

392 Influenza Vaccine Products, H5N1

- Extracted from [Biopharmaceutical Products in the U.S. and European Markets](#), the only biopharmaceuticals reference database/book. Visit www.biopharma.com for more information. See also the [description/flyer](#), copies of [reviews](#), and the public [products database](#) and [products database](#). Contact the [author/publisher](#) for further information about database subscriptions and book purchases.

- **Pandemic Influenza vaccine, surface antigen, inactivated; influenza virus H5N1, inactivated, vaccine; bird flu vaccine; avian influenza vaccine; pandemic influenza vaccine;**
- **Company roles:**
 - [Misc. products manufacturers](#) --
- **Monograph size** = 32484 characters (not including indexing, nomenclature, links, etc. on this page)

- ***Partial monograph text:***

392 Influenza H5N1 Vaccine Products influenza virus H5N1, inactivated, vaccines; bird flu

vaccines; avian influenza vaccines; pandemic influenza vaccines

Cross Ref.: See the entries below concerning currently approved pandemic influenza vaccines and those being added to the U.S. stockpile. See the Influenza Vaccine Products entry.

Description: Various vaccines are in development and some have received approval (essentially conditional) for use in case of an epidemic or pandemic caused by avian (bird) H5N1 strains of influenza virus (bird flu). Influenza H5N1 is spreading worldwide among birds and poultry, and is expected to sooner or later mutate and become infectious and communicable in humans by the inhalation route (i.e., become airborne). With no prior exposure or immunity to type H5N1 viruses in the general populace anywhere in the world, with the advent of human-to-human transmissible inhalable H5N1, serious epidemics and even a worldwide

pandemic could result.

So far, few humans have been infected with H5N1, generally by occupational direct contact with infected birds. Among these generally relatively healthy farmers and poultry workers, there is commonly a rapid onset of symptoms and about 20% mortality (i.e, a ... **truncated (just the beginning)**)

- **Nomenclature:**
- Influenza H5N1 Vaccine Products [BIO]
- Pandemic Influenza vaccine, surface antigen, inactivated [EU]
- bird flu vaccines [SY]
- influenza vaccines, pandemic [SY]
- influenza virus H5N1, inactivated, vaccine [SY]
- influenza virus H5N1, inactivated, vaccines [SY]

- **Index Terms:**

Product Class Index:

- biopharmaceutical products
- chicken source materials
- influenza vaccines, pandemic
- vaccines, inactivated
- vaccines, subunit
- vaccines, viral

- SB001 BIOPHARMA prod. (mainstream)

Regulatory/Status Index:

- EU666 Biodefense stockpile
- UM100 Controlled/Gov't Distribution in US
- US666 Biodefense stockpile
- EM160 Controlled/Gov't Distribution in EU

Biological Index:

- influenza virus, H5N1
- virus culture

393 Influenza Vaccine, H5N1/GSK

- Extracted from [Biopharmaceutical Products in the U.S. and European Markets](#), the only biopharmaceuticals reference database/book. Visit www.biopharma.com for more information. See also the [description/flyer](#), copies of [reviews](#), and the public [products database](#) and [products database](#). Contact the [author/publisher](#) for further information about database subscriptions and book purchases.

- **Prepandrix; Pandemrix - influenza virus H5N1, inactivated, vaccine, with AS03 adjuvant; bird flu vaccine; avian influenza vaccine; pandemic influenza vaccine**
- **Company roles:**
 - [Centers for Disease Control and Prevention \(CDC\)](#) -- R&D ; Tech. ; USA mark.
 - [GlaxoSmithKline Biologicals S.A. \(GSK\)](#) -- Manuf. ; R&D ; Tech. ; Europe mark.
 - [GlaxoSmithKline plc \(GSK\)](#) -- Parent
- **Monograph size** = 15988 characters (not including indexing, nomenclature, links, etc. on this page)

- ***Partial monograph text:***

393 Influenza Vaccine, H5N1/GSK Pandemic Influenza vaccine, surface antigen, inactivated; influenza vaccine, pandemic - Prepandrix; Pandemrix; influenza virus H5N1 vaccine; bird flu vaccine; influenza virus H5N1, inactivated, vaccine; avian influenza vaccine; influenza H5N1 virus (A/Indonesia) vaccine
Status: vaccine approved in EU in May 2008; being added to U.S. and other countries' stockpiles
Organizations involved:
GlaxoSmithKline Biologicals S.A. - Manuf.: R&D; Tech.; Europe mark.
GlaxoSmithKline plc - Parent
Centers for Disease Control & Prevention (CDC) - R&D; Tech.; U.S.

mark..

