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## **DEALTALK-Race to copy biotech drugs creates odd bedfellows**

2011 shaping up to be record year for biosimilar deals. Asian tech firms and conglomerates join biotech race. Hurdles high but production costs now falling

By Ben Hirschler

LONDON, June 22 (Reuters) - What have South Korean smartphone maker Samsung , petrochemicals group Hanwha Chemical , Indian industrial giant Reliance and Japanese digital camera maker Fujifilm got in common?

An interest in biotech drugs for cancer, anaemia and rheumatoid arthritis is the surprising answer.

With the business of making copies of complex biological drugs tipped to become a multibillion-dollar market in the next few years, some unexpected brands are scrambling to strike deals with drugmakers and join the race.

Few companies have all the manufacturing, development and marketing skills needed to produce and sell such products, which are made in living cells, so the hunt is on for smart partnerships.

Last week, Merck & Co clinched a deal worth up to \$720 million with Hanwha for rights to its copy of Amgen's best-selling arthritis drug Enbrel, which is given by injection, underlining the potential of the nascent industry.

Hanwha, like Samsung, sees biosimilars as a next-generation business that will help it diversify and provide a hedge against the possible decline in mainstream operations.

Samsung, South Korea's largest conglomerate, earlier this year set up a biosimilars joint venture with pharmaceutical services provider Quintiles to create a contract manufacturer for biotech drugs.

Overall, 2011 is on track to be a record year for such tie-ups, according to Thomson Reuters Newport Premium, which tracks developments in the global generic drugs industry.

There have already been nine deals for manufacturing, supply, distribution or licensing of so-called biosimilars this year, up from seven during the whole of 2010 and 11 in 2009, when the spate of such alliances really kicked off.

The prize is huge. Over the next decade, patents on biotech drugs with global sales of 90 billion euros (\$127.5 billion) are set to expire, according to the European Generic Medicines Association (EGA), opening the door to copycat products.

But producing biosimilars is far from simple. Tiny differences in manufacturing mean biological drugs are impossible to replicate exactly, so clinical trials are needed before approval. That makes them much more costly to develop than copies of conventional "white pill" chemical medicines.

Making and marketing them therefore takes a mix of skills, which companies like Merck hope to bring together via alliances.

"This is a business that is going to be characterised by partnering, because no one company has all the components they need," Mike Kamarck, president of Merck Bioventures, the U.S. drugmaker's biosimilars division, told Reuters.

## ASIAN FOCUS

The fact that Merck found a promising copy of Enbrel in Hanwha's research labs reflects the growing focus on biotechnology in Asia, particularly in South Korea, where the government has championed the sector.

Celltrion and LG Life Sciences are other South Korean players with global ambitions in biosimilars, while Dr Reddy's has been selling a copycat version of Roche's Rituxan cancer drug in India since 2007.

"Companies in India, China and Korea have had products out in the market for a few years now and are gaining very, very valuable experience," said Kate Kuhrt, director of generics and pharmaceutical ingredients intelligence at Thomson Reuters.

Western markets are further behind. Europe has approved two major biosimilar products, EPO and filgrastim for blood disorders, and is consulting on rules for antibodies, while U.S. general guidance on biosimilars are only due later this year.

On average, biosimilars will require about \$100 million and five to six years to develop, reflecting the need for clinical trials to prove safety and efficacy in regulated markets such as Europe and the United States, according to industry analysts at Bernstein.

But production advances mean the pure cost of manufacture is tumbling and now accounts for only around 2 percent of the branded product price of antibody drugs, Bernstein estimates.

Merck's Kamarck sees a nuanced market developing, with many smaller Asian companies focused on local sales, where regulatory barriers will be lower, leaving only a few large drugmakers with the resources to offer a truly global portfolio.

The global heavyweights are likely to include top makers of traditional generic drugs, such as Israel's Teva and Sandoz, the generics unit of Switzerland's Novartis, as well as Big Pharma interlopers like Merck and Pfizer, which inked a deal with India's Biocon last year.

Asian companies may not find the going so easy outside their home markets. Reliance, for example, hit a road bump in Europe in March when regulators asked for more data on its copy of EPO, prompting it to withdraw its application for now.

"Companies that aren't going to make large investments aren't going to play globally," said Kamarck, who puts the likely cost of developing a typical biosimilar at more than \$100 million. (Reporting by Ben Hirschler; Editing by Will Waterman)

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