

Marketspace

The immunotherapies markets, 2003–2008

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Keywords: monoclonal antibodies, therapeutic vaccines

Abstract

Analysis of 170 leading and emerging therapeutic antibodies (Ab) and vaccine companies unveils two different business growth trends. The therapeutic antibodies sector will see strong revenue growth with 15 new fully human and humanised product launches and its sales growing from US\$5bn in 2002 to more than US\$16bn in 2008. However, the therapeutic vaccines sector, despite its highly innovative nature and newly developed personalised approach, is unlikely to be able to achieve high market penetration with 2008 sales forecast less than US\$0.5bn.

INTRODUCTION

In the past 20 years, the immunology sector has evolved from 'non-specific' (short-term polyclonal and long-term whole cell prophylaxis) vaccinations for the prevention of infectious disease to the modern era of 'specific' (passive in the form of therapeutic antibodies or active in the form of therapeutic vaccines) immunisation for new therapeutic areas such as cancer, inflammatory disorders,

respiratory and central neural system (CNS) (see Figure 1). Following the success of recombinant proteins, therapeutic antibodies (Abs) represent the second largest wave of innovation created by the biotechnology industry. In analysing the Ab market, Datamonitor has utilised a database that includes the pipelines, technologies and partnerships of 95 key companies and a 'virtual' dialogue with some of the Ab sector's industrial

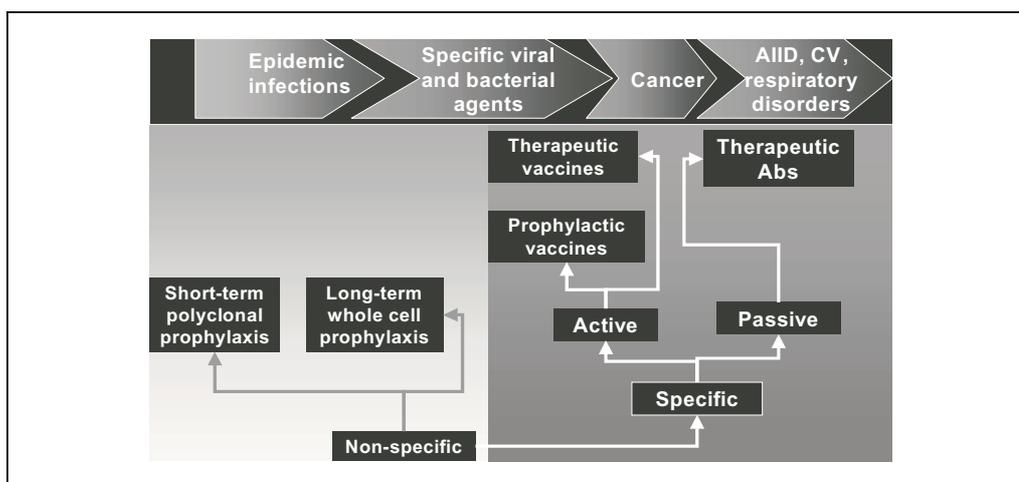


Figure 1: The evolution of immunology-based medicine (AIID = arthritis, inflammation and immune disorders, CV = cardiovascular)
Source: Datamonitor

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leaders to produce a thorough analysis of the sector's growth potential.

In addition, therapeutic vaccines (natural, recombinant or synthetic biomolecular structures that can elicit or alter human immune responses to block or slow the progress of a disease) represent another trajectory of immunology-based innovation in development. However, the therapeutic vaccine market is in its infancy, with no significant products launched across the seven major markets. Datamonitor has identified 65 companies developing therapeutic vaccines, with 167 novel therapeutic vaccines in preclinical and clinical development, and two products on the market (following M-Vax's withdrawal from the Australian market in September 2002).

KEY TECHNOLOGICAL TRAJECTORIES

Therapeutic antibodies

Between 2001 and 2002, the value of the therapeutic antibody market grew by 37.5 per cent to US\$5.4bn, of which chimeric antibodies generated 70.5 per cent. However, as Figure 2 highlights, the technological focus of the Ab sector is changing as humanised and fully human products dominate the pipeline. Of the 376 development programmes identified by Datamonitor (from preclinical to marketed) across 95 key companies, 132

are currently in clinical development, of which 92 involve humanised (55 or 41.7 per cent of the Ab clinical pipeline) and fully human products (37 or 28 per cent of the clinical Ab pipeline). The strength of humanised and human platforms is reflected in the product approval trajectories in terms of technological exposure between 2003 and 2008, as highlighted in Figure 3.

