

MEDIA RELEASE

Embargoed until: 00.01 hrs Wednesday 31st March 2010

**New vaccine can protect travellers against four types
of meningitis**

*British travellers ignorant of potentially fatal meningitis risk
when visiting Africa, survey finds*

A new vaccine launched today can protect British travellers from four major strains of meningitis that they are at risk of contracting while travelling to different parts of the world, particularly Africa.

The new vaccine, called Menveo[®] ▼, protects against the meningitis strains A, C, W-135 and Y. It is the first of a new type of four-strain meningitis vaccine, called conjugated, to be available in Europe.

Its launch comes as a new survey has found that more than half of its respondents did not, or will not, get a meningitis vaccination for their trip to African countries within the Meningitis Belt, while two thirds of those who had already visited the Meningitis Belt were not vaccinated. ¹

A huge swathe of Africa south of the Sahara, stretching from Senegal in the west to Ethiopia in the east, is known as the Meningitis Belt because of the frequency and severity of epidemics of the illness. ²

The predominant strains of meningitis across the world vary, making broad protection against the disease vital. In certain parts of Africa the A strain causes a huge toll of illness and death and cases of W-135, once considered rare, are also increasing. The Y strain is common in the USA and is increasingly being seen in South America. ³

Although children have been routinely vaccinated against meningitis C in the UK since 2000 this is not so for adults, and there is no routine vaccination in the national schedule against other world strains such as A, W-135 or Y.

The survey carried out by TNS amongst 300 recent or would-be British travellers to Meningitis Belt countries found that two-thirds of respondents were or will be holiday makers, with 40% going on safari, and over a quarter visiting friends and relatives. ¹

Almost half had visited Kenya and 35% were planning to visit in the next six months. Gambia was the second most popular destination with a fifth of respondents having visited in the last three years. ¹

The survey found that over half of the travellers had not heard of the Meningitis Belt and only 6% were able to name a country within it. ¹

Respondents consulted a variety of sources for travel health information including travel websites (43%), health websites (32%), their GP (71%) and a higher proportion of frequent visitors use a travel clinic (34%). ¹

The age of respondents determined their behaviour as 45% of under 35 year olds did or will get a vaccination, while 60% of over 35 year olds did not. ¹

Only a third of respondents knew that meningitis was a disease which could be caught in Africa and almost half did not know they could pass meningitis onto family, friends and colleagues when returning from their trip. ¹

The survey found that more than a third of respondents did not know that there were different types of meningitis.

However, certain symptoms of meningitis are well known by respondents, with 73% recognising 'spots or rashes that do not fade' and 'fever'. Over half distinguishing 'stiff neck' and 'aversion to light' as symptoms with more than a third (36%) identifying drowsiness. ¹

Commenting on the findings Dr Jane Zuckerman, Director of the WHO Collaborating Centre for Travel Medicine, University College London Medical School, London said: "British travellers may not have enough knowledge about common travel diseases like meningitis and how to prevent them which is a risk to their health. As the survey demonstrated, there is still work that needs to be done to highlight the risks of meningitis to the public especially as it can be easily passed on from person to person."

Dr Zuckerman added: "Travellers should consider visiting specialist travel health centres where they can be advised and be provided with expert knowledge on the diseases they might be exposed to and the vaccines and medicines they require to keep well and protected against travel-related infectious diseases."

Dr Zuckerman suggested that as more children and gap year students are beginning to travel than have previously done so before, the use of conjugated vaccines, like Menveo[®], is even more important.

“The A, C, W135 and Y strains of meningitis are not only found in the Meningitis Belt of the sub-Saharan” she said.

Researchers have begun to warn that epidemics are occurring outside of the traditional Meningitis Belt nations and have been seen in countries like Tanzania, Kenya and Namibia. Widespread cases have also been seen in some parts of South Africa.⁴

Some of the main research into the Meningitis Belt has been carried out at Liverpool School of Tropical Medicine.⁴

One of the leaders of the research, Dr Anna Molesworth, said: “The Meningitis Belt gets these recurrent, often massive, dry-season epidemics every five to ten years. In recent years we have also seen an increase in the number of outbreaks reported elsewhere. Other outbreaks are not on the same scale but to say that the risk of meningitis in Africa, outside of the traditional Meningitis Belt countries, may be increasing is reasonable.”

“There may be climatic factors and it does seem the areas worst affected are the drier parts of Africa. Outside the Meningitis Belt these conditions can be found down the Rift Valley and in the Great Lakes area and in some parts of southern Africa bordering desert regions.”

Dr Molesworth, now working in Malawi for the London School of Hygiene and Tropical Medicine, said that British travellers to Africa should think carefully about meningitis vaccination.

“The public health importance of vaccination for a preventable disease cannot be stressed enough. My view is that if there is a risk of you getting a potentially serious disease, and there is a safe vaccine available, then you should get the vaccine.”

Menveo[®] is the first vaccine available in Europe to provide four-strain meningitis protection using a production technique called conjugation. Against other infectious diseases, conjugate vaccines have shown a number of advantages over the currently available polysaccharide vaccines, principally in making the body’s immune system respond in a stronger way.⁵

Some of the most dramatic beneficial effects of conjugate vaccines have been seen against Meningitis C. Three meningitis C conjugate vaccines, introduced in the UK in 2000, including the meningitis C conjugate vaccine, Menjugate[®] manufactured by Novartis Vaccines and Diagnostics, have virtually eliminated the disease from Britain, not just by protecting the vaccinated individual but also the community.

