



# NEW DATA ON THE BURDEN OF EMERGING S. PNEUMONIAE SEROTYPES PUBLISHED IN ISPPD 2020 ONLINE DIGITAL LIBRARY

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## **Pfizer-funded research finds that 20 S. pneumoniae serotypes are associated with a substantial burden of pneumococcal disease globally<sup>1,2,3</sup>**

NEW YORK, June 23 - Pfizer Inc. (NYSE:PFE) today announced that new data on the evolving burden of S. pneumoniae serotypes will be included as part of an online digital library created by the International Symposium on Pneumococci and Pneumococcal Diseases (ISPPD) in place of its 2020 Scientific Program, which was postponed until 2021 due to the COVID-19 pandemic.

Among the available research are several studies suggesting that, globally, 20 S. pneumoniae serotypes (1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F, and 33F) are responsible for the majority of currently circulating pneumococcal disease.<sup>1,2,3</sup> In two separate studies of U.S.-only data, the 20 serotypes were estimated to cause up to 1.2 million cases of pneumococcal disease (invasive pneumococcal disease (IPD), inpatient and outpatient community-acquired pneumonia (CAP), and acute otitis media (AOM)) in children under age 5 years,<sup>4</sup> and up to 250,000 cases of pneumococcal disease (bacteremia, meningitis, and CAP) in adults ages 18 or older.<sup>5</sup>

Two other epidemiology studies found that these 20 serotypes were responsible for more than half of all cases of IPD among children under age 5 years and in adults  $\geq 60/\geq 65$  years in the U.S., Japan, Germany, England/Wales, and France.<sup>2,3</sup>

“We are excited to share data from nearly a dozen studies highlighting the evolving epidemiology of *S. pneumoniae* serotypes, and the potential for our investigational 20-valent pneumococcal conjugate vaccine (20vPnC) candidate to offer broad coverage,” said Luis Jodar, Pfizer Vaccines, Chief Medical and Scientific Affairs Officer. “For the past two decades, Pfizer has remained at the forefront in the fight against pneumococcal disease. Our 20vPnC vaccine candidate represents the next evolution in Pfizer’s steadfast commitment to the development of a next generation of pneumococcal conjugate vaccine potentially capable to help prevent the remaining burden of pneumococcal disease in a highly variable epidemiological environment.”

#### **Research of *S. pneumoniae* Serotypes in Adults**

The new Pfizer data posted to the ISPPD online digital library includes six studies examining *S. pneumoniae* serotype distribution against IPD as well as pneumococcal CAP in adults ages 18 or older.<sup>1,2,6,7,8,9</sup>

These studies include the following:

1. Coverage of the 20-Valent Conjugate Vaccine Against Invasive Pneumococcal Disease By Age Group in the United States, 2017. (L. Grant)
2. Coverage of Next Generation Pneumococcal Conjugate Vaccines for IPD in Older Adults of High-Income Countries. (L. Grant)
3. Streptococcus Pneumoniae Serotype Distribution and Coverage of Pneumococcal Conjugate Vaccines in Adults Hospitalized with Community-Acquired Pneumonia in the United States. (L. Grant)
4. Pneumococcal Serotype Distribution in Adults Hospitalized with Radiologically-Confirmed Community-Acquired Pneumonia in Malmö, Sweden. (C. Theilacker)
5. *S. pneumoniae* Serotypes in Hospitalized Patients with Severe Pneumococcal Pneumonia and Clinical Failure. (J. Ramirez)
6. Association of *S. pneumoniae* Serotypes with Myocardial Infarction and Other Cardiac Events in Hospitalized Patients with Pneumococcal Pneumonia. (J. Ramirez)

#### **Research of *S. pneumoniae* Serotypes in Infants and Children**

In addition to data in adults, the ISPPD online digital library includes two new studies exploring serotype distribution in children (aged <18 years).<sup>1,3</sup>

These studies include the following:

