Case Study: Personalized Cancer Therapy - Anticipated Competition Threatens to Dampen Commercial Potential of New Approvals

Description:
Overview of targeted cancer therapies and biomarkers, with in-depth analysis of drug and companion diagnostic development, commercial potential, role of regulatory authorities in the seven major markets and key pipeline personalized cancer therapies.

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
- 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
- Extensive analysis of Zelboraf and Xalkori, including seven major market sales forecasts 2011-21 and detailed development timelines

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.

- The development of BRAF inhibitor resistance and anticipated launch of GlaxoSmithKline's two personalized therapies will undoubtedly impact Zelboraf's commercial potential. The question remains as to whether a small subgroup of patients in one indication can commercially support two almost identical drugs.

- 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.

Reasons to Purchase
- Gain extensive insight into the clinical and commercial aspects of Zelboraf and Xalkori, including 2011-21 forecasts
- Identify key decisions when developing a drug and companion diagnostic, including internal or external development and when to start development
- Assess the changes in regulatory processes in the seven major markets as the paradigm of personalized cancer medicine grows

Contents:
OVERVIEW
- Catalyst
- Summary

EXECUTIVE SUMMARY
- Strategic scoping and focus
- Datamonitor key findings
INTRODUCTION
- Oncology overview
- A move toward personalized therapy with the development of targeted drugs

BIOMARKERS
- Oncology biomarkers
  - Definition
  - Classification of cancer biomarkers
  - Targeted therapies and predictive biomarkers

DRUG AND COMPANION DIAGNOSTIC DEVELOPMENT
- Case study
  - Iressa (gefitinib; AstraZeneca)
  - Development approach
    - Overview
    - When to develop companion diagnostics
    - Internal or external companion diagnostic development

COMMERCIAL POTENTIAL
- Patient population
  - Herceptin (trastuzumab; Roche/Genentech/Chugai)
  - Erbitux (cetuximab; Bristol-Myers Squibb/Eli Lilly/Merck KGaA) and Vectibix (panitumumab; Amgen)
  - Cost-effectiveness
  - Companion diagnostics make cancer treatments more cost-effective
  - Reimbursement
  - Reimbursement policies must consider personalized cancer therapy

REGULATORS
- Regulators and personalized cancer therapy
  - Regulations are changing to encourage companion diagnostic co-development
  - US regulatory authorities
  - EU regulatory authorities
  - Japanese regulatory authorities

KEY MARKETED PERSONALIZED CANCER THERAPIES
- Zelboraf (vemurafenib; Roche/Daiichi Sankyo)
  - Personalized therapy profile
  - Drug overview
  - Companion diagnostic overview
  - Development path
  - Commercial potential
  - Clinical and commercial assessment
- Xalkori (crizotinib; Pfizer)
  - Drug overview
  - Companion diagnostic overview
  - Development path
  - Commercial potential
  - Clinical and commercial potential

KEY PIPELINE PERSONALIZED CANCER THERAPIES
- Dabrafenib (GSK-2118436; GlaxoSmithKline)
  - Personalized therapy profile
  - Drug overview
  - Companion diagnostic overview
  - Market potential
- Trametinib (GSK-1120212; GlaxoSmithKline)
  - Personalized therapy profile
  - Drug overview
  - Companion diagnostic overview
  - Market potential
- Tomtovok (afatinib; Boehringer Ingelheim)
  - Personalized therapy profile
  - Drug overview
  - Companion diagnostic overview
  - Market potential
- Other pipeline personalized cancer therapies
  - Overview of other pipeline personalized cancer therapies

BIBLIOGRAPHY
- Journals
- Websites
- Datamonitor reports
- Other

APPENDIX
- Forecast methodology
  - Volume and value forecast methodology
  - Price assumptions
- Contributing experts
- Report methodology

TABLES

- Table: Biomarker classification according to modality
- Table: Examples of available companion diagnostics for targeted cancer therapies, 2012
- Table: Approved cancer drugs with biomarkers on label, 2012
- Table: Iressa: key historical events, 1994–2010
- Table: Pharmaceutical company acquisitions of diagnostic companies, 2012
- Table: Examples of diagnostic and pharmaceutical company partnerships for cancer therapies, 2010–12
- Table: FDA-approved HER2 diagnostic tests, 2012
- Table: FDA- and EMA-approved drugs with mandatory biomarker tests, 2012
- Table: Zelboraf – drug profile, 2012
- Table: Zelboraf sales forecast, by country ($m), 2011–21
- Table: Xalkori – drug profile, 2012
- Table: Xalkori sales forecast, by country ($m), 2011–21
- Table: Dabrafenib – drug profile, 2012
- Table: Trametinib – drug profile, 2012
- Table: Tomtovok – drug profile, 2012
- Table: Key pipeline personalized cancer therapies

FIGURES

- Figure: "Big four" cancer development pipelines, by therapy class
- Figure: Biomarker classification
- Figure: Stages of cancer progression where biomarkers could be used
- Figure: Drug and companion diagnostic co-development process key steps
- Figure: Summary of advantages and disadvantages of companion diagnostic development models
- Figure: Patient population for Herceptin, Erbitux, Vectibix, Xalkori, and Zelboraf compared to total incidence in approved indications in the seven major markets, 2012f
- Figure: Company-reported and forecast sales for Vectibix, highlighting the influence of companion diagnostics, 2012
- Figure: Summary of reimbursement uncertainty on diagnostics
- Figure: US: summary of parties involved in drug and companion diagnostic development and regulation
- Figure: Interactions between FDA centers during drug and companion diagnostic development
- Figure: EU: summary of parties involved in drug and companion diagnostic development and regulation
- Figure: Summary of interactions between the PMDA and MHLW during drug and device development
- Figure: Overview of Zelboraf and companion diagnostic development
- Figure: Eligible patient population for Zelboraf compared to melanoma incidence in the seven major markets, 2011–20f
- Figure: Zelboraf sales forecast, by country ($m), 2011–21
- Figure: Overview of Xalkori and companion diagnostic development
- Figure: Target patient population for Xalkori compared to total incidence of NSCLC in the seven major markets, 2010–20f
Figure: Xalkori sales forecast, by country ($m), 2011–21

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