Vaccines

Every day, we work toward a healthier world by taking on bacterial, viral and infectious diseases that threaten people around the globe.

We do this by inventing, developing and championing vaccines, which provide essential health benefits to people of all ages; in other words, Pfizer helps people be "Ready for Life." We are also progressing and shaping the future of vaccines through investment in research and development (R&D), technology and expanding access to those in need.

Expanding Pneumococcal Protection

In 2016, Prevnar 13® (Pneumococcal 13-valent Conjugate Vaccine [Diphtheria CRM197 Protein]) – known as Prevenar 13 outside the United States (U.S.) – became the only pneumococcal vaccine approved in the U.S. for patients six weeks of age through adulthood when it received U.S. Food and Drug Administration (FDA) approval for an expanded age indication to include adults 18 through 49 years of age. This builds on the already approved indications for adults 50 years and older for active immunization for the prevention of pneumonia and invasive disease caused by 13 *Streptococcus pneumoniae (S. pneumoniae)* serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F). Prevnar 13 is also approved for children six weeks through 17 years of age (prior to the 18th birthday) for the prevention of invasive disease caused by the 13 strains of *S. pneumoniae* in the vaccine, and for children six weeks through five years (prior to the sixth birthday) for the prevention of ear infections caused by seven of the 13 strains in the vaccine.

Pfizer also received approval from the Chinese Food and Drug Administration (CFDA) to market Prevenar 13 in China for the prevention of invasive diseases (including bacteremic pneumonia, meningitis, septicemia and bacteremia) caused by *S. Pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F in infants and children aged six weeks to 15 months. *S. Pneumoniae* is the most common cause of invasive disease as well as pneumonia and upper respiratory tract infections.

In Turkey, Prevenar 13 was officially recommended and funded by the Turkish Ministry of Health, as part of the recently launched National Adult Immunization Program, for the prevention of pneumococcal diseases of adults over 65 years of age and aged 18-64 with comorbid diseases. This funding builds on the successful pediatric National Immunization Program and is expected to help protect over 15 million eligible adults in Turkey.

Prevenar 13's reach is truly global, approved for infants and young children in more than 150 countries, and for adults aged 50 years and older in more than 100 countries.

Manufacturing and delivering world-class vaccines is complex. For example, one dose of Prevenar 13 requires 580 manufacturing steps, over 1,700 employees, 678 quality tests, 400 different raw materials, and more than two-and-a-half years to manufacture from start to finish.

Prevnar 13's Global Reach

Approved for young children and infants in
150+
countries

Approved for adults **50**yrs+ in
100+
countries

One dose of Prevenar 13 requires:

400
different raw materials

580
manufacturing steps

678
quality tests

1,700
employees

2 1/2+
years to manufacture
from start to finish

According to the U.S. Centers for Disease Control and Prevention (CDC), there has been a 99 percent reduction of invasive pneumococcal disease of the vaccine type among children under five years of age, following the addition of Prevnar 13 to the routine pediatric immunization program in the U.S., compared to the previous base.

Learn more about what Pfizer is doing to promote access to Prevenar 13 around the world.

Accelerating Protection against Meningococcal Disease

Our meningococcal vaccines portfolio is built with vaccines that help protect against the five most common disease-causing serogroups – A, C, W-135, Y and B (approvals varying by country).

An important update for the dosing of Trumenba® (Meningococcal Group B Vaccine), the first meningitis B vaccine approved in the U.S., was recommended by the CDC Advisory Committee on Immunization Practices (ACIP) in 2016, offering guidance to health care providers administering Trumenba. Trumenba helps to prevent meningococcal group B disease, also known as MenB, in healthy adolescents and young adults, as well as those at increased risk for the disease. This new recommendation enables flexible vaccination dosing intervals depending on one's risk of exposure to MenB, which makes it easier for health care providers to help protect individuals from this uncommon but life-threatening disease.

Additionally, the European Medicines Agency (EMA) accepted the Marketing Authorization Application (MAA) for Trumenba for review. The acceptance marks the beginning of the regulatory review process for this vaccine in the European Union (EU).

In 2016, the European Commission (EC) approved an expanded indication for Nimenrix™ (meningococcal group A, C, W-135 and Y, or MenACWY, conjugate vaccine) for active immunization against invasive meningococcal disease (IMD) caused by *Neisseria meningitidis* serogroups A, C, W-135 and Y in infants as early as six weeks of age. Nimenrix is now the first and only MenACWY conjugate vaccine in the European Union (EU) that can be administered from six weeks of age with no upper age limit. With this approval, Nimenrix now has the broadest age indication of any conjugate vaccine in Europe against invasive meningococcal disease caused by Neisseria meningitidis serogroups A, C, W-135 and Y.

Finding Solutions for Health Care-Associated Infections

There is an urgent global health need for a vaccine that could protect pregnant women and their infants against group B *Streptococcus* (GBS) infection, a leading cause of a serious neonatal blood infection (sepsis), pneumonia and meningitis. In many cases, GBS bacteria are passed from mother to baby during labor and birth. In an effort to protect these newborns and their mothers, Pfizer was awarded a grant from the Bill & Melinda Gates Foundation in 2016 to support its Phase 1/2 clinical trial of Pfizer's vaccine candidate against GBS infection, particularly in developing countries where prophylactic administration of antibiotics is not routine. The investigational vaccine would protect newborns via maternal immunization.

About one out of every four pregnant women carries group B *Streptococcus* bacteria, which can be passed from mother to baby during labor and birth

Pfizer is also investigating a vaccine that targets the two main disease-causing toxins produced by *Clostridium difficile (C. difficile)*, a hospital-acquired infection that causes watery diarrhea, fever, loss of appetite, nausea and abdominal pain. In severe cases, it causes hospitalization and death. The FDA granted Fast Track designation to our investigational *C. difficile* vaccine candidate, and we have initiated a Phase 2 clinical trial to investigate the candidate's safety, immunogenicity and tolerability in healthy older adults.

Similarly, Pfizer is investigating a vaccine candidate for *Staphylococcus aureus (S. aureus)*, a type of bacteria that about 30 percent of people carry in their noses. Most of the time, *S. aureus,* or staph, does not cause any harm; however, it may lead to infections. In health care settings, these infections can be serious or fatal. Clinical presentations range from benign carriage and superficial skin and soft-tissue infections to life-threatening deep-wound and organ/space infections, prosthesis-related infections, bacteremia and sepsis. Our *S. aureus* vaccine candidate received a Fast Track designation in 2014 with a Phase 2b clinical trial underway.

Research and development does not stop at the walls of our research facilities; partnerships play a critical role in driving our mission to protect people across all stages of life. We have long-standing global collaborations with leading academic institutions and investigators in diverse areas, including with Tufts University for Cytomegalovirus (CMV) structural biology, the CDC for meningitis B surveillance, Vanderbilt University for *S. aureus* immunopathology, and Drexel University for *C. difficile* epidemiology.

Innovating Vaccines for the Future

We are helping to usher in a new era of vaccine innovation with a focus on investigational vaccines that have the potential to help prevent hospital-acquired infections such as *S. aureus* and *C. difficile*, investigating maternal immunization with research in group B *Streptococcus* and respiratory syncytial virus, and investigating the potential of cancer vaccines with vaccine-based immunotherapy regimen and oncoloytics-based immunotherapy regimen.