New antibiotic for Europe

In September 2014, Clinigen Group plc, the UK-based specialty global pharmaceutical company, announced that the new first-in-class bactericidal, once-daily, injectable antibiotic VIBATIV® (telavancin), was available to prescribe in Europe for the treatment of adults with nosocomial pneumonia (also known as hospital acquired pneumonia - HAP), including ventilator associated pneumonia (VAP), known or suspected to be caused by methicillin-resistant Staphylococcus aureus (MRSA) when other alternatives are not suitable. Sarah Pharaoh, Clinigen's European Brand Director, says that with VIBATIV®, Clinigen hopes to provide a lifeline to patients with difficult to treat infections, who might otherwise die. "Antibiotic resistance is a global health issue. We need more options to treat these extremely serious infections. The widespread availability of a new and effective antibiotic such as VIBATIV® is therefore very good news for Europe."

Ms. Pharaoh was appointed in 2013 specially to manage the VIBATIV® brand. In March of 2013, Clinigen had in-licensed V IBATIV® from Theravance, Inc. for commercialisation in Europe; however, at that time the European Marketing Authorisation for the drug was suspended due to stopped operations at the previous manufacturer. Clinigen worked closely with a new contract manufacturer and the relevant European authorities to have the suspension lifted. The European Commission (EC) confirmed this in March 2014 enabling Europe-wide, licensed supply to commence. This will be the first time the licensed product will be available in Europe.

Ms. Pharaoh explains that VIBATIV® is a hospital only, specialist antibiotic for the treatment of hospital acquired pneumonia. "Patients go into hospital for different reasons, but whilst in hospital they pick up an infection. Many infections that are acquired in hospital are more aggressive than infections you contract in everyday life: these are the hospital super bugs that the media frequently report on. Hospital acquired pneumonia, specifically, is a very tricky disease to treat. It also is one of the most prevalent infections in hospitals, and one of the most common infection-related causes of death. Depending on country and the treatment they receive, 30 to 70% of patients who acquire hospital acquired pneumonia currently die. There are currently only a couple of treatment options, including an

antibiotic that was first developed in the 1950s which increasingly has resistance issues. Clearly, a new treatment option is needed to offer patients hope."

VIBATIV® offers a dual mechanism of action, enabling it to kill even drug resistant strains of Staphylococcus aureus. This drug's dual mechanism of action means that even a strain resistant to one of the mechanisms of action may still be affected by the other, suggesting that VIBATIV® may be less prone to resistance than other antibiotics. VIBATIV® was discovered and developed by Theravance, Inc., and transferred to Theravance Biopharma, Inc. in connection with the separation of the two companies in June 2014. Theravance Biopharma Antibiotics, Inc. has granted Clinigen exclusive commercialisation rights to VIBATIV® in the EU and certain other European countries (including Switzerland and Norway).

Ms. Pharaoh explains that VIBATIV® is one of the five products currently in Clinigen's Specialty Pharmaceuticals (SP) portfolio. Interesting to point out in that regard is that compared to most pharmaceutical marketing companies, Clinigen has an unusual business model and history. It was established in its current structure in 2010, with the merger of two smaller businesses. It combined Keats Healthcare, now Clinigen Clinical Trials Supply (CTS), and Clinigen Healthcare, a supplier of unlicensed medicines largely into the UK with a turnover of about £20 million ($32.2 million), which is now Clinigen GAP, the group's Global Access Programs division. Together with Clinigen Pharma, formed in 2010 and now called Clinigen Specialty Pharmaceuticals (SP), it formed the Clinigen Group comprising of three distinct but complementary divisions. The catalyst for this merger was the antiviral Foscavir (foscarnet sodium), acquired from AstraZeneca in 2010. Foscavir became the model for a successful transaction; having earned £4.5 million a year with AstraZeneca, in Clinigen's hands it has become their lead product, growing more than five-fold over the last three years. The company's growth can only be described as supersonic, with a 54% increase in sales over the last two years. In 2011 Clinigen was recognised as the fast-growing private company in the UK by the Sunday Times Virgin Fast Track 100, thanks to an exceptional three-year sales growth. These results generated a lot of private equity interest but the decision was taken instead to do an Initial Public Offering (IPO) in September 2012. The IPO valued the company at £135 million and raised £50 million, including £10 million for the Group to drive further product acquisition. Since the IPO, the Group has continued to deliver on its promises adding four more products, including VIBATIV, to the already owned Foscavir. The products acquired complement each other, the group now owns and manages an anti-infective portfolio of two products and an oncology support portfolio of three products.

Foscavir remains Clinigen's lead SP product, with sales continuing to grow. Clinigen initially licensed Foscavir for the treatment of cytomegalovirus (CMV) retinitis in HIV patients, and acyclovir-resistant mucocutaneous herpes simplex virus (HSV) infections in immunocompromised patients. Clinigen then applied for an indication for Foscavir as an antiviral for bone marrow transplant patients who are prone to infections. Being immunosuppressed, any virus can become overwhelming and it's the second cause of death in these patients after rejection.

Ms. Pharaoh points out that while Clinigen does not have its own research and development programme, it does have specific criteria for potential

acquisition candidates that could complement its SP business. "More often than not, the large pharma companies look to divest products that no longer 'fit' with their portfolio. Clinigen looks to acquire Specialist, hospital only products. We can take control and revitalise sales for these products. Also, we can deliver to hospitals directly." In addition, the ability to supply unlicensed markets with GAP, the group's Global Access Programs division, means that no patient loses access to it.

The Clinigen GAP division focuses on managing the supply of unlicensed medicines throughout the product lifecycle, whether that be early access to potentially life-saving drugs for patients with no other options, or to drugs still in clinical trials but which have demonstrated good efficacy through named patient or compassionate use Programs (also known as Expanded Access in the USA). By managing the supply of these unlicensed medicines on a global basis, Clinigen is fulfilling a vital service on behalf of pharma and biotech companies and for those with orphan diseases and rare cancers. As a marker of growth of the GAP division, shipments of products increased from 2,000 in FY12 to 58,000 in FY14, as the customer base grew. This broadening of the business drove a six fold growth in revenues in FY13 and a further 53% increase in FY14. Most companies don't have a sales force in every country, however, Clinigen's unique SP and GAP business model enables it to supply into the markets where there isn't a presence to ensure that patients are able to access the vital drugs they need.

Clinigen at a glance

The Clinigen Group is a specialty global pharmaceutical company headquartered in the UK, with offices in the US and Japan. The Group, dedicated to delivering 'the right drug, to the right patient at the right time', has three operating businesses; Specialty Pharmaceuticals (SP), Clinical Trials Supply (CTS), and Global Access Programmes (GAP). SP focuses on acquiring and in licensing specialist, hospital only medicines worldwide and revitalising and commercialising them within niche markets. CTS sources and supplies commercial medical products for use solely in global clinical studies, including comparator drugs and co-therapies. GAP specialises in the global development, management and execution of early, extended and mature access programmes for patients and their clinicians to drugs not available (unlicensed) in their markets.

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