Description: Prepandrix "prepandemic vaccine" is a conventional egg-cultured influenza virus H5N1 (A/VietNam/1194/2005 NIBRG-14) clade 2 inactivated split-antigen vaccine. The H5N1 clade 2 bulk material is being manufactured from a laboratory version seed virus of the wild-type virus provided by the U.S. Centers for Disease Control and Prevention (CDC). The reference virus, A/Vietnam/1194/2004 (H5N1) NIBRG-14, was developed using reverse genetics, with reassortment strain combining the H5 and N1 segments to with an influenza virus PR8 strain backbone. In addition the H5 was engineered to eliminate the polybasic stretch of amino-acids at the HA cleava ... **truncated (just the beginning)**

- **Nomenclature:**

- Influenza Vaccine, H5N1/GSK [BIO]
- Prepandrix [TR]
- Pandemrix [TR]
- Pandemic Influenza vaccine, surface antigen, inactivated [EU]
- Prepandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted) A/VietNam/1194/2004 NIBRG-14 [EU]
- Pandemic influenza vaccine (H5N1) (split, inactivated, adjuvanted) [EU]
- avian influenza vaccine [SY]
- bird flu vaccines [SY]
- influenza H5N1 virus (A/Indonesia)vaccine [SY]
- influenza vaccine, pandemic [SY]
- influenza virus H5N1, inactivated, vaccine with AS03 adjuvant [SY]

- **Index Terms:**

[Product Class Index:](#)

- biopharmaceutical products
- bovine materials used<!-- bovinesource -->
- chicken source materials
- vaccines, inactivated
- vaccines, subunit
- vaccines, viral

- SB001 BIOPHARMA prod. (mainstream)

Regulatory/Status Index:

- EU200 Currently Approved in EU
- **EU666 Biodefense stockpile**
- UM100 Controlled/Gov't Distribution in US
- **US666 Biodefense stockpile**
- EM160 Controlled/Gov't Distribution in EU

Biological Index:

- chicken embryos (eggs)
- influenza virus, H5N1
- virus culture

Chemical Index:

- alpha-tocopherol
- aluminum adjuvant
- AS03 adjuvant
- Daronrix
- disodium phosphate
- formaldehyde
- magnesium chloride
- octoxynol 10
- polysorbate 80 (Tween 80)
- potassium chloride
- potassium dihydrogen phosphate
- sodium chloride
- sodium deoxycholate
- squalene
- thiomersal
- vitamin E

<http://208.69.231.70/biopharma/full7.lasso?Order=486&S=x&-token=none&-nothing>

394 Influenza Vaccine, H5N1/MedImmune

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- **influenza virus H5N1, inactivated, intranasal, recombinant, cell cultured vaccine; CAIV-T (H5N1); FluMist (H5N1); bird flu vaccine; avian influenza vaccine; pandemic influenza vaccine**

- **Company involvement:**

- [MedImmune, Inc.](#) -- Manuf. ; R&D ; Tech.
- [AstraZeneca plc](#) -- Parent
- [St. Jude Children's Research Hospital](#) -- Tech.
- [University of Wisconsin](#) -- Tech.
- [Mount Sinai School of Medicine](#) -- Tech.
- [Centers for Disease Control and Prevention \(CDC\)](#) -- USA mark.

- **Monograph size** = 6720 characters (not including indexing, nomenclature, links, etc. on this page); What you would see, if you had a subscription.

- ***Partial monograph text:***

Influenza Vaccine, H5N1/MedImmune influenza virus H5N1, inactivated, intranasal, recombinant, cell cultured vaccine; CAIV-T (H5N1); FluMist (H5N1); bird flu vaccine; avian influenza vaccine; pandemic influenza vaccine

Status: being added to U.S. stockpile

Organizations involved:

MedImmune, Inc. - Manuf.; R&D; Tech.

Astra Zeneca plc - Parent

Centers for Disease Control & Prevention (CDC) - U.S. mark.

Mount Sinai School of Medicine - Tech.

University of Wisconsin (WARF) - Tech.

St. Jude Children's Research Hospital - Tech.

Cross ref.: See the Influenza Vaccine, live rDNA, liquid (current FluMist

formulation) and Influenza Vaccine, live rDNA, frozen (original FluMist formulation) entries (#190 and #191, respectively) for further information about the current and original seasonal versions of this vaccine. See the Influenza Vaccine Products entry (#470).

