SYNOPSIS

<table>
<tr><td>Name of Sponsor/Company:
Omninvest Vaccine Manufacturing, Researching and Trading Ltd.</td><td rowspan="3">Individual Study Table Referring to Part of the Dossier

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<tr><td>Name of Finished Product:
Fluval AB-like influenza vaccine</td></tr>
<tr><td>Name of Active Ingredient:
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<tr><td>Title of Study:</td><td colspan="2">A Randomized, Active Controlled, Double-blind, Multi-Centre Study to Evaluate Safety and Immunogenicity of One Dose of FLUVAL AB-like (Trivalent, Whole Virus, Aluminium Phosphate Gel Adjuvanted) Influenza Vaccine Containing 6µgHA of Seasonal A/H1N1, A/H3N2 and B Influenza Antigens in Non-elderly Adult and Elderly Subjects</td></tr>
<tr><td>Study Number</td><td colspan="2">FluvalAB-H-15</td></tr>
<tr><td>EudraCT Number</td><td colspan="2">2011-003314-16</td></tr>
<tr><td>Investigators and Study Centres:</td><td colspan="2">Coordinating Investigator:
Ferenc TAMÁS MD.
District Doctor’s Office, Pilisvörösvár
Investigators:
Ágnes HASITZ, MD.
District Doctor’s Office, Szentendre
Judit SIMON MD.
District Doctor's Office Budapest
Barna BŐZE MD.
District Doctor's Office, Hatvan
Péter TORZSA MD.
District Doctor's Office, Budapest
Péter VAJER MD.
District Doctor's Office, Biatorbágy
Tibor HRUTKA MD.
District Doctor's Office, Vecsés</td></tr>
<tr><td>Publication (reference):</td><td colspan="2">None</td></tr>
<tr><td>Phase of development:</td><td colspan="2">Phase III</td></tr>
<tr><td>Studied period

Date of first enrolment:

Date of last completed:</td><td colspan="2">

Oct. 24, 2011

March 21, 2012</td></tr>
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<tr><td>Objectives:</td><td colspan="2">Immunogenicity Objectives
Primary immunogenicity objective
To assess immunogenicity of one 0.5 mL intramuscular (IM) injection of FAB-6011 trivalent influenza vaccine containing 6µgHA of seasonal A/H1N1, A/H3N2 and B influenza antigens, as measured by haemagglutination inhibition (HI) test 21 days after vaccination in compliance with the requirements of the current European Union recommendations as determined in CPMP/BWP/214/96.
Secondary immunogenicity objectives
a) To assess immunogenicity of one 0.5 mL IM injection of FAB-6011 trivalent influenza vaccine containing 6µgHA of seasonal A/H1N1, A/H3N2 and B influenza antigens, as measured by HI test 120 days after vaccination in compliance with the requirements of the current European Union recommendations as determined in CPMP/BWP/214/96.
b) To assess non-inferiority of one 0.5 mL IM injection of FAB-6011 trivalent influenza vaccine containing 6µgHA of seasonal A/H1N1, A/H3N2 and B influenza antigens against FLUVAL AB trivalent influenza vaccine containing 15µgHA of seasonal A/H1N1, A/H3N2 and B influenza antigens in terms of post-immunization geometric mean titers (GMTs) as measured by HI test 21 days after vaccination.
c) To assess non-inferiority of one 0.5 mL IM injection of FAB-6011 trivalent influenza vaccine containing 6µgHA of seasonal A/H1N1, A/H3N2 and B influenza antigens against FLUVAL AB trivalent influenza vaccine containing 15µgHA of seasonal A/H1N1, A/H3N2 and B influenza antigens in terms of post-immunization geometric mean titers (GMTs) as measured by HI test 120 days after vaccination.
Safety and Tolerability Objective
To evaluate the safety of the administration of one 0.5 mL IM injection of FAB-6011 trivalent influenza vaccine containing 6µgHA of seasonal A/H1N1, A/H3N2 and B influenza antigens.</td></tr>
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Methodology:

Subjects were randomly assigned in a 1:1 ratio to one of the following vaccine groups, and vaccinated as follows:

Group 1: one 0.5 mL injection of FAB-6011 trivalent influenza vaccine containing 6µgHA of seasonal A/H1N1, A/H3N2 and B influenza antigens;

Group 2: one 0.5 mL injection of FLUVAL AB trivalent influenza vaccine containing 15µgHA of seasonal A/H1N1, A/H3N2 and B influenza antigens.

