

**MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG****Novartis receives approval in Switzerland for Celtura<sup>®</sup>, a cell culture-based Influenza A(H1N1) pandemic vaccine**

- *Swissmedic approval allows Novartis to begin shipments of Celtura to Switzerland, providing supplies of A(H1N1) vaccine immediately*
- *Approvals in Germany and Switzerland demonstrate expanded adoption of new cell culture technology -- an important milestone in replacing 50 year-old egg-based influenza vaccine production with modern biotechnology*
- *Clinical trials in more than 1,900 individuals across all age groups demonstrate that the vaccine was well tolerated and elicited a strong immune response*

**Basel, November 13, 2009** — Novartis announced today that Celtura<sup>®</sup>, the company's adjuvanted cell culture-based Influenza A(H1N1) 2009 monovalent vaccine, has received approval in Switzerland from Swissmedic, the Swiss Agency for Therapeutic Products. This is the second marketing approval for the cell-culture based A(H1N1) pandemic vaccine in Europe. Celtura was approved in Germany earlier in November 2009. The company also has submitted a registration for Celtura in Japan, and will seek approval in a number of other countries.

Celtura is an MF59<sup>®</sup> adjuvanted inactivated influenza virus vaccine, approved by Swissmedic for the active immunization of persons three years of age and older against influenza disease caused by the novel pandemic A(H1N1) influenza virus. The vaccine will be available in Switzerland in pre-filled syringes and contains 3.75 micrograms (µg) of antigen and 0.125 ml of MF59<sup>®</sup>.

Clinical trials conducted in more than 1,900 subjects evaluated Celtura's tolerability and immunogenicity. The studies showed that even with the lowest antigen content (3.75µg), a single Celtura dose can induce immune responses associated with protection against Influenza A(H1N1) in children over three and adults up to 40 years old. Safety and tolerability profiles showed the cell culture-derived influenza vaccine had a similar safety profile to adjuvanted egg-based vaccines approved by the European Medicines Agency (EMA). Local injection site (redness, swelling and pain) and systemic complaints of mild fever, headache and fatigue were the most frequent side effects reported and were of short duration.

"Cell-based flu vaccine production is cleaner and potentially faster than egg-based technologies," said Andrin Oswald, CEO of Novartis Vaccines and Diagnostics. "After Germany, Switzerland will be the second country in the world to benefit from our R&D investments aimed at improving the quality and speed of flu vaccine manufacturing. Our vaccine production capacity has now grown significantly at our licensed facility in Marburg, Germany. We are nearing completion of a second manufacturing site for cell culture-based influenza vaccines in the United States. This new facility was built in partnership with the US Department of Health and Human Services (HHS), in Holly Springs, North Carolina<sup>1</sup>."

Novartis has invested significant resources to increase production of much-needed A(H1N1) pandemic vaccine through cell culture-based manufacturing technology. Celtura uses a validated cell culture line for production of viral antigen components rather than the traditional method of chicken eggs. The technology has previously been licensed in Europe for the production of Novartis' seasonal flu vaccine, Optaflu®.

Celtura contains Novartis proprietary adjuvant, MF59 which has an established safety profile supported by more than 12 years of clinical safety data in Europe and more than 45 million doses of commercial use in the influenza vaccine Flud® (licensed in Europe).

Novartis has already begun delivery of the company's egg-based pandemic vaccines: A(H1N1) monovalent vaccine to the US, manufactured using Novartis' established seasonal Fluvirin® platform, and Focetria® A(H1N1) monovalent vaccine to countries around the world. The US Food and Drug Administration approved the former A(H1N1) vaccine on September 15, 2009, and the EMEA approved the Focetria A(H1N1) vaccine on September 29, 2009.

### **Disclaimer**

The foregoing release contains forward-looking statements that can be identified by terminology such as "will," "can," "potentially," or similar expressions, or by express or implied discussions regarding potential additional marketing approvals for Novartis' A(H1N1) vaccines, potential future deliveries of influenza vaccines, or regarding potential future revenues from influenza 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 Novartis' A(H1N1) vaccines will be approved for sale in any additional countries. Nor can there be any guarantee that Novartis will successfully meet its delivery obligations for its influenza vaccines. Neither can there be any guarantee that Novartis' influenza vaccines will achieve any particular levels of revenue in the future. In particular, management's expectations regarding Novartis' influenza vaccines could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; unexpected manufacturing difficulties or delays, including continued unexpected difficulties with seed virus yields, and unexpected difficulties with our flu cell culture manufacturing facility and processes; unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; 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 prevents the spread of infections through the development and marketing of innovative technologies

that enable early detection of pathogens to protect the world's blood supply and prevent the spread of infectious diseases.

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 each of these areas. In 2008, the Group's continuing operations achieved net sales of USD 41.5 billion and net income of USD 8.2 billion. Approximately USD 7.2 billion was invested in R&D activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 99,000 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit <http://www.novartis.com>.

## References

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