori*.)

### **Bilcare launches clinical services facility in Pune**

Bilcare, a pharma packaging research and solutions company, launched its clinical services facility in Pune. Dr Christoph Moeschli, head, clinical packaging of Novartis Pharma AG, Switzerland inaugurated the facility. With the addition of the new facility, Bilcare claims to be the first company in Asia to have an operations facility for clinical supplies. This facility will support the pharma companies in packaging and distribution of their clinical supplies and integrate their global clinical trial requirements efficiently.

Mohan Bhandari, chairman and managing director, Bilcare, said, "This facility is one more milestone in Bilcare's quest for global leadership in pharma services. With this facility, Bilcare is now capable to serve its global pharma clients in the management of their global clinical trials anywhere in Asia, Americas and Europe."

### **Goa to announce state biotech policy**

Encouraged by the growing market potential for biotechnology industry, the government of Goa will announce its state biotechnology policy in November 2005 to attract potential investors to the state. Disclosing this at an international pharma summit organized by the Confederation of Indian Industries (CII) in Mumbai, Luizinho Faleiro, minister for industries, education and factories and boilers, Goa, said, "The state government is setting up a pharmaceutical and biotechnology park in the state's Special Economic Zone (SEZ)." He also invited the pharmaceutical companies to establish a 100 percent export oriented units (EOUs) in the state.

### **Bejo Sheetal to license IARI Bt Brinjal**

Bejo Sheetal Seeds Pvt Ltd has signed an agreement with Indian Agriculture Research Institute (IARI) for Bt Brinjal. The MoU was signed by Suresh Agrawal, managing director, Bejo Sheetal Seeds and Dr Parmar, joint director, IARI. As per the agreement, IARI will give transgenic brinjal seeds containing CRY1X gene (T2 generation) it developed to Bejo Sheetal. This gene is resistant to fruit and shoot borer pest. The product will be launched once the necessary approvals are got informed Agrawal. Bejo Sheetal is a market leader in brinjal and is into several other hybrid seeds.

### **"IBPL will generate employment for 7,500 in the next one year"**

Prasanta K Biswal, CEO, International Biotech Park Ltd (IBPL), Pune.

### **Which are the companies that have taken space at the IBPL?**

So far 13 companies have signed up with the International Biotech Park Ltd. Companies like Chembiotek and Advinus Discovery Labs have taken space at Genesis Square—a multi tenant campus for bioscience labs while others like Centaur Pharma, Hikal Pharma, Hikal Technologies, Omni-Actives and Kard Scientific have opted for open and developed space. Advantium Pharma has taken space at Chrysalis Enclave—built to suit facility for research labs with a concept "bench-to bedside". A couple of these companies will start their operations at the Park from October onwards.

### **What is the USP of IBPL?**

Considering the needs and requirements of the biotechnology companies and our own understanding of this niche industry through our group companies like LabVantage, Chembiotek and ClinInvent, we have three kinds of offerings to the biotech companies—Genesis Square, Chrysalis enclave and a developed open space. For small and medium size companies, we have Genesis Square developed on a four-acre campus with 100,000 sq ft of bioscience labs. It offers a range of lease options with labs available in modules of 2,000 sq ft and 3,400 sq ft. The second one is Chrysalis Enclave, a nine-acre campus with 10,00,000 sq ft of research labs. It will be a tailor-made facility which will be leased out to medium and large companies. The labs are available in the modules of 20,000 sq ft and 30,000 sq ft. Finally we have open and developed space on offer. We also have a bio-resource center with 30,000 sq ft of shared research facilities like NMR, HPLC, GCMS, high throughput screening systems, freezers, common rooms, incubation units and business suites. The objective of offering these things is to support the entrepreneurs looking at biotech industry as a growth ladder. Our facilities at the Park will act as "Plug & Play" for the biotech entrepreneurs and companies.

### **What is the entire project cost?**

The entire project cost will be about Rs 250 crore against our previous estimate of Rs 215 crore. We have already invested about Rs 50 crore. Looking at opportunity in biotechnology and the facilities that we are offering to the companies, we see that the Park will generate employment opportunities for 7,5000 in the next one year.

### **Chiltern India launches CINISTA network**

Chiltern India, a Mumbai-based clinical research organization, has developed an innovative way to build on its growing relationships with some of the country's best investigators. Chiltern India's Network of Investigators in Select Therapeutic Areas (CINISTA) is a forum consisting of 30 select eminent medical and clinical research experts in 11 therapeutic areas and is spread over 15 cities. Its members are the key opinion leaders in their respective therapeutic areas in India and have a rich experience of undertaking global multi-centric trials. All of them are well trained in GCP and a number of them are ACRP-certified investigators.

