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## **Novartis Holly Springs cell culture influenza vaccine manufacturing facility first to be declared pandemic ready by US government**

- *State-of-the-art manufacturing facility utilizes cell culture flu manufacturing technology that could allow for quick response to an influenza pandemic*
- *Facility represents a public-private investment toward shared goals of helping to protect public health and better pandemic preparedness and response*
- *Site now employs more than 400 with plans to expand to more than 500 employees by end of 2012*

**Holly Springs, December 12, 2011** – Novartis and the US Department of Health and Human Services (HHS) Office of the Assistant Secretary for Preparedness and Response today announced the readiness of the Holly Springs, N.C., flu cell culture vaccine manufacturing facility to produce cell-based influenza vaccines that could be authorized by the U.S. Food and Drug Administration for emergency use during a pandemic. It is the first facility of its kind in the United States.

“Novartis is proud that our Holly Springs facility is the first of its kind in the United States, a testament to our commitment to help protect public health by providing innovative vaccines,” said Vas Narasimhan, MD, President, US Vaccines, Head, North America Vaccines. “We expect that this facility will play an important part toward ensuring a sufficient supply of flu vaccines in the event of a pandemic.”

At a ceremony today with Novartis officials, Dr. Robin Robinson and Dr. Nicole Lurie of HHS presented Novartis with a plaque commemorating the public-private partnership between the United States government and the company, through which the facility was built. North Carolina Governor Bev Perdue, Senator Richard Burr, Senator Kay Hagan and Congressman David Price joined the event to mark this important milestone.

The Novartis Holly Springs site consists of 6 connected buildings comprising 430,000 square feet of manufacturing, laboratory and office space on a 167-acre site. Total investment in the cell culture facility is nearly \$1 billion, through a collaboration between Novartis and HHS to support the design, construction, validation and licensing of flu manufacturing operations at the site. Its designation as pandemic ready highlights a key step in efforts to improve influenza vaccine manufacturing technology in the US and enhance domestic pandemic preparedness.

At Holly Springs, Novartis utilizes modern, cell culture-based manufacturing technology. In comparison to traditional egg-based vaccine production, cell culture-based production is better controlled and can be scaled up more quickly to respond to a pandemic.

In December, 2010, Novartis announced that it would invest an additional \$36 million for the construction of a development laboratory and pilot plant facility at Holly Springs. Construction began in February, 2011 and is on track to be completed in early 2012.

Novartis employs about 400 colleagues at the Holly Springs facility, with plans to expand to 500 by the end of 2012. Novartis works together with North Carolina State University's Biomanufacturing Training and Education Center (BTEC) program, BioNetwork's community college program, and multiple other university programs across the country to build a source of talent for future highly-skilled positions in the biopharmaceutical sector.

According to a 2011 report by the Pharmaceutical Research and Manufacturers of America (PhRMA), the biopharmaceutical sector is one of the most research-driven in the US. The biopharmaceutical industry spent \$67.4 billion on research and development in 2010, and invests as much as five times more in research and development, relative to their sales, than the average US manufacturing firm<sup>1</sup>.

### **Disclaimer**

The foregoing release contains forward-looking statements that can be identified by terminology such as "could," "plans," "commitment," "expect," "will," "on track," "plans," or similar expressions, or by express or implied discussions regarding the potential completion of the Holly Springs facility and the potential size of the work force there or its source; regarding the ability of the Holly Springs facility to respond in the event of a future pandemic; or regarding potential future revenues from the Holly Springs facility. 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 guarantees as to when the Holly Springs facility will be finally completed, or regarding the size of the workforce that will ultimately be employed there, or its source. Nor can there be any guarantees regarding the ability of the Holly Springs facility to respond quickly or at all in the event of a future influenza pandemic. Neither can there be any guarantee that Novartis will achieve any particular levels of revenue as a result of this approval. In particular, management's expectations 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, and unexpected reimbursement decisions; unexpected manufacturing issues; 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. This project has been funded in whole or in part with Federal funds from the Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, under Contract No. HHSO100200900101C.

### **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.

Located in Cambridge, Massachusetts, Novartis Vaccines and Diagnostics is an affiliate of Novartis AG, which provides innovative healthcare solutions that address the evolving needs of patients and societies. Headquartered in Basel, Switzerland, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, eye care, cost-saving generic pharmaceuticals, preventive vaccines and diagnostic tools, over-the-counter and animal health products. Novartis is the only global 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. Novartis Group companies employ approximately 121,000 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

1. The US Biopharmaceuticals Sector: Economic Contribution to the Nation. Prepared by the Battelle Technology Partnership Practice. Prepare for the Pharmaceutical Research and Manufacturers of America (PhRMA). July 2011.

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