Recent BayBio Life Science Series VC Spotlight Panel Discussion: Follow-on Biologics, Biosimilars, and Biobetters

Posted by Heidi A. Guetschow on May 13, 2011

BayBio Life Science Series VC Spotlight hosted an interesting panel discussion entitled Follow-on Biologics, Biosimilars, Biobetters on May 5, 2011 in South San Francisco. Rob Jacoby of Deloitte Consulting LLP moderated the event, which included panelists Sarah Bodary of SV Life Sciences; Ted Buckley of Bloomberg Government; Robert Kastelein of Merck & Co., Inc.; Andrew McMillan of 5AM Ventures; and H. Daniel Perez of Bay City Capital.

The panelists' comments reflected guardedly positive views on prospects for development of biosimilar products in the US. McMillan remarked that 5AM Ventures has invested in at least one biosimilar project and anticipates additional investments as attractive opportunities arise. Bodary envisioned greater biosimilar development success for small, nimble biotech companies than large ones. Buckley noted that there has been much faster market adoption of biosimilar products in Europe than was predicted. For example, Germany has already seen almost 60% market adoption of biosimilar products, although many analysts predicted only 10-30% within the first two years after approval. Several panelists noted that the market adoption rate is highly dependant on insurance reimbursements, tiered pricing regimes, and the medical payor situation, which are currently in flux in the US. Buckley also observed that development of biosimilars will depend on the level of certainty regarding regulatory requirements for drug approval, and noted that Dr. Rachel Behrman, Associate Director of Medical Policy at CDER, recently predicted in an interview on BioCentury This Week that FDA's requirements for establishing biosimilarity will be determined on a case-by-case basis, and that the FDA will not provide advice regarding necessary any animal and human testing until after it has reviewed the biosimilar applicant's analytical data for the biosimilar in comparison to the reference biologic.

On a more cautionary note, Kastelstein observed that because it already appears that the requirements on biosimilar products will be so high, and because the market exclusivity period for innovator drugs is discouragingly long, many qualified companies will opt to develop innovator products rather than attempt to navigate the uncertain biosimilar pathway. Other panelists agreed and added that those companies that do choose to develop biosimilar drugs must use extraordinary care to avoid safety problems, as any problems with the first few approved biosimilars would almost certainly tank prospects for development of the industry in the US.