

**R&D for Avian / Pandemic Influenza Vaccines by IFPMA Influenza Vaccine Supply International Task Force (IVS ITF) members**

(Updated 1 May 2006)

#	Company (Site Location)	Strain	Type	Culture	Adjuvant	Doses (µg)	Trials	Timing	Additional Information
1	Baxter (Austria)	H5N1 Wild type (A/Vietnam/120 3/2004)	Inactivated Whole virion	Cell Vero	Alum	3.7 / 7.5 / 15 / 30 / 45	Ph I&II	Start: Q2 2006	
2	Berna Biotech - CruceIl Company (Switzerland)*	H9N2	Inactivated Whole virion	Egg	Alum	1.7 / 5 / 15 / 45***	Ph II	Start: 2006 End: Q4 2006	2 doses * with Leicester University ** Formulated with Virosomes as a carrier/adjuvant system *** Intramuscular **** Intradermal
			Inactivated Whole virion	Egg	None	5 / 15****			
			Virosome**	Egg	**	1.7 / 5 / 15 / 45***			
3	Biken (Japan)*	H5N1 (NIBRG-14)	Inactivated Whole virion	Egg	Alum	1.7 / 5 / 15	Ph I	Start: Mar. 2006 End: July 2006	Intramuscular + subcutaneous Ph II & III Q3-4 2006 * with NIID
4	Chiron Vaccines (Italy)	H5N3 (A/duck/Singap ore/1997, NIB 40)	Inactivated Surface antigen	Egg	MF59	7.5 / 15 / 30	Ph I	End: 2000	<ul style="list-style-type: none"> <li>• <i>Lancet</i> 2001 357: 1937-1943</li> <li>• <i>Vaccine</i> 2003 21: 1687-1693</li> <li>• <i>JID</i> 2005 191: 1210-1215</li> </ul>
5	Chiron Vaccines / Novartis Vaccines (Italy)	H9N2 (G9/PR8)	Inactivated Surface antigen	Egg	MF59	3.75 / 7.5 / 15 / 30	Ph I&II* Adult**	Start: Mar. 2005 End: Nov. 2005	2 doses Mock-up file submitted to EMEA Jan. 2006 * Trial conducted by NIAID ** 18-34 year olds
6	Chiron Vaccines / Novartis Vaccines (UK)	H5N1 (A/Vietnam/120 3/2004)	Inactivated Surface antigen	Egg	MF59	7.5 / 15	Ph I&II* Adult**	Start: Mar. 2006 End: Jul. 2006	2 doses * Trial conducted by NIAID ** 18-64 year olds

© 2006 IFPMA - Note: where an adjuvant is employed, standard practice is to evaluate it against the same vaccine without an adjuvant. Where alum is indicated as adjuvant, this refers to aluminum salt; AlPO<sub>4</sub> is aluminum phosphate. The dose, in µg, refers to the volume of haemagglutinin (HA).

NIAID: National Institute of Allergy and Infectious Diseases (USA) <http://www3.niaid.nih.gov/>

NIID: National Institute of Infectious Diseases (Japan) <http://www.nih.go.jp/niid/index-e.html>

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7	Chiron Vaccines / Novartis Vaccines (Italy)	H5N1 (NIBRG-14)	Inactivated Surface antigen	Egg	MF59	7.5 / 15	Ph II*	Start: Q1 2006	* Trial conducted by Novartis Vaccines
8	CSL Limited (Australia)	H5N1 (NIBRG-14)	Inactivated Split virus	Egg	AlPO <sub>4</sub>	7.5 / 15 (1 <sup>st</sup> set*) 30 / 40 (2 <sup>nd</sup> set**)	Ph I Adult***	Start: Oct. 2005 End: Jan. 2007	* 1 <sup>st</sup> set results announced Feb 2006 ** 2 <sup>nd</sup> set testing in broader population to commence mid-2006 *** 18-45 year olds
9	Denka Seiken (Japan)*	H5N1 (NIBRG-14)	Inactivated Whole virion	Egg	Alum	1.7 / 5 / 15	Ph I	Start: Mar. 2006 End: July 2006	Intramuscular + subcutaneous Ph II & III Q3-4 2006 * with NIID
10	GSK Biologicals (Germany)	H2N2	Inactivated Whole virion	Egg	Alum	1.9 / 3.8 / 7.5 / 15	Ph I&II	Trials finished	Mock-up file submitted to EMA Dec. 2005
11	GSK Biologicals (Germany)	H9N2	Inactivated Whole virion	Egg	Alum	1.9 / 3.8 / 7.5 / 15	Ph I&II	Trials finished	Mock-up files submitted to EMA Dec. 2005
12	GSK Biologicals (Canada & Germany)	H5N1	Inactivate Whole virion	Egg	Alum	3.8 / 7.5 / 15 / 30	Ph II Adult*	Start: Mar. 2006	2 doses * 18-60 year olds
13	GSK Biologicals (Canada & Germany)	H5N1	Inactivated Split virus	Egg	yes*	3.8 / 7.5 / 15 / 30	Ph I&II Adult**	Start: Mar. 2006	2 does * Novell Adjuvant ** 18-60 year olds
14	Kaketsuken (Japan)*	H5N1 (NIBRG-14)	Inactivated Whole virion	Egg	Alum	1.7 / 5 / 15	Ph I	Start: Mar. 2006 End: July 2006	Subcutaneous Ph II & III Q3-4 2006 * with NIID

