Tanzania Expands Immunization Program To Include Pfizer’s Prevenar 13 For Prevention Of Pneumococcal Disease

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More than 1.7 Million Infants and Young Children in Tanzania to Receive Coverage Against Pneumococcal Disease, a Leading Cause of Pediatric Death in Developing Countries1,2,3

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(BUSINESS WIRE)--Pfizer Inc. (NYSE: PFE) welcomes today’s announcement from the GAVI Alliance that Pfizer’s pneumococcal conjugate vaccine, Prevenar 13* (pneumococcal polysaccharide conjugate vaccine [13-valent, adsorbed]), is now included in the expanded pediatric immunization program in Tanzania. Pneumococcal disease is one of the leading causes of vaccine-preventable deaths worldwide in children younger than 5 years of age and results in more than one out of every five deaths in children younger than 5 years of age in Tanzania.2,3

The availability of Prevenar 13 in Tanzania is made possible by the Advance Market Commitment (AMC), an innovative funding mechanism that provides newer vaccines on a sustainable, affordable and accelerated basis to the world’s poorest countries. In just two years, 20 countries, including Tanzania, have introduced Prevenar 13 into their immunization programs as part of the AMC. This potentially lifesaving vaccine is being offered to help protect an estimated 10.5 million infants and children in these developing countries from pneumococcal pneumonia and invasive disease caused by the serotypes in the vaccine.1,4

“Pfizer is accelerating access to Prevenar 13 to infants and children who are most vulnerable, and our partnership with the GAVI Alliance helps ensure that this goal is realized,” says Susan Silbermann, president, vaccines, Pfizer. “Since pneumococcal pneumonia continues to be a major threat to young children in Tanzania, the AMC has the potential to significantly contribute to the achievement of the United Nation’s fourth Millennium Development Goal of reducing infant mortality two-thirds by 2015.”5

While public health interventions have helped to decrease infant mortality in Tanzania by 47 percent between 1990 and 2010,5 mortality rates are still among the highest in the world. There are more than 100,000 deaths of Tanzanian children under the age of 5 every year.6

On Dec. 6, 2012, representatives from the GAVI Alliance, including board chair Dagfinn Høybråten; the United Nations; government officials, including Tanzania’s Minister of Health and Social Welfare, Hussein Ali Mwinyi; and the country’s first lady, Salma Kikwete, will gather at a health and vaccination center in Morogoro, outside Dar es Salaam, for the official launch and immunization of the first Tanzanian child with Prevenar 13.

Pfizer will supply up to 480 million doses of Prevenar 13 under the AMC to help expand immunization programs against pneumococcal disease by 2023.7

About the Advance Market Commitment (AMC)

Pfizer has been a long-standing partner of the GAVI Alliance, since March 2010, when the Company entered into the first 10-year agreement to provide Prevenar 13 to infants and young children in the world’s poorest countries under the AMC framework. Pneumococcal vaccines are expected to reach more than 50 GAVI-supported countries by 2015.

In December 2010, Nicaragua became the first GAVI-eligible country to launch a pneumococcal conjugate vaccine, Prevenar 13, through the AMC. To date, Prevenar 13 has been introduced into the national immunization programs of the following GAVI-eligible countries: Benin, Burundi, Cameroon, Central African Republic, Congo, Democratic Republic of Congo, Djibouti, Gambia, Ghana, Guyana, Honduras, Malawi, Mali, Nicaragua, Rwanda, Sao Tome, Sierra Leone, Tanzania, Yemen and Zimbabwe.7

To meet the growing global need for Prevenar 13, Pfizer is increasing its manufacturing capabilities through a combination of capital investment, process improvements and efficiency measures throughout its supply network. Additionally, Pfizer is engaged in the development of a preserved, multi-dose vial which, subject to the required regulatory

approval, World Health Organization prequalification and AMC eligibility requirements, would provide an alternative option for developing world countries.7

About Prevenar 13

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 120 countries worldwide. It is already the most widely used pneumococcal conjugate vaccine in the world, and more than 500 million doses of Prevenar/Prevenar 13 have already been distributed worldwide.7 Currently, Prevenar 13 is included as part of a national immunization program in more than 60 countries, offering coverage against invasive pneumococcal disease to more than 30 million children per year.7