Description: MedImmune is developing cell cultured H5N1 vaccines using its using its proprietary live, attenuated, needle-free, intranasally-administered influenza vaccine (CAIV-T/FluMist) technology, i.e., attenuated (natural recombinant), live influenza antigen is formulated for administration by intranasal spray. The seed influenza virus H5N1 strains used are and will be developed using MedImm ... **truncated (just the beginning)**

- **Nomenclature:**
- Influenza Vaccine, H5N1/MedImmune [BIO]
- avian influenza vaccine [SY]
- bird flu vaccines [SY]
- CAIV-T (H5N1) [SY]
- Cold Adapted Influenza Vaccine (Liquid Formulation) (H5N1 formulation) [recombinant] [SY]
- FluMist (H5N1) [SY]
- influenza virus H5N1, inactivated, intranasal, vaccine [SY]
- influenza virus H5N1, inactivated, vaccine [SY]
- Pandemic Influenza vaccine, surface antigen, inactivated [SY]

- **Index Terms:**

[Product Class Index:](#)

- biopharmaceutical products
- chicken source materials
- influenza vaccines, pandemic
- **live microorganisms** (as active agent)
- mammalian cells/tissue/organism source
- recombinant DNA
- **vaccines, intranasal**
- **vaccines, live**
- **vaccines, viral**

[Regulatory/Status Index:](#)

- biodefense stockpile (U.S.)
- Collaborative R&D Agreements (CRADA)
- controlled/gov't distribution in U.S.
- not available, currently, in EU or European countries (not marketed)
- EU000 Not yet/Never filed with EU
- UM100 Controlled/Gov't Distribution in US
- US666 Biodefense stockpile
- EM999 Not Available/Not Marketed in EU

Biological Index:

- influenza virus, cold-adapted
- influenza virus, H5N1
- reassortant viruses
- reverse genetics
- virus culture

395 Influenza Vaccine, H5N1/Novartis

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- **Pandemic Influenza vaccine, surface antigen, inactivated - Focetria; influenza virus H5N1 vaccine, inactivated; Pandemic Influenza vaccine, surface antigen, inactivated; H5N1 MPH**
- **Company roles:**
 - [Centers for Disease Control and Prevention \(CDC\)](#) -- USA mark.
 - [MedImmune, Inc.](#) -- Tech.

- [National Institute of Biological Standards and Control \(NIBSC\)](#)
-- Tech.
 - [Novartis AG](#) -- Manuf. ; R&D ; Tech.
- **Monograph size** = 15479 characters (not including indexing, nomenclature, links, etc. on this page)

- ***Partial monograph text:***

395 Influenza Vaccine, H5N1/Novartis Pandemic Influenza vaccine, surface antigen, inactivated - Focetria; Influenza virus H5N1, inactivated; H5N1 MPH; influenza virus H5N1, inactivated, vaccine; bird flu vaccine; avian influenza vaccine; pandemic influenza vaccine
Status: approved in EU; being added to U.S. stockpile

Organizations involved:

Novartis AG - Manuf.; R&D; Tech.

Centers for Disease Control & Prevention (CDC) - U.S. mark.

National Institute for Biological Standards and Control (NIBSC) - Tech.

MedImmune - Tech.

Astra Zeneca plc - Parent

Cross Ref.: See Influenza Virus H5N1 Vaccines (entry #484) and Influenza Virus Vaccines (entry #470).

Description: **Focetria** is an aqueous egg-cultured split formaldehyde-inactivated monovalent influenza pandemic (non pre-pandemic) vaccine formulation with **MF59C.1 adjuvant** (squalene-based) for injection that, at least for the "mock-up" or model vaccine approved by the European Union, contains primarily the outer membranes of an influenza virus derived by reverse genetics from influenza virus A/Viet Nam/1194/2004 (H5N1). In EU terms, the Drug Substance (active agent) is the Monovalent Pooled Harvest (MPH) of Pandemic Influenza vaccine, surface antigen, inactivated. & nbs ... **truncated (just the beginning)**

- **Nomenclature:**
- Influenza Vaccines, H5N1/Novartis [BIO]
- **Focetria** [TR]
- Pandemic Influenza vaccine, surface antigen, inactivated [EU]
- avian influenza vaccine [SY]

- bird flu vaccines [SY]
- H5N1 MPH [SY]
- influenza virus H5N1, inactivated, vaccine [SY]
- Monovalent Pooled Harvest (MPH) [SY]
- pandemic influenza vaccine [SY]

- **Index Terms:**

Product Class Index:

