

Medical Press Release

Avelox[®] (Moxifloxacin) IV Granted UK Licence for the Treatment of Community-Acquired Pneumonia and Complicated Skin and Skin Structure Infections

Newbury, Berkshire, 10th March 2010 – Bayer Schering Pharma is pleased to announce that Avelox[®] IV (moxifloxacin HCl, solution for infusion) is now available in the UK for the treatment of Community-Acquired Pneumonia (CAP) and complicated Skin and Skin Structure Infections (cSSSI) when antibacterial agents that are commonly recommended for the initial treatment of these infections are considered inappropriate.¹ This UK launch follows a recommendation from the European Medicines Agency (EMA) for the marketing authorisation of Avelox[®] IV. This now offers UK physicians a valuable treatment option in the fight against CAP and cSSSIs.²

“Moxifloxacin retains excellent antimicrobial activity against respiratory pathogens in the UK and Ireland, as well as MSSA and B.haemolytic streptococci which are commonly associated with complicated skin and skin structure infections”, said Professor Alasdair MacGowan, Professor of Clinical Microbiology & Antimicrobial Therapeutics at the North Bristol NHS Trust. “Intravenous moxifloxacin, therefore, is a welcome addition in terms of antimicrobial chemotherapy for those patients who have not responded to more standard therapies.”

Approximately 30–50% of patients admitted to hospital with CAP will initially require treatment with parenteral antibiotics.³ The British Thoracic Society multi-centre study reported a mortality of 5.7% in CAP in adults in British hospitals between 1982–1983.⁴ Other UK studies have reported mortalities of 8%⁵, 12%⁶ and 14%.⁷

In 2007 it was reported that Skin and skin structure infections (SSSI) were an emerging issue in healthcare.⁸ Complicated skin and skin structure infections (cSSSIs) are an important healthcare concern worldwide, as they can be life-threatening and challenging to treat.⁹

Avelox IV provides targeted coverage of key pathogens in CAP, including *Streptococcus pneumoniae* and atypicals.¹ It also offers a simple 400mg od dosage regimen in both indications with no dose adjustment for elderly patients or those with renal impairment.¹ Initial treatment with Avelox IV can then be followed by Avelox oral.^{1,10-13}

Moxifloxacin IV provides similar clinical improvement in CAP compared to ceftriaxone ±erythromycin. Five to twenty days after the final dose, the rates of continued clinical resolution were 85.7% in the moxifloxacin IV group (138 of 161 patients) and 86.5% in the ceftriaxone ±erythromycin group (135 of 156 patients) ($P>.1$).¹²

A separate study looking at the efficacy, safety and tolerability of moxifloxacin IV (400mg od) followed by oral moxifloxacin compared to a comparator regimen of co-amoxiclav IV (1.2g tds) followed by oral co-amoxiclav (625 mg tds) with or without clarithromycin (500 mg bd) (IV or orally), showed that clinical success rates were statistically significantly higher for moxifloxacin (93.4%), compared to the comparator regimen (85.4% $P=0.004$). Bacteriological success rates were higher for moxifloxacin (93.7%) compared to the comparator regimen (81.7%). This was seen despite the fact that half of the population in this study had severe pneumonia.¹⁰

Over 112 million patients have taken Avelox oral and 4.5 million patients have received Avelox IV worldwide.¹⁴

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About Moxifloxacin

Moxifloxacin is an antimicrobial of the fluoroquinolone class. It is marketed under the brand names Avelox[®], Avalox[®], Izilox[®], Actira[®], Octegra[®], Proflox[®], Actimax[®], Havelox[®], Avelon[®], Megaxin[®] and Promira[®]. World-wide, moxifloxacin is currently approved in 115 countries for the oral formulation and 105 countries for the intravenous (IV) formulation. Moxifloxacin has been studied in over 17,951 patients in clinical trials and 134,000 patients in post marketing surveillance studies. Furthermore, moxifloxacin oral and IV have been used to treat 117 million patients worldwide.

About Bayer Schering Pharma

Bayer Schering Pharma is a worldwide leading specialty pharmaceutical company. Its research and business activities are focused on the following areas: Diagnostic Imaging, General Medicine, Haematology & Neurology, Oncology and Women's Healthcare. With innovative products, Bayer Schering Pharma aims for leading positions in specialised markets worldwide. Using new ideas, Bayer Schering Pharma aims to make a contribution to medical progress and strives to improve the quality of patients' lives.

Further information can be found at www.bayerscheringpharma.co.uk

Forward-Looking Statements

This release may contain forward-looking statements based on current assumptions and forecasts made by Bayer Group or subgroup management. Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performance of the company and the estimates given here. These factors include those discussed in Bayer's public reports which are available on the Bayer website at www.bayer.com. The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.

References

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