Prevenar 13 offers the broadest serotype coverage of any currently available pneumococcal conjugate vaccine for prevention of pneumococcal disease including invasive pneumococcal disease, pneumonia and otitis media.8 The 13 pneumococcal serotypes in Prevenar 13 (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F) are among the most prevalent invasive-disease causing strains in children worldwide.8,9

Prevenar 13 is also approved for use in adults 50 years of age and older in more than 100 countries, and is the first and only pneumococcal vaccine to be granted World Health Organization prequalification in the adult population.7

Prevenar 13 is marketed in the United States as Prevnar 13® (Pneumococcal 13-valent Conjugate Vaccine [Diphtheria CRM197 Protein]).10 In the United States, Prevnar 13 is not indicated for the prevention of pneumococcal pneumonia in the pediatric population .10

Pneumococcal Disease

Pneumococcal disease is a group of illnesses caused by the bacterium Streptococcus pneumoniae (S. pneumoniae), also known as pneumococcus.11 It includes invasive infections such as bacteremia and meningitis, as well as non-invasive disease such as pneumonia and acute otitis media.11 While pneumococcus can infect people of all ages, infants and young children and the elderly are at heightened risk.12 The World Health Organization estimates that more than 1.6 million people – including more than 800,000 children under 5 years of age – die every year from pneumococcal infections. Nearly all these deaths occur in the world’s poorest countries.13

Indications for Prevnar 13 in the United States

In the United States, Prevnar 13 is indicated for use in children six weeks through 5 years of age for the prevention of invasive disease (e.g., meningitis, bacteremia) caused by 13 Streptococcus pneumoniae serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F). The vaccine is also indicated in adults 50 years of age and older for active immunization for the prevention of pneumonia and invasive disease caused by the 13 Streptococcus pneumoniae serotypes contained in the vaccine (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F). Indication is based on immune responses.

World Health Organization Indication for Prevenar 13

The World Health Organization prequalified Prevenar 13 for active immunization of infants and children from 6 weeks through five years of age against invasive disease, pneumonia and otitis media and for active immunization of adults 50 years of age and older against pneumonia and invasive disease caused by the 13 pneumococcal serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F) contained in the vaccine. The World Health Organization prequalification allows for the procurement of Prevenar 13 by United Nations agencies. The prequalification is for global use of the vaccine in a single-dose vial.

Important Safety Information for Prevnar 13

•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 common side effects were pain, redness, or swelling at the injection site; limitation of arm movement; fatigue; headache; muscle pain; joint pain; decreased appetite; chills; or rash

•In adults, immune responses to Prevnar 13 were reduced when given with injected seasonal flu vaccine

•A temporary pause of breathing following vaccination has been observed in some infants born prematurely

•The most commonly reported serious adverse events in children were bronchiolitis (an infection of the lungs) (0.9%), gastroenteritis (inflammation of the stomach and small intestine) (0.9%), and pneumonia (0.9%)

•In infants and toddlers, the most common side effects were tenderness, redness or swelling at the injection site, irritability, decreased appetite, decreased or increased sleep, and fever

For the full prescribing information for Prevnar 13 in the U.S., please click here http://www.pfizer.com/products/#prevnar13.

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At Pfizer, we apply science and our global resources to improve health and well-being at every stage of life. We strive to set the standard for quality, safety and value in the discovery, development and manufacturing of medicines for people and animals. Our diversified global health care portfolio includes human and animal biologic and small molecule medicines and vaccines, and many of the world's best-known consumer products. 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 the world's leading biopharmaceutical company, we also 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, Pfizer has worked to make a difference for all who rely on us. To learn more about our commitments, please visit us at www.pfizer.com.

DISCLOSURE NOTICE: The information contained in this release is as of December 5, 2012. 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 that involves substantial risks and uncertainties regarding Prevenar 13, including its potential benefits and the success of the AMC project for vaccines. Such risks and uncertainties include, among other things, the uncertainties inherent in research and development; whether and when regulatory authorities in countries where applications for Prevenar 13 and/or for the preserved, multi-dose vial for Prevenar 13 have been or may be submitted will approve such applications and their decisions regarding labeling and other matters that could affect its availability or commercial potential; 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, 2011 , and in its reports on Form 10-Q and Form 8-K.

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