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U.S. FDA Accepts Biologics License Application for Pfizer's Respiratory Syncytial Virus Maternal Vaccine Candidate for Priority Review

Tuesday, February 21, 2023 - 06:45am

- *U.S. FDA has set an action date for August 2023. If approved, RSVpreF would be the first vaccine for administration to pregnant individuals to help protect against the complications of RSV disease in infants from birth through six months*
- *This action follows the recent acceptance of the Marketing Authorization Application (MAA) for Pfizer's RSV vaccine candidate by the European Medicines Agency (EMA) under accelerated assessment for both older adults and maternal immunization*
- *The maternal immunization regulatory filings are supported by results of the pivotal Phase 3 trial **MATISSE**, which will be presented to the CDC's Advisory Committee on Immunization Practices (ACIP), as well as during the ReSViNET Foundation's 2023 Global Conference, on February 23*

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE:PFE) today announced that the U.S. Food and Drug Administration (FDA) has accepted for review a Biologics License Application (BLA) for its respiratory syncytial virus (RSV) vaccine candidate PF-06928316 or RSVpreF for the prevention of medically attended lower respiratory tract illness (MA-LRTI) and severe MA-LRTI caused by RSV in infants from birth up to six months of age by active immunization of pregnant individuals. This decision follows the FDA's Breakthrough Therapy Designation for RSVpreF in March 2022. The FDA has accepted the BLA for priority review and has set a Prescription Drug User Fee Act (PDUFA) action date of August 2023.

"If approved, RSVpreF would help protect infants at their first breath from the devastating effects of this infectious disease, which though well-known, has been particularly evident throughout this RSV season," said Annaliesa Anderson, Ph.D., Senior Vice President and Chief Scientific Officer, Vaccine Research & Development, Pfizer. "We look forward to progressing the review of Pfizer's RSV maternal vaccine candidate with the FDA and other regulatory authorities, given its significant potential to positively contribute to global health in the prevention of RSV in infants."

In addition, the European Medicines Agency (EMA) has accepted Pfizer's marketing authorization application (MAA) under accelerated assessment for its RSV vaccine candidate for both older adults and maternal immunization to help protect infants. A decision is expected in the second half of 2023.

The maternal immunization regulatory submission is supported by the positive top-line results from **MATISSE** (**MAT**ernal **I**mmunization **S**tudy for **S**afety and **E**fficacy), a Phase 3 clinical trial evaluating the efficacy, safety, and immunogenicity of RSVpreF against MA-LRTI and severe MA-LRTI in infants born to healthy women vaccinated during pregnancy. These data will be presented on February 23 to the U.S. Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) and, separately, during

the ReSViNET Foundation's 2023 Global Conference on Novel RSV Preventive and Therapeutic Interventions.

Additional ACIP Presentations
During the ACIP meeting on February 22-23, the company also will present positive Phase 3 results supporting the regulatory filings of Pfizer's pentavalent meningococcal vaccine (MenABCWY) candidate, as well as Pfizer's 20-valent pneumococcal conjugate vaccine (20vPnC) candidate for pediatric use.

In December 2022, Pfizer announced that the FDA had accepted for review a BLA for its MenABCWY candidate for the prevention of meningococcal disease caused by the most common serogroups in individuals 10 through 25 years of age. The PDUFA goal date for a decision by the FDA on the MenABCWY application is in October 2023. If approved and recommended, MenABCWY could help simplify the meningococcal vaccination schedule and provide the broadest serogroup coverage of any meningococcal vaccine. Top-line results from a randomized, active-controlled, and observer-blinded Phase 3 trial of Pfizer's pentavalent meningococcal vaccine candidate (NCT04440163) were previously announced in September 2022.

Similarly, in January 2023, Pfizer announced that the FDA had granted priority review to a supplemental BLA for its 20vPnC candidate for the prevention of invasive pneumococcal disease (IPD) caused by the 20 *Streptococcus pneumoniae* (pneumococcus) serotypes contained in the vaccine in infants and children 6 weeks through 17 years of age, and for the prevention of otitis media caused by seven of the 20 *Streptococcus pneumoniae* serotypes contained in the vaccine. The PDUFA goal date for the FDA's decision on the 20vPnC application is in April 2023. If approved, 20vPnC would have the potential to cover more of the clinically significant remaining burden of infant pneumococcal disease than any other available pneumococcal conjugate vaccine. In August 2022 Pfizer announced top-line results from its pivotal U.S. Phase 3 study (NCT04382326), which support the FDA application.