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15	Kitasato Institute (Japan)*	H5N1 (NIBRG-14)	Inactivated Whole virion	Egg	Alum	1.7 / 5 / 15	Ph I	Start: Mar. 2006 End: July 2006	Intramuscular + subcutaneous Ph II & III Q3-4 2006 * with NIID
16	MedImmune (USA)*	H5N1 (A/Vietnam/120 3/2004)	Live attenuated	Egg	None	Intranasal	Ph I	Start: 2006	* CRDA with NIAID (Collaborative Research & Development Agreement)
17	MedImmune (USA)*	H5N1 (A/HongKong/4 92/1997)	Live attenuated	Egg	None	Intranasal	Ph I	Start: 2006	* CRDA with NIAID
18	MedImmune (USA)*	H9N2	Live attenuated	Egg	None	Intranasal	Ph I	End: 2005 Expanded Ph I start in 2006	* CRDA with NIAID
19	MedImmune (USA)	H5N1	Live attenuated	Cell	None	Intranasal	Pre- clinical		
20	Merck & Co. Inc (USA)	M-2	Conserved Protein	Cell	None		Ph I	Start: 2006	
21	Nobilon International BV (Netherlands)	H5N1 (NIBRG-14)	Inactivated Whole virion	Cell	Alum	3.8 / 7.5 / 15 / 30	Ph I&II	Start: Q4 2006	
22	sanofi pasteur (France)	H5N1	Inactivated Split virus	Egg	Alum	7.5 / 15 / 30	Ph II*	Start: Q2 2006	* Ph I completed in 2005
23	sanofi pasteur (USA)	H5N1	Inactivated Split virus	Egg	None	7.5 / 15 / 45 / 90	Ph I&II* Adult**	Start: April 2005 End: Feb. 2006	2 doses * Trial conducted by NIAID ** 18-64 year olds
24	sanofi pasteur (USA)	H5N1	Inactivated Split virus	Egg	None		Ph I&II* Elderly**	Start: Oct. 2005 End: Aug. 2006	* Trial conducted by NIAID ** > 65 year olds

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#	Company (Site Location)	Strain	Type	Culture	Adjuvant	Doses (µg)	Trials	Timing	Additional Information
25	sanofi pasteur (USA)	H5N1	Inactivated Split virus	Egg	None	7.5 / 15 / 45 / 90	Ph I&II* Child**	Start: Jan. 2006 End: Feb. 2007	* Trial conducted by NIAID ** 2-10 year olds
26	sanofi pasteur (USA)	H5N1	Inactivated Split virus	Egg	Alum	7.5 / 15 / 45	Ph I* Adult	2006	* Trial conducted by NIAID
27	sanofi pasteur (USA)	H5N1	Inactivated Split virus	Egg	None	*	Ph I** Adult	2005	* Intramuscular vs Intradarmal **Trial conducted by NIAID
28	sanofi pasteur (USA)	H7N7	Inactivated Split virus	Egg	Alum		Ph I* Adult	2006	* Trial conducted by NIAID
29	sanofi pasteur (France)*	H7N1	Inactivated Split virus	Cell	Alum		Ph I Adult	2006	* with EU Flupan Project <a href="http://www.nibsc.ac.uk/spotlight/fluplan/">http://www.nibsc.ac.uk/spotlight/fluplan/</a>
30	Solvay Pharmaceuticals (Netherlands)	H5N1	Inactivated Surface antigen	Egg	Alum	To be determined	Ph I Adult*	Start: Q4 2006	* 18-49 year olds
31	Solvay Pharmaceuticals (Netherlands)	H5N1	Inactivated Surface antigen	Cell MDCK	Alum	To be determined	Ph I Adult*	Start: Q3 2006	* 18-49 year olds