Conjugate vaccines can bring about herd immunity – that is, they protect people who have not been vaccinated by cutting circulating levels of the bacteria in the community.⁶

Vaccine researcher Professor Ray Borrow, Head of the Health Protection Agency's Vaccine Evaluation Unit, in Manchester, said there were a number of scientific reasons why conjugate vaccines were superior to polysaccharide ones.

"Firstly, conjugates are immunogenic (provide protection) in infants and young children, particularly those less than two years of age, whereas polysaccharides are not. The next most important thing is that conjugates actually prevent the acquisition of carriage of the meningococcal bacterium, and thus can result in herd immunity.

"Thirdly they induce immune memory and thus you get booster responses when you re-vaccinate as opposed to polysaccharides which produce a reaction called hyporesponsiveness, where you get reduced responses to re-vaccination."

Professor Borrow said the primary use of the new vaccine in the UK was likely to be as a travel vaccine. "I imagine travel clinics will have no problem using a conjugate over a polysaccharide vaccine," he added.

ENDS

Notes to Editors

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as "risk," "intends," "will," "can," "priority," "potential," or similar expressions, or by express or implied discussions regarding potential new indications or labeling for Menveo, potential future approvals of additional Novartis vaccines or regarding potential future revenues from such vaccines. You should not place undue reliance on these statements. Such forward-looking statements reflect the current views of management regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Menveo will be approved for any additional indications or labeling in any market. Nor can there be any guarantee that any additional vaccines will be approved for sale in any markets. Neither can there be any guarantee that Menveo or any additional vaccines will achieve any particular levels of revenue in the future. In particular, management's expectations regarding Menveo or any additional vaccines could be affected by, among other things, unexpected clinical trial results, including unexpected new clinical data and unexpected additional

analysis of existing clinical data; unexpected regulatory actions or delays or government regulation generally; competition in general; government, industry and general public pricing pressures; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; the impact that the foregoing factors could have on the values attributed to the Novartis Group's assets and liabilities as recorded in the Group's consolidated balance sheet, and other risks and factors referred to in Novartis AG's current Form 20-F on file with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, believed, estimated or expected. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

Backgrounders are available on What is Menveo[®], the Global Risks of ACWY, and Differences between Conjugate and Polysaccharide Vaccines.

Menveo[®], made by Novartis Vaccines and Diagnostics, has a licence for use in people aged 11 years and over.⁷

Menveo[®] has been studied in trials covering 18,500 people.⁸

Conjugate vaccines overcome the limitations of polysaccharide vaccines⁹:

- a. **Immunogenicity** - conjugate vaccines work in all patient types. Polysaccharides produce a limited immune response in the immunocompromised and children.^{6,9}
- b. **Carriage** - conjugates have been shown to reduce non-symptomatic carriage of meningococcal bacteria reducing disease transmission. Polysaccharides have little effect on meningococcal carriage rates.^{6,9}
- c. **Hypo-responsiveness** - conjugates induce an immune memory and are therefore boostable. Polysaccharides induce hyporesponsiveness on re-vaccination.^{6,9}

Countries that survey respondents were asked if they had visited or were planning to visit¹

- Benin
- Burkina Faso
- Cameroon
- Central African Republic

- Chad
- Cote d'Ivoire
- Eritrea
- Ethiopia
- Ghana
- Guinea
- Guinea-Bissau
- Kenya
- Mali
- Niger
- Nigeria
- Senegal
- Sudan
- The Gambia
- Togo
- Uganda

For further information please contact:

Chris Mihill, Craig Haslop or Sheetal Morzaria
 Clew Communications
 020 7580 7550
 Chris Mihill mobile: 07710 279702
chris.mihill@clew.com

Or

Jo Taylor or Zarina Baloch
 Public Relations Department
 Novartis Vaccines and Diagnostics UK
 Frimley Business Park
 Frimley, Camberley, Surrey GU16 7SR
 United Kingdom
 01276 698 001
 Jo Taylor mobile: 07525 257568

References

1 Survey conducted by Taylor Nelson Sofres amongst 300 respondents who had either been to Africa in the last 3 years or were planning to go in the next 6 months. Data on file. Novartis Vaccines

2 WHO Fact Sheet No 141. Available at <http://www.who.int/mediacentre/factsheets/2003/fs141/en/>
 Accessed March 2010

3 Harrison *et al.* Global epidemiology of meningococcal disease. *Vaccine* 2009; 27S: B51-B63

4 Molesworth *et al.* Where is the Meningitis Belt? Defining an area at risk of epidemic meningitis in Africa. *Transactions of the Royal Society of Tropical Medicine and Hygiene* 2002; 96: 242-249

5 Bröker *et al.* Chemistry of a New Investigational Quadrivalent Meningococcal Conjugate Vaccine that is Immunogenic at all ages. *Vaccine* 2009; 27: 5574-5580

6 Maiden MCJ *et al.* Impact of meningococcal serogroup C conjugate vaccines on carriage and herd immunity. *Journal of Infectious Diseases* 2008; 197: 737-743

7 Menveo[®] Summary of Product Characteristics, 15 March 2010

8 Data on file. Novartis Vaccines

9 Wilder-Smith A. Meningococcal disease: risk for international travellers and vaccine strategies. *Travel Med Infect Dis.* 2008; 6(4):182-186