What's fueling the biotech engine—2011 to 2012

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Sales in the biologics sector show modest but healthy growth rates for the fourth consecutive year, with cancer drugs garnering the greatest revenues. As the diabetes epidemic grows and innovation of insulins continues, drug companies in that space are moving up in the ranks.

In 2011, the US biotech sector grew modestly, with total sales reaching $53.8 billion, or a 4.9% increase over 2010 sales (**Fig. 1a**). Driven by rising uptake of monoclonal antibodies (mAbs) and insulin products, this increase was slightly better than the overall pharmaceutical sector, which experienced growth of 3.0% in 2011 (ref. 1). The outlook for 2012–2013 seems to be improving, as several promising products, which are driving the current growth, reach the market (**Fig. 1b**). However, in the long term, the sector faces increasing difficulties with reimbursement and the potential launch of biosimilars, which could impose downward pressure on unit sales and pricing in this sector.

In the following article, I analyze the market trends observed in 2011 and the first half of 2012 for nine classes of biologics (**Box 1** and **Fig. 2**). For each of these classes, I provide a discussion on sales volume, pricing, indication expansions, competition within biologics and from small-molecules drugs, safety issues and promising new candidates. I also provide a ranking of the top companies in terms of the size of US sales of biologics (**Box 2** and **Fig. 3**). On the basis of the sales trends, I have categorized products within each respective therapeutic class as market leaders (where sales are greatest for an indication), rising stars (where sales show rapid growth) or laggards (where sales underperformed). The methodology applied in this article is essentially the same as I used in previous biotech market overviews published in this journal[2–4]. Blockbuster products are defined as those with US sales of at least one billion dollars. The following sections cover each of the nine classes of biologics in descending order of the sales they accrued.

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mAbs

In 2011, mAbs maintained their ranking as the best-selling class of biologics, with US sales reaching ~$20.3 billion, a 10.1% growth over their 2010 sales (**Fig. 2**), keeping companies with mAb products in the lead in revenues (**Fig. 3**). Last year's growth rate is similar to the growth during 2009–2010 (9.7%). The growth of the mAbs sector would have been greater if it had not been offset by a decline in sales of the mega-blockbuster antibody Roche/Genentech's (Basel) Avastin (bevacizumab), which was due to the reversal of accelerated approval for breast cancer. If Avastin is excluded from the calculation, the total sales of all mAbs grew by 17% during 2011. $2.0 billion in this growth in sales was driven by several new product launches: Human Genome Sciences (Rockville, MD, USA)/GlaxoSmithKline's (GSK, London) anti–B-lymphocyte stimulator human mAb Benlysta (belimumab); Seattle Genetics (Seattle)/Takeda's (Osaka, Japan) anti-CD30 chimeric IgG1 mAb–monomethyl auristatin E conjugate Adcetris (bretuximab vedotin); Amgen's (Thousand Oaks, CA, USA) human mAb targeting RANK ligand denosumab (Xgevz); and Bristol-Meyer Squibbs's (New York, USA) anti-PD1 antibody Yervoy (ipilimumab). There are now 36 US Food and Drug Administration (FDA)-approved mAbs, sales of which constitute ~38% of the total biologics market.

Ten mAb products constitute 86% of the total sales of this sector (**Fig. 4**). Among them, six products experienced high double-digit growth, whereas four products either did not change or declined in sales. The mega-blockbuster Remicade (infliximab, Janssen's (Horsham, PA, USA), which was the first anti-tumor necrosis factor (TNF)-alpha product to be approved in the United States in 1998, had a slight decline in sales, as it lost market share to other rapidly expanding anti-TNF products, such as Abbott's (Deerfield, IL, USA) human IgG1 mAb Humira (adalimumab) and UCB's (Brussels) Cimzia (certolizumab pegol; recombinant PEGylated anti-TNF-alpha humanized mAb fragment). On the other hand, another market leader Genentech/Biogen Idec's (Cambridge, MA, USA) anti-CD20 chimeric mAb Rituxan (rituximab) grew by 9%, driven by new clinical data from the PRIMA trial supporting longer-duration treatment in lymphoma[5].

Two other notable mega blockbusters, in terms of their 2011–2012 trends are Humira and Avastin. Last year, Humira gained the status of the best-selling biologic in the United States and globally. In 2011, Humira's US sales reached $3.5 billion; global sales were $7.3 billion, posting a record 20% sales growth over previous year sales. Humira's growth is more than double the overall growth rate of the anti-TNF market (~8%), implying that its sales growth was driven by both indication expansion and taking market share from other products. Humira's near-term sales catalyst is the newly approved indication for ulcerative colitis, though in the long term, Humira and the anti-TNF market could face some competition from Pfizer's (New York) small-molecule Janus kinase (JAK-3) inhibitor tofacitinib[6], which was approved by the FDA in November 2012. In pivotal trials, including one head-to-head with Humira, tofacitinib showed impressive efficacy in various indications[7,8]. As an oral product, tofacitinib could be a game changer in this market.

The other mega-blockbuster mAb, Avastin, suffered a major setback in 2011, as its sales declined by 13%, falling to $2.6 billion, compared with $3.0 billion in 2010. This decline, which was expected, was mainly due to the FDA withdrawal of its indication for metastatic breast cancer. Near term, there remain two