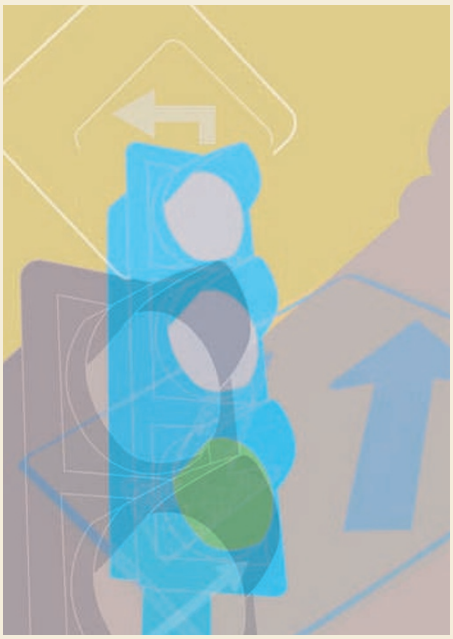
NEWS IN BRIEF

Green light for Victoza



The US FDA has granted approval of Novo Nordisk's long-acting glucagon-like peptide 1 (GLP1) analogue liraglutide (Victoza).

The lowdown: The decision to approve liraglutide had been long-awaited since the FDA's Endocrinologic and Metabolic Drugs Advisory Committee met to discuss the peptide in April 2009. The original regulatory decision had been expected by March 2009, but this was extended to May 2009. Initially, this was thought to be due to the requirement that companies developing new drugs for diabetes should provide clinical data to rule out an increased risk of cardiovascular disease associated with the investigational drug. At their meeting, the advisory committee voted 8 to 5 that Novo Nordisk had provided sufficient evidence to rule out an unacceptable cardiovascular risk in a group of patients at low risk of developing such complications. However, the committee was concerned about preclinical data showing an increase in thyroid C-cell tumour development in rats and mice. The same safety concern was not observed in monkeys or humans but the committee voted 6 to 6, with one abstention, regarding whether the rodent cancer data should preclude marketing. This left the decision completely up to the FDA.

On 25 January 2010, the FDA approved liraglutide in patients with type 2 diabetes, to be prescribed alongside diet, exercise and selected other diabetes medicines. It is not intended for use as an initial therapy in patients owing to the concerns about thyroid cancer. As a condition of approval, Novo Nordisk must meet some additional post-marketing requirements: performance of a study to specifically evaluate the cardiovascular safety of liraglutide in a higher-risk population and a 5-year epidemiological study using a health claims database to evaluate thyroid and other cancer risks, as well as risks for hypoglycaemia, pancreatitis, and allergic reactions. In addition, the company is required to establish a cancer registry to monitor the rate of thyroid cancer in the United States over the next 15 years.

NICE continues to say no to new cancer drugs

The UK's National Institute for Health and Clinical Excellence (NICE) has issued guidance for three anticancer agents stating that they are not recommended for use on the UK's National Health Service (NHS), partly owing to their high cost.

The lowdown: Early in February, NICE issued draft guidance stating that dasatinib (Sprycel; Bristol Myers–Squibb) and nilotinib (Tasigna; Novartis) are not recommended for the treatment of patients with chronic myeloid leukaemia (CML) who are intolerant to imatinib (Glivec/Gleevec; Novartis). The appraisal committee made the assessment that the clinical evidence to support the prescription of either dasatinib or nilotinib in this indication was not adequate, particularly as there were no data comparing either drug with other treatments. Given the paucity of data, the committee concluded that both drugs are not considered cost-effective for use by the NHS.

In a statement that described their decision, Peter Littlejohns, NICE's Clinical and Public Health Director, said: "It would be heartening to hear that the pharmaceutical company manufacturers are prepared to share some of the very high cost of the drugs with the NHS." Indeed, the latest in a growing line of cost-sharing schemes indicates that NICE is open to discussions with pharmaceutical companies regarding sharing the financial risk. In January, NICE recommended the use of certolizumab pegol (Cimzia; UCB) for the treatment of rheumatoid arthritis, on the condition that the company implements a patient access scheme in which the NHS only starts paying for the drug after the first 12 weeks of treatment.

Big pharma restructuring continues

Pfizer, AstraZeneca (AZ), and GlaxoSmithKline (GSK) have all recently announced restructuring plans that may result in R&D-related job cuts.

The lowdown: On 27 January 2010, Pfizer announced the first details of its pipeline following the completed acquisition of Wyeth. The company has cut ~100 R&D programmes, with the majority of the remaining 500 falling into six areas of research: oncology, pain, inflammation, Alzheimer's disease, psychoses and diabetes. At the end of 2009, Pfizer announced that it would reduce its global R&D square footage by 35% to concentrate R&D from 20 R&D sites worldwide, following the acquisition of Wyeth, into 5 main sites and 9 specialized units.

AZ, as part of their end of year conference call for analysts and investors on 28 January, also announced further restructuring plans to reduce R&D expenditure. The planned changes may affect ~3,500 R&D positions, with a net loss of ~1,800 people following relocation, investment in new skills and capabilities, and expansion of the company's biologics activities. This adds to the loss of ~12,600 positions from all divisions across the company since 2007. They estimate that these changes will cost US$1 billion, but save the same amount by 2014. Despite the cuts, AZ highlighted its commitment to R&D, stating that "the Company expects that between 40 and 50% of its pre-R&D post-tax cash flows will be reinvested in internal and external R&D and capital investments to drive future value and growth."

Continuing the trend, also during its end of year conference call on 4 February, GSK announced plans to restructure R&D with the aim of delivering pre-tax savings of UK£500 million by 2012. The company did not provide targets for job reductions, but did announce proposals to stop R&D in depression and pain indications. The company plans to focus its neuroscience research activities in neurodegenerative and neuroinflammatory diseases (such as Alzheimer's disease, multiple sclerosis and Parkinson's disease) and has launched a new standalone unit specializing in the development of medicines for rare diseases.