- biopharmaceutical products
- chicken source materials
- influenza vaccines, pandemic
- vaccines, inactivated
- vaccines, viral
- SB001 BIOPHARMA prod. (mainstream)

Regulatory/Status Index:

- EU200 Currently Approved in EU
- UM100 Controlled/Gov't Distribution in US
- US666 Biodefense stockpile
- EM160 Controlled/Gov't Distribution in EU

Biological Index:

- chicken embryo (egg) culture
- influenza strain A/Viet Nam/1194/2004 (H5N1)
- influenza virus H5N1 Reverse Genetics Strain NIBRG 14
- influenza virus, H5N1
- virus culture

Chemical Index:

- calcium chloride
- cetyltrimethylammonium bromide (CTAB)
- chicken proteins
- citric acid
- disodium phosphate
- egg
- formaldehyde
- kanamycin

- magnesium chloride
- **MF59C.1 adjuvant**
- neomycin sulfate
- phosphate buffered saline (PBS)
- polysorbate 80 (Tween 80)
- polysorbate 90 (Tween 90)
- **polystyrene**
- potassium chloride
- potassium dihydrogen phosphate
- sodium chloride
- sodium citrate
- sorbitan trioleate
- **squalene-based**
- sucrose
- **thimerosal** (mercury derivative)

<http://208.69.231.70/biopharma/full7.lasso?Order=488&S=x&-token=none&-nothing>

396 Influenza Vaccine, H5N1/Sanofi

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- **influenza virus H5N1, inactivated, vaccine; bird flu vaccine; avian influenza vaccine; pandemic influenza vaccine; influenza virus A/Indonesia (H5N1, clade 2) vaccine**
- **Company involvement:**
 - [MedImmune, Inc.](#) -- Tech.
 - [Sanofi Pasteur S.A.](#) -- Parent
 - [Sanofi Pasteur Inc.](#) -- Manuf. ; R&D ; Tech.

○ [AstraZeneca plc](#) -- Parent

- **Monograph size** = 17957 characters (not including indexing, nomenclature, links, etc. on this page); What you would see, if you had a subscription.

- ***Partial monograph text:***

Influenza Vaccine, H5N1/Sanofi Influenza Virus Vaccine, H5N1; bird flu vaccine; avian influenza vaccine; influenza virus H5N1, inactivated; influenza virus A/Indonesia (H5N1, clade 2) vaccine

Status: approved in U.S.; being added to U.S. and other countries' stockpiles

Organizations involved:

Sanofi Pasteur Inc. - Manuf.; R&D; Tech.

Sanofi Pasteur S.A. - Parent

Centers for Disease Control & Prevention (CDC) - U.S. mark.

MedImmune, Inc. - Tech.

AstraZeneca plc - Parent

Description: Various influenza virus H5N1 vaccines from Sanofi Pasteur are in development and being stockpiled by the U.S. and other governments. These conventional egg-cultured monovalent influenza virus H5N1 vaccines are similar in many respects to other current seasonal vaccines, except containing hemagglutinin (HA) from an isolate/strain of influenza virus H5N1 (bird flu), currently influenza virus A/Vietnam/1203/2004 (H5N1, clade 1) and/or from influenza virus A/Indonesia (H5N1, clade 2). Sanofi Pasteur has essentially received conditional U.S. approval for its clade 1 vaccine, allowing for large-scale manufacture and distribution if need, e.g., in case of a threat from or actual influenza H5N1 (bird flu) epidemic or pandemic.

The currently U.S.-approved Influenza Virus Vaccine, ... **truncated (just the beginning)**

- **Nomenclature:**
- Influenza Vaccine, H5N1/Sanofi [BIO]
- Influenza Virus Vaccine, H5N1 [FDA]
- avian influenza vaccine [SY]

- bird flu vaccines [SY]
- influenza virus A/Indonesia (H5N1, clade 2)vaccine [SY]
- influenza virus H5N1, inactivated, vaccine [SY]
- Pandemic Influenza vaccine, surface antigen, inactivated [SY]
- NDC 49281-600-01 [NDC]
- **FDA Class:** Biologics BLA

- **Index Terms:**

Product Class Index:

- biopharmaceutical products
- chicken source materials
- influenza vaccines, pandemic
- vaccines, inactivated
- vaccines, viral

Regulatory/Status Index:

- accelerated approval (based on surrogate endpoints) (FDA approved)
- approvals, FDA, as biologic
- biodefense stockpile (U.S.)
- controlled/gov't distribution in U.S.
- not available, currently, in EU or European countries (not marketed)
- EU000 Not yet/Never filed with EU
- UM100 Controlled/Gov't Distribution in US
- US200 Currently Approved in US
- US666 Biodefense stockpile
- EM999 Not Available/Not Marketed in EU

