Targeted Therapeutics Market Analysis

In this section, we analyze the market for targeted therapeutics in the United States for the period, 2006 to 2013, for all the seven targeted therapy classes distinguished by their mechanism of action.

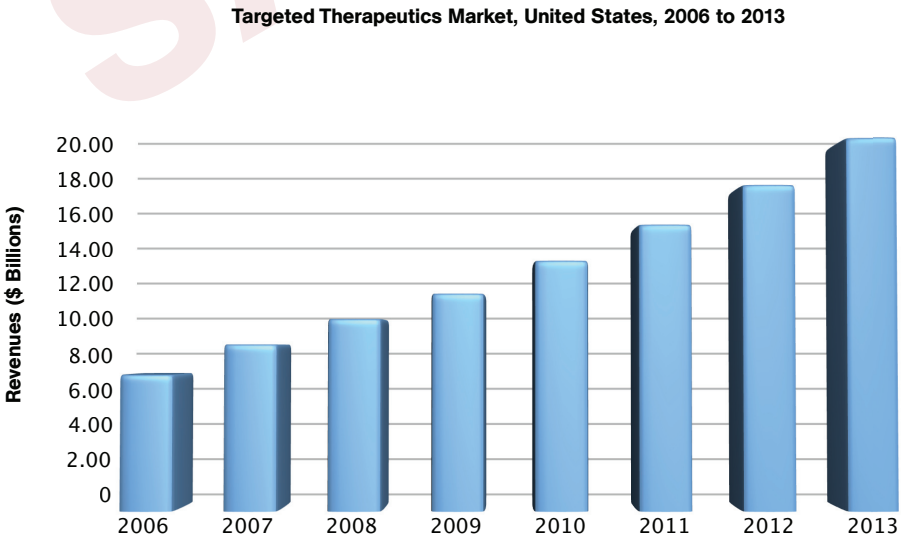
Table 26. Targeted Therapeutics Market, United States, 2006 to 2013

YEAR	REVENUE ($ BILLIONS)	GROWTH RATE (PERCENTAGE)
2006	6.98	-
2007	8.53	22.2
2008	9.84	15.3
2009	11.13	13.2
2010	12.82	15.2
2011	14.68	14.5
2012	16.72	13.9
2013	19.14	14.5

The above table shows the revenue analysis of the total targeted therapeutics market in the United States for the period, 2006 to 2013. The targeted therapeutics market is a high growth area in cancer therapy. The cumulative aggregate growth rate of this market is estimated to be 14.2 percent.

In the base year, 2008, the targeted therapy market revenues were valued at $9.84 billion. The growth rate of the market in that year was recorded to be 15.3 percent. The targeted therapeutic market is estimated to generate $19.14 billion by 2013. The growth rate of this market is considerably high but continues to decrease as years pass. The main reason for the decrease in growth rate is relatively reduced consumption of certain drugs and classes which impacts the overall growth rate. Otherwise, this market is poised for very high growth in some classes.

Figure 6. Targeted Therapeutics Market, United States, 2006 to 2013



During the next 4 to 5 years, most of current drugs would have or close to gaining approval for additional indications and cancer types. New drugs such as Recentin and Pazopanib will have entered the market, raising the market revenues.

Avastin will continue to lead the oncology market through the forecast period. In comparison to 2007, Avastin sales in the United States grew by 17 percent to $2.68 billion in 2008. With two additional indications approved in 2009 and two awaiting FDA reply, Avastin sales are set to cross $3 billion in 2009. In 2010 Roche is planning to file for approval of Avastin in metastatic gastric cancer, metastatic breast cancer and 1st line ovarian cancer. The approval is expected around 2012 which will give further impetus to the growing Avastin sales. The 1st line ovarian cancer will be of special mention as this type of cancer does not have any targeted drug approved. Filing for hormone resistant prostate cancer and GIST is expected in 2011, thereby approval is expected by 2013. The patent protection for Avastin expires in 2017 so Avastin has a long time before its generic versions enter the market.

Table 31. Avastin Sales: United States, 2006 to 2013

	2006	2007	2008	2009	2010	2011	2012	2013
Revenues ($millions)	1,746	2,289	2,686	3,150	3,670	4,110	4,590	4,970

