Therapeutic Trends

Disease Dynamics: An Excerpt from IMS Health's Intelligence.360

Insight and Outlook from IMS Health

No matter what the class, the fate of new therapies often depends on a balance—between risk and benefit, benefit and cost, access and reasonable profit. In 2006, questions of balance were literally everywhere. In oncologics, an ever-widening array of effective, premium priced treatment options left stakeholders marvelling at success rates—yet worrying about the costs. In antidiabetics, the question was which of the several new and soon-to-be launched therapies would manage to strike the best balance between efficacy and convenience. Finally, in the fight against autoimmune disorders, anti-tumour necrosis factor (TNF) therapies faced their own question of balance—that is, whether their obvious benefits could outweigh troubling side effects, particularly with a host of alternative agents now moving up through the clinical pipeline.

ONCOLOGICS

Of all key pharma business sectors, oncology is currently the most significant for all stakeholders involved—and one that is approaching a tipping point that may affect business dynamics for years to come.

The $35 billion US global oncology market is growing at 21%, adding nearly $6 billion US in 2006. Much of the growth in oncology sales can be attributed to targeted therapies. In 2006 such sales reached $13 billion US, compared to $1.3 billion US in 2001. Of the oncology products in late stage development, 50% are targeted therapies. In solid tumours, most new research is centered around small molecule receptor inhibitors and neutralizing antibodies of one or more of the VEGF, EGFR, TKI and HER2 proteins. Most of these approaches target key processes of cancer cells—either preventing cancerous cell growth, reproduction, or both—while some target apoptosis, or programmed cell death. In leukemias, the associated weakening of the immune system can limit treatment options significantly. The exciting new agents in this area work by boosting the immune system or selectively targeting cancerous cells with antibodies or receptor blockers. All of these targeted therapies have many potential applications within (and sometimes outside) the cancer space, giving pharmaceutical companies strong incentive to broaden the focus of their

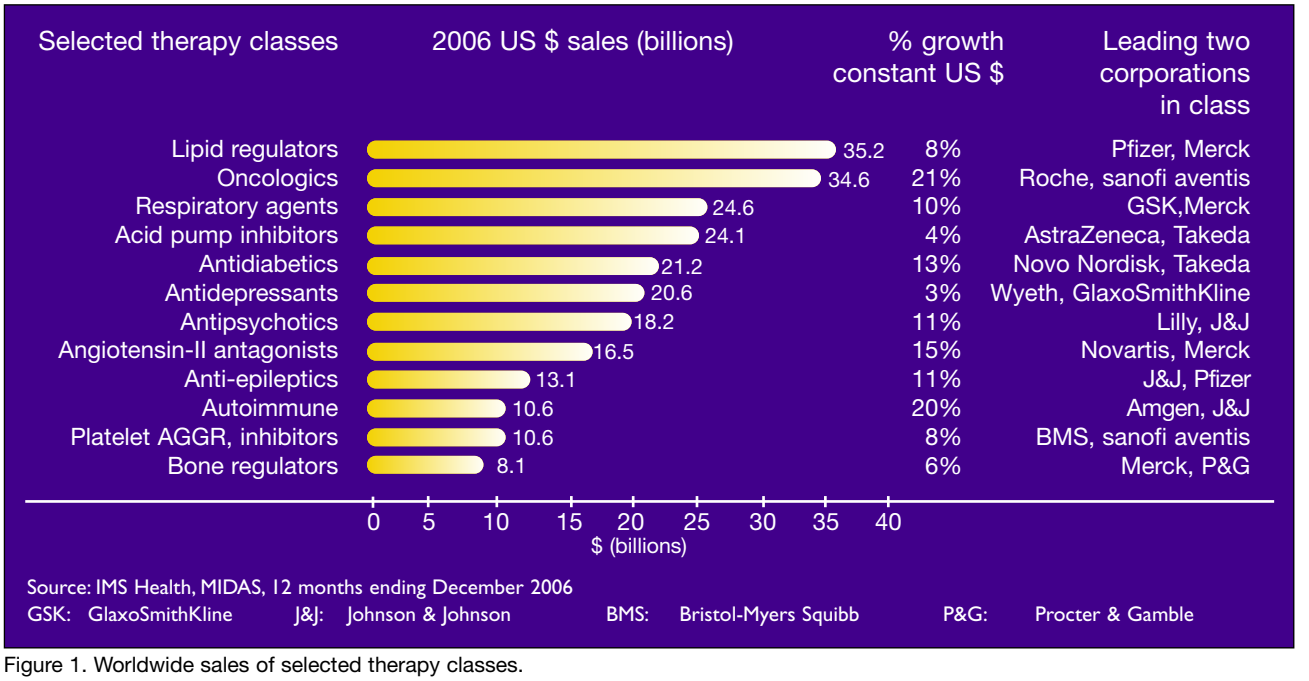

Figure 1. Worldwide sales of selected therapy classes.