Biological Index:

- chicken embryo (egg) culture
- influenza virus A/Indonesia) (H5N1, clade 2)
- influenza virus A/Vietnam/1203/2004 (H5N1, clade 1)
- influenza virus, H5N1
- virus culture

Chemical Index:

- formaldehyde

- octoxynol
- phosphate buffered saline (PBS)
- polyethylene glycol p-isooctylphenyl ether (Triton X-100)
- sodium phosphate
- sucrose
- thimerosal (mercury derivative)

<http://www.biopharma.com/Samples/679.html>

679 Aluminum-based Vaccine Adjuvants

- Extracted from [Biopharmaceutical Products in the U.S. and European Markets](#), the only biopharmaceuticals reference database/book. Visit www.biopharma.com for more information. See also the [description/flyer](#), copies of [reviews](#), and the public [products database](#) and [products database](#). Contact the [author/publisher](#) for further information about database subscriptions and book purchases.

- **Aluminum hydroxide and aluminum phosphate**

- **Company roles:**

-
- [Reheis Inc.](#) -- Manuf. ; World mark.
- [Sanofi Aventis S.A.](#) -- Manuf. ; World mark.
- [Superfos](#) -- Manuf. ; World mark.

- **Monograph size** = 9930 characters (not including indexing, nomenclature, links, etc. on this page)

- ***Partial monograph text:***

679 Aluminum-based Vaccine Adjuvants

Aluminum hydroxide; Aluminum phosphate

Status: approved; marketed

Organizations involved (major manufacturers):

Reheis Inc. - Manuf.

Superfos - Manuf.

Sanofi Aventis S.A. - Manuf.

Description: Aluminum hydroxide and aluminum phosphate-based vaccine adjuvants are used as matrices or carriers for vaccine antigens, and act to increase immune response to co-formulated vaccine antigens. These highly purified amorphous colloidal gels have a positive charge and readily adsorb most negatively charged substances, such as proteins, at neutral pH. The protein adsorbing capacity of an adjuvant is a major determinant of the amount of aluminum per dose. Aluminum adjuvants with higher protein-binding capacity allow use of lower amounts of aluminum per dose. Adsorption of protein is dependent on the pI (isoelectric pH) of the protein and the pH of the medium. A protein with a lower pI adsorbs to the positively charged aluminum ions more strongly than a protein with a higher pI. Adsorptive capacity is also affected by the types and concentrations of electrolytes present. Aluminum adjuvants generally appear as white, translucent or gels (similar to some aluminum-based antiperspirants).

Adjuvants a ... **truncated (just the beginning)**

- **Nomenclature:**
- Aluminum-based Adjuvants [BIO]
- Alhydrogel [TR assigned to Superfos]
- Rehydrigel [TR assigned to Reheis]
- Rehydraphos [TR assigned to Reheis]
- Adju-fos [TR assigned to Superfos]
- alum [SY]
- aluminum hydroxide [SY]
- aluminum oxyhydroxide [SY]
- aluminum phosphate [SY]
- amorphous aluminum hydroxyphosphate [SY]
- amorphous aluminum hydroxyphosphate sulfate [SY for alum]
- potassium aluminum sulfate [SY]

- **Index Terms:**

[Product Class Index:](#)

- adjuvants
- inorganic substances
- nonbiopharmaceutical products
- synthetic manufacture

- SB999 Generic Entry/Chapter

Regulatory/Status Index:

- EU200 Currently Approved in EU
- UM001 Marketed Product in US
- US200 Currently Approved in US
- EM001 Marketed Product in EU

Chemical Index:

- aluminum hydroxide
- aluminum phosphate

<http://www.biopharma.com/Samples/680.html>

680 Monophosphoryl Lipid A

- Extracted from [Biopharmaceutical Products in the U.S. and European Markets](#), the only biopharmaceuticals reference database/book. Visit www.biopharma.com for more information. See also the [description/flyer](#), copies of [reviews](#), and the public [products database](#) and [products database](#). Contact the [author/publisher](#) for further information about database subscriptions and book purchases.