Burden of RSV
RSV is a contagious virus and a common cause of respiratory illness.[1] The virus can affect the lungs and breathing passages of an infected individual and can potentially cause severe illness in young infants, older adults, and individuals with certain chronic medical conditions.[2,3,4]

Among children younger than five years old in the U.S., RSV infections account for approximately 2.1 million outpatient visits and 58,000 hospitalizations each year.[5,6] Virtually all children get an RSV infection by the time they are 2 years old[7], and RSV is a leading cause of hospitalization in children <1 year of age.[8] Worldwide, RSV results in the death of approximately 102,000 children annually, with about half of those in infants less than six months old and the vast majority in developing countries.[9,10]

RSV bronchiolitis is the leading cause of infant hospitalization due to viral respiratory illness, characterized by respiratory distress that can result in death. There is no specific treatment for RSV, only supportive care measures like oxygen and fluids. Currently, there is no vaccine to help prevent RSV in the U.S., leaving most infants without protection. The only available preventive agent is recommended for use among the highest-risk infants in limited settings as a monthly injection with five doses administered during the RSV season.

Among adults 65 years and older, RSV infections account for approximately 60,000–160,000 hospitalizations and 6,000–10,000 deaths each year in the U.S. alone.[11,12,13,14,15,16,17,18] There are currently no targeted prophylactic, therapeutic, or vaccine options for RSV in older adults, and treatment is limited to offering supportive care for adults with the illness.

About RSVpreF
Pfizer's investigational RSV vaccine candidate builds on foundational basic science discoveries including those made at the National Institutes of Health (NIH), which detailed the crystal structure of prefusion F, a key form of

the viral fusion protein (F) that RSV uses to enter human cells. The NIH research showed that antibodies specific to the prefusion form were highly effective at blocking virus infection, suggesting a prefusion F-based vaccine may confer optimal protection against RSV. After this important discovery, Pfizer tested numerous versions of a stabilized prefusion F protein and identified a candidate that elicited a strong anti-viral immune response in pre-clinical evaluations. The bivalent vaccine candidate is composed of equal amounts of recombinant RSV prefusion F from subgroups A and B.

Pfizer is currently the only company with a maternal RSV vaccine candidate in late-stage development to help protect against RSV. In December 2022, Pfizer announced that the FDA had granted priority review to a biologics license application for RSVpreF for the prevention of RSV disease in older adults.

About the Pentavalent Meningococcal Vaccine Candidate (MenABCWY)
Pfizer's pentavalent meningococcal vaccine candidate combines the components from its two licensed meningococcal vaccines, Trumenba® (meningococcal group B vaccine) and Nimenrix® (meningococcal groups A, C, W-135, and Y conjugate vaccine); approvals of Nimenrix® and Trumenba® vary by country. Together, the 5 serogroups included in MenABCWY are responsible for the majority of currently circulating meningococcal disease globally.[19]

INDICATIONS FOR TRUMENBA® IN THE U.S.

- Trumenba® is a vaccine indicated for individuals 10 through 25 years of age for active immunization to prevent invasive disease caused by *Neisseria meningitidis* group B

IMPORTANT SAFETY INFORMATION

- Trumenba® should not be given to anyone with a history of a severe allergic reaction to any component of Trumenba®
- Some individuals with weakened immune systems may have a reduced immune response
- Persons with certain complement deficiencies and persons receiving treatments such as Soliris® (eculizumab), are at increased risk for invasive disease caused by *Neisseria meningitidis* group B even with receipt of vaccination with Trumenba®
- Vaccination with Trumenba® may not protect all vaccine recipients against *N meningitidis* group B infections
- Fainting can occur in association with administration of injectable vaccines, including Trumenba®
- The most common adverse reactions in adolescents and young adults were pain at injection site, fatigue, headache, and muscle pain
- Data are not available on the safety and effectiveness of using Trumenba® and other meningococcal group B vaccines interchangeably to complete the vaccination series
- Tell your health care provider if you are pregnant, or plan to become pregnant
- Ask your health care provider about the risks and benefits of Trumenba®. Only a health care provider can decide if Trumenba® is right for you or your child

INDICATION FOR NIMENRIX® IN THE E.U.

