***Date Issued: Embargoed until Tuesday 18th October,***
***10.00 Seattle (PST), 13.00 (EST) New York, 18.00 London (BST), 19.00 Brussels (CEST)***

# First results from ongoing Phase III trial show malaria vaccine candidate, RTS,S* reduces the risk of malaria by half in African children aged 5 to 17 months

**Half the world's population is at risk of malaria which is responsible for close to 800,000 deaths each year, most of whom are children under five in sub-Saharan Africa**

**Seattle, 18 October 2011 —** First results from a large-scale Phase III trial of RTS,S, published online today in the *New England Journal of Medicine (NEJM)*, show the malaria vaccine candidate to provide young African children with significant protection against clinical and severe malaria with an acceptable safety and tolerability profile. The results were announced today at the Malaria Forum hosted by the Bill & Melinda Gates Foundation in Seattle, Washington.

### 5 to 17 month-old children

The trial, conducted at 11 trial sites in seven countries across sub-Saharan Africa, showed that three doses of RTS,S reduced the risk of children experiencing clinical malaria and severe malaria by 56% and 47%, respectively. This analysis was performed on data from the first 6,000 children aged 5 to 17 months, over a 12-month period following vaccination. Clinical malaria results in high fevers and chills. It can rapidly develop into severe malaria, typified by serious effects on the blood, brain, or kidneys that can prove fatal. These first Phase III results are in line with those from previous Phase II studies.

The widespread coverage of insecticide-treated bed nets (75%) in this study indicated that RTS,S can provide protection in addition to that already offered by existing malaria control interventions.

### 6 to 12 week-old infants

The trial is ongoing and efficacy and safety results in 6 to 12 week-old infants are expected by the end of 2012. These data will provide an understanding of the efficacy profile of the RTS,S malaria vaccine candidate in this age group, for both clinical and severe malaria.

### Combined data in 6 to 12 week-old infants and 5 to 17 month-old children

An analysis of severe malaria episodes so far reported in all 15,460 infants and children enrolled in the trial at 6 weeks to 17 months of age has been performed. This analysis showed 35% efficacy over a follow-up period ranging between 0 and 22 months (average 11.5 months).

### Long-term efficacy

The RTS,S malaria vaccine candidate is still under development. Further information about the longer-term protective effects of the vaccine, 30 months after the third dose, should be available by the end of 2014. This will provide evidence for national public health and regulatory authorities, as well as international public health organisations, to evaluate the benefits and risks of RTS,S.

### Safety

The overall incidence of serious adverse events (SAEs)** in this trial was comparable between the RTS,S candidate vaccine (18%) recipients and those receiving a control vaccine (22 %)

Differences in rates of SAEs were observed between the vaccines groups for specific events, such as seizures and meningitis, and were higher in the malaria vaccine group. Seizures were considered to be related to fever and meningitis was considered unlikely to be vaccine-related. These events will continue to be monitored and additional information about the safety profile of the RTS,S malaria vaccine candidate will become available over the next three years.

**Tsiri Agbenyega, a principal investigator of the trial and Chair of the Clinical Trials Partnership Committee, said:** "The publication of the first results in children aged 5 to 17 months marks an important milestone in the development of RTS,S. These results confirm findings from previous Phase II studies and support ongoing efforts to advance the development of this malaria vaccine candidate. Having worked in malaria research for more than 25 years, I can attest to how difficult making progress against this disease has been. Sadly, many have resigned themselves to malaria being a fact of life in Africa. This need not be the case. Renewed interest in malaria by the international community, and scientific evidence such as that we are reporting today, should bring new hope that malaria can be controlled."

**Andrew Witty, CEO, GSK said**: "These data bring us to the cusp of having the world's first malaria vaccine, which has the potential to significantly improve the outlook for children living in malaria endemic regions across Africa. The addition of a malaria vaccine to existing control interventions such as bed nets and insecticide spraying could potentially help prevent millions of cases of this debilitating disease. It could also reduce the burden on hospital services, freeing up much needed beds to treat other patients who often live in remote villages, with little or no access to healthcare. Today's results are a testament to the dedication and tenacity of many scientists, led at GSK by Jean Stéphenne and his vaccine team, including Joe Cohen, the co-inventor of RTS,S, in partnership with many others from across the world. Development is however only half the task, but GSK remains committed to further research into malaria and most importantly, to ensuring that this vaccine will reach those who need it."

