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## Novartis MF59™-adjuvanted influenza vaccine (Fluad®) significantly reduces hospitalization in elderly

- *The influenza season coincides with high rates of cardiovascular-related and pneumonia related morbidity and mortality in elderly, emphasizing need for enhanced protection*
- *In this study, the Novartis vaccine Fluad® significantly reduced risk of hospitalization for pneumonia (by 69%), acute coronary syndrome (by 87%) and cerebrovascular accident (by 93%)*

Basel, [19 October] — Vaccinating elderly subjects with an MF59™-adjuvanted seasonal influenza vaccine (Fluad® from Novartis) resulted in a significant reduction in hospitalization for major conditions such as pneumonia, acute coronary syndrome (ACS) and cerebrovascular accident (CVA) during the influenza season. Data published in this week's international journal *Vaccine* illustrate the positive outcomes provided by an adjuvanted seasonal influenza vaccine.

These data support the efficacy of the MF59™-adjuvanted seasonal influenza vaccine in stimulating the immune system, especially in elderly people who have a waning immune system. The results also provide evidence of the relationship between influenza infection and the activation of undesirable atherosclerotic events. In addition, the relationship between influenza infection and increased susceptibility to *Streptococcus pneumoniae* (pneumonia) is well established.

“We see that the sustained protection provided by an adjuvanted vaccine against seasonal influenza in an elderly population shows promise for reduced hospitalization,” said Joan Puig-Barberá, Ph.D., M.P.H., M.D., lead study investigator, Center of Public Health of Castellón, Castellón, Spain. “As so many of these elderly people have a diminishing immune system and are often affected by serious medical conditions, providing improved influenza prevention during a time of increased vulnerability can be a major factor in boosting their overall health outcomes.”

Three studies were performed in the people greater than 64 years of age during the 2004-2005 influenza season in three health districts in Valencia, Spain. The districts included 105,454 subjects who received vaccination with MF59™-adjuvanted sub-unit influenza vaccine. Each case was paired with one or two controls; controls were matched for hospital, hospitalization date and gender. The risk of hospitalization after the start of the influenza season was significantly lower in vaccinated subjects compared with non-vaccinated subjects. Adjusted odds ratios were: 0.13 or 87 percent reduction, [p=0.013] for ACS; 0.07 or 93 percent reduction, [p=0.007] for CVA; 0.31 or 69 percent reduction, [p=0.005] for pneumonia.

“Novartis has been leading the adjuvanted influenza vaccine category since the introduction of Fluad® in 1997. This new study demonstrates the advantages seen, in terms of reductions in hospitalization, in a vulnerable population vaccinated with Fluad®. These

findings further validate previous data, from more than 25 million doses of Flud® administered, and support the improvement in efficacy seen with Flud® in the elderly,” said Joerg Reinhardt, Chief Executive Officer, Novartis Vaccines and Diagnostics. “Our proprietary adjuvant, MF59™, is also utilized in the development of our pandemic and pre-pandemic influenza vaccines.”

Puig-Barberá and colleagues published their study in *Vaccine* 16 October 2007, Volume 25: Issue 42, pages 7313-7321 (doi 10.1016/j.vaccine.2007.08.039). Elsevier Ltd. publishes *Vaccine*. Full article text can be found online at: [www.elsevier.com/locate/vaccine](http://www.elsevier.com/locate/vaccine).

### **About Flud®**

Flud®, the only MF59™-adjuvanted seasonal influenza vaccine, is licensed for active immunization against influenza in elderly subjects (65 years of age and over) in 12 European Union countries (Austria, Belgium, Denmark, France, Germany, Greece, Italy, Luxembourg, Portugal, Republic of Ireland, Spain and Sweden) with a Mutual Recognition Procedure and an additional 13 countries worldwide (Argentina, Australia, Czech Republic, Colombia, Croatia, Hong Kong, Mexico, Philippines, Republic of South Africa, Singapore, China, New Zealand and Thailand).

Flud® is registered under different brand names by Novartis Vaccines including Gripguard® in France and Chiromas® in Spain.

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### **About Novartis**

Novartis Vaccines and Diagnostics is a division of Novartis focused on the development of preventive treatments and tools. Novartis Vaccines is the world's fifth-largest manufacturer and second-largest supplier of influenza 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. For more information, please visit <http://www.novartisvaccines.com>.

Novartis AG (NYSE: NVS) is a world leader in offering medicines to protect health, cure disease and improve well being. Our goal is to discover, develop and successfully market innovative-products to treat patients, ease suffering and enhance the quality of life. We are strengthening our medicine-based portfolio, which is focused on strategic growth platforms in innovation driven pharmaceuticals, high-quality and low-cost generics, human vaccines and leading self-medication OTC brands. Novartis is the only company with leadership positions in these areas. In 2006, the Group's businesses achieved net sales of USD 37.0 billion and net income of USD 7.2 billion. Approximately USD 5.4 billion was invested in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 100,000 associates and operate in over 140 countries around the world.

For more information, please visit <http://www.novartis.com>.

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### **Novartis Media Relations**

#### **John Gilardi**

Novartis Global Media Relations  
+41 61 324 3018 (direct)  
+41 79 596 1408 (mobile)  
[john.gilardi@novartis.com](mailto:john.gilardi@novartis.com)

#### **Beth Birke**

Novartis Global Vaccines Communications  
+1-617 871 4281 (direct)  
+1-617 803 4359 (mobile)  
[beth.birke@novartis.com](mailto:beth.birke@novartis.com)

e-mail: [media.relations@novartis.com](mailto:media.relations@novartis.com) or [nvd.communications@novartis.com](mailto:nvd.communications@novartis.com)

### **Novartis Investor Relations**

#### **International**

**Ruth Metzler-Arnold**  
Katharina Ambuehl  
Nafida Bendali  
Pierre-Michel Bringer  
Jason Hannon  
Thomas Hungerbuehler  
Richard Jarvis

#### **North America**

**Ronen Tamir** +1 212 830 2433  
Jill Pozarek +1 212 830 2445  
Edwin Valeriano +1 212 830 2456

Central phone no: +41 61 324 7944

e-mail: [investor.relations@novartis.com](mailto:investor.relations@novartis.com)

e-mail: [investor.relations@novartis.com](mailto:investor.relations@novartis.com)

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