- **3-deacylated monophosphoryl lipid A; MPL; AS(04); AS04; SBAS4 [adjuvant]**
- **Company roles:**
 -
 - [Corixa Corp.](#) -- Manuf. ; R&D ; Tech.
 - [GlaxoSmithKline Biologicals S.A. \(GSK\)](#) -- R&D ; Tech.
- **Monograph size** = 8094 characters (not including indexing, nomenclature, links, etc. on this page)
- ***Partial monograph text:***

680 Monophosphoryl Lipid A 3-Deacylated monophosphoryl lipid A; MPL; AS(04); SBAS4 [vaccine adjuvant]

Status: a vaccine containing this adjuvant is nearing approval in U.S., one already marketed in Europe

Organizations involved:

Corixa Corp. - Manuf.; R&D; Tech.

Ribi ImmunoChem Res., Inc. - R&D; Tech.; Former

GlaxoSmithKline Biologicals S.A. - R&D; Tech.

GlaxoSmithKline Inc. - USA mark.

GlaxoSmithKline plc - Intl. mark.; Parent

SmithKline Beecham Biologicals S.A. - Former

Cross Ref.: See the entries for vaccines containing this adjuvant - Fendrix, a recombinant hepatitis B virus (HBV) vaccine, and Cervarix, a human papillomavirus (HPV) vaccine, both from GlaxoSmithKline (GSK). See also the Aluminum-based Adjuvants entry.

Description: 3-Deacylated monophosphoryl lipid A is a monophosphorylated and 3-acylated derivative of lipid A, a bacterial endotoxin and one of the most potent immunostimulants known, found in the cell wall of Gram-negative bacteria. 3-Deacylated monophosphoryl lipid A (3-deacylated MPL), commonly referred to simply as monophosphoryl lipid A (MPL), is chemically similar to lipid A but lacks an acid-labile phosphoryl group and a base-labile acyl group at position 3. 3-Deacylated monophosphoryl li ... **truncated (just the beginning)**

• **Index Terms:**

[Product Class Index:](#)

- adjuvants

- SB001 BIOPHARMA prod. (mainstream)

[Regulatory/Status Index:](#)

- EU200 Currently Approved in EU
- UM999 Not Available/Not Marketed in US
- US001 FDA application expected
- EM999 Not Available/Not Marketed in EU

[Biological Index:](#)

- bacterial culture <!-- bacterialculture -->

- Salmonella minnesota

<http://www.biopharma.com/Samples/389.html>

389 Influenza Vaccine, cell cultured/ Novartis

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- **Optaflu; Influenza virus vaccine, inactivated**
- **Company roles:**
 - [Chiron Corp.](#) -- R&D ; Tech. ; Former
 - [Novartis AG](#) -- Parent
 - [Novartis Vaccines and Diagnostics Ltd.](#) -- Manuf. ; R&D ; Tech. ; World mark.
- **Monograph size** = 4922 characters (not including indexing, nomenclature, links, etc. on this page)

- **Nomenclature:**
- ***Partial monograph text:***

389 Influenza Vaccine, cell cultured/Novartis

Optaflu; Influenza virus vaccine, inactivated

Status: recently approved in the EU; U.S. filing expected in 2008

Organizations involved:

Chiron Corp. - R&D; Tech.; Former

Novartis AG - Manuf.; R&D; Tech.; World mark.

MedImmune, Inc. - Tech

Astra Zeneca plc - Parent

Description: Optaflu is a cell cultured trivalent detergent-disrupted (inactivated) seasonal split-virion (subunit, not whole virus) influenza virus vaccine cultured in Madin Darby Canine Kidney (MDCK) cells in phosphate buffered saline (PBS). This is the first cell cultured influenza vaccine approved in a major market. As with other seasonal trivalent influenza vaccines, the Optaflu contains 15 μg /doses of hemagglutinin (HA) antigen from the influenza strains officially recommended for the upcoming/current flu season. Optaflu is preservative-free, non-adjuvanted and presented in pre-filled syringes filled up to 0.5 mL with phosphate buffered saline (PBS) buffer. Additives, such as antibiotics, are avoided in the production process.

