Pfizer Receives European Approval to Extend Use of Prevenar 13 to Adults 50 Years and Older for the Prevention of Invasive Pneumococcal Disease

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(BUSINESS WIRE)--Pfizer Inc. (NYSE: PFE) announced today that the European Commission has approved the Company’s pneumococcal conjugate vaccine, Prevenar 13* (pneumococcal polysaccharide conjugate vaccine [13-valent, adsorbed]), for active immunization for the prevention of vaccine-type invasive disease caused by Streptococcus pneumoniae in adults aged 50 years and older.

“Prevenar 13, the first and only pneumococcal conjugate vaccine approved by the European Commission for use in adults, has the potential to prevent invasive pneumococcal disease in adults aged 50 and older – a time of life when the risk for contracting the disease begins to increase,” said Emilio Emini, Ph.D., chief scientific officer, Vaccine Research, Pfizer Inc. “It is important that older adults talk to their health care provider about pneumococcal disease prevention and Prevenar 13 as part of a plan for healthy aging.”

The European Commission’s decision to authorize this new indication for Prevenar 13 followed a review of clinical immunogenicity and safety data involving more than 6,000 adults aged 50 years and older.

Indication for Prevenar 13 in Adults 50+ in the European Union

Prevenar 13 is indicated for active immunization for the prevention of invasive pneumococcal disease caused by Streptococcus pneumoniae in adults aged 50 years and older.

This indication covers the prevention of invasive pneumococcal disease caused by the 13 serotypes contained in the vaccine and is for a single dose of Prevenar 13 in adults aged 50 years and older. Regardless of prior pneumococcal vaccination status, if the use of 23-valent polysaccharide vaccine is considered appropriate, Prevenar 13 should be given first.

About Prevenar 13 and Conjugate Technology

Prevenar 13 was first introduced for use in infants and young children in December 2009 in Europe and is now approved for such use in more than 100 countries worldwide. Prevenar 13, like Prevenar*(Pneumococcal saccharide conjugated vaccine, adsorbed), uses company-pioneered conjugation technology that has been shown to confer a high antibody response in infants and toddlers.

The 13 pneumococcal serotypes in Prevenar 13 (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F) are responsible for causing a significant proportion of invasive pneumococcal disease (IPD) in adults aged 50 years and older, including disease caused by antibiotic-resistant serotypes.

Invasive Pneumococcal Disease

Pneumococcal disease is caused by the bacterium Streptococcus pneumoniae, also known as pneumococcus, which can infect people of all ages, although young children, older adults and individuals with certain chronic medical conditions are at heightened risk. IPD occurs when bacteria invade parts of the body that are normally free from bacteria, such as blood or spinal fluid.

While less common than non-invasive pneumococcal disease, IPD is usually more severe, and it results in significant morbidity and mortality in older adults. It includes bacteremic pneumonia (lung infection with bacteria in the blood), bacteremia (bacteria in the blood) and meningitis (infection of the tissues surrounding the brain and spinal cord). Based on

epidemiological studies, approximately 80 percent of IPD in adults is bacteremic pneumonia.

Important Safety Information for Prevenar 13 in Adults 50+

Prevenar 13 is not expected to provide 100 percent protection against vaccine serotypes or protect against nonvaccine serotypes. The approval of Prevenar 13 was based upon functional antibody responses in adults aged 50 years and older. An efficacy study in adults is ongoing. The most commonly reported solicited local and systemic adverse reactions (≥20 percent) in clinical trials with Prevenar 13 were redness, swelling, tenderness, hardness, and pain at the injection site, limitation of arm movement, decreased appetite, headache, diarrhea, chills, fatigue, rash, and worsening of or new joint or muscle pain. Hypersensitivity (e.g., anaphylaxis) to any component of Prevenar 13 or any diphtheria toxoid–containing vaccine is a contraindication to the use of Prevenar 13.
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