Case Study: Personalized Cancer Therapy - The era of biomarker identification and companion diagnostic co-development

Description: The treatment of cancer has seen a dramatic shift with the addition of molecular targeted therapies. The mixed and unpredictable responses to these targeted therapies are driving the pharmaceutical industry to search for disease and patient characteristics which confer the best response rates. Identification of biomarkers and companion diagnostics will pave the way for personalized cancer therapy.

Scope of this research
- In-depth analysis of companion diagnostic development – when to start development, internal or partnership development, with case study examples
- In-depth analysis of personalized cancer therapy commercial potential – with patient population analysis and case studies
- In-depth analysis of US, EU, and Japanese current and developing regulatory processes for personalized cancer therapy
- Sales forecasts for two key personalized therapies in late stage development - 2010 to 2019 across the seven major markets

Research and analysis highlights
- Pharmaceutical companies face a number of important decisions regarding personalized therapy development. Selecting the correct time to begin companion diagnostic development will help improve the chances of approval and drive new drug uptake. Developers must also assess their position in the market before choosing internal or external development.

- Drug developers are cautious of personalized therapies due to the small patient populations and associated commercial potential. However, Herceptin has been able to dominate a well defined segment of the breast cancer market and companion diagnostics have recovered the commercial potential of Erbitux and Vectibix.

- Regulators have now realized that the regulatory framework must be altered to incorporate both drugs and companion diagnostics. The US, EU and Japanese authorities are all starting to change their guidelines to encourage personalized therapy development. However, there are still hurdles to overcome before co-development becomes common practice.

Key reasons to purchase this research
- Identify key decisions when developing a drug and companion diagnostic, including internal or external development and when to start development
- Identify the commercial benefits of personalized cancer therapy by assessing drugs currently in development or approved
- Assess the changes in regulatory processes in the seven major markets as the paradigm of personalized cancer medicine grows

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