Datamonitor's analysis suggests that there will be two major approval waves over the next five years. More specifically, the period 2003–2008 will see the launch of eight fully human antibodies, of which six are projected to receive approval between 2007 and 2008. In addition, there will be seven launched humanised products, of which six will receive approval between 2004 and 2005. Based on these trends, the global therapeutic antibody market is expected to grow at a compound annual growth rate (CAGR) of 20.9 per cent between 2002 and 2008, to US\$16.7bn. Current marketed products are still expected to dominate the market, with chimeric antibodies led by Remicade and Rituxan representing 49.3 per cent of sales.

The second most important technology in terms of 2008 sales will be humanised antibodies with sales forecast to grow from US\$1.4bn to US\$5.2bn, capturing a 31.2 per cent market share by 2008. In addition, fully human antibodies are expected to reach 2008 sales of US\$1.9bn representing 11.4 per cent of the market share in 2008.

Therapeutic vaccines

As Figure 4 displays, the industry is taking two routes to market through the development of generalised and personalised vaccines. Datamonitor's analysis suggests that generalised and personalised approaches will have almost equal success over the time period. More specifically, between 2004 and 2008, personalised vaccine sales will grow from US\$33m to US\$268m, capturing a 54.3 per cent market share by 2008. Meanwhile, generalised product sales are

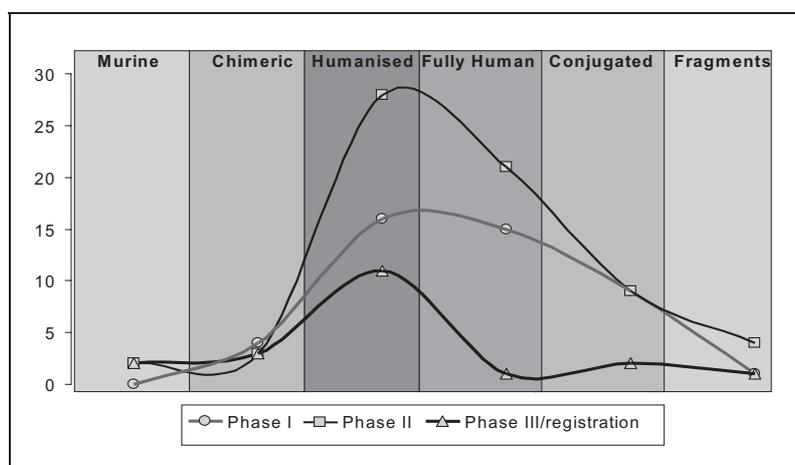


Figure 2: Technological exposure of the Ab clinical pipeline, 2003
Source: Datamonitor, company reports