**Christopher Elias, president and CEO of PATH , said:** "This trial represents a powerful example of the high-quality science that is moving us toward controlling and someday potentially eliminating malaria. The results made public today are encouraging and certainly something to feel good about, but let's also remember the human dimension. The PATH Malaria Vaccine Initiative's mission is to deliver a vaccine to the children of Africa so that instead of carrying near lifeless babies to crowded pediatric wards, mothers will carry their infants past noisy school playgrounds to bustling immunization clinics. Today, we are an important step closer to realizing that vision, and we look forward to continuing our drive, together with our partners, to bring this vaccine home to the children of Africa."

**Bill Gates, co-chair of the Bill & Melinda Gates Foundation, said**: "A vaccine is the simplest, most cost-effective way to save lives. These results demonstrate the power of working with partners to create a malaria vaccine that has the potential to protect millions of children from this devastating disease."

The vaccine is being developed in partnership by GSK and the PATH Malaria Vaccine Initiative (MVI), together with prominent African research centers. The partners are all represented on the Clinical Trials Partnership Committee, which is responsible for the conduct of the trial. Major funding for clinical development comes from a grant by the Bill & Melinda Gates Foundation to MVI. An extended team of organisations continues to work on RTS,S, including scientists from across Europe, North America and Africa. Should it be approved by regulatory authorities and recommended by the World Health Organisation (WHO), it will be used for African children, who are most at risk from the disease. Successful development of an effective vaccine to be used alongside other measures such as bed nets and anti-malarial medicines would represent a decisive step toward sustained malaria control.

The impact of the RTS,S Phase III trial extends beyond the vaccine being researched. The trial has made a considerable contribution to many of the African communities that host the trial sites through improved healthcare and hospital facilities. Research capacity at many of the research centres has been strengthened through the training of staff, provision of state-of-the-art laboratories, equipment, and construction of new facilities. This enhanced capacity bodes well for the centres to expand further their leadership in developing remedies for malaria and other infectious diseases for years to come.

### Looking ahead

GSK and MVI are committed to making this vaccine available to those who need it most, should it be approved and recommended for use. In January 2010, GSK announced that the eventual price of RTS,S will cover the cost of manufacturing the vaccine together with a small return that will be reinvested in research and development for second-generation malaria vaccines or vaccines against other neglected tropical diseases.

If the required public health information, including safety and efficacy data from the Phase III programme, is deemed satisfactory, the WHO has indicated that a policy recommendation for the RTS,S malaria vaccine candidate is possible as early as 2015, paving the way for decisions by African nations regarding large scale implementation of the vaccine through their national immunisation programmes.

### Notes to editors

#### About RTS,S

RTS,S is a scientific name given to this malaria vaccine candidate and represents the composition of this vaccine candidate. RTS,S aims to trigger the immune system to defend against *Plasmodium falciparum* malaria parasite when it first enters the human host's bloodstream and/or when the parasite infects liver cells. It is designed to prevent the parasite from infecting, maturing and multiplying in the liver, and from re-entering the bloodstream and infecting red blood cells, at which point the affected person would begin to show symptoms of the disease.

The vaccine, based on a protein first identified in the laboratory of Drs Ruth and Victor Nussenzweig at New York University, was invented, developed and manufactured in laboratories at GSK Biologicals' headquarters in Belgium in the late 1980s and initially tested in US volunteers as part of a collaboration with the US Walter Reed Army Institute of Research.

In 2001, the PATH Malaria Vaccine Initiative (MVI) entered into partnership with GSK to study the vaccine candidate's ability to protect young children in sub-Saharan Africa. Over time, the partnership expanded to include the 11 African research centres and, in some instances, associated scientific institutions from Europe and the United States.

With more than US$200 million in grant monies from the Bill & Melinda Gates Foundation, MVI contributes financial, scientific, managerial, and field expertise to the development of RTS,S. GSK takes the lead in the clinical development and in the interactions with regulatory agencies and has invested more than $300 million to date and expects to invest another $50-100 million before the completion of the project.