Nomenclature: Influenza Vaccine, cell cultured/Novartis [BIO]; Optaflu [TR]

Companies: Novartis, formerly Chiron Vaccines, developed and manufactures this vacc ... **truncated (just the beginning)**

- Influenza Vaccine, cell cultured/Novartis [BIO]
- Optaflu [TR]
- Influenza Virus Vaccine [FDA]

- **FDA Class:** Biologics BLA

- **Index Terms:**

Product Class Index:

- biopharmaceutical products
- chicken source materials
- vaccines, inactivated
- vaccines, subunit

- SB001 BIOPHARMA prod. (mainstream)

Regulatory/Status Index:

- EU200 Currently Approved in EU
- UM999 Not Available/Not Marketed in US
- US001 FDA application expected
- EM001 Marketed Product in EU

Biological Index:

- influenza virus
- mammalian cell culture
- virus culture

Chemical Index:

- detergent
- influenza prophylaxis

<http://www.medicalnewstoday.com/articles/45286.php>

MedImmune And National Institutes Of Health Begin Clinical Testing Of A Live, Attenuated Intranasal Vaccine Against An H5N1 Avian Influenza Virus

Main Category: [Immune System / Vaccines](#)

Also Included In: [Bird Flu / Avian Flu](#); [Clinical Trials / Drug Trials](#)

Article Date: **16 Jun 2006** - 0:00 PDT

MedImmune, Inc. (Nasdaq: MEDI) announced today that the National Institutes of Health (NIH) has begun enrolling participants in a Phase 1 study of an intranasal H5N1 influenza vaccine candidate based on the company's live, attenuated vaccine technology. Investigators at MedImmune and Johns Hopkins Bloomberg School of Public Health Center for Immunization Research, where the study will be conducted, are hopeful that a live, attenuated intranasal influenza vaccine would be as effective against potential pandemic A strains as it has been shown to be against seasonal A strains of influenza.

"We believe that our influenza vaccine technology may provide several advantages over the flu shot that will be critically important in protecting people against a pandemic influenza virus," said James F. Young, Ph.D., president, research and development. "In pivotal clinical trials conducted in children 6 months to 59 months of age, our live, attenuated intranasal vaccine technology has been shown to be significantly more effective against seasonal A strains, including those both matched and not matched to the strains used in the vaccine. Additionally, because of its intranasal delivery, our technology may provide a faster and broader immune response, including providing both systemic and mucosal protection at the site where a flu infection takes hold - which is in the nose."

Results from a recently completed Phase 3 clinical study showed that MedImmune's next-generation, investigational influenza vaccine, CAIV-T (cold adapted influenza vaccine, trivalent), was 89 percent more effective than the flu shot in reducing influenza illness caused by matched H1N1 A strains and 79

percent more effective than the flu shot against circulating mismatched H3N2 A strains. CAIV-T is the investigational, next-generation of MedImmune's currently marketed vaccine, [FluMist](#)(R) (Influenza Virus Vaccine Live, Intranasal).

The H5N1 vaccine candidate is being developed under MedImmune's Cooperative Research and Development Agreement (CRADA) with the NIH's National Institute of Allergy and Infectious Diseases (NIAID) to produce and test versions of MedImmune's live, attenuated intranasal influenza vaccine for use against different subtypes of potential pandemic influenza strains. This first study is an open-label Phase 1 trial designed to evaluate the safety and immunogenicity of an attenuated, intranasal H5N1 vaccine (based on the A/VietNam/1203/2004 H5N1 strain) in approximately 20 healthy individuals from 18 to 49 years of age. Participants in an isolation unit will receive two doses of vaccine administered 28 to 62 days apart.

The initiation of this trial is the next step in MedImmune's ongoing commitment to ensure the nation is adequately protected against seasonal influenza and prepared for a potential influenza pandemic by using the latest in scientific and medical advancements. Toward this end, the company recently received a \$170-million contract from the U.S. Health and Human Services Department to expedite the development of cell-culture-based production of its flu vaccine. Further, MedImmune has notified the World Health Organization and other governmental agencies of its intent to license the key intellectual property for reverse genetics technology, which the company either owns or exclusively licenses, to governmental organizations and companies developing pandemic influenza vaccines for public health purposes. For pandemic vaccines, reverse genetics is important because the technology allows vaccine manufacturers to work with a segment of the infectious, circulating pandemic virus strain's genome rather than directly with the infectious strain itself. Using this technology, it is also possible to make changes to the virus to make it easier and safer to grow.

About CAIV-T

CAIV-T is an investigational intranasal, cold-adapted trivalent influenza vaccine. It is the next-generation, refrigerator-stable formulation of FluMist, which is a frozen, live attenuated cold-adapted trivalent influenza vaccine. To date, the safety, tolerability and efficacy of CAIV-T has been studied in both healthy and at-risk populations between the ages of 6 weeks and 98 years.