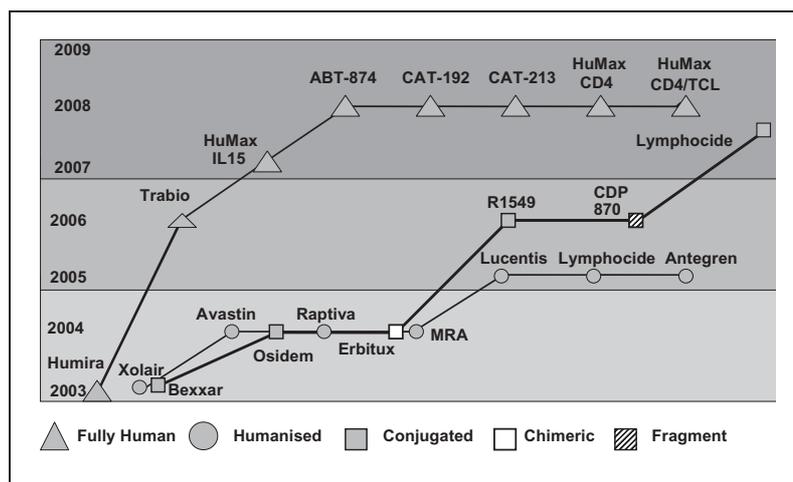


Figure 3: New product approval trajectories in terms of technological exposure

Source: Datamonitor, company reports

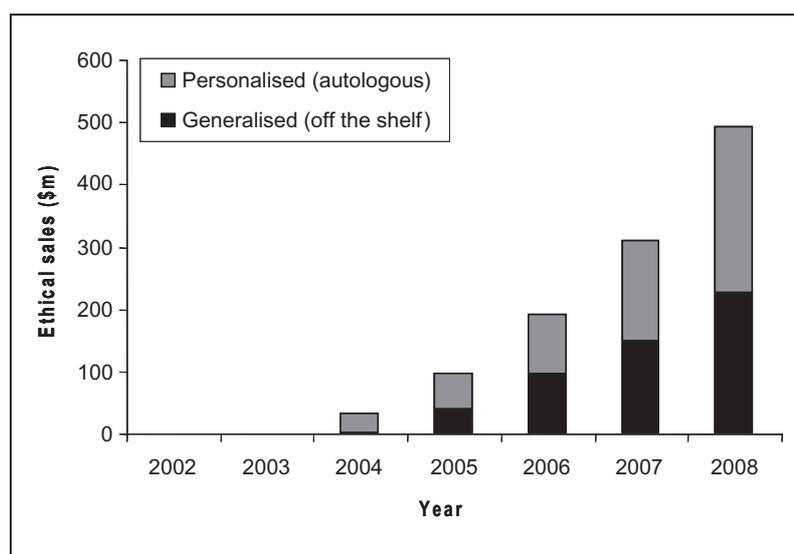


Figure 4: Personalised versus generalised vaccines: ethical sales, 2002–2008

Source: Datamonitor

forecast to grow from US\$39m in 2005 to US\$226m in 2008. Personalised approaches can very quickly (within 48–72 hours) prepare highly reproducible (using patient's exact disease antigenic fingerprint) and safe (autologous antigenic structures cause minimal adverse effects) products. However, personalised players have not yet managed to have their leading products partnered (validated) by

a wide spectrum of leading biotech or pharma players. Therefore, the lack of partners with strong marketing capabilities limits their products' market penetration. The current business models of the leading biotech and pharma players are not designed to support the promotion of personalised products, as the latter would need new regulatory, promotional and pricing strategies and significant cash injections. It will take years and possibly some dramatic clinical results in order to attract the attention of leading biotech and pharma players and increase investor confidence.

KEY THERAPEUTIC AREAS

Therapeutic antibodies

The Ab industry, as Figure 5 illustrates, is, and will remain, heavily focused on oncology and arthritis, immune and inflammatory disorders (AIID). In terms of the global Ab portfolio (from preclinical to marketed products), Datamonitor has identified 193 oncology programmes representing 51.3 per cent of the Ab portfolio, followed by 81 AIID programmes with a portfolio share of 21.5 per cent. Together, these areas represent more than 72 per cent of the global Ab portfolio. For the period 2002–2008, oncology will be the leading ethical income earner with sales growing from US\$2.2bn to US\$7.2bn, representing a 43.2 per cent market share. Meanwhile, AIID is expected to post stronger growth than oncology, as sales almost quadruple from US\$1.7bn in 2002 to US\$6.7bn in 2008, accounting for 40 per cent of the global market.

Therapeutic vaccines

Products in development for cancer indications dominate both the late stage and full pipeline of therapeutic vaccines in development. Nine out of the 11 late stage (Phase III trials upwards) and marketed products are indicated for cancer, while 61 per cent (103 therapeutic vaccines) of the total marketed and pipeline products are in development to treat cancer (see Figure 6). Melanoma is

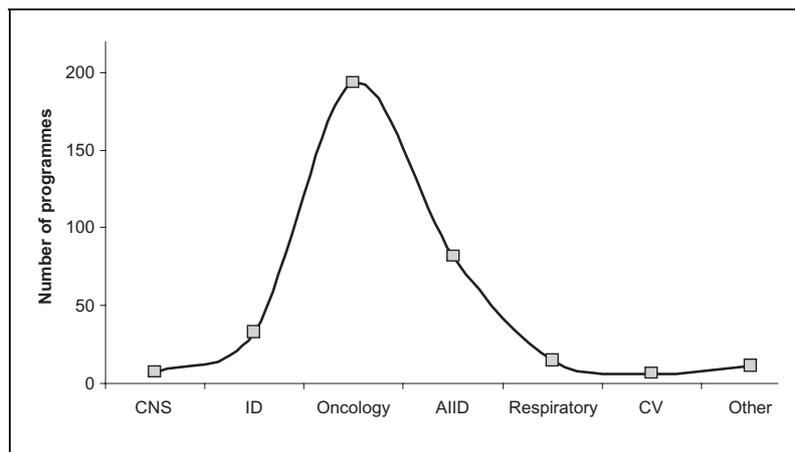


Figure 5: Therapeutic focus of antibody development, 2003 (AIID = arthritis, inflammation and immune disorders, CNS = central neural system, CV = cardiovascular, ID = infectious disease)
Source: Datamonitor, company reports

