

Vaccine reduces visits for rotavirus gastroenteritis

New results presented at the Interscience Conference on Antimicrobial Agents and Chemotherapy/Infectious Diseases Society of America congress in Washington (Mast et al, 2008) show that the pentavalent oral rotavirus vaccine RotaTeq reduced hospitalizations and accident and emergency department visits related to rotavirus gastroenteritis by up to 100%, consequently also avoiding the related costs.

The nationwide observational study, conducted in the USA by Sanofi Pasteur MSD's parent company Merck & Co. Inc, evaluated the effectiveness of RotaTeq during winter seasons in 2007 and 2008 (from 1 January to 30 April 2007 and the first month of the rotavirus season, January 2008) in

33 135 infants who received three doses of RotaTeq and 27 954 infants who had not been vaccinated with RotaTeq.

In June 2008, the US health authorities reported that rotavirus disease and related hospitalizations and accident and emergency department visits were dramatically reduced from November 2007 to May 2008 compared to previous years. Data from Quest Diagnostics also suggest that rotavirus vaccination reduced the transmission of the virus to non-vaccinated infants (herd immunity).

The data are also consistent with those from the large clinical studies during the development of RotaTeq.

Professor Marc Van Ranst from the University of Leuven,

Belgium, said: 'The new observational data confirm the high efficacy of pentavalent rotavirus vaccination in real life to prevent severe rotavirus gastroenteritis demonstrated before in the clinical development. The dramatic and fast reduction of infant hospitalization and accident and emergency visits are very encouraging also for rotavirus vaccination in Europe.'

He continued: 'Each winter season we see the burden of rotavirus epidemics which can be particularly severe on babies and young children.'

Mast TC, Wang FT, Goli V, Loughlin J, Bulotsky M, Seeger JS (2008) Post-Licensure Effectiveness of RotaTeq® in Preventing Gastroenteritis. 48th ICAAC/ 46th IDSA. Washington DC USA, 25–28 October (poster and abstract with updated data)

Entacavir improves liver histology

Data from two cohort evaluations, presented at the 59th Annual Meeting of the American Association for the Study of Liver Diseases, found long-term treatment with entecavir (Baraclude) was associated with improved liver histology, including fibrosis, in chronic hepatitis B patients.

Four-type HPV vaccine effective in men

The four-type human papillomavirus (HPV) vaccine Gardasil is also effective in men according to the primary analysis of a phase III clinical study. In previously uninfected men aged 16–26 years, Gardasil prevented 90% of external genital lesions caused by HPV types 6, 11, 16 or 18. The data were presented at the congress of the European Research Organisation on Genital Infection and Neoplasia in Nice, France.

Guidelines for inflammatory bowel disease in children

The British Society of Paediatric Gastroenterology, Hepatology and Nutrition has launched the first UK guidelines on the management of children and adolescents who have ulcerative colitis and Crohn's disease (http://bspghan.org.uk/working_groups/ibd.shtml).

Beyond the monoamine hypothesis: a new melatonergic agonist to treat major depression

Agomelatine (Valdoxan) has received a positive opinion from the European Medicines Agency's Committee for Medicinal Products for Human Use for its use in the treatment of adult patients with major depressive episodes.

Agomelatine is an innovative approach to the treatment of major depressive episodes and has shown convincing efficacy in depressed patients with moderate–severe depression, offering hope to many of the more than 2.9 million people in the UK diagnosed as having depression at any one time.

Data from its clinical development programme show that agomelatine is effective against the core symptoms of depression, including depressed mood, anxiety, psychomotor retardation, sleep disturbances and daytime fatigue.

Agomelatine takes a different approach to the treatment of depression, going a step beyond the monoamine hypothesis. Agomelatine is an MT1 and MT2 melatonergic receptor agonist with 5-HT_{2C} receptor antagonist properties.

As a result of this novel mode of action, agomelatine has demonstrated convincing antidepressant efficacy in addition to circadian rhythm resynchronization. This mechanism of action is unlike those of commonly prescribed antidepressants such as selective serotonin-reuptake inhibitors, and serotonin and noradrenaline-reuptake inhibitors, since agomelatine has no impact on serotonin levels.

The research programme, which included nearly 4000 adults with major depressive disorder, supported the antide-

pressant efficacy of agomelatine compared with placebo, selective serotonin-reuptake inhibitors and serotonin and noradrenaline-reuptake inhibitors.

This programme also showed that agomelatine's antidepressant efficacy was combined with a favourable tolerability profile. Indeed, most patients treated with agomelatine did not present with any symptoms of sexual dysfunction. Furthermore, in double-blind placebo controlled trials patients treated with agomelatine exhibited a body weight variation profile similar to that of placebo. Agomelatine showed beneficial effects on disturbed sleep patterns as early as the first week of treatment.

Subject to approval by the European Commission agomelatine will be marketed by Servier in the UK in 2009.