

**MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG**

## **Novartis successfully demonstrates capabilities of cell-based technology for production of A(H1N1) vaccine**

- *First results achieved with A(H1N1) wild type strain shows significant time savings of cell-based production over egg-based manufacturing approach confirming its value in pandemic situations.*
- *Based on this success Novartis expects to be able to achieve rapid production and scale up of influenza A(H1N1) vaccine manufacture with reassortant seed.*
- *More than thirty governments have made influenza A(H1N1) vaccine supply requests to Novartis for cell-based and egg-based antigen and MF59<sup>®</sup>.*

**Basel, June 12 2009** — Novartis has successfully completed the production of the first batch of influenza A(H1N1) vaccine, weeks ahead of expectations. Cell-based manufacturing technology<sup>1</sup> allows vaccine production to be initiated once a pandemic virus strain is identified without the need to adapt the virus strain to grow in eggs, as with traditional vaccine technologies. This advance has cut weeks off the time required to begin vaccine production. This first batch of ten liters of wild type influenza A(H1N1) vaccine monobulk will be used for pre-clinical evaluation and testing and is also being considered for use in clinical trials. It demonstrates the value of the cell-based production approach, that is also being used by Novartis with reassortant influenza A(H1N1) seed.

The Novartis state of the art cell-culture vaccine production facility is located in Marburg, Germany. As well as speed, another advantage of cell-based production is the ability to rapidly increase production, so the facility has the potential to produce millions of doses of vaccine each week. A second facility, in collaboration with the US Department of Health and Human Services, is under construction in Holly Springs, North Carolina<sup>1</sup>.

“The speed advantages of our cell-based production approach and our unwavering commitment to address this public health emergency have resulted in our ability to provide the fastest possible response to this outbreak,” said Dr. Andrin Oswald, CEO of Novartis Vaccines and Diagnostics. “This achievement is also a testament to the technical skills and innovation of Novartis Vaccines and Diagnostics people and our partners. I believe it highlights our reputation as a leader in influenza vaccine research, development and production.”

Based on this success with the wild type, Novartis expects to be able to achieve rapid scale up of influenza A(H1N1) vaccine manufacture with reassortant seed which was provided by the Centers for Disease Control and Prevention (CDC) on May 27<sup>th</sup>. The company plans to start clinical trials with that vaccine in July and expects licensure in the fall of 2009.

### **More than thirty supply requests received from Governments**

More than 30 governments have made requests to Novartis to supply them with influenza A(H1N1) vaccine ingredients. These are a combination of pre-existing

pandemic vaccine supply agreements and new requests for vaccines across all our production platforms including egg-based manufacturing. The US Department of Health and Human Service's \$289 million order in May 2009<sup>1</sup> with Novartis was the largest of the US government's commitments to influenza A(H1N1) vaccine ingredients. That order included Novartis proprietary adjuvant MF59<sup>®</sup>, which can be added to influenza vaccines to help stimulate the human body's immune response to the vaccine. Data published in April 2009 in the *Proceedings of the National Academy of Sciences of the United States of America* reinforced the potentially broad applicability of MF59. MF59 is the only influenza adjuvant with an established safety profile which is supported by more than ten years of clinical safety data in Europe, and more than 40 million doses of commercial use in the influenza vaccine Fluad<sup>®</sup>. Fluad is licensed in Europe but not the US.

The Novartis pandemic vaccine developmental program began in 1997 under the leadership of Dr. Rino Rappuoli who is Head of Research at Novartis Vaccines.

#### **Footnote**

1. Development of Novartis' cell-based influenza vaccine, construction of the cell-based influenza manufacturing facility at Holly Springs, NC and purchase of H1N1 antigen and adjuvant are being funded in whole or in part with Federal funds from the Office of Public Health Emergency Preparedness, Office of Research and Development Coordination, under Contract Numbers HHSO100200600012C, HHSO100200900101C and HHSO1002008000721, respectively.

#### **Disclaimer**

The foregoing release contains forward-looking statements that can be identified by terminology such as "will," "potential," "commitment," "expects," "plans", "can", "potentially", or similar expressions, or by express or implied discussions regarding potential marketing approvals for an influenza A(H1N1) vaccine, potential production timing and volumes for such a vaccine or regarding potential future revenues from such a vaccine. 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 influenza A(H1N1) vaccines will be approved for sale in any market. Nor can there be any guarantee that influenza A(H1N1) vaccines will be produced by any particular date, or in any particular volumes. Neither can there be any guarantee that influenza A(H1N1) vaccines will achieve any particular levels of revenue in the future. In particular, management's expectations 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; unexpected manufacturing difficulties or delays, including unexpected difficulties with our flu cell culture manufacturing facility and processes; 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 Novartis division focused on the development of preventive treatments. The division has two businesses: Novartis Vaccines and Chiron. 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. Chiron, 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 AG 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 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 98,000 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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