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Medivir's hepatitis antiviral MIV-210 (FLG prodrug) enters clinical trials

Medivir has now been granted permission to commence phase I clinical trials with MIV-210, a new inhibitor of hepatitis B virus, HBV. The trials will be performed in the United Kingdom. The phase I trials are expected to be completed during the third quarter of 2001. The goal of phase I trials is to ensure the compound's safety profile, investigate its pharmacokinetics and oral uptake, and establish dose levels for continued phase II trials.

WHO estimates that 350 million individuals have chronic hepatitis B (jaundice). Almost a third of these are in China. The most common form of treatment, interferon, has only a moderate efficacy and has significant side effects. In Asia, the predominant route of infection is mother to child (vertical transmission). In these cases, the efficacy of interferon treatment is not satisfactory.

In 1998, Glaxo Wellcome launched lamivudine (Zeffix, 3TC), the first and only compound in its class (nucleoside analogues) which has been approved for treatment of HBV. Lamivudine has proven to have fewer side effects than interferon. When treating chronic HBV patients where the infection has arisen from horizontal transmission (person to person), lamivudine and interferon show comparable efficacy. Independent market analysts suggest that a whole new market is arising, where lamivudine as early as 2003 is estimated to reach sales of USD 420 million in China alone.

MIV-210 is a nucleoside analogue whose preclinical development has primarily focussed on HBV. In animal tests, MIV-210 shows good efficacy against HBV replication. MIV-210 and lamivudine in combination show additive efficacy. MIV-210 also shows good efficacy against HBV which has become resistant to lamivudine.

Long term clinical studies with lamivudine suggest that in around 25% of patients, HBV will have become resistant after one year's treatment. After two years the degree of resistance has increased to around 35%. Resistance development exacerbates the need for new pharmaceuticals with different resistance profiles to allow for combination treatment in order to prevent resistance arising and for improved efficacy.

Medivir's patent applications will, when granted, provide protection for MIV-210 extending to 2019.

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