1. Coverage of the 20-Valent Conjugate Vaccine Against Invasive Pneumococcal Disease By Age Group in the United States, 2017. (L. Grant)
2. Coverage of Next Generation Pneumococcal Conjugate Vaccines for IPD in Children of High-Income Countries. (L. Grant)

#### **Burden of Disease Associated with S. Pneumoniae Serotypes**

New evidence also demonstrates the overall burden of disease associated with these 20 S. pneumoniae serotypes, including substantial number of cases, deaths, and overall direct medical costs.<sup>4,5</sup>

These studies include the following:

1. Estimated Pneumococcal Disease and Economic Burden for Current and Future Vaccine Serotypes in United States in Children under Five Years of Age. (J. Perdrizet)
2. Current and Future Pneumococcal Conjugate Vaccine Serotype-specific Burden in the United States Adult Population. (J. Perdrizet)

#### **About 20vPnC**

On September 20, 2018, Pfizer announced the U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy Designation for 20vPnC for the prevention of invasive disease and pneumonia in adults age 18 years or older. Breakthrough Therapy Designation is designed to expedite the development and review of drugs and vaccines that are intended to treat or prevent serious conditions and preliminary clinical evidence indicates that the drug or vaccine may demonstrate substantial improvement over available therapy on a clinically significant endpoint(s).<sup>10</sup> Drugs and vaccines that receive Breakthrough Therapy Designation are eligible for all features of the FDA's Fast Track designation, which may include more frequent communication with the FDA about the drug's development plan and eligibility for Accelerated Approval and Priority Review, if relevant criteria are met.<sup>11</sup>

The FDA previously granted Fast Track designation for 20vPnC in September 2017 for use in adults aged 18 years or older.<sup>12</sup> The FDA's Fast Track approach is a process designed to facilitate the development and expedite the review of new drugs and vaccines intended to treat or prevent serious conditions and address an unmet medical need.<sup>25</sup>

Additionally, in May 2017 the FDA granted Fast Track status for a pediatric indication for 20vPnC.<sup>13</sup>

If approved and licensed by the FDA, Pfizer's 20vPnC vaccine candidate would cover the 13 *S. pneumoniae* serotypes already in Prevnar 13® (Pneumococcal 13-valent Conjugate Vaccine [Diphtheria CRM197 Protein]) – 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F – plus seven additional serotypes (8, 10A, 11A, 12F, 15B, 22F, and 33F).

#### **INDICATIONS FOR PREVNAR 13®**

Prevnar 13® is a vaccine approved for adults 18 years and older for the prevention of pneumococcal pneumonia and invasive disease caused by *S. pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F. Prevnar 13® is also approved for children 6 weeks through 17 years of age (prior to the 18th birthday) for the prevention of invasive disease caused by the 13 strains of *Streptococcus pneumoniae* in the vaccine, and for children 6 weeks through 5 years (prior to the 6th birthday) for the prevention of ear infections caused by 7 of the 13 strains in the vaccine. Prevnar 13® is not 100% effective and will only help protect against the 13 strains in the vaccine.

#### **IMPORTANT SAFETY INFORMATION**

Prevnar 13® should not be given to anyone with a history of severe allergic reaction to any component of Prevnar 13® or any diphtheria toxoid-containing vaccine. Children and adults with weakened immune systems (eg, HIV infection, leukemia) may have a reduced immune response. In adults, the most common side effects were pain, redness, and swelling at the injection site, limitation of arm movement, fatigue, headache, muscle pain, joint pain, decreased appetite, vomiting, fever, chills, and rash. A temporary pause of breathing following vaccination has been observed in some infants born prematurely. The most commonly reported serious adverse events in infants and toddlers were bronchiolitis (an infection of the lungs) (0.9%), gastroenteritis (inflammation of the stomach and small intestine) (0.9%), and pneumonia (0.9%). In children 6 weeks through 17 years, the most common side effects were tenderness, redness, or swelling at the injection site, irritability, decreased appetite, decreased or increased sleep, and fever. Ask your healthcare provider about the risks and benefits of Prevnar 13®. Only a healthcare provider can decide if Prevnar 13® is right for you or your child.