- Nimenrix® is a vaccine indicated for individuals six weeks of age and older for active immunization to prevent invasive disease caused by *Neisseria meningitidis* groups A, C, W-135 and Y

IMPORTANT SAFETY INFORMATION

- Nimenrix® should not be given to anyone with a history of a severe allergic reaction after a previous dose of Nimenrix®
- Some individuals with weakened immune systems may have a reduced immune response
- Persons with certain complement deficiencies and persons receiving treatments such as Soliris® (eculizumab), are at increased risk for invasive disease caused by *Neisseria meningitidis* groups A, C, W, and Y, even with receipt of vaccination with Nimenrix®
- As with any vaccine, vaccination with Nimenrix® may not protect all vaccine recipients against *N. meningitidis* groups A, C, W and Y
- Fainting can occur shortly before or after injecting vaccines, including Nimenrix®
- The most common adverse reactions were loss of appetite, irritability, drowsiness, headache, fatigue, fever, and pain, redness, and swelling at the injection site
- Tell your healthcare provider if you are pregnant, or plan to become pregnant
- Ask your healthcare provider about the risks and benefits of Nimenrix®. Only a healthcare provider can decide if Nimenrix® is right for you or your child

Menveo® and Nimenrix® are trademarks of GlaxoSmithKline Biologicals S.A.

Soliris® is a trademark of Alexion Pharmaceuticals, Inc.

About 20vPnC
Pfizer's 20vPnC pediatric vaccine candidate includes the 13 serotypes already included in Prevnar 13® – 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F. The seven new serotypes included in 20vPnC are global causes of IPD.[20,21,22,23,24] and are associated with high case-fatality rates[25,26,27,28] antibiotic resistance[29,30] and or meningitis.[31,32] Together, the 20 serotypes included in 20vPnC are responsible for the majority of currently circulating pneumococcal disease in the U.S. and globally.[33,34,35,36,37,38,39]

The supplemental Biologics License Application (sBLA) for 20vPnC includes for review indications in the following pediatric populations:

- The prevention of 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 infants and children 6 weeks through 17 years of age.
- The prevention of otitis media caused by *Streptococcus pneumoniae* serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F in infants and children 6 weeks through 5 years of age.

In September 2022, Pfizer announced positive top-line results from its pivotal Phase 3 study (NCT04546425) in infants in the European Union and, in November 2022, submitted the 20vPnC pediatric indication to the European Medicines Agency (EMA).

INDICATIONS FOR PREVNAR 13 ®

- Prevnar 13® is 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 *S. 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 (e.g., 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

About Pfizer: Breakthroughs That Change Patients' Lives

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 170 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. In addition, to learn more, please visit us on www.Pfizer.com and follow us on Twitter at @Pfizer and @Pfizer News, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

DISCLOSURE NOTICE:

The information contained in this release is as of February 21, 2023. 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 respiratory syncytial virus vaccine candidate (RSVpreF), Pfizer's 20-valent pneumococcal conjugate vaccine candidate (20vPnC) for pediatric use and Pfizer's pentavalent meningococcal vaccine candidate (MenABCWY), including their 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 biologic license applications may be filed in any other jurisdictions for RSVpreF, 20vPnC or MenABCWY for any potential indications; whether and when any applications that may be pending or filed for RSVpreF, 20vPnC or MenABCWY 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 RSVpreF, 20vPnC and

MenABCWY 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 RSVpreF, 20vPnC or MenABCWY; uncertainties regarding the ability to obtain recommendations from vaccine advisory or technical committees and other public health authorities regarding RSVpreF, 20vPnC and MenABCWY and uncertainties regarding the commercial impact of any such recommendations; uncertainties regarding 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, 2021, 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 and www.pfizer.com .

