The Impact of Biomarker Testing on the Oncology Market

The era of personalized medicine is already well established in oncology. Biomarker-driven targeted therapies are among the top-selling oncology products today, and the impact of molecular biomarker testing on the oncology therapy market remains strong. The influence of biomarker testing can be evaluated on multiple levels: the market share of leading targeted therapies, the R&D pipelines of top pharmaceutical companies, the NMEs approved by the FDA in 2013 for oncology that use biomarkers, and the oncology agents granted breakthrough therapy designation by the FDA in 2013 that have companion biomarkers. The ability to identify appropriate patients for treatment based on molecular biomarkers created the flourishing targeted therapy oncology market. Numerous indications, including breast cancer, gastric cancer, colorectal cancer, non-small-cell lung cancer (NSCLC), malignant melanoma, and chronic myeloid leukemia, have all benefited from validated molecular biomarkers as a companion to the therapeutic agent. Emerging biomarkers and associated targeted therapies reaching the oncology market in the near term are expected to continue fueling the growth of this market segment. However, as additional biomarkers are added, their developers will have to differentiate them to ensure their acceptance and reimbursement. Other clinical challenges in biomarker development include the need for biomarker assays with a faster turnaround time, the ability to test only small amounts of tissue, and the ability to test for several biomarkers at once (a multiplex panel).

Questions Answered in This Report:

- Currently, biomarker-driven targeted therapeutics are some of the top-selling oncology products, capturing 43% of sales of the top 20 products in 2012. Biomarker-driven therapies accounted for half of the NME oncology approvals in the United States in 2013. What impact has biomarker-driven prescribing had on the oncology market, and what does the regulatory path ahead look like?

- R&D pipelines in oncology attract the most research, and biomarker diagnostics are an essential component of many agents under study. Emerging biomarkers and associated targeted therapies reaching the market in the near term are expected to fuel the growth of this market segment. Although the HER-2 targeted therapies for breast and gastric cancers will still dominate the biomarker-driven therapy market, some new targeted therapy drug classes will gain market share by 2022. What classes will drive growth and reach new patient subgroups in the oncology segment of personalized medicine?
In oncology, molecular biomarker testing is a part of clinical practice that will continue to expand. The proven success of several biomarker-driven targeted therapies has solidified the need for this approach, but challenges remain to optimize biomarker testing—e.g., more-rapid tests, smaller sample sizes, multipanel testing, reimbursement. What are oncologists’ key suggestions to enhance biomarker use in the targeted oncology market?

Scope:
Markets covered: United States, France, Germany, Italy, Spain, United Kingdom.

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