SWOT Analysis

Figure 13. SWOT Analysis for Avastin

STUDY	INDICATION	PHASE	DATE OF COMPLETION
STUDIES RECRUITING PATIENTS			
Panitumumab Combination Study With AMG 102 or AMG 479 in Wild-type KRAS mCRC	Colon Cancer/Colorectal Cancer/Gastrointestinal Cancer/Metastatic Colorectal Cancer/Rectal Cancer	phase 1 / phase 2	May 2011
Safety and Efficacy Study of FOLFOX4+Panitumumab vs.FOLFIRI+Panitumumab in Subjects WT KRAS Colorectal Cancer and Liver-only Metastases	Colorectal Cancer	2	February 2013
Ph2 Biomarker (Mechanism of K-ras Dependency) in Wt KRAS Metastatic Colorectal Cancer Patients	Metastatic Colorectal Cancer	2	February 2012
Panitumumab Pediatric Study	Solid Tumors	1	April 2011
New Individualized Therapy Trial for Metastatic Colorectal Cancer	Colorectal Neoplasm/ Colorectal Cancer	phase 1 / phase 2	December 2011
Safety of AMG 706 Plus Panitumumab Plus Chemotherapy in the Treatment of Subjects With Metastatic Colorectal Cancer	Colon Cancer/Rectal Cancer	1	April 2010
PEAK: A Phase 2 Study of Panitumumab Plus mFOLFOX6 vs. Bevacizumab Plus mFOLFOX6 for First Line Treatment of Metastatic Colorectal Cancer Subjects With Wild-Type KRAS Tumors	Colon Cancer/Colorectal Cancer/Rectal Cancer/ Metastatic Colorectal Cancer	2	March 2012
Irinotecan With or Without Panitumumab or Cyclosporine in Treating Patients With Advanced or Metastatic Colorectal Cancer That Did Not Respond to Fluorouracil	Colorectal Cancer	3	March 2010
BEP Study Phase I (Bevacizumab, Everolimus, Panitumumab)	Solid Tumors	1	November 2009
Radiotherapy Plus Panitumumab Compared to Chemoradiotherapy With Unresected, Locally Advanced Squamous Cell Carcinoma of the Head and Neck	Cancer/Head and Neck Cancer/Oncology/ Squamous Cell Carcinoma	2	October 2011
Perioperative Panitumumab and Epirubicin, Oxaliplatin and Xeloda (EOX) in Patients With Gastroesophageal Adenocarcinoma	Esophageal Adenocarcinoma/Gastric Adenocarcinoma	phase 1 / phase 2	April 2010
Phase II Study of Irinotecan and Panitumumab	Esophageal Cancer	2	January 2012
Panitumumab Plus Chemoradiotherapy and Induction Chemotherapy for Locally Advanced Squamous Cell Cancer of the Head and Neck	Squamous Cell Carcinoma of the Head and Neck/ Basaloid Squamous Cell Carcinoma/Undifferentiated Carcinoma/Adenosquamous Cell Carcinoma	1	April 2010
Trial of Postoperative Radiation, Cisplatin, and Panitumumab in Locally Advanced Head and Neck Cancer	Head and Neck Cancer	2	November 2013
Study of Preoperative Panitumumab and Radiotherapy in Rectal Cancer	Rectal Cancer	2	September 2011
Study of Gemcitabine, Irinotecan and Panitumumab in Patients With Advanced and Metastatic Biliary Tract Adenocarcinoma	Biliary Cancer/ Cholangiocarcinoma	2	April 2011
SPIRITT - Second-Line Panitumumab Irinotecan Treatment Trial	Cancer/Colon Cancer/ Colorectal Cancer/Metastatic Cancer/Rectal Cancer/ Metastatic Colorectal Cancer	2	July 2010
REAL 3 Version 1.3: Trial of the Efficacy of Epirubicin, Oxaliplatin and Capecitabine (EOX) With or Without Panitumumab in Previously Untreated Advanced Oesophago-Gastric Cancer	Oesophago-Gastric Cancer	3	February 2013
Panitumumab and Pegylated Liposomal Doxorubicin for Platinum-Resistant Epithelial Ovarian Cancer With Kirsten Rat Sarcoma Viral Oncogene Homolog (KRAS) Wild-Type	Epithelial Ovarian Cancer	2	January 2010

SWOT Analysis

Figure 35. SWOT Analysis of IMC-11F8

strengths	weaknesses	opportunities	threats
• Late stage studies for colorectal cancer and NSCLC have started • Side effects profile milder than Erbitux • Inclusion into Lilly's pipeline will ensure high importance and worldwide coverage • ImClone's acquisition by Eli Lilly will strengthen position of ImClone drugs as they will be associated with the pharma giant	• Long way to go for first approval or NDA • Colorectal cancer area will become highly competitive by the time IMC-11F8 enters the market • Comparisons to Vectibix, as both are fully human monoclonal antibody, is definite	• Areas of colorectal cancer, NSCLC and solid tumors • Patent expiry of Erbitux will facilitate in conversion of Erbitux customers to IMC-11F8 customers	• Too early to measure its benefits and risks • Risk of discontinuation of studies due to unfavorable results in clinical trials and delay in FDA approval can impact some of the pipeline indications • Other pipeline drugs being studied for IMC-11F8's indications may threaten its position once they enter the market

ZD4054

Introduction

ZD4054 is a novel drug currently in late stages of clinical development for the treatment of hormone resistant prostate cancer. The drug is a novel endothelin A receptor antagonist and currently in phase 3 clinical studies. It is being developed by AstraZeneca and its NDA filing is expected around 2011. Data from Phase II studies suggested that ZD4054 10mg has the potential to increase median overall survival time by approximately seven months in men with metastatic hormone-resistant prostate cancer (HRPC). The drug is a once-daily oral pill, with a milder side effect profile.

Mechanism of Action (MoA)

ZD4054 (napthalene sulfonamide) is a specific endothelin A (ETA) receptor agonist. Endothelins are proteins that facilitate tissue repair, constrict blood vessels and raise blood pressure. There are studies which prove that endothelins can modulate mitogenesis, apoptosis, angiogenesis, tumor invasion and development of metastases. In prostate cancer, endothelin A is over expressed which assists in metastases of the cancer. By inhibiting the action of endothelin A, the tumor cells will be cut off from their blood supply, nutrients and thereby preventing proliferation.

Similar to Erbitux, IMC-11F8 is a fully human monoclonal antibody which targets the epidermal growth factor receptor (EGFR) in the cancer cells. Hence it can be used only in cases where EGFR is over expressed. EGFR is responsible for maintaining cellular signaling and is highly over expressed in cancer cells. IMC-11F8 binds to the EGFR receptor site, blocking the signals. It helps in limiting cell growth and induction of apoptosis.