

Cytotoxic Therapies: Drug Launches in Rare Indications to Offset Sales Decline

Introduction

Growth of cytotoxics will remain static over the forecast period with a CAGR of -0.1%. Several blockbuster products are due to undergo patent expiry and the loss of their branded sales will negatively impact the growth of this market. However, the launch of a number of drugs in rare indications will stabilize growth and offset its decline from generic entry.

Scope

*In-depth analysis of the current and future cytotoxic therapies market across the US, five major European countries and Japan, plus a rest of world snapshot.

*Cytotoxic therapy sales forecasts for brands and generics from 2009 to 2019

*Assessment of the leading cancer brands and drug classes to identify key success factors within this sector

*Strategies of the leading companies in the cytotoxics market

Highlights

Sales of cytotoxic drugs are forecast to decline in the seven major markets from \$14 billion in 2009 to \$13.9 billion by 2019. The launch of Dacogen (decitabine; Eisai/Johnson & Johnson) and Vidaza (azacitidine; Celgene) in the five major European markets and Japan will slow down the decline in cytotoxic sales over the forecast period.

In 2009, Taxotere (docetaxel; Sanofi-Aventis), Eloxatin (oxaliplatin; Sanofi-Aventis) and Alimta (pemetrexed; Eli Lilly) were the top three cytotoxics, with sales over \$1 billion. Alimta will remain among the top three brands in 2019, along with Dacogen and Vidaza.

The key events to impact the cytotoxics market in the forecast period involve new drug launches, approvals of new indications and patent expiries. Several products with annual sales of over \$1 billion are due to undergo patent expiry over the forecast period, however, new drug launches in rarer indications will compensate for this loss of sales.

Reasons to Purchase

*Quantify the performance of each of the marketed cytotoxic therapy cancer brands in the seven major markets over the period 2009 to 2019.

*Acquire a detailed account of cytotoxic therapy cancer brand dynamics and the events that drive and limit their market growth

*Benchmark the cytotoxic therapy cancer brands against their generics and rest of class and align the \$7 billion performance with the rest of world snapshot

Table of Contents

OVERVIEW 1

Catalyst 1

Summary 1

About Datamonitor healthcare 2

About the oncology pharmaceutical analysis team 2

EXECUTIVE SUMMARY 3

Strategic scoping and focus 3

Datamonitor insight into the cytotoxic therapies market 3

Related reports 4

Upcoming related reports 5

Table of Contents 6

1. MARKET DEFINITION 7

Market definition for this report 7

Cytotoxic therapies by ATC class 7

L1A -Alkylating agents 7

L1B -Antimetabolites 7

L1C -Vinca alkaloids and other plant-derived products 8

L1D -Antineoplastic antibiotics 8

L1X2 -Platinum compounds 8

L1X9 -All other antineoplastics 8

2. MARKET OVERVIEW 9

Seven major markets 9

Current and future market overview 9

The cytotoxics therapies market is set to experience negative growth to 2019 with a large number of products losing their patents over the next 5 years 9

Patent expiries on the leading cytotoxic brands are set to occur within the next 5 years 10

The US is due to lose nearly half its value by 2019 due to generic erosion of key branded products 12

The antimetabolites are forecast to account for the largest proportion of market share through to 2019 13

The current leading cytotoxic brands are forecast to lose significant market share by 2019 due to patent expiry 15

The cytotoxics market will experience contract from \$14 billion in 2009 to \$13.9 billion in 2019 across the seven major pharmaceutical markets 16

Opportunities and threats 18

Opportunity 1: aging population will result in increasing cancer incidence 18

Opportunity 2: oncology therapy sales continue to experience strong growth 19

Opportunity 3: high levels of unmet need 20

Threat 1: Pharma's transition towards specialist secondary care indications may further increase competition in the oncology market 21

Threat 2: the cost of drug development continues to rise 21

Threat 3: ongoing cost-containment measures 21

US 22

Current and future market assessment 22

The large impact that generic erosion has on sales of branded drugs will cause a decrease in the US cytotoxics market 22

The cytotoxics market will shrink from \$7 billion in 2009 to \$4.4 billion in 2019 in the US 24

Opportunities and threats 26

Opportunity 1: with a large population and high healthcare expenditure, the US will continue to offer commercial opportunities for drug developers 26

Opportunity 2: healthcare reform will lead to an increase in the number of insured in the US 27

Opportunity 3: closure of the Medicare Part D coverage gap is good news for branded Pharma 27

Threat 1: growing regulatory pressures increase costs and decrease market penetration for Pharma 27

Threat 2: patent expiries and the resulting generic competition will erode branded sales revenues 28

Threat 3: in the long run, US health reform law will intensify cost-containment pressures 28

Japan 29

Current and future market assessment 29

The cytotoxics market in Japan will experience growth of nearly 2% from 2009 to 2019 29

The cytotoxics market will grow from \$2.4 billion in 2009 to \$2.8 billion in 2019 in Japan 31

