NEW YORK PHARMA FORUM

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TOPIC: **Biosimilars Status Update:**
Current Regulatory Landscape and Business Strategies

SPEAKERS: **Frank Clyburn**, S.V.P. & General Manager of Merck BioVentures
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The worldwide biologics market is the fastest-growing segment of the pharmaceutical industry. In 2007, its sales totaled $75 billion, and 13 of the leading biologics achieved mega-blockbuster status. As these biologics lose patent protection, they face the emerging threat of biosimilar competition.

Europe is leading the biosimilars charge: seven biosimilars have launched there and four more were recently approved. Since the EU approved the sale of biosimilars in 2006, the U.S. has debated allowing approval for generic biologics. President Obama and Congress have made affordable healthcare a priority, and therefore, 2009 is expected to be the year that the way is cleared for FDA-approved biosimilars in the U.S. However, after legislation was introduced by Reps. Henry Waxman (D-CA), Frank Pallone (D-NJ), and Nathan Deal (R-GA) to establish a pathway for the approval of biosimilars last month, the Biotechnology Industry Organization (BIO) issued a statement that the proposed bill would take patients and the industry down the wrong path.

How attractive is the biosimilars market? How are pharma companies approaching it? And, are biosimilars really feasible? Key players in the biotechnology industry are leading an effort to obtain global approval processes for biosimilars. Some big pharma companies are also becoming aggressive about the biosimilar business. In February 2009, Merck announced that it is acquiring Insmed's portfolio of biosimilars for $130 million. "This agreement represents a strong strategic fit for Merck as we aggressively expand and advance our portfolio of developmental follow-on-biologics," said Frank Clyburn, S.V.P. and General Manager of Merck BioVentures, who will be one of the panelists at this program.

At this program, three experts will give you an overview of and discuss crucial issues surrounding the biosimilars market and players, changing regulatory landscape, lessons to be learned from the European experience, and what pharma companies should be doing now to be ready for biosimilars in the U.S. (Please also see the enclosed speakers' bios.)