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## R&D for Avian / Pandemic Influenza Vaccines by IFPMA Influenza Vaccine Supply International Task Force (IVS ITF) members

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### About the Pandemic R&D table:

The table lists all the prototype avian / pandemic influenza vaccines under development by IFPMA Influenza Vaccine Supply International Task Force member companies. As such, it covers the vast majority of R&D projects being undertaken in this field. The number of projects and the commitment of these companies to undertake the necessary clinical trials underline the innovative vaccine industry's commitment to help minimize the global health impact of avian and pandemic influenza.

The 28 avian/pandemic vaccine projects listed in January 2006 have now increased to 31, conducted by 15 manufacturers, located in Australia, Austria, Canada, France, Germany, Italy, Japan, the Netherlands, Switzerland, UK and USA. sanofi pasteur has no less than eight different vaccine trials either recently completed or underway. Altogether, eleven Phase II Clinical trials are either on-going or planned for 2006. Three prototype vaccines, one from Chiron / Novartis and two from GSK, have been submitted as "Mock Up" dossiers for approval by the EU regulatory authority (EMEA).

The majority of projects target specific strains of influenza virus (H2N2, wild type H5N1, H5N1, H5N3, H7N1, H7N7, H9N2), but Merck focuses on development of a universal influenza vaccine, using a M-2 peptide conjugate protein. Among the influenza strain-targeted projects, 26 use an inactivated virus (10 using whole virus, 10 split virus, 6. surface antigen), and 4 use a live attenuated virus.

Almost all use a traditional injection delivery system, while MedImmune uses a nasal spray. Sixteen projects use Aluminum salt as an adjuvant. Berna/Crucell uses a virosome carrier/adjuvant system; CSL, Aluminum phosphate; Chiron/Novartis, MF59 and GSK, a novel adjuvant system. Twenty-five projects use the traditional egg culture technology currently used to manufacture seasonal influenza vaccines, while 6 use cell culture systems.

### About the IFPMA ([www.ifpma.org](http://www.ifpma.org)):

The International Federation of Pharmaceutical Manufacturers & Associations is the global non-profit NGO directly representing twenty-six research-based pharmaceutical, biotech and vaccine companies and sixty national industry associations in developed and developing countries. The industry's R&D pipeline contains hundreds of new medicines and vaccines being developed to address global disease threats, including cancer, heart disease, HIV/AIDS and malaria. The IFPMA Clinical Trials Portal ([www.ifpma.org/clinicaltrials](http://www.ifpma.org/clinicaltrials)) and the IFPMA Health Partnerships Survey help make the industry's activities more transparent. The IFPMA strengthens patient safety by improving risk assessment of medicines and combating their counterfeiting. It also provides the secretariat for the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).

### About the IFPMA Influenza Vaccine Supply International Task Force:

The IFPMA Influenza Vaccine Supply Interventional Task Force (IVS ITF), established in February 2002, brings together research-based influenza vaccine manufacturers from around the world, which are conducting the R&D necessary to develop safe, effective, high-quality vaccines against avian and pandemic influenza threats. The IVS ITF works within the constraints of anti-trust law to address the advocacy, communication, policymaking, regulatory, scientific and technical issues related to inter-pandemic and pandemic influenza vaccines. IVS ITF members are committed to make their unique expertise in R&D, logistics, manufacturing, safety and regulatory issues available to help governmental and intergovernmental bodies in pandemic planning and decision-making.

For more information, see: [http://www.ifpma.org/pdf/pandemic\\_backgroundunder\\_23\\_01\\_06.pdf](http://www.ifpma.org/pdf/pandemic_backgroundunder_23_01_06.pdf)

IFPMA IVS ITF members are: Baxter, Berna Biotech (a Crucell Company), Biken, CSL Limited, Crucell, Denka Seiken, GlaxoSmithKline Biologicals (including former ID Biomedical), Kaketsuken, Kitasato Institute, MedImmune, Nabilon International BV, Novartis Vaccines and Diagnostics (former Chiron Vaccines), sanofi pasteur, Sanofi Pasteur MSD and Solvay Pharmaceuticals.

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