New Report available from Bridgehead International Strategies for Biogeneric Success
Jim Furniss and Helen Durrant, Bridgehead International (71 pages), published June 2004

Strategies for Biogeneric Success
Jim Furniss and Helen Durrant
The strategies employed by companies developing generic biopharmaceuticals for the European market. Biogenerics are generic forms of biopharmaceuticalsâ€”molecules developed using biological processes, usually through modern biotechnology activity. Development of biogeneric molecules for sale in the lucrative Western Europe markets depends on the ability to answer three key questions positively: * Can you make the product to GMP and demonstrate its similarity to originator products? * Can you get it to market? * Are you able to make a profit from the sales of your biogeneric product? This report focuses on specific strategies answering these questions.

Â£950/Euro1500/US$1800

(PRWEB) June 24, 2004 -- Strategies for Biogeneric Success
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Description:
What will determine success?

Development of biogeneric molecules for sale in the potentially highly lucrative US and Western European markets depends on the ability to answer three key questions positively:
* Can you make the product consistently to GMP and demonstrate its essential similarity to originator products?
* Having made the product, can you get it to market?
* Having accessed the market, are you able to make a profit from the sales of your biogeneric product?

This report focuses on the specific strategies adopted by companies involved in the biogenerics arena, asking:
* Why are specific strategies likely to be effective?
* Why are particular companies more likely to be successful in the race to enter and profit from the biogenerics market in Europe and the US?

Biogenerics companies tend to adopt four main approaches. Often any one company will take more than one approach:
* Focus on strategic partnerships.
* Expand through acquisition.
* Supply into developing markets initially, followed by Europe and eventually the US.
* Develop second-generation products.

For any of these approaches to be successful, biogenerics companies will need to:
* Be well financed
* Possess sufficient technical capability, and be operating to Western GMP standards
* Be sufficiently focused, usually on only one or two products, since they will need to understand the market segment they are entering and have sufficient finances to operate in the chosen market
* Have developed or be developing effective working relationships with the regulatory authorities
* Have a strong market presence

Whichever products these companies choose to develop they need to be certain that:
* There is no intellectual property barrier
* The product's market characteristics are such that it could deliver worthwhile profit to the producer

* Is the market big enough?
* What is the competition like?
* Are there many entrenched players in the market already?
* Are there many other biogenerics players entering this market?
* Are biogeneric players already producing this product outside the Western markets?
* How likely are other biogenerics players to enter the market?

The earliest that biogenerics are likely to come to market is 2006, for the simpler products, such as G-CSF, rh GM-CSF and first-generation rh EPOs. However there is significant potential for delay along the route from:

* Regulators wrestling with the application of new rules. An example of this is Omnitrop (recombinant human growth hormone), which the Committee for Proprietary Medicinal Products (CPMP), the scientific committee of the European Agency for the Evaluation of Medicinal Products (EMEA), recommended for approval in Europe in June 2003. Omnitrop was ultimately rejected by the European Commission in April 2004.

* Innovators employing delaying tactics aimed at preventing biogenerics from taking shorter routes to approval.

* Development of second-generation products that are significantly better than the originals, meaning that original products are unlikely to take significant market share.

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