On May 1, 2006 at the Pediatric Academic Societies' annual meeting, MedImmune presented its pivotal Phase 3 study for CAIV-T, entitled, "Comparison of the Efficacy and Safety of Cold-Adapted Influenza Vaccine, Trivalent With Trivalent Inactivated Influenza Vaccine in Young Children 5 to 59 Months of Age." The study included 8,475 children at 249 sites in 16 countries in North America, Europe, the Middle East and Asia. Study participants were randomized one-to-one to receive either CAIV-T or the flu shot during the 2004-2005 influenza season. Each participant also received a placebo nasal spray or placebo injection to preserve the double-blind design of the study. Participants were followed through the influenza season and evaluated to identify illnesses caused by influenza virus. The trial included more

than 6,300 previously unvaccinated children with nearly 50 percent of those children less than 2 years of age.

The results of this trial showed that CAIV-T was 55 percent more effective than the trivalent injectable inactivated influenza vaccine (TIV) in reducing influenza illness caused by any influenza strain in children 6 months to 59 months of age, including both matched and mismatched strains. The influenza attack rate was 8.6 percent for study participants receiving the flu shot compared to 3.9 percent for those who received CAIV-T ($P < 0.001$). Against matched strains alone, CAIV-T was 44 percent more effective than the flu shot (attack rates: TIV = 2.4 percent, CAIV-T = 1.4 percent; $P < 0.001$). In this study, CAIV-T was 89 percent more effective than the flu shot in reducing influenza illness caused by the matched H1N1 A strain (attack rates: TIV = 0.7 percent, CAIV-T = 0.1 percent; $P < 0.001$) and 79 percent more effective than the flu shot against circulating mismatched H3N2 A strains (attack rates: TIV = 4.5 percent, CAIV-T = 1.0 percent; $P < 0.001$). No mismatched H1N1 strains or matched H3N2 strains were isolated from subjects in the trial. While there were 16-percent fewer children with illnesses associated with B strains in the CAIV-T group compared to TIV (attack rates: TIV = 3.5 percent, CAIV-T = 3.0 percent), this difference was not statistically significant.

In the study, the overall incidence of adverse events and serious adverse events was similar in both groups except for a higher incidence of runny nose and nasal congestion in CAIV-T recipients (2.5 - 5.6 percent increase) and a higher incidence of injection site reactions in those receiving the flu shot (3.6 - 7.6 percent increase). There were no significant differences through the whole study period for all reported wheezing or for medically significant wheezing (MSW), a pre-specified safety endpoint. Previously unvaccinated children between 6 and 23 months of age had a small but statistically significant increase in MSW at 42 days following their first dose (2.0 percent for TIV vs. 3.2 percent for CAIV-T). Statistically significant differences were not seen beyond 42 days after this first dose or at any time after the second dose.

About FluMist

FluMist is indicated for active immunization for the prevention of disease caused by influenza A and B viruses in healthy children and adolescents, 5 to 17 years of age, and healthy adults, 18 to 49 years of age. There are risks associated with all vaccines, including FluMist. Like any vaccine, FluMist does not protect 100 percent of individuals vaccinated. In studies of people between the ages of 5 and 49 years, runny nose was the most commonly reported side effect. Other common side effects included various cold-like symptoms, such as headache, cough, sore throat, tiredness/weakness, irritability, and muscle aches.

FluMist should not be used, under any circumstances, in anyone with an allergy to any part of the vaccine, including eggs; in children and adolescents receiving aspirin therapy; in people who have a history of Guillain-Barre syndrome; and in people with known or suspected immune system problems. Pregnant women and

people with certain medical conditions, asthma, or reactive airways disease should not get FluMist.

About MedImmune, Inc.

MedImmune strives to provide better medicines to patients, new medical options for physicians, rewarding careers to employees, and increased value to shareholders. Dedicated to advancing science and medicine to help people live better lives, the company is focused on the areas of infectious diseases, cancer and inflammatory diseases. With more than 2,300 employees worldwide, MedImmune is headquartered in Maryland. For more information, visit the company's website at <http://www.medimmune.com>.

This announcement contains, in addition to historical information, certain forward-looking statements that involve risks and uncertainties, in particular, related to the research and development of a potential pandemic influenza vaccine. Such statements reflect management's current views and are based on certain assumptions. Actual results could differ materially from those currently anticipated as a result of a number of factors, including risks and uncertainties discussed in MedImmune's filings with the U.S. Securities and Exchange Commission. There can be no assurance that such development efforts will succeed, that such products will receive required regulatory clearance or that, even if such regulatory clearance is received, such products will ultimately achieve commercial success.

MedImmune, Inc.

<http://www.medimmune.com>

View drug information on [FluMist](#)

<http://www.bioplanassociates.com/es/index.htm>



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By **[Ronald A. Rader](#)**
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