Opportunities and threats 33

Opportunity 1: the aging population represents a large and growing patient base 33

Opportunity 2: generic sales erosion remains low in Japan 33

Opportunity 3: decrease in lag times for launch of new drugs could accelerate new launches 34

Threat 1: government-enforced biennial cuts continue to have a negative effect on market growth 34

Threat 2: healthcare proposal to change current pricing system will be of limited benefit to Japanese Pharma 35

Threat 3: changes to reference pricing will bring down launch prices 36

Five major European markets (5EU) 36

Current and future market assessment 36

The cytotoxics therapies market in the five major EU markets will grow through to 2019 as a result of several key product launches 36

The cytotoxics market will grow from \$4.6 billion in 2009 to \$6.5 billion in 2019 in the five major European markets 38

Opportunities and threats 40

Opportunity 1: EU Cancer Task Force will improve the availability of information while generating funds for research 41

Opportunity 2: reorganization of the European Medicines Agency (EMA) expected to streamline the EU regulatory process 42

Threat 1: new European drug price reductions are likely to impact the growth of the pharma industry 42

Threat 2: higher generic uptake in less mature EU markets will impact on branded sales revenues 43

Threat 3: the European Commission inquiry into delays in generics market entry will have wide-ranging ramifications for the branded and generics industry 43

Threat 4: Spain's price cuts and reference groups are driving drug prices down 44

Threat 5: new low reimbursement rate created in France signals the growing pressure for cost-containment 45

Threat 6: NICE will remain a significant hurdle to commercialization of cancer drugs in the UK, despite relaxation of its cost-effectiveness criteria 45

Threat 7: Germany's new cost-effectiveness analysis system could add to the downward pressure on drug prices 48

Threat 8: additional cuts to the price of oncology drugs are forthcoming in Italy under its pay-for-performance scheme 48

France 49

Current and future market assessment 49

The cytotoxics market will grow from \$1.5 billion in 2009 to \$1.8 billion in 2019 in France 49

Germany 52

Current and future market assessment 52

The cytotoxics market will grow from \$1.1 billion in 2009 to \$1.6 billion in 2019 in Germany 52

Italy 56

Current and future market assessment 56

The cytotoxics market will grow from \$0.8 billion in 2009 to \$1.2 billion in 2019 in Italy 56

Spain 60

Current and future market assessment 60

The cytotoxics market will grow from \$0.7 billion in 2009 to \$1.1 billion in 2019 in Spain 60

UK 63

Current and future market assessment 63

The cytotoxics market will grow from \$5m in 2009 to \$1 billion in 2019 in the UK 63

Rest of the world snapshot	66
Current market assessment	66
Rest of the World sales represent 22% of the global cytotoxics market	66
Opportunities and threats	69
Opportunity 1: incidence of cancer is forecast to increase in the BRIC countries	69
Opportunity 2: emerging markets continue to attract despite challenges	69
Threat: cost of new therapies is a barrier to market penetration	70
3. BRAND DYNAMICS	71
Overview of competitive landscape	71
Alimta and Taxotere will remain among the top 4 leading cytotoxic brands in both 2009 and 2019	71
Efficacy and toxicity of a drug are the most important drivers of cytotoxic brand choice	73
Trends in marketing strategies	74
Leading cytotoxic brands	75
Taxotere (docetaxel; Sanofi-Aventis)	75
Drug profile	75
Product positioning	76
SWOT analysis	76
Brand forecast to 2019	77
Taxotere sales are forecast to fall after 2010 to \$723m in 2019	77
Eloxatin (oxaliplatin; Sanofi-Aventis)	79
Drug profile	79
Product positioning	80
SWOT analysis	81
Brand forecast to 2019	81

Eloxatin sales will continue to fall through to 2019 in response to genericization 81

Alimta (pemetrexed; Eli Lilly) 83

Drug profile 84

Product positioning 84

SWOT analysis 85

Brand forecast to 2019 85

Alimta's sales are forecast to exceed \$2 billion in 2016 before dropping to \$0.7 billion in 2019 85

Gemzar (gemcitabine; Eli Lilly) 87

Drug profile 87

Product positioning 88

SWOT analysis 89

Brand forecast to 2019 89

Gemzar sales are forecast to decrease after 2012, losing more than 50% of sales after 2013 89

4. KEY DEVELOPERS 92

Strategic overview 92

Trends in corporate strategy 93

Approval in multiple tumor types is most likely to result in significant sales 93

A mature and heavily genericized market means Big Pharma's experience is crucial 93

