



**STAMP OF APPROVAL**  
(l-r) IBPL chief technical officer Dhananjay Patanakar, director Mani Iyer and senior V-P (global marketing) R Chandrashekhar at a press conference in Ahmedabad on Tuesday.

## Intas first Indian biotech firm to get EU GMP certification

EU is the world's second largest biopharma market

**DNA Money Correspondent**  
Ahmedabad

Intas Biopharmaceuticals Limited (IBPL) has become India's first company to receive the European Union's Good Manufacturing Practices (GMP) certification for its biotech manufacturing facility here, paving the way for the company to enter the lucrative European market, the second largest in the world.

The company is planning to introduce three of its therapeutic recombinant proteins - Neukine (rHu G-CSF), Erykine & Epoift (rHu EPO) and Intalife (rHu IFN Alfa-2b) in the European market within 18-20 months. These have already been launched in the domestic market and some international markets.

"The European market

### First mover

The certification would give Intas an early entrant advantage in the biogenerics mkt

The biogenerics markets in Europe and the US have the potential to generate sales of \$16bn by 2011

G-CSF is around \$660 million. We will take these three drugs to the European market apart from 56 other products that are in the pipeline," said R Chandrashekhar, senior vice president, global marketing.

G-CSF will go off patent in 2008 while EPO will go off patent between 2010 and 2012. Interferon is already off patent.

The global market for these three drugs is about \$16 billion, said Chandrashekhar. On the prices of the drugs, he said they were between \$60-120 abroad and \$30-40 in India. "We will price our drugs at about

10% lower than the patented drug where we are the first mover and where there are two or three generic players, our price will be 70 to 90% lower," he said.

The company has teamed up with a European partner to conduct clinical trials there that are mandatory before a company can market its products in the 25-member European Union, according to Mani Iyer, director, IBPL.

He said the certification, given by European Agency for the evaluation of medicinal products (EMA), would give Intas Biopharma an early entrant advantage in the biogenerics market that is fast emerging as an attractive segment.

Biogenerics are the copied version of the biopharmaceuticals or the drugs and vaccines derived from living organisms through biotechnological tools. They offer better survival benefits to patients than traditional pharma products.