Category: Vaccines

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[1] Centers for Disease Control and Prevention. Respiratory Syncytial Virus Infection (RSV). https://www.cdc.gov/rsv/index.html. Updated December 18, 2020. Accessed November 18, 2022.
[2] Centers for Disease Control and Prevention. RSV Transmission. https://www.cdc.gov/rsv/about/transmission.html. Updated December 18, 2020. Accessed November 18, 2022.
[3] Centers for Disease Control and Prevention. Respiratory Syncytial Virus Infection (RSV) – Older Adults are at High Risk for Severe RSV Infection Fact Sheet. https://www.cdc.gov/rsv/factsheet-older-adults.pdf. Accessed November 18, 2022.
[4] Centers for Disease Control and Prevention. RSV in Infants and Young Children. https://www.cdc.gov/rsv/high-risk/infants-young-children.html. Updated December 18, 2020. Accessed November 18, 2022.
[5] Rha B, Curns AT, Lively JY, et al. Respiratory Syncytial Virus-Associated Hospitalizations Among Young Children: 2015-2016. Pediatrics. 2020;146(1):e20193611. doi:10.1542/peds.2019-3611
[6] Hall CB, Weinberg GA, Iwane MK, et al. The burden of respiratory syncytial virus infection in young children. N Engl J Med. 2009;360(6):588-598. doi:10.1056/NEJMoa0804877
[7] Glezen WP, Taber LH, Frank AL, Kasel JA. Risk of primary infection and reinfection with respiratory syncytial virus. Am J Dis Child. 1986;140(6):543-546. doi:10.1001/archpedi.1986.02140200053026
[8] Hall CB, Weinberg GA, Blumkin AK, et al. Respiratory syncytial virus-associated hospitalizations among children less than 24 months of age. Pediatrics. 2013;132(2):e341-e348. doi:10.1542/peds.2013-0303
[9] Li et al. Global, regional, and national disease burden estimates of acute lower respiratory infections due to respiratory syncytial virus in children younger than 5 years in 2019: a systematic analysis. Lancet 2022; 399: 2047-64.
[10] Scheltema NM, Gentile A, Lucion F, et al. Global respiratory syncytial virus-associated mortality in young children (RSV GOLD): a retrospective case series [published correction appears in Lancet Glob Health. 2017 Dec;5(12):e1190]. Lancet Glob Health. 2017;5(10):e984-e991. doi:10.1016/S2214-109X(17)30344-3.
[11] Centers for Disease Control and Prevention. RSV Surveillance & Research. https://www.cdc.gov/rsv/research/index.html#ref04. Updated October 28, 2022. Accessed Feb 6, 2023.
[12] Branche AR, Saiman L, Walsh EE, et al. Incidence of Respiratory Syncytial Virus Infection Among Hospitalized Adults, 2017-2020. Clin Infect Dis. 2022;74(6):1004-1011. doi:10.1093/cid/ciab595
[13] McLaughlin JM, Khan F, Begier E, Swerdlow DL, Jodar L, Falsey AR. Rates of Medically Attended RSV Among US Adults: A Systematic Review and Meta-analysis. Open Forum Infect Dis. 2022;9(7):ofac300. Published 2022 Jun 17. doi:10.1093/ofid/ofac300