research beyond different stages of the same disease type to new disease areas. Newer products now account for a very high percentage of oncology sales, particularly in Europe and North America. In Japan, a more cautious approval process has led to half as many introductions of new entities over the past 10 years as in Europe and the US. Nevertheless, oncology is still the largest franchise in Japan, at $3.9 billion US and rising at a rate of 7% in 2006 (vs. > 20% in Europe and North America).The US oncology market leads all others at $16 billion and is growing at a rate of 23%. The European oncology market—at $12 billion US and growing at a rate of 22%—is one of the key factors driving greater interest in cost control by European regulators.

ANTIDIABETICS

Diabetes is now a global pandemic identified by the World Health Organization as "a major threat to global public health that is rapidly getting worse." This disease affects 171 million people worldwide and it is likely to afflict more than twice that number by 2030. In 2006, the global antidiabetic market grew 13% to $21 billion US, with 53% of sales in North America, 27% in Europe, 9% in Japan and 11% in the rest of the world. By 2010, it is expected to grow at a compound annual growth rate of 7% to 10%, reaching $25 to $29 billion US. Given the size and potential of the market, pharmaceutical companies are now in a race to capture share in combating both Type 1 and Type 2 diabetes. New approaches range from enzyme inhibitors and inhaled insulins to Acomplia®, a drug that lowers blood glucose while reducing weight, an advantage for a disease in which obesity is a primary factor.

In this race for share, two distinct drug classes are designed to mitigate dipeptidyl peptidase-4 (DPP-4), an enzyme that degrades an essential protein responsible for controlling blood glucose. The first class of drugs, glucagon-like peptide-1 analogues, mimic the degraded protein and appear not only to lower blood glucose, but also to promote weight loss. The second class, DPP-4 inhibitors, acts to block DPP-4, thereby lowering blood glucose levels without GI side-effects.

AUTOIMMUNE AGENTS

Over the past decade, biological response modifiers that target critical mediators of inflammation, such as TNF-α, have revolutionized the therapeutic landscape for many different autoimmune disorders. Three biological agents that inhibit TNF-α are already available: Remicade® and Humira®, which are monoclonal antibodies directed against TNF-α and Enbrel®, which is a soluble receptor that acts as a "decoy receptor" for TNF-α. A fourth, certolizumab pegol, is likely to be FDA approved and launched in the US shortly. TNF-α therapies have demonstrated broad clinical utility in treating:

- Crohn's disease,
- ulcerative colitis,
- rheumatoid arthritis,
- ankylosing spondylitis,
- psoriatic arthritis and
- psoriasis.

Global audited sales of the three existing agents reached $9.9 billion US in 2006, a growth of 23% over 2005. Revenue is still concentrated in North America (69.2%), but growth increased in Europe (33.1%). Japan still accounts for only 2% of global revenue, but growth has accelerated following the launch of the second entrant, Enbrel®, in late 2005.

LIPID REGULATORS

Lipid regulators treat a number of conditions in which cholesterol and/or triglycerides in blood plasma are raised. Studies confirm that an elevated cholesterol level is one of the most critical risk factors for coronary heart disease (CHD). Incidence of CHD increases with sedentary lifestyles and secondary conditions, including diabetes and obesity. The lipid regulator market was worth $35 billion US in 2006, an 8% increase over 2005. North America accounted for 65% of sales, Europe 22%, Japan 6%, Latin America 2% and the rest of the world 5%.

Of the $2.5 billion US in lipid regulator sales added to the market in 2006, North America contributed $2 billion, with growth of 10%, whereas the European market added only $96 million. The European market was essentially flat, up only 1%, while the Japanese market declined 0.5%. Market dynamics within the US drove 2006 growth. Lipid regulators are well known to the population > 65-years-of-age and the introduction of Medicare Part D fueled new demand. For Part D patients, induced demand (a measure combining new starts and improved compliance) for statins was among the highest of all leading therapy areas studied. CPM