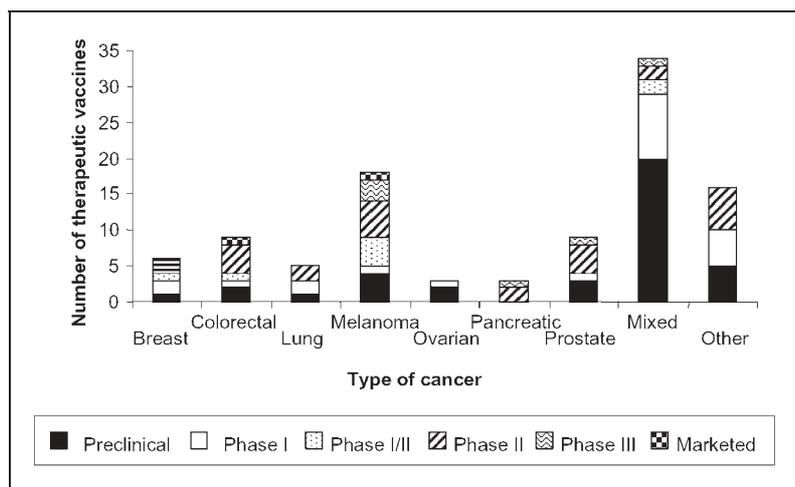


Figure 6: Colorectal, melanoma and prostate cancer have the most therapeutic vaccines in development
Source: Datamonitor, company reports

seemingly the most popular cancer vaccine target, with 18 therapeutic vaccines targeting the disease, one of which (Melacine) is already on the market, and one (M-Vax) which has been marketed in Australia, but has since been withdrawn to allow the company to focus on Phase III development of the vaccine in the major markets.

LEADING PRODUCTS

Therapeutic antibodies

In Datamonitor's view, the sector's dependence on blockbusters will increase, with five Ab drugs forecast to achieve annual sales of over US\$1bn by 2008 (see Figure 7). More specifically, Rituxan, Remicade, Humira, Synagis and Herceptin are expected to generate combined sales of over US\$11.4bn in 2008, capturing a market share of 68 per cent. The industry's leading Ab will continue to be the chimeric Remicade, with sales forecast to reach US\$3.8bn by 2008, still representing almost one-quarter of the market value. Each of the five leading antibody drugs in 2003 is marketed by two or more companies to ensure maximum global penetration. The value of the therapeutic antibodies market makes it attractive to big pharma's sales and marketing engines. By 2008, Datamonitor forecasts that only 2 of the 16 Ab-related therapies that will generate sales over US\$200m will be marketed without the involvement of a top 20 company. Both of these drugs will be marketed by Biogen-IDEc, the only company brave enough to attempt self-marketing.

Therapeutic vaccines

The therapeutic vaccine sector is still in early development, in a similar position to that of the monoclonal antibodies market in the early 1990s when the class initially saw a slow uptake and lack commercial success. Dendreon's Provenge, indicated for prostate cancer, is positioned to be the next therapeutic vaccine to market and its pathway to regulatory approval will influence subsequent filings. It is vital that Dendreon successfully recruits a medium to large pharma company to take on the marketing of its product and secure maximum sales. Datamonitor has created three scenario forecasts to quantify the potential directions the therapeutic vaccine market could take, depending on the success of the leading developmental products (see Figure 8). Datamonitor forecasts that sales growth is likely to

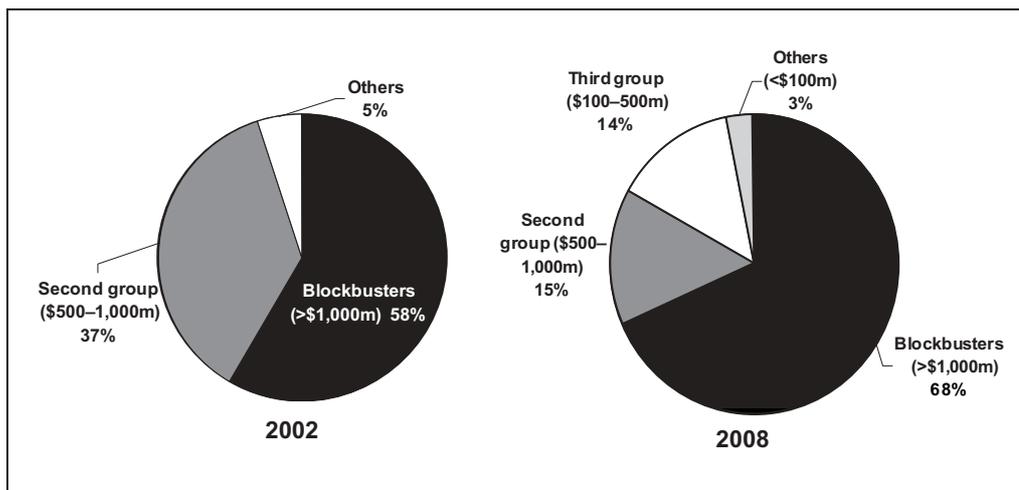


Figure 7: Contribution of blockbuster Abs to the sector's total ethical revenues, 2002 and 2008
Source: Datamonitor, company reports

