

**MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG****Novartis application for expanded Menveo<sup>®</sup> indication from 2 months of age accepted for review by FDA**

- *Submission includes data in more than 6,000 infants and toddlers worldwide<sup>1</sup>*
- *Protecting infants is critical as they are at highest risk of contracting meningococcal disease<sup>2</sup>*

**Basel, June 16, 2011** – Novartis announced today that the US Food and Drug Administration (FDA) has accepted for review its supplemental Biologics License Application (sBLA) to expand the Menveo<sup>®</sup> (Meningococcal [Groups A, C, Y and W-135] Oligosaccharide Diphtheria CRM<sub>197</sub> Conjugate Vaccine) indication to include infants and toddlers from 2 months of age. Menveo is already approved in the US for use in individuals 2 years to 55 years of age<sup>3</sup>.

The sBLA is supported by data from pivotal trials which included more than 6,000 infants and toddlers worldwide. In the trial measuring the body's immune response (immunogenicity) to the vaccine one month after completion of a four dose Menveo series administered at 2, 4, 6 and 12-16 months of age, 100% of subjects achieved the correlated protection level (hSBA titers  $\geq 8$ ) against serogroups W-135 and Y, and 94% and 98% of subjects achieved this level against serogroups A and C, respectively<sup>1</sup>. Menveo was generally well tolerated when administered either alone or with other pediatric vaccines<sup>4</sup>.

The application accepted today includes infant data aged 2 to 12 months as well as additional data that support the use of Menveo in toddlers from 12 to 23 months of age.

The highest rates of meningococcal disease occur early in the first year of life, with most cases occurring within the first 7 months<sup>2, 5</sup>. About one in 16 infants who contract meningococcal disease may die<sup>5</sup>. Survivors may suffer permanent brain damage, learning disabilities, hearing loss and limb loss<sup>6</sup>. In most cases, the resulting side effects require life-long, expensive medical treatment and ongoing assistance<sup>7</sup>.

**About Menveo**

As of June 2011, Menveo is registered in more than 40 countries for active immunization to prevent invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, W-135 and Y. Menveo has been administered to more than 21,500 participants in clinical trials across all age groups worldwide, and studies are ongoing in infants, toddlers, adolescents and adults. Menveo received FDA approval in February 2010 for use in adolescents and adults (11 to 55 years of age) and approval for use in children 2 to 10 years of age in January 2011.

In the European Union, Menveo is indicated for use in persons 11 years and above. Novartis plans to submit additional data to the European Medicines Agency to support the use of Menveo in infants and children 0 to 10 years of age in the coming months. An application to support a label extension for use in children 2 to 10 years of age has been submitted in Canada.

### **Important Safety Information**

Menveo is contraindicated in individuals who have experienced a severe allergic reaction after a previous dose of Menveo, any component of this vaccine, or any other CRM<sub>197</sub>, diphtheria toxoid or meningococcal-containing vaccine. Appropriate medical treatment must be available should an acute allergic reaction, including an anaphylactic reaction, occur following administration of Menveo.

Vaccinees may develop syncope, sometimes resulting in falling with injury associated with seizure-like movements. Observation for 15 minutes after vaccination is recommended. Patients who are immunocompromised or receiving immunosuppressive therapy may have an inadequate response to vaccination.

Following vaccination with another US-licensed meningococcal quadrivalent polysaccharide conjugate vaccine, an evaluation of postmarketing adverse events suggested a potential for an increased risk of Guillain-Barré syndrome (GBS). Data are not available to evaluate the potential risk of GBS following administration of Menveo.

In clinical trials, the most frequently occurring adverse events in subjects 11 to 55 who received Menveo were pain at the injection site, headache, myalgia, malaise, and nausea. The most frequently occurring adverse events in subjects 2-10 years of age who received Menveo were pain at the injection site, erythema, irritability, induration, sleepiness, malaise, and headache. Some events were severe. Safety has not been established in pregnant women. Vaccination with Menveo may not protect all individuals. Before administering Menveo, please see full Prescribing Information.

### **Disclaimer**

The foregoing release contains forward-looking statements that can be identified by terminology such as “would,” “plans,” or similar expressions, or by express or implied discussions regarding potential new indications or labeling for Menveo or regarding potential future revenues from Menveo. 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 with Menveo 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 or regarding the timing of any such approvals. Nor can there be any guarantee that Menveo will achieve any particular levels of revenue in the future. In particular, management’s expectations regarding Menveo could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; 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.

### **About Novartis**

Novartis Vaccines and Diagnostics is a division of Novartis, focused on the development of preventive treatments. The division has two businesses: Novartis Vaccines and Novartis Diagnostics. Novartis Vaccines is the world's fifth-largest vaccines manufacturer

and second-largest supplier of flu vaccines in the US. The division's products also include meningococcal, pediatric and travel vaccines. Novartis Diagnostics, the blood testing business, is dedicated to preventing the spread of infectious diseases through the development of novel blood-screening tools that protect the world's blood supply.

Novartis provides healthcare solutions that address the evolving needs of patients and societies. Focused solely on healthcare, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, eye care, cost-saving generic pharmaceuticals, consumer health products, preventive vaccines and diagnostic tools. Novartis is the only company with leading positions in these areas. In 2010, the Group's continuing operations achieved net sales of USD 50.6 billion, while approximately USD 9.1 billion (USD 8.1 billion excluding impairment and amortization charges) was invested in R&D throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 119,000 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit <http://www.novartis.com>.

Novartis is on Twitter. Sign up to follow @Novartis at <http://twitter.com/novartis>.

## References

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