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Vaccine Prevents Deadly Pneumonia in African Children, New Clinical Trial Confirms

First major randomized, controlled vaccine clinical trial in nearly 20 years to show significant reduction in child mortality

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Washington, DC; March 25, 2005 - Global health leaders today presented new research showing that vaccinating infants against *Streptococcus pneumoniae* – a bacterium that causes deadly pneumonia, meningitis and sepsis – could substantially reduce death and serious illness among children in the developing world. If used widely, a pneumococcal conjugate vaccine could prevent hundreds of thousands of child deaths each year.

In a four-year study a team led by the UK Medical Research Council's Felicity Cutts vaccinated and followed over 17,000 young children in the Gambia to study whether a vaccine that has been shown to prevent pneumococcal disease in the United States, Finland and urban South Africa would also work in rural Africa. The results, to be published in the March 26 issue of *The Lancet* show that the vaccine reduced childhood mortality by 16 percent in children who received the pneumococcal conjugate vaccine. This study is the first major randomized, controlled vaccine clinical trial in nearly twenty years to show a statistically significant reduction in overall child mortality.

"The results of this vaccine trial hold great promise for improving health and saving lives in resource-poor populations, said Dr. Lee Jong-wook, the Director-General of the World Health Organization (WHO). "The international community's task now is to continue to work together productively to make the pneumococcal conjugate vaccine widely available to children in Africa, as lives are lost every minute to pneumococcal disease. Immunizing children with pneumococcal conjugate vaccine in developing countries will be a critical intervention towards achieving a two-thirds reduction in the under-five mortality rate, a Millennium Development Goal."

Streptococcus pneumoniae, or pneumococcus, is the bacterium that causes pneumococcal disease. When they invade the lungs, these bacteria cause the most common kind of bacterial pneumonia and can then invade the bloodstream (bacteremia) or the tissues and fluids surrounding the brain and spinal cord (meningitis). According to WHO, pneumococcal pneumonia and meningitis are responsible for about 1.6 million deaths each year, even more than malaria. And more than 90 percent of pneumococcal pneumonia deaths in children occur in developing countries.

Previous studies had shown that this vaccine was effective in reducing the number of pneumococcal infections in children in the United States, Finland and in urban South Africa. But many of the children suffering from pneumococcal disease in Africa live in rural areas with high infant mortality rates, significant rates of malaria transmission and very limited access to healthcare. The Gambia is representative of these areas, and the results of the study suggest that the deaths caused by pneumococcal infections in rural Africa are preventable. "The trial results are highly positive and promising, and most importantly, they demonstrate that pneumococcal vaccination can prevent these serious infections even in a rural African setting," said Professor Cutts.

Sponsors of and participants in this successful trial included the National Institute of Allergy and Infectious Diseases, part of the National Institutes of Health; the World Health Organization (WHO); PATH's Children's Vaccine Program (CVP); the U.S. Agency for International Development; Johns Hopkins Bloomberg School of Public Health and the Centers for Disease Control and Prevention. Wyeth Pharmaceuticals provided the trial vaccine.

Summary of trial results

In this trial:

- This vaccine significantly reduced the need for hospitalization: children receiving the pneumococcal vaccine had 15 percent fewer hospital admissions than those who did not.
- The nine-valent pneumococcal conjugate vaccine was 77 percent effective in preventing pneumococcal infections caused by the vaccine serotypes.
- As a result, there were 37 percent fewer cases of pneumonia in the children who received the vaccine compared with children who received the control vaccine.

Working with the Global Alliance for Vaccines and Immunization (GAVI), Wyeth Pharmaceuticals has offered to provide the pneumococcal conjugate vaccine Prevnar to The Gambia for introduction into their national immunization program. Wyeth is also working with GAVI's PneumoADIP and other public health partners to facilitate access to Prevnar and future pneumococcal conjugate vaccines with expanded serotype coverage to children in developing countries.

[ENDS]

The Gambia Pneumococcal Vaccine Trial

The Gambia Vaccine Trial was a randomized, double-blind, placebo-controlled trial – the most scientifically rigorous design for a clinical trial – of the efficacy of nine-valent pneumococcal conjugate vaccine against pneumonia, meningitis, and sepsis. The study was carried out in Upper and Central River divisions of The Gambia between August 2000 and April 2004. All 17,437 infants enrolled in the trial received DTP (diphtheria, tetanus, and pertussis) and *Hib* vaccines. Children had follow-up visits for two years, on average.

Pneumococcal Disease

Pneumococcal disease is an infection caused by *Streptococcus pneumoniae*. When these bacteria invade the lungs, they cause the most common kind of bacterial pneumonia and can then invade the bloodstream (bacteremia) and/or the tissues and fluids surrounding the brain and spinal cord (meningitis). According to WHO, pneumococcal pneumonia and meningitis are responsible for 700,000 to 1 million child deaths each year and more than 90 percent of pneumococcal pneumonia deaths in children occur in developing countries.