Currently there are relatively few novel cytotoxics in development 93

Sanofi-Aventis 94

Corporate strategy 94

Oncology cytotoxics portfolio assessment 94

Eli Lilly	96
Corporate strategy	96
Oncology cytotoxics portfolio assessment	96
Portfolio assessment of other leading companies	97
BIBLIOGRAPHY	99
Journal papers	99
Websites	99
Other	104
Datamonitor reports	104
Appendix A - Market Assumptions	106
Forecasting assumptions	106
New product launches	106
Patent expiries	106
Rest of class definition	107
Data definitions, limitations and assumptions	108
Standard units	108
Country group definitions	108
Rest of the World	108
The 'all other EU countries' group	108
The 'Other non-EU countries' group	108
Forecast methodology	109
Derivation of sales forecasts and pricing trends	109
Exchange rates	109
Report methodology	109
Appendix B	110
About Datamonitor	110
About Datamonitor Healthcare	110

About the Oncology analysis team 111

Disclaimer 112

List of Tables

Table 1: Definition of the cytotoxic therapies market, 2010 7

Table 2: Sales and growth of cytotoxic therapy drug classes in the seven major markets (\$m), 2009-2019 9

Table 3: Key events impacting cytotoxic therapies in the seven major markets, 2009-2019 11

Table 4: Cytotoxic therapy sales forecasts in the seven major markets (\$m), 2009-2019 16

Table 5: Summary of opportunities and threats too impact the cytotoxics market across the seven major markets, 2010-19 18

Table 6: Sales and growth of cytotoxic therapy drug classes in the US (\$m), 2009-2019 22

Table 7: Top 5 branded cytotoxics in the US in 2009 and 2019 24

Table 9: Summary of opportunities and threats to impact the cytotoxics market in the US, 2010-19 26

Table 10: Sales and growth of cytotoxic therapy drug classes in Japan (\$m), 2009-2019 29

Table 11: Top 5 branded cytotoxic therapies in Japan in 2009 and 2019 31

Table 12: Cytotoxic therapy sales forecasts in Japan (\$m), 2009-2019 31

Table 13: Summary of opportunities and threats to impact the cytotoxics market in Japan, 2010-19 33

Table 14: Sales and growth of cytotoxic therapy drug classes in the five major EU markets (\$m), 2009-2019 36

Table 15: Top 5 branded cytotoxics in the five major European markets in 2009 and 2019 38

Table 16: Cytotoxic therapy sales forecasts in the five major European markets (\$m), 2009-2019 38

Table 17: Summary of opportunities and threats to impact the cytotoxics market in the five major EU markets, 2010-19 41

Table 18: Risk-sharing agreements entered into with NICE in the UK, 2009-2010 47

Table 19: Top 5 branded cytotoxics in France in 2009 and 2019 50

Table 20: Cytotoxic therapy sales forecasts in France (\$m), 2009-2019 51

Table 21: Top 5 branded cytotoxics in Germany in 2009 and 2019 54

Table 22: Cytotoxic therapy sales forecasts in Germany (\$m), 2009-2019 55

Table 23: Top 5 branded cytotoxics in Italy in 2009 and 2019 58

Table 24: Cytotoxic therapy sales forecasts in Italy (\$m), 2009-2019 58

Table 25: Top 5 branded cytotoxics in Spain in 2009 and 2019 61

Table 26: Cytotoxic therapy sales forecasts in Spain (\$m), 2009-2019 61

Table 27: Top 5 branded cytotoxics in the UK in 2009 and 2019 64

Table 28: Cytotoxic therapy sales forecasts in the UK (\$m), 2009-2019 64

Table 29: Comparison of cytotoxic drug class sales in the seven major markets and Rest of the World (\$m), 2009 68

Table 30: Comparison of cytotoxic drug class sales in the BRIC countries, other EU countries and all other non-EU countries (\$m), 2009 69

Table 31: Leading branded cytotoxic drug sales in the seven major markets (\$m), 2009-2019 71

Table 32: Marketing strategies employed by the companies behind the top three cytotoxic brands, 2010 74

Table 33: Taxotere (docetaxel)-drug profile, 2010 75

Table 34: Impacting factors on the revenues of Taxotere, 2009-2019 79

Table 35: Eloxatin (oxaliplatin)-drug profile, 2010 80

Table 36: Impacting factors on the revenues of Eloxatin, 2009-2019 83

Table 37: Alimta (pemetrexed)-drug profile, 2010 84

Table 38: Impacting factors on the revenues of Alimta, 2009-2019 87

Table 39: Gemzar (gemcitabine)-drug profile, 2010 88

Table 40: Impacting factors on the revenues of Gemzar, 2009-2019 91

Table 41: Leading companies in the cytotoxic therapies market in the seven major markets (\$m), 2009-2019 92

Table 42: Assessment of Sanofi-Aventis's cytotoxics portfolio, 2010 95

Table 43: Assessment of Eli Lilly's cytotoxics portfolio, 2010 96

Table 44: Assessment of Merck/Schering Plough's cytotoxics portfolio, 2010 97

Table 45: Assessment of Roche's cytotoxics portfolio, 2010 98

Table 46: Regional launch dates for new cytotoxics in the seven major markets, 2009-2019 106

Table 47: Patent expiry dates for the approved cytotoxics in the seven major pharmaceutical markets, 2009-2019 107