"We are delighted to announce the setting up of this network," said Dr Umakanta Sahoo, general manager, Chiltern India. "With the support of CINISTA's members, Chiltern will enable a mutually beneficial relationship to be built between biopharmaceutical companies and the growing Indian clinical research fraternity. In line with the expansion of Chiltern India, the membership of CINISTA will grow to accommodate other therapeutic areas and cities."

### **Bird flu has pharma companies in feverish activity**

Indian companies are now gearing up with the generic version of Tamiflu.

Fear of a global pandemic due to the deadly H5N1 flu virus has led to spiralling demands for Tamiflu, the only anti-influenza drug considered effective against bird flu so far. The Swiss pharma giant Roche Holding AG holds the patent for Tamiflu and is its sole manufacturer till date. The orders for the drug have soared as bird flu has spread from Asia to southeast Europe, and the company is now coming under increasing pressure from a number of countries to allow others to produce a copy of the drug.

Roche has meanwhile ruled out relinquishing the patent on the anti-viral drug, which is protected until 2016 but has said it is seeking other companies to help speed up Tamiflu's production. At the same time it has advised against countries simply breaking its patent, asking them instead to work with Roche to produce the drug under license.

Interestingly in India, it is reported that Roche does not have a "product patent" for Tamiflu, which means that Indian companies can now manufacture generic versions of the drug for Indian markets but cannot export these products. Confirming this, Dr Ashwani Kumar, Drug Controller General of India said, "Roche does not have a product patent in India and international patent is not enough according to Indian patent laws. The companies can manufacture generic versions of the drug medicine by filing a licensing application with the government." But the government has not received any applications from Indian companies yet. The health ministry has sought legal advice from the Industrial Development Department for manufacturing the generic version of the drug in the country as Roche's patent is pending.

On this issue, Roche has clarified that the firm had a patent pending in India. According to Roche officials, the issue is not about patents but about the manufacturing capacity. They claim that the manufacturing of Tamiflu is lengthy and expensive and its scientists have a lot of experience in it.

Roche has now approached the Union Health Ministry for permission to sell Tamiflu in India, though as of now there has been no reported case of avian flu in the country either in birds or humans. The Indian government has said that it is "processing the application on fast track," in view of the threat. If the application clears all norms set by the Health Ministry, officials said, the medicine would be stockpiled as migratory birds pose a risk of bringing the disease to the country. This strain of influenza struck bar-headed geese in Quinghai, China. Most of the birds from the lake migrate to India and Myanmar.

Meanwhile Indian drug firm Cipla has announced that it is ready to make a cheaper version of the drug. "Right or wrong, we are going to commercialize and make Oseltamivir," Yusuf K. Hamied, chairman of Mumbai-based Cipla, said. Oseltamivir is the drug's generic name. He said that Cipla's scientists had finished "reverse-engineering the drug" two weeks ago and could have small commercial quantities available as early as January 2006.

Both Ranbaxy and Cipla have written to Roche expressing their desire to manufacture Tamiflu's generic version. Higher officials at Ranbaxy claim that the company would take about six months to make the generic version available in the market.

Neither Cipla nor Ranbaxy have said how much a generic version would cost, but it is expected to be cheaper than Tamiflu, which costs up to \$60 for a strip of 10 tablets. Roche had admitted receiving a number of requests to make licensed versions and is currently evaluating the offers.

The H5N1 virus has so far resulted in the death of millions of birds and has infected about 100 persons across the world. It has the potential of jumping from animals to humans. Though no reports of jumping from humans to humans have come so far, experts fear the virus can be deadly if transmission from one person to another is reported. The H5N1 virus has not been found in India so far. The High Security Animal Disease Laboratory in Bhopal, the apex laboratory for testing diseases among animals, says not a single strain of the deadly H5N1 virus has been found in India in the last five years.

The laboratory has tested 22,000 samples and only a negligible percentage have shown the H9N2 strain. In the last three months, the laboratory has tested 3207 samples and none of them tested positive for the virus.

The government is monitoring 50 bird sanctuaries across the country. Soon a team of experts from the lab will visit bird sanctuaries, including Bharatpur, to check migratory birds for the deadly H5N1 avian flu strain.

Rolly Dureha