[14] Zheng Z, Warren JL, Shapiro ED, Pitzer VE, Weinberger DM. Estimated incidence of respiratory hospitalizations attributable to RSV infections across age and socioeconomic groups. Pneumonia (Nathan). 2022;14(1):6. Published 2022 Oct 25. doi:10.1186/s41479-022-00098-x
[15] Centers for Disease Control and Prevention. ACIP Adult RSV Work Group Considerations. https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-10-19-20/04-RSV-Adults-Melgar-508.pdf. Accessed Feb 6, 2023.
[16] Thompson WW, Shay DK, Weintraub E, et al. Mortality associated with influenza and respiratory syncytial virus in the United States. *JAMA*. 2003;289(2):179-186. doi:10.1001/jama.289.2.179
[17] Matias G, Taylor R, Haguinet F, Schuck-Paim C, Lustig R, Shinde V. Estimates of mortality attributable to influenza and RSV in the United States during 1997-2009 by influenza type or subtype, age, cause of death, and risk status. *Influenza Other Respir Viruses*. 2014;8(5):507-515. doi:10.1111/irv.12258
[18] Hansen CL, Chaves SS, Demont C, Viboud C. Mortality Associated With Influenza and Respiratory Syncytial Virus in the US, 1999-2018. *JAMA Netw Open*. 2022;5(2):e220527. Published 2022 Feb 1. doi:10.1001/jamanetworkopen.2022.0527
[19] National Library of Medicine. Global estimate of Neisseria meningitidis serogroups proportion in invasive meningococcal disease: A systematic review and meta-analysis. September 2019. Available at: https://doi.org/10.1016/j.micpath.2019.103571. Accessed February 7, 2023.
[20] Baisells E, Guillot L, Nair H, et al. Serotype distribution of Streptococcus pneumoniae causing invasive disease in children in the post-PCV era: A systematic review and meta-analysis. PlosOne. 2017;12(5): e0177113.
[21] Hausdorff W & Hanage W. Interim results of an ecological experiment – Conjugate Vaccination against the pneumococcus and serotype replacement. Hum Vaccin Immunother. 2016;12(2):358-374.
[22] Cohen R, Cohen J, Chalumeau M, et al. Impact of pneumococcal conjugate vaccines for children in high- and non-high income countries. Expert Rev Vaccines. 2017;16(6):625-640.
[23] Moore M, Link-Gelles R, Schaffner W, et al. Effect of use of 13-valent pneumococcal conjugate vaccine in children on invasive pneumococcal disease in children and adults in the USA: analysis of multisite, population-based surveillance. Lancet Infect Dis. 2015;15(3):301-309.
[24] Metcalf B, Gertz RE, Gladstone RA, et al. Strain features and distributions in pneumococci from children with invasive disease before and after 13-valent conjugate vaccine implementation in the USA. Clin Microbiol Infect. 2016;22(1):60. e9-60. e29.
[25] Oligbu G, Collins S, Sheppard CL, et al. Childhood Deaths Attributable to Invasive Pneumococcal Disease in England and Wales, 2006–2014. Clin Infect Dis. 2017;65(2):308-314.
[26] van Hoek, Andrews N, Waight PA, et al. Effect of Serotype on Focus and Mortality of Invasive Pneumococcal Disease: Coverage of Different Vaccines and Insight into Non-Vaccine Serotypes. PlosOne. 2012;7(7: e39150.
[27] Stanek R, Norton N, Mufson M. A 32-Years Study of the Impact of Pneumococcal Vaccines on Invasive Streptococcus pneumoniae Disease. Am J Med Sci. 2016;352(6):563-573.
[28] Harboe ZB, Thomsen RW, Riis A, et al. Pneumococcal Serotypes and Mortality following Invasive Pneumococcal Disease: A Population-Based Cohort Study. PlosOne. 2009;6(5): e 1000081.
[29] Tomczyk S, Lynfield R, Schaffner W, et al. Prevention of Antibiotic-Nonsusceptible Invasive Pneumococcal Disease With the 13-Valent Pneumococcal Conjugate Vaccine. Clin Infect Dis. 2016;62(9):1119-1125.
[30] Mendes RE, Hollingsworth RC, Costello A, et al. Noninvasive Streptococcus pneumoniae Serotypes Recovered from Hospitalized Adult Patients in the United States in 2009 to 2012. Antimicrob Agents Chemother. 2015;59(9):5595-5601.
[31] Olarte L, Barson WJ, Lin PL, et al. Impact of the 13-valent pneumococcal conjugate vaccine on pneumococcal meningitis in US children. Clin Infect Dis. 2015;61(5):767-775.
[32] Thigpen MC, Whitney CG, Messonnier NE, et al. Bacterial Meningitis in the United States, 1998–2007. NEJM. 2011;364(21):2016-2025.
[33] Centers for Disease Control and Prevention. Active Bacterial Core (ABCs) surveillance. National Center for Immunization and Respiratory Diseases. Atlanta, GA.

[34] Ladhani, SN, Collins S, Djennad A, et al. Rapid increase in non-vaccine serotypes causing invasive pneumococcal disease in England and Wales, 2000–17: a prospective national observational cohort study. Lancet Infect Dis. 2018;18(4):441-451.
[35] Menéndez R, España PP, Pérez-Trallero E, et al. The burden of PCV13 serotypes in hospitalized pneumococcal pneumonia in Spain using a novel urinary antigen detection test. CAPA study. Vaccine. 2017;35(39):5264-5270.
[36] Azzari C, Cortimiglia M, Nieddu F, et al. Pneumococcal serotype distribution in adults with invasive disease and in carrier children in Italy: Should we expect herd protection of adults through infants' vaccination? Hum Vaccin Immunother. 2016;12(2):344-350.
[37] Pivlishi T. Impact of PCV13 on invasive pneumococcal disease (IPD) burden and the serotype distribution in the U.S. Centers for Disease Control and Prevention. Advisory Committee on Immunization Practices. October 24th, 2018.
[38] European Centre for Disease Prevention and Control. Invasive pneumococcal disease. In: ECDC. Annual epidemiological report for 2016. Stockholm: ECDC; 2018.
[39] Beall B, Chochua S, Gertz RE Jr, et al. A population-based descriptive atlas of invasive pneumococcal strains recovered within the U.S. during 2015-2016. Front Microbiol. 2018;19(9).

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Source: Pfizer Inc.