#### About the study

This is one of the final stages in evaluating the efficacy and safety of the vaccine candidate in infants and young children on a large scale before regulatory file submission.

The partners in the development of RTS,S have placed the utmost emphasis on the health and safety of the study participants. The Phase III trial has been designed in consultation with the appropriate regulatory authorities and the WHO. It is conducted in accordance with the highest international standards for safety, ethics, and clinical practices and is overseen by an independent data safety monitoring committee.

#### About GSK Biologicals

GlaxoSmithKline Biologicals (GSK Biologicals), GlaxoSmithKline's vaccines business, is one of the world's leading vaccine companies and a leader in innovation. The company is active in vaccine research, development and production with over 30 vaccines approved for marketing and 20 more in development - both in the prophylactic and therapeutic fields. Headquartered in Belgium, GSK

Biologicals has 14 manufacturing sites strategically positioned around the globe. In 2010, GSK Biologicals distributed 1.43 billion doses of vaccines to 179 countries in both the developed and the developing world.

Through its accomplished and dedicated workforce, GSK Biologicals applies its expertise to the discovery of innovative vaccines that contribute to the health and well-being of people of all generations around the world.

**About the PATH Malaria Vaccine Initiative (MVI)**

The PATH Malaria Vaccine Initiative (MVI) is a global program established at PATH through an initial grant from the Bill & Melinda Gates Foundation. MVI's mission is to accelerate the development of malaria vaccines and ensure their availability and accessibility in the developing world. MVI's vision is a world free from malaria. For more information, please visit www.malariavaccine.org.

PATH is an international non-profit organization that creates sustainable, culturally relevant solutions, enabling communities worldwide to break longstanding cycles of poor health. By collaborating with diverse public- and private-sector partners, PATH helps provide appropriate health technologies and vital strategies that change the way people think and act. PATH's work improves global health and well-being. For more information, please visit www.path.org.

*contains QS-21 Stimulon® adjuvant licensed from Antigenics Inc, a wholly owned subsidiary of Agenus Inc. (NASDAQ: AGEN), MPL and liposomes.

**A serious adverse event refers to any medical event that occurs during the course of a clinical trial and that results in death, is life threatening, requires inpatient hospitalization, or results in a persistent or significant disability or incapacity needs, regardless of whether the SAE is considered to be caused by the study vaccination. All SAEs are reported to regulatory authorities.

**PATH Malaria Vaccine Initiative Enquiries:**

All Media enquiries:

Preeti Singh (+1) 301-280-5722 (office)
(+1) 703-862-2515 (mobile/SMS)
psingh@burnesscommunications.com

Kelsey Mertes (+1) 202-540-4422 (office)
(+1) 301-312-7844 (mobile/SMS)
kmertes@path.org

**GlaxoSmithKline Enquiries:**

| | | |
|---|---|---|
| UK Media enquiries: | David Mawdsley | (020) 8047 5502 |
| | Stephen Rea | (020) 8047 5502 |
| | Sarah Spencer | (020) 8047 5502 |
| | Janet Morgan | (020) 8047 5502 |
| | David Daley | (020) 8047 5502 |
| US Media enquiries: | Nancy Pekarek | (919) 483 2839 |
| | Mary Anne Rhyne | (919) 483 2839 |
| | Kevin Colgan | (919) 483 2839 |
| | Sarah Alspach | (919) 483 2839 |

# PRESS RELEASE


| | | |
|---|---|---|
| European Analyst/Investor enquiries: | Sally Ferguson | (020) 8047 5543 |
| | Gary Davies | (020) 8047 5503 |
| | Ziba Shamsi | (020) 8047 3289 |
| US Analyst/ Investor enquiries: | Tom Curry | (215) 751 5419 |
| | Jeff McLaughlin | (215) 751 7002 |


**Cautionary statement regarding forward-looking statements**
Under the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995, GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Factors that may affect GSK' s operations are described under 'Risk Factors' in the 'Business Review' in the company' s Annual Report on Form 20-F for 2010.