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IP Policy Forum: The Increasing Importance of Biologics-Based Drugs in Pharmaceutical Pipelines

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THE INCREASING IMPORTANCE OF BIOLOGICS-BASED DRUGS IN PHARMACEUTICAL PIPELINES

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For the first time in modern history, worldwide total prescription drug sales experienced negative year-over-year growth in 2012. In contrast to conventional pharmaceuticals for which negative sales growth is projected for several more years, sales of biologic products (those derived through biotechnology) grew year-over-year in 2012 and are projected to grow continuously through at least 2018 at a CAGR greater than 7%. These growth trends reflect the relatively lower clinical failure rate for biologics vs small molecules; notably, the phase II failure rate of small molecules is nearly twice that of biologics. The industry shift toward biologics reflects their relatively greater on-target efficacy and lower risk of off-target toxicity compared to conventional pharmaceutical drugs.

Several prominent pharmaceutical firms have set explicit targets ranging from roughly 20% to greater than 75% for the biologics portions of their R&D pipelines. This extent of emphasis on large molecules represents a radical evolution of thought from the late 90's and early 2000's when most major Pharma companies viewed biologics as niche products; prior to the dramatic commercial success of Rituxan® and Herceptin®, Big Pharma viewed monoclonal antibodies as research reagents that could not be developed as financially and therapeutically successful products. Humira® was the top-selling drug in the world in 2012 at $9.6B in total sales with 2018 sales projected to be $12.8B.[12]

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1. *Report | EvaluatePharma World Preview 2013, Outlook to 2018*, EVALUATE (2013), *available at* http://www.evaluategroup.com/public/reports/Evaluate-World-Preview-2013-Outlook-to-2018.aspx.

2. *KMR Group R&D Performance 2011*, KMR GROUP, *available at* http://www.kmrgroup.com.

Not only are biologics projected to comprise an ever greater component of the biopharmaceutical product mix, they are also providing what are arguably the most exciting treatment effects in recent clinical trials. Recent regulatory approval of the antibody-drug conjugate products Adcetris™ and Kadcyla® were assured based on impressive clinical outcomes in lymphoma[3] and breast cancer,[4] respectively. Response rates in late-stage metastatic melanoma for the immunotherapy monoclonal antibodies MK-3475 and nivolumab are unprecedented with responses anticipated to be highly durable after cessation of treatment.[5] It is this kind of meaningful benefit to patients that is sure to drive continued growth of biologics over the years and decades to come.

3. *FDA Approval for Brenuximab Vedotin*, NATIONAL CANCER INSTITUTE AT THE NATIONAL INSTITUTES OF HEALTH, July 1, 2013, *available at* http://www.cancer.gov/cancertopics/druginfo/fda-brentuximabvedotin.

4. *Overall Survival*, KADCYLA, http://www.kadcyla.com/hcp/clinical/efficacy.

5. John Carroll, *Merck's 'breakthrough' PD-1 cancer drug in showdown with Bristol-Myers combo*, FIERCEBIOTECH, June 2, 2013, *available at* http://www.fiercebiotech.com/story/mercks-breakthrough-pd-1-immunotherapy-promising-melanoma-study/2013-06-02.