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## **Novartis Vaccines begins shipment of seasonal influenza vaccine Fluvirin® to U.S. market to help protect ahead of 2010-2011 flu season**

- *Novartis Vaccines plans to supply approximately 40 million doses of Fluvirin vaccine to support U.S. seasonal influenza vaccination in people 4 years of age and older*
- *CDC universally recommend annual seasonal flu vaccination for everyone 6 months of age and older for the first time starting with 2010-2011 flu season<sup>1</sup>*
- *Timely delivery of Fluvirin will allow for early vaccination of priority individuals, including seniors, pregnant women, those with chronic illnesses<sup>1</sup>*
- *A(H1N1) strain included in this year's seasonal influenza vaccine offering single vaccination to protect against all major circulating flu viruses*

**Cambridge, MA, July 29, 2010** — Novartis Vaccines has started shipping seasonal influenza vaccine to U.S. customers for the 2010-2011 season, allowing health care professionals to initiate protection of their patients well in advance of this year's flu season. The company plans to supply the U.S. market with approximately 40 million doses of Fluvirin® influenza virus vaccine, which has been approved by the U.S. Food and Drug Administration (FDA) for patients 4 years of age and older<sup>2</sup>. Fluvirin will be available to health care professionals in both pre-filled syringes and multi-dose vials.

The 2010-2011 season is the first year that the U.S. Centers for Disease Control and Prevention (CDC) recommend influenza vaccination for all people 6 months of age and older<sup>1</sup>. In previous seasons, the CDC recommended vaccination of high-risk individuals, including children 6 months through 18 years of age, individuals 50 years of age and older, adults at risk for medical complications from influenza and close contacts of high-risk individuals. This is the first year that the CDC has included a recommendation to routinely vaccinate all adults between 19 and 49 years of age. The CDC recommends that children between 6 months and 9 years of age receiving a flu vaccine for the first time receive two doses separated by at least 4 weeks<sup>3</sup>. Fluvirin is approved for use in patients 4 years of age and older.

"We are pleased to provide influenza vaccines in the U.S. ahead of schedule this season, meeting an essential public health need. Early vaccine delivery will ensure health care providers can protect as many individuals as possible against influenza, including those most at risk," said Andrin Oswald, Division Head of Novartis Vaccines and Diagnostics. "As part of our commitment to influenza protection, we accelerated our manufacturing timeline and increased supply in an effort to ensure physicians and public health officials are equipped to respond to greater demand for vaccines."

Certain individuals, including seniors, pregnant women, people with chronic illnesses, such as asthma, diabetes or heart disease, and healthcare workers, are considered at high-risk of having serious flu-related complications. The CDC advises that it is especially important for high-risk groups, as well as people who care for those at high-risk, to receive a flu vaccine each flu season<sup>1,4</sup>.

An estimated 36,000 people in the U.S. die each year from the flu and its complications and another 200,000 are hospitalized<sup>4,5</sup>. Early arrival of the seasonal influenza vaccine will allow public health officials to begin administering vaccinations weeks ahead of their normal schedule, which is in accordance with guidelines from the Advisory Committee on Immunization Practices (ACIP) of the CDC<sup>1,6</sup>. Federal health officials advise that the single best way to protect against the flu is to get vaccinated each year, and that in general anyone who wants to reduce their chances of getting the flu should get vaccinated<sup>1,3</sup>.

Fluvirin vaccine contains antigens to the three influenza virus strains for this year's vaccine recommended by the World Health Organization (WHO):

- A/California/7/2009 (H1N1)-like virus
- A/Perth/16/2009 (H3N2)-like virus
- B/Brisbane/60/2008-like virus<sup>7</sup>

This year, the WHO recommended the inclusion of A(H1N1) – represented by A/California/7/2009 (H1N1)-like virus – the pandemic flu strain that sickened millions in 2009-2010 in the seasonal influenza vaccine, so that people will be able to receive a single flu vaccination to protect against all of the major circulating flu viruses<sup>1,7</sup>. The unexpected emergence of the A/California/7/2009 (H1N1) strain last year prevented it from being included in the 2009-2010 seasonal influenza vaccine.

### **About seasonal influenza**

Seasonal influenza is a highly communicable, acute viral infection that predominantly attacks the respiratory tract and sometimes the lungs. It can cause mild to severe illness and can also lead to death<sup>4</sup>.

The number of people in the U.S. who die every year from the flu and its complications is comparable to the more than 40,000 people in the U.S. estimated to die from breast cancer every year<sup>9</sup> and to about half of the estimated 70,000 people who die annually of diabetes and its complications<sup>10</sup>. During the 2009-2010 seasonal influenza season, which was marked by the A(H1N1) pandemic flu outbreak, 276 children in the U.S. died from the flu between Aug. 30, 2009, and May 22, 2010 – 225 caused by A(H1N1), 50 associated with an influenza A virus for which the subtype was undetermined, and one influenza B infection<sup>8</sup>.

By comparison, in the U.S., 134 children died from the flu in the 2008-2009 flu season, 88 died in the 2007-2008 season, and 77 died in the 2006-2007 season<sup>8</sup>.

Influenza vaccination is one of the most effective public health interventions ever implemented, sparing millions of people from complications, including death, from the infectious disease. Use of currently available seasonal flu vaccines has been calculated to save more than 8 million lives annually worldwide, translating to one person saved every five seconds<sup>11</sup>.

### **Important safety information**

Serious allergic reactions, including anaphylactic shock, have been observed in people receiving Fluvirin Influenza Virus Vaccine. Fluvirin vaccine should not be administered to individuals with a history of systemic hypersensitivity reaction to eggs or egg proteins or

other components of Fluvirin vaccine, including thimerosal, or to anyone who has had a life-threatening reaction to previous influenza vaccination. In clinical trials, the most common adverse events in adults were headache, fatigue, injection site reactions (pain, mass, redness, and induration), and malaise. These adverse events were generally mild/moderate and transient. Vaccination with Fluvirin vaccine may not protect all individuals who are susceptible to influenza. Immunocompromised persons, including individuals receiving immunosuppressive therapy, may have a reduced immune response to Fluvirin vaccine. If Guillain-Barré syndrome has occurred within 6 weeks of receipt of prior influenza vaccine, the decision to use Fluvirin vaccine should be based on careful consideration of the potential benefits and risks. All people, including those who are pregnant, nursing, and/or taking other medications, should consult their healthcare providers before receiving Fluvirin vaccine.

### **Disclaimer**

The foregoing release contains forward-looking statements that can be identified by terminology such as “plans,” “will,” “commitment,” “can,” or similar expressions, or by express or implied discussions regarding Novartis’ potential production output for its Fluvirin vaccine, or regarding potential future revenues from Fluvirin. 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 Fluvirin to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Novartis will achieve any particular production output for its Fluvirin vaccine. Nor can there be any guarantee that Fluvirin will achieve any particular levels of revenue in the future. In particular, management’s expectations regarding Fluvirin 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; unexpected manufacturing difficulties or delays; the company’s ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry and general public pricing pressures; 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 and molecular diagnostics 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, cost-saving generic pharmaceuticals, preventive

vaccines, diagnostic tools and consumer health products. Novartis is the only company with leading positions in these areas. In 2009, the Group's continuing operations achieved net sales of USD 44.3 billion, while approximately USD 7.5 billion was invested in R&D activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 102,000 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit <http://www.novartis.com>.

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