

## ZOSTAVAX® OBTAINS EUROPEAN LICENCE FIRST AND ONLY VACCINE TO PREVENT SHINGLES AND POST-HERPETIC NEURALGIA

On 19th May 2006, the European Commission has granted a marketing authorisation for ZOSTAVAX® (zoster vaccine live). ZOSTAVAX® is indicated for prevention of herpes zoster (zoster or shingles) and herpes zoster-related post-herpetic neuralgia (PHN). ZOSTAVAX® is indicated for immunization of individuals 60 years of age or older. ZOSTAVAX® is the first and only vaccine registered in Europe approved for the prevention of shingles and post-herpetic neuralgia.

Shingles could not be prevented so far and pain control is often difficult and unsatisfactory. Many patients are refractory to current existing treatments of PHN (1). Prevention through vaccination would be the best strategy to reduce the burden of shingles (2,3). In this context ZOSTAVAX® can be considered a major breakthrough.

### *Shingles (herpes zoster): a painful disease which can lead to post-herpetic neuralgia, a long lasting, painful and debilitating complication*

Shingles may first appear as a tingling, itching pain on one side of the body or the face and then progresses to a blistering unilateral rash accompanied in almost every case by pain that varies in severity and duration (4).

Shingles is associated with an acute phase which involves significant pain associated with the rash. This can develop into the chronic phase known as PHN (5).

PHN is the most frequent and painful complication of shingles. It is a persistent nerve pain that occurs after the shingles rash has healed. PHN can last for months, or even years (6), and can range from a tender, burning pain to a throbbing, stabbing one (7) up to allodynia, the pain provoked by light tactile stimulation (such as cloth or wind) (8).

### *Everybody is at risk of developing shingles*

Although people may not feel at risk of getting shingles, it is estimated that one in four people will suffer from the disease at some point in their lives (9,10). Shingles can affect anyone who has had chickenpox (varicella), as the disease is caused by the reactivation of the same virus (11). Conditions that weaken the immune system (including age) could facilitate the reactivation of the virus, latent in dorsal root ganglia following the initial childhood infection (12). There is no way yet to predict who will develop shingles (13).

### *Increasing occurrence with age*

While shingles can occur at any time in life, both its incidence and that of PHN increase markedly with age in association with an age-related decline in the specific immune response beginning before the fifth decade of life (14). Two thirds of shingles' cases occur in people over the age of 50 (15). It can be estimated that around 1.5 million cases of shingles occur every year in the European Union (16). This incidence can be expected to increase as the population ages (17).

### *About ZOSTAVAX®*

In a large Phase III study, including 38,546 men and women aged 60 and older who received one dose of vaccine or placebo, ZOSTAVAX® reduced the incidence of shingles by 51% when compared to placebo. ZOSTAVAX® also reduced by 67% the incidence of PHN\* and the total burden of pain and discomfort caused by shingles by 61 %, when respectively compared to placebo. The results of the study show that vaccination of immunocompetent persons 60 years of age and older with ZOSTAVAX® markedly decreased the morbidity associated with shingles and the incidence of post-herpetic neuralgia. The most common side effects were injection site reactions and headache. This Phase III Shingles Prevention Study (SPS) was published in June 2005 in the New England Journal of Medicine (18).

ZOSTAVAX® was developed by Merck & Co., Inc. and Sanofi Pasteur MSD and will be marketed in Europe by Sanofi



Pasteur MSD. The U.S. Food and Drug Administration (FDA) has approved ZOSTAVAX® (zoster vaccine live) on 25th May 2006. / The U.S. Food and Drug Administration's (FDA) review goal date for the marketing authorisation application for ZOSTAVAX® is May 25, 2006. / In the United States, a marketing authorisation application was submitted by Merck & Co, Inc. to the Food and Drug Administration (FDA) in April 2005. The licences concern the frozen formulation of the vaccine. Sanofi Pasteur MSD will file a variation with the EMEA for the refrigerated formulation as soon as the final analysis of the last scientific data has been completed.

## About Sanofi Pasteur MSD

Sanofi Pasteur MSD is a joint venture between Sanofi Pasteur, the vaccine division of Sanofi-Aventis, and Merck & Co., Inc. Combining innovation and expertise, Sanofi Pasteur MSD is the only company in Europe dedicated exclusively to vaccines. Sanofi Pasteur MSD is able to draw on the research expertise of Sanofi Pasteur and Merck & Co., Inc., together with their teams throughout the world, to focus on the development of new vaccines for Europe, which aim to extend protection to other diseases and perfect existing vaccines in order to improve the acceptability, efficacy and tolerability of vaccination.

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