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ASIA EDITION

U.S. FDA approves Pfizer's Pneumococcal 20-valent Conjugate Vaccine

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First approval of a conjugate vaccine that helps protect against 20 serotypes responsible for the majority ofinvasive pneumococcal disease and pneumonia,1,2,3,4,5,6,7 for adults ages 18 yor older

Pfizer Inc. announced that the U.S. Food and Drug Administration (FDA) has approved PREVNAR 20™ (Pneumococcal 20-valent Conjugate Vaccine) for the prevention of invasive disease and pneumonia caused by the 20 *Streptococcus pneumoniae* (pneumococcus) serotypes in the vaccine in adults ages 18 years and older.

PREVNAR 20 includes capsular polysaccharide conjugates for the 13 serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F) already included in Prevnar 13® (Pneumococcal 13-valent Conjugate Vaccine [Diphtheria CRM_{197} Protein]). The vaccine also contains capsular polysaccharide conjugates for seven additional serotypes (8, 10A, 11A, 12F, 15B, 22F and 33F) that cause invasive pneumococcal disease (IPD), and have been associated with high case-fatality rates, antibiotic resistance, and/or meningitis.

Indications for PREVNAR 20™

- PREVNAR 20™ is a vaccine indicated for active immunization for the prevention of pneumonia and invasive disease caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F, and 33F in adults 18 years of age and older
- The indication for preventing pneumonia caused by *S. pneumoniae* serotypes 8, 10A, 11A, 12F, 15B, 22F, and 33F is approved based on immune responses. Continued approval may depend on a supportive study.

U.S. Important Safety Information

- PREVNAR 20™ should not be given to anyone with a history of severe allergic reaction to any component of PREVNAR 20™ or to diphtheria toxoid
- Adults with weakened immune systems may have a lower response to PREVNAR 20™. Safety data are not available for these groups. Your healthcare provider can tell you if PREVNAR 20™ is right for you
- In adults 18 years of age and older, the most common side effects were pain at the injection site, muscle pain, fatigue,

headache, and joint pain. Additionally, injection site swelling was also common in adults 18 through 59 years of age