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at [www.pfizer.com](http://www.pfizer.com). In addition, to learn more, please visit us on [www.pfizer.com](http://www.pfizer.com) and follow us on Twitter at @Pfizer and @Pfizer\_News, LinkedIn, YouTube, and like us on Facebook at [Facebook.com/Pfizer](https://www.facebook.com/Pfizer).

**DISCLOSURE NOTICE:** The information contained in this release is as of June 23, 2020. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments. This release contains forward-looking information about Pfizer's 20- Valent Pneumococcal Conjugate Vaccine (20vPnC) candidate, including its potential benefits, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for our clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from our clinical studies; whether and when any biologics license applications may be filed in any jurisdictions for 20vPnC for any indications; whether and when any such applications may be approved by regulatory authorities, which will depend on myriad factors, including making a determination as to whether the product's benefits outweigh its known risks and determination of the product's efficacy and, if approved, whether 20vPnC will be commercially successful; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of 20vPnC; uncertainties regarding the ability to obtain recommendations from vaccine technical committees and other public health authorities regarding 20vPnC and uncertainties

regarding the commercial impact of any such recommendations; the impact of COVID-19 on our business, operations and financial results; and competitive developments. A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2019 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at [www.sec.gov](http://www.sec.gov) and [www.pfizer.com](http://www.pfizer.com).

- 1 Grant L, Suaya J, Pugh S, et. al. Coverage of the 20-Valent Conjugate Vaccine Against Invasive Pneumococcal Disease By Age Group in the United States, 2017. Abstract No. ISP20-237.
- 2 Grant L, Slack M, Theilacker C, et. al. Coverage of Next Generational Pneumococcal Conjugate Vaccines for Invasive Pneumococcal Disease in Older Adults of High-Income Countries. Abstract No. ISP20-612.
- 3 Grant L, Slack M, Theilacker C, et. al. Coverage of Next Generational Pneumococcal Conjugate Vaccines for Invasive Pneumococcal Disease in Children of High-Income Countries. Abstract No. ISP20-608.
- 4 Perdrizet J, Wasserman M, Farkouh R, et. al. Estimated pneumococcal disease and economic burden for current and future vaccine serotypes in United States in children under five years of age. Abstract No. ISP20-288.
- 5 Perdrizet J, Chilson E, Wasserman M, et. al. Current and future pneumococcal conjugate vaccine serotype-specific burden in the United States adult population. Abstract No. ISP20-287
- 6 Grant L, Ramirez J, Self W, et. al. Streptococcus Pneumoniae Serotype Distribution and Coverage of Pneumococcal Conjugate Vaccines in Adults Hospitalized with Community-Acquired Pneumonia in the United States. Abstract No. ISP20-879.
- 7 Theilacker C, Hansen K, Rünow E, et. al. Pneumococcal Serotype Distribution in Adults Hospitalized with Radiologically-Confirmed Community-Acquired Pneumonia in Malmö, Sweden. Abstract No. ISP20-904.
- 8 Ramirez J, Furmanek S, Pena S, et. al. S. pneumoniae Serotypes in Hospitalized Patients with Severe Pneumococcal Pneumonia and Clinical Failure (J. Ramirez).. Abstract No. ISP20-807.
- 9 Ramirez J, Furmanek S, Pena S, et. al. Association of S. pneumoniae Serotypes with Myocardial Infarction and Other Cardiac Events in Hospitalized Patients with Pneumococcal Pneumonia. Abstract No. ISP20-805.
- 10 U.S. Food and Drug Administration. Breakthrough Therapy <https://www.fda.gov/forpatients/approvals/fast/ucm405397.htm>
- 11 U.S. Food and Drug Administration. Fast Track <https://www.fda.gov/ForPatients/Approvals/Fast/ucm405399.htm>
- 12 Data on file. Pfizer Inc., New York, NY
- 13 Data on file. Pfizer Inc., New York, NY

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