A Phase III, Open-Label, Single-Arm Study to Evaluate the Safety and Immunogenicity of a Trivalent, Surface Antigen Inactivated Subunit Influenza Virus Vaccine Produced in Mammalian Cell Culture (Optaflu®) in Healthy Adults

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Inclusion Criteria

In order to participate in this study, a subject was to meet all of the following inclusion criteria:

- a male or female volunteer ages 18 years or older, mentally competent, willing and able to give written informed consent prior to study entry;
- was able to comply with all the study requirements; and
- was in good health as determined by the outcome of medical history, physical examination, and clinical judgment of the investigator.

Exclusion Criteria

In order to participate in this study, a subject was not to meet any of the following exclusion criteria:

- behavioral or cognitive impairment or psychiatric disease that, in the opinion of the investigator, might have interfered with the subject’s ability to participate in the study;
- serious chronic or acute disease (in the judgment of the investigator) including, but not limited to
  - medically significant cancer (except for benign or localized skin cancer, cancer in remission for ≥ 10 years, or localized prostate cancer that had been clinically stable for > 2 years without treatment)
  - medically significant advanced congestive heart failure (ie, New York Heart Association class III and IV)
  - chronic obstructive pulmonary disease (ie, Global initiative for chronic Obstructive Lung Disease stage III and IV)
- autoimmune disease (including rheumatoid arthritis and excepting Hashimoto’s thyroiditis that has been clinically stable for ≥ 5 years)
- diabetes mellitus type I
- poorly controlled diabetes mellitus type II
- advanced arteriosclerotic disease
- history of underlying medical condition such as major congenital abnormalities requiring surgery, chronic treatment, or associated with developmental delay (eg, Down’s syndrome)
- acute or progressive hepatic disease
- acute or progressive renal disease
- severe neurological (especially Guillain–Barré syndrome) or psychiatric disorder
- severe asthma
  ◦ history of any anaphylactic reaction and/or serious allergic reaction to any component of the study vaccine;
  ◦ known or suspected (or had a high risk of developing) impairment/alteration of immune function (excluding that normally associated with advanced age) resulting, for example, from:
    - receipt of immunosuppressive therapy\(^1\) (any parenteral or oral corticosteroid or cancer chemotherapy/radiotherapy) within the past 60 days and for the full length of the study,
    - receipt of immunostimulants within the past 6 months,
    - receipt of parenteral immunoglobulin preparation, blood products, and/or plasma derivates within the past 3 months and for the full length of the study, or
    - suspected or known human immunodeficiency virus (HIV) infection or HIV-related disease
  ◦ known or suspected drug or alcohol abuse within the past 2 years;
  ◦ bleeding diathesis or conditions associated with prolonged bleeding time that, in the investigator’s opinion, would have interfered with the safety of the subject;

\(^1\) Inhaled, topical, and intraarticular corticosteroids were permitted.
was not able to comprehend and to follow all required study procedures for the whole period of the study;

history or any illness that, in the opinion of the investigator, would have posed additional risk to the subjects because of participation in the study;

had the following within the past 6 months:
- any laboratory-confirmed seasonal or pandemic influenza disease
- received any seasonal or pandemic influenza vaccine

received any other vaccine within 4 weeks prior to enrollment in this study or who were planning to receive any vaccine during the study;

had acute or chronic infections requiring antiviral therapy within the last 7 days;

had experienced fever (ie, body temperature [preferably oral] ≥38.0°C) within the last 3 days of intended study vaccination;

had been participating in any clinical trial with another investigational product 4 weeks prior to first study visit or intended to participate in another clinical study at any time during the conduct of this study;

was part of study personnel or had close family members conducting this study;

had a body mass index (BMI) > 35 kg/m2 (BMI was calculated by dividing the subject’s weight in kilograms by the subject’s height in meters multiplied by the subject’s height in meters);

was pregnant (confirmed by positive urine pregnancy test) or nursing (breastfeeding) or was a female of childbearing potential who refused to use an acceptable method of birth control for the whole duration of the study.

Female of childbearing potential was defined as a post onset menarche and premenopausal female capable of becoming pregnant. This did not include females who met any of the following conditions: (1) menopause at least 2 years earlier, (2) tubal ligation at least 1 year earlier, or (3) bilateral oophorectomy or hysterectomy.