The World Health Organization (WHO)

The World Health Organization is the United Nations specialized agency for health. It was established on 7 April 1948. WHO's objective, as set out in its Constitution, is the attainment by all peoples of the highest possible level of health. Health is defined in WHO's Constitution as a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.

The National Institute of Allergy and Infectious Diseases (NIAID)

NIAID is a component of the National Institutes of Health, an agency of the U.S. Department of Health and Human Services. NIAID supports basic and applied research to prevent, diagnose and treat infectious diseases such as HIV/AIDS and other sexually transmitted infections, influenza, tuberculosis, malaria and illness from potential agents of bioterrorism. NIAID also supports research on transplantation and immune-related illnesses, including autoimmune disorders, asthma and allergies.

The United States Agency for International Development (USAID)

The U.S. Agency for International Development has provided economic and humanitarian assistance worldwide for more than 40 years. The Agency's programs in global health represent the commitment and determination of the U.S. government to prevent suffering, save lives, and create a brighter future for families in the developing world. Since 1990, USAID has provided over \$2.5 billion in assistance to help child survival programs save children's lives through essential interventions, and has supported research to help develop new approaches and technologies that save millions of lives each year.

The Centers for Disease Control and Prevention (CDC)

The Centers for Disease Control and Prevention (CDC) is recognized as the lead federal agency for protecting the health and safety of people - at home and abroad, providing credible information to enhance health decisions, and promoting health through strong partnerships. CDC serves as the national focus for developing and applying disease prevention and control, environmental health, and health promotion and education activities designed to improve the health of the people of the United States.

CDC, located in Atlanta, Georgia, USA, is an agency of the Department of Health and Human Services. Dr. Julie L. Gerberding is the Director.

Wyeth Pharmaceuticals

Wyeth Pharmaceuticals, a division of Wyeth (NYSE:WYE), has leading products in the areas of women's health care, cardiovascular disease, central nervous system, inflammation, , transplantation, hemophilia, oncology, vaccines and nutritional products. Wyeth is one of the world's largest research-driven pharmaceutical and health care products companies. It is a leader in the discovery, development, manufacturing, and marketing of pharmaceuticals, vaccines, biotechnology products and nonprescription medicines that improve the quality of life

for people worldwide. The Company's major divisions include Wyeth Pharmaceuticals, Wyeth Consumer Healthcare, Wyeth Nutrition and Fort Dodge Animal Health.

PATH's Children's Vaccine Program (CVP)

PATH is an international, nonprofit organization that works to create sustainable, culturally relevant solutions that enable communities worldwide to break longstanding cycles of poor health. Since 2000, PATH's Children's Vaccine Program has supported pneumococcal disease research in Africa, Asia, and South America. PATH's CVP has been a funding partner of the pneumococcal vaccine effectiveness trial in The Gambia since its inception. PATH is also collaborating with partners to encourage development of affordable pneumococcal vaccines for infants in the developing world.

PATH collaborates with diverse public- and private-sector partners to achieve its mission goals. Visit www.path.org for more information about PATH, or www.childrensvaccine.org for more specific information about PATH's Children's Vaccine Program.

Pneumococcal Vaccines Accelerated Development and Introduction Plan (PneumoADIP)

PneumoADIP is a small, dedicated team based at Johns Hopkins Bloomberg School of Public Health and is supported by a \$30 million grant from the Global Alliance for Vaccines and Immunization and its partner, the Vaccine Fund. PneumoADIP's mission is to improve child survival and health by accelerating the evaluation of and access to new, lifesaving pneumococcal vaccines for the world's children. PneumoADIP aims to achieve its goals through partnerships with countries, donors, academia, international organizations and industry. PneumoADIP coordinates its activities through a strategic alliance with the World Health Organization.

Please also visit the following website for further information and to view press materials:
www.preventpneumo.org

For further information, please contact:

Chris Thomas

U.S. Agency for International
Development, Washington, DC
w. +1 202-712-1092
Email: chthomas@usaid.gov

Ellen Cole

PATH, Seattle, WA
Email : ecoleoley@path.org
Direct Tel: +1 206 285-3500
Fax: +1 206 788-2007

Hans Kvist

PneumoADIP, Baltimore, MD
Mobile: +1 410 736 8243
Email: hkvist@jhsp.edu

Melinda Henry

WHO, Geneva
Email : henrym@who.int
Direct Tel: +41 22 791 2535
Fax: +41 22 791 4227

Nancy Glick

Ruder Finn, Washington, DC
Office: +1 202-974-5083
Email: glickn@ruderfinn.com

Natalie De Vane

Office: +1 484-865-5139
Email: devanen@wyeth.com

News Office

National Institute of Allergy and Infectious
Diseases
Office: +1 301-402-1663
niaidnews@niaid.nih.gov