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Research paper

The therapeutic antibodies market to 2008

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Abstract

The therapeutic biologics market is currently dominated by recombinant protein products. However, many of these products are mature, and growth of the biologics market will increasingly rely on the expansion of the therapeutic monoclonal antibody sector. Successive technology waves have driven the growth of the monoclonal antibody sector, which is currently dominated by chimeric antibodies. Chimeric products, led by Remicade and Rituxan, will continue to drive market share through to 2008. However, over the forecast period, humanized and fully human monoclonal antibodies, together with technologies such as Fabs and conjugated antibodies, will play an increasingly important role, driving monoclonal antibody market growth at a forecast compound annual growth rate of 20.9%, to reach $16.7 billion by 2008. In terms of therapeutic focus, the monoclonal antibody market is heavily focused on oncology and arthritis, immune and inflammatory disorders, and products within these therapeutic areas are set to continue to be the key growth drivers over the forecast period. Underlying the growth of the market is the evolution of the monoclonal antibody company business model, set to transition towards the highly successful innovator model.

Keywords: Monoclonal antibody; Chimeric; Murine; Humanized; Fabs; Fully human; Market analysis

1. Introduction

In the early 1970s, the biotechnology industry began to benefit more directly from an explosion in public funding. From the middle 1970s onwards, substantial advances in physiology, pharmacology, enzymology and cell biology, with the vast majority stemming from publicly funded research, led to enormous progress in the ability to understand the biochemical and molecular roots of many diseases. This new knowledge had a profound impact on the process of discovery for new drugs. Advances in molecular genetics and recombinant protein (rDNA) technology opened an entirely new frontier for biopharmaceutical innovation.

The application of these advances initially followed two relatively distinct technical trajectories. The first used advances in genetics and molecular biology as tools to enhance the productivity of the discovery of conventional 'small molecule' synthetic chemical drugs. Meanwhile, the second trajectory was rooted in the use of molecular biology as a process technology to manufacture protein-based biomolecules.

The production of murine monoclonal antibodies (mAbs) was first reported in 1975 [1] and, by 1980, mAbs had entered studies in humans. Chimeric and humanized mAbs, first reported in 1984 [2] and 1986 [3], respectively, were developed to address the problems associated with the murine mAbs. Such problems included their short serum half-life and the human antimouse antibody (HAMA) immunogenic response [4]. Early antibody specialists initially advanced their basic technological platform in the 1980s helped mainly by public and venture capital funding.

Later, as technology evolved further, the sector was able to attract a wave of alliance networking with the large pharma sector, allowing several companies in the 1990s to build their own or partnered pipelines. Eventually, some were able to create in-house manufacturing and sales and marketing capabilities to integrate their businesses further,

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Table 1
The current leading monoclonal antibodies approved to date, highlighting sponsor company, the mAb indication, type and stage of development, the date of approval and the sponsor company website

Brand name	Common/chemical name	Sponsor company	Therapy area	Stage	US approval	Website address
Murine						
Orthoclone OKT3	Muromonab-CD3	J&J	AIID	M	Jun-1986	www.jnj.com
Panorex	Edrecolomab	Glaxo/Centocor	ONCO	D	n/a	www.gsk.com/ www.centocor.com
Chimeric						
ReoPro	Abciximab	Centocor	CV	M	Dec-1994	www.centocor.com
Rituxan	Rituximab	Biogen-IDEC	ONCO	M	Nov-1997	www.biogen.com
Simulect	Basiliximab	Novartis	AIID	M	May-1998	www.novartis.com
Remicade	Infliximab	Centocor	AIID	M	Aug-1998	www.centocor.com
Erbitux	Cetuximab	ImClone Systems	ONCO	M	Feb-2004	www.imclone.com
Humanized						
Zenapax	Daclizumab	Protein Design Labs	AIID	M	Dec-1997	www.pdl.com
Synagis	Palivizumab	MedImmune	ID	M	Jun-1998	www.medimmune.com
Herceptin	Trastuzumab	Genentech	ONCO	M	Sep-1998	www.gene.com
Campath	Alemtuzumab	Millennium/ ILEX*	ONCO	M	May-2001	www.mlnm.com/ www.ilexonc.com
Raptiva	Efalizumab	Genentech	AIID	M	Oct-2003	www.gene.com
Xolair	Omalizumab	Genentech	RESP	M	Jun-2003	www.gene.com
Avastin	Bevacizumab	Genentech	ONCO	M	Feb-2004	www.gene.com
Conjugated						
Mylotarg	Gemtuzumab ozogamicin	Wyeth	ONCO	M	May-2000	www.wyeth.com
Zevalin	Ibritumomab tiuxetan	Biogen-IDEC	ONCO	M	Feb-2002	www.biogen.com
Bexxar	Tositumomab-I131	Corixa	ONCO	M	Jun-2003	www.corixa.com
Human						
Humira	Adalimumab	Abbott	AIID	M	Dec-2002	www.abbott.com

AIID, arthritis, inflammation and immune disorders; CV, cardiovascular; ID, infectious disease; ONCO, oncology; RESP, respiratory; D, discontinued; M, currently in the market; *, ILEX is now part of genzyme; Source: datamonitor, company-reported information.

towards the fully integrated pharma or biotech company model.

Driving this business activity was the market's need to generate an economic environment of sustainable profitability. The attractiveness of antibody developers to investors is closely linked to the successes or failures in other biotech technological platforms such rDNA or gene therapies. During the late 1990s the perception that genomics would rapidly revolutionize medical practice had created a bull market with cross-platform unrealistic stock overvaluations, driving up the market capitalization of public mAb developers.

Later, as investors realized that the use of genomics data could take more than 10 years to create real drug pipelines, the industry entered a bearish environment with significant stock devaluations and a very low level of IPO (Initial Public Offering) activity, even in areas, where biotech activity (e.g. antibody development) was maturing and concentrating on actual drug development rather than data exploration.

The exit strategy from the current bear market revolves around the creation of sustainable profitability.

Utilizing a number of verified industry databases [5] and in-house primary and secondary analysis to analyse the antibody market, Datamonitor [6] has constructed a database that includes the pipelines, technologies and partnerships of 95 key companies and a 'virtual' dialogue with some of the antibody sector's industrial leaders to produce thorough analysis of the sector's growth potential. Of these 95 companies, the leading companies and their products are detailed in Table 1.

2. Methods

In analyzing the antibody market, Datamonitor has constructed a database of 376 preclinical-to-market products that includes the pipelines, technologies and partnerships of 95 key companies (Fig. 1). This analysis was performed in May 2004. Table 1 highlights the characteristics of the leading marketed mAb therapeutics.

Analysis was performed on this information, utilizing a bottom-up methodology as shown in Fig. 1, to draw out the strategy underlying mAb market dynamics. The database formed the basis to identify and benchmark the leading biotech and pharma antibody-oriented business models according to strategic, portfolio and financial measures, enabling Datamonitor to evaluate the most successful operating strategies.

The analysis assesses the strategic implications for the antibody companies as well as the most significant steps that the industry's emerging players and leaders are taking to