With UK locations in Cambridge and Uxbridge, and an award-winning pipeline, Amgen is establishing itself as a leading voice in the UK healthcare market. *Katrina Megget* talks drugs, biotech and NICE with the local company's executives. Photos: *Magnus Rew*

# Brave new biotech

John Kearney and Charles Brigden

In industry terms, Amgen is still a relative newcomer, having only established its US roots in 1980. But with several first-in-class drugs, including Epogen (epoetin alfa), the first ever biotech blockbuster, plus more possible hits in the pipeline, the company has launched itself into an enviable position. Considered the largest and most successful independent biotechnology company in the world, and one of best companies to work for in the UK, Amgen has become a role model for other smaller biotechs.

It is a position Amgen is taking very seriously. "Externally we are adopting a high profile role in shaping what is happening in the UK environment," explains John Kearney, general manager in the UK and Ireland. The key issues, he says, are a review of health technology assessment methodologies as used by the drugs watchdog, the National Institute for Health and Clinical Excellence, access to medicines, and the long-term health of the industry in the UK. "There is considerable interest in government circles to stimulate the life sciences sector, to have the Amgens of the future based here in the UK. So what we have to say should be important." Already this has been seen with the company's involvement in Sir Ian Kennedy's review of NICE and the value of innovation, where Amgen was the only company to present its submission in person.

Not only is reform of health technology assessment in the UK one of the biggest challenges facing the industry, but so is the country's lack of attractiveness for company-sponsored clinical research, adds Charles Brigden, Amgen's UK & Ireland medical director. At present, Amgen is conducting more than 50 clinical trials in around 320

hospitals involving more than 2,000 patients in the UK and Ireland.

Given the competitive nature of recruitment into global research programmes, the issue surrounding the clinical trial landscape in the UK is a hot topic. But, says Brigden, "the various bureaucracy-busting initiatives championed by the Department of Health and the Office for Life Sciences will, we hope, encourage more clinical research in the UK".

While the UK presents a unique environment, the company is rapidly extending its international reach, with more than 50 molecules between late stage discovery and Phase III development being tested in some 45,000 patients in 50 countries around the world. Amgen focuses on specific therapeutic areas including: bone, inflammation, oncology and metabolic disorders. Its approach allows researchers to first choose the best target for a disease, and then use the modality most likely to have an effect on that target, whether it be a protein, small molecule, antibody, peptibody or nucleic acid.

Forming part of this extensive global clinical trial programme, Amgen's cancer therapeutics portfolio represents a bold move away from a core area of cancer supportive care into the competitive world of targeted therapeutics. The UK company is involved in the development of five therapeutic cancer drugs and recently launched Vectibix (panitumumab), a fully humanised monoclonal antibody approved as a monotherpay for the treatment of advanced metastatic colorectal cancer. Results of more recent studies will hopefully lead to the approval of Vectibix in the treatment of earlier stages of the disease in the near future.

## A game changer

One of the company's most talked about drugs in development is denosumab, a monoclonal antibody that is being tipped as a double blockbuster in both osteoporosis and oncology. The drug is currently awaiting regulatory approval for the treatment of post-menopausal osteoporosis and the treatment of bone loss caused by various cancer therapies. A broad development programme evaluating the use of denosumab in the treatment of bone metastases in a number of advanced malignancies is nearing completion. Kearney does not mince his words – denosumab is a "game changer". ›

For osteoporosis sufferers, the drug – which if approved would be the first monoclonal antibody for the condition – is exciting news and Brigden hopes it will "shift the status quo" when it comes to treatment options. Bisphosphonates are the current gold standard, but studies have found that only 50% of patients on these drugs are still compliant a year after starting treatment. Denosumab hopes to hit this low rate by making compliance easier as it is a twice-yearly subcutaneous injection. "The promise of denosumab," says Kearney, "is to combine best-in-class efficacy together with the real promise of significant patient compliance."

According to a pivotal Phase III study of nearly 8,000 patients – of which almost 800 were recruited in the UK – there was a 40% reduction in hip fractures, 68% reduction in vertebral fractures and 20% reduction in non-vertebral fractures when compared with placebo. A Phase III trial in breast cancer has shown denosumab to be superior to the current standard treatment, while results from Phase III trials in prostate cancer are eagerly awaited next year. Of course it is not all plain sailing for the company, with the NICE hurdle still to be overcome, which Kearney says "has to be taken seriously".

Another key challenge for Amgen with denosumab is that it is the company's first move into a primary care market outside of the USA and Canada. This is where the recent partnership with GlaxoSmithKline in the UK becomes important, he says, as Amgen will utilise GSK's experience of working with primary care payers to demonstrate the value of denosumab. "What we were looking for was a partner who could provide a set of primary care capabilities, have an understanding of the osteoporosis area and be a good cultural fit with Amgen. GSK met all those criteria and is a credible partner to help convince the local payer that this medicine is worth investing in."

## Breaking the mould

And as Amgen gears up for prospective launches of the drug in the UK and the USA next year, the company is also ramping up its recruitment by looking for top talent. To date, Kearney is encouraged by the number and quality of candidates coming forward

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who clearly share his desire to work for a "small dynamic organisation where you feel you can make a difference. There is a deep interest in the science we are trialling and the prospect of working with innovative breakthrough medicines", he explains. "It's an organisation where you can get things done. The head office is in California and there is still a sense of a young innovative biotech-focused company wanting to break the mould with a real can-do attitude. I find that energising."

Malcolm Bates, human resources director, agrees, saying the company sets itself apart by its strong leadership, strong principles and strong values. "The company's mission to serve patients appeals to a lot of people. For Amgen it is important to have happy employees who will stay for the long-haul, especially when one considers the time it takes for a drug to go through the development process," Bates adds. And results are being seen, with the company placed 56 in *The Sunday Times* Top 100 Best Companies to Work For in the UK. "Amgen will be aiming to improve this ranking next year," Kearney says. To add to that, in November Amgen won two awards at the Scrip Awards. The company's Nplate (romiplostim) won best new drug because of its novel mode of action and as it addresses an unmet medical need. It is a first-in-class thrombopoietin mimetic agent for the treatment of chronic immune thrombocytopenic purpura (ITP) in patients who have had an insufficient response to corticosteroids, immunoglobulins or splenectomy. Amgen also won best overall pipeline based not only on the size of its pipeline and the mix across development stages, but also the quality, novelty and market potential of its components.

As a result, the company is in a perfect position to reap the rewards. At a time when the market is becoming increasingly focused on biotech drugs, Amgen's voice is likely to be heard for many years to come.

AMG-GBR-AMG-586-2009. Date of preparation: November 2009