accelerate between 2005 and 2008 as more vaccines reach the market and physician acceptance of the technology increases. There is a large difference in market size between the most likely (US\$494m in 2008) and the worst-case scenario. If the late stage products continue to suffer problems during clinical trials, the market may reach just US\$198m in 2008. The difference between the most likely scenario and best case (US\$794m) is mainly the penetration

that the vaccines achieve, combined with the support given by partner companies.

CONCLUSION

Success in the area of immunotherapies will rely on the growth of the therapeutic Ab market. It is Datamonitor's view that following the success of recombinant proteins, the Ab sector, with over 200 players involved in their discovery, development, delivery and marketing, is forecast to reach US\$16.7bn by 2008.

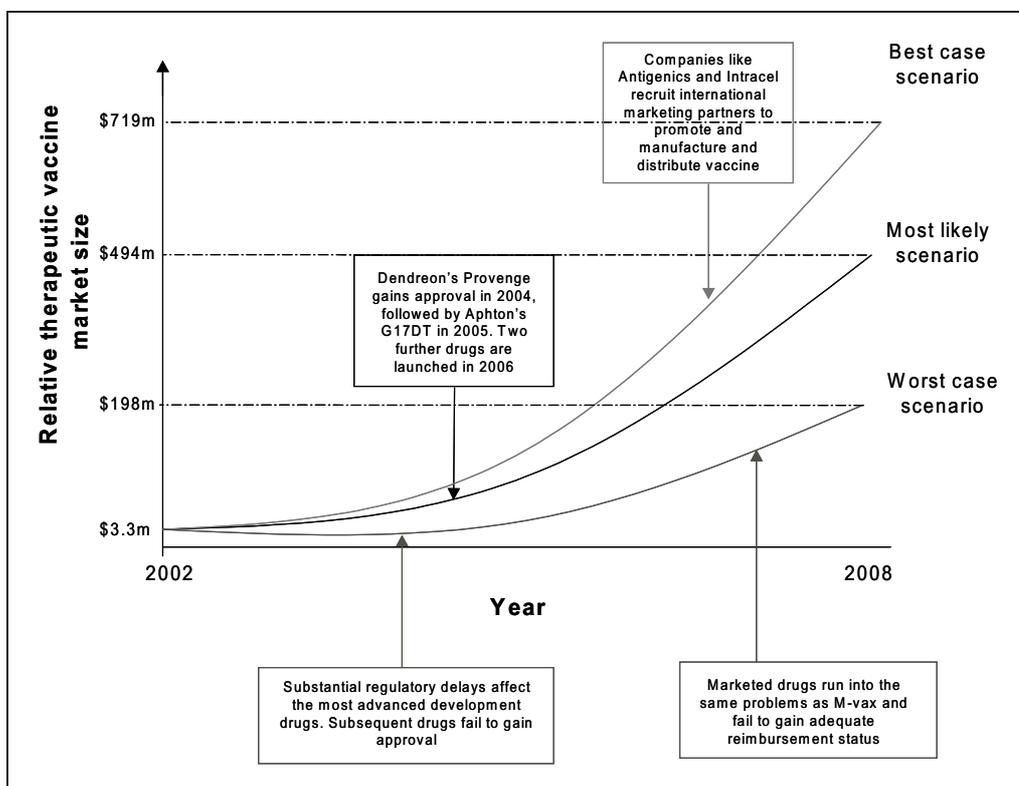


Figure 8: In the best-case scenario, the therapeutic vaccine market could be worth US\$719m by 2008
Source: Datamonitor

Although the growth will rely on the rise of humanised and fully human antibodies, chimeric products, led by Remicade and Rituxan, will continue to dominate market share in 2008. Oncology will continue to be the leading therapy area both for antibody and vaccine players both in terms of commercial success and

pipeline development. The therapeutic vaccine market with a best-case scenario 2008 forecast of less than US\$800m will not receive significant attention from the wider pharmaceutical industry until a product is launched and achieves significant uptake across the seven major markets.