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Novartis on track to deliver Influenza A (H1N1) vaccine for the US

- *Novartis on track to produce 90 million units of bulk antigen in line with commitment to US Department of Health and Human Services, despite very low yields of initial seed virus*
- *90 million units of bulk antigen expected to result in 60 million vaccine doses due to required overage and overfills in the filling process of multi-dose vials and pre-filled syringes*
- *To date, Novartis has shipped more than 7.5 million doses of Influenza A (H1N1) vaccines in multi-dose vials and pre-filled syringes ready to use, and expects to reach 25 to 30 million doses by the end of November*
- *Novartis also initiated deliveries against the 90 million doses of proprietary adjuvant, which could be used to double the amount of vaccine doses produced*

Basel, October 29, 2009 — Novartis confirmed today that it has shipped over 7.5 million doses of Influenza A(H1N1)¹ vaccine ready to use and expects 25 to 30 million doses of unadjuvanted vaccine to become available in pre-filled syringes and multi-dose vials by the end of November. Smaller changes in delivery timelines and volumes can result out of the variability of the underlying biological production process. The deliveries are in line with commitments made to the US Department of Health and Human Services (HHS).

In addition, the company is progressing with the production of its proprietary adjuvant MF59™ for the US. Adjuvants have shown to be antigen sparing and can double the number of vaccine doses produced.

“Overall, we are pleased with the progress achieved to date, given the many challenges and uncertainties of the current pandemic. Not only did we complete our commitment to provide seasonal vaccine ahead of schedule, we are making every effort to make as much H1N1 vaccine available as quickly as possible,” said Andrin Oswald, CEO of Novartis Vaccines and Diagnostics. “However, we acknowledge the limitations of the old manufacturing sites and technologies for influenza vaccines to rapidly respond to the needs of a pandemic. Over the last three years, Novartis has made major R&D investments to develop new technologies. And in partnership with HHS, we are building the first cell based flu manufacturing facility in the US. The opening of the site is planned later this year.”

Production of the H1N1 vaccine is progressing, despite the unexpected very low yields observed with the initial seed virus at 23 percent as compared to average yield seen with seasonal vaccines. Novartis started production with a new seed virus in the middle of September which provides an improved yield of 63 percent. To date, 42 million bulk units of vaccine have been produced. The company expects to complete production of 90 million doses of bulk antigen by December and will continue to rapidly fill-finish the bulk antigen as it is produced and ordered by HHS.

Novartis is fully utilizing its manufacturing capacity and has entirely dedicated one of its two major flu manufacturing sites, based in Liverpool, U.K., to supplying H1N1 vaccine antigen for the US. Production capacity at the Liverpool site has been maximized by hiring and training 300 additional staff, as well as the acceleration of the opening of a new facility and egg incubation unit at the site. Following a more than USD 200 million investment over three years, the additional facility was recently approved by the US Food and Drug Administration (FDA) as suitable to manufacture vaccines for the USA.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as “on track,” “commitment,” “expected,” “expects,” “could,” “planned,” “will,” or similar expressions, or by express or implied discussions regarding potential future deliveries of A (H1N1) vaccines, or regarding potential future revenues from A (H1N1) 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 with A (H1N1) vaccines to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that that Novartis will successfully meet its delivery obligations for its A (H1N1) vaccines. Nor can there be any guarantee that the A (H1N1) vaccines will achieve any particular levels of revenue in the future. In particular, management’s expectations regarding the A (H1N1) vaccines could be affected by, among other things, 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 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; 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 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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