Personalized Medicine Can Increase Revenues

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The approval of Herceptin in 1998 was the opening shot that heralded in the era of personalized medicine. Prior to that, it was generally accepted within the industry that while patient stratification and personalized medicine was a good idea for patients, it was not a good business model. And although the multi-billion dollar success of Herceptin completely debunked that theory, the industry has still been slow to embrace biomarkers and targeted medicine. This is reflected number of deals done in the biomarker space since 2007, despite the plethora biomarker starts-ups. In that time frame, only 34 biomarker deals were publically announced and these were primarily licensing and research collaborations.

It now appears that economics and the industry have evolved to the point where personalized medicine is becoming increasingly important, driven by two key developments. First is the FDA's Critical Path Initiative, which started in 2004 in response to the high failure rate of drugs in the clinic and unforeseen toxicology. As a result of the Critical Path Initiative, it is expected that the global demand for biomarkers will grow to $12.8 billion by 2012. Second, the economics of health care are changing. As the cost of health care increases, governmental and health insurance agencies are increasingly denying payment of treatments for which there isn't data supporting a reasonable likelihood of success.

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Examples of success are now emerging from pharmaceutical companies, who have figured out how to use biomarkers to their advantage. A good example of this is the use of biomarkers for prescribing Erbitux for colorectal patients. The drug is sold by Bristol-Myers-Squibb in the US and Merck KGaA outside the US and Canada. These two companies have diverse philosophies regarding the use of biomarkers. BMS has resisted the use of biomarker tests to select patients, while Merck KGaA has embraced the idea of using biomarkers to identify patients who will respond to the drug. The launch of this EGFR targeted drug was not immediately a success in the US. Though approved for use in colorectal cancer in 2004 it has been slow to gain in acceptance by clinicians in the US. Avastin, in combination with intravenous 5-fluorouracil–based chemotherapy, remains the standard of care in the US. In Europe however, the story is different; Erbitux use has been adopted by physicians for the EGFR+ patients and has become the standard of care there.

In 2008 a link between efficacy of the drug in colorectal cancer and the status of a patient's KRAS gene was discovered. Merck KGaA has aggressively added this information to the selection of patients with colorectal cancer who can be prescribed the drug. By using this better understanding of which patients will respond to aggressively market the efficacy of the drug in this subset of patients, Merck KGaA Erbitux sales rose 20% in 2008 to 565 million euros. In contrast BMS' Erbitux sales in the U.S. fell 2 percent to $182 million in the fourth quarter of 2008.

Currently only about 12% of the trials that large pharma and biotech carry out include biomarker analyses. That number will undoubtedly increase since all indications are that the future success of these companies will depend on their ability to incorporate an effective biomarker strategy into the product development and clinical designs.