The subjects were enrolled into two subgroups according to their age (18-60 years and over 60 years).

Control visits at Day 21 and Day 120 were planned to collect blood samples for HI test to assess immunogenicity and to record adverse events to assess safety of the vaccination.

Number of patients (planned and analysed):

The planned enrolment was minimum 1106 and maximum 1232 subjects (with minimum 225 and maximum 504 subjects aged 18-60 years and minimum 328 and maximum 728 subjects aged over 60 years) overall. This headcount ensures a statistical power of 80%.

Group 1: 252 subjects aged 18-60 years /Group 1A/ and 364 subjects aged over 60 years /Group 1E/;

Group 2: 252 subjects aged 18-60 years /Group 2A/ and 364 subjects aged over 60 years /Group 2E/).

Actually 1206 subjects were enrolled in the study, randomly assigned to two vaccine groups, and vaccinated by double-blind medication (ITT population). The data of these 1206 subjects were included in the safety evaluation.

Out of the 1206 subjects vaccinated 1179 subjects attended both Visit 2 at Day 21 and Visit 3 at Day 120 (PP population).

Actual number of subjects completing the study

Age group	**Vaccine group**		
	Group 1: FAB-6011 influenza vaccine. (6 µgHA/0.5mL)	Group 2: FluvalAB influenza vaccine. (15 µgHA/0.5mL)	**Total**
18-60 years	241	237	**478**
over 60 years	347	354	**701**
Total	**588**	**591**	**1179**

The data of these 1179 subjects were included in the immunogenicity evaluation.

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<tr><td>Diagnosis and main criteria for inclusion:</td><td colspan="2">Inclusion criteria
• Subjects eligible for enrolment into this study were:
- male and female adult volunteers aged 18 years or older,
- mentally competent,
- able to understand and comply with all study requirements,
- willing and able to give written informed consent prior to initiation of study procedures,
- in good health (as determined by clinical judgement of the investigator on the basis of medical history and existing medical condition) or are in stable medical condition.
• Female subjects aged 18 to 60 years (i.e. participants of childbearing potential) with a negative result from the urine pregnancy test prior to vaccination who agreed to use an acceptable contraception method or abstinence throughout the trial and not become pregnant for the duration of the study.
• Absence of existence of any exclusion criteria.
Exclusion criteria:
• Pregnancy, breast feeding or positive urine pregnancy test at baseline prior to vaccination. Female subjects who are able to bear children but not willing to use an acceptable contraception method for the duration of the study.
• Hypersensivity to eggs, chicken protein, thiomersal, formaldehyde, gentamycin, ciprofloxacin, neomycin or any other component of the vaccine;
• History of anaphylactic shock or neurological symptoms or signs following administration of any vaccine;
• History of Guillain-Barré syndrome;
• Serious disease, such as cancer, autoimmune disease, advanced arteriosclerotic disease, complicated diabetes mellitus, acute or progressive hepatic disease, acute or progressive renal disease, congestive heart failure;
• Immunosuppressive therapy within 36 months prior to vaccination;
•Concomitant corticosteroid therapy, including high-dose inhaled corticosteroids;
• Receipt of immunostimulants;
• Receipt of parenteral immunoglobulin, blood products and/or plasma derivates within 3 months prior to vaccination;
• Suspected or known HIV, HBV or HCV infection;
• Acute disease and/or axillary temperature ≥37oC within 3 days prior to vaccination;
• Vaccine therapy within 4 weeks prior to vaccination;
• Influenza vaccination (any kind) within 6 months prior to vaccination;</td></tr>
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<tr><td>Diagnosis and main criteria for inclusion (cont):</td><td colspan="2">• Experimental drug therapy within 4 weeks prior to vaccination;
• Concomitant participation in another clinical study;
• Any condition which, in the opinion of the investigator, may interfere with the evaluation of the study;
• Past or current psychiatric disease of the subject that upon judgement of the investigator may have effect on the objective decision-making of the subject;
• Alcohol or drug abuse of the subject.</td></tr>
<tr><td>Test product, dose and mode of administration, batch number:</td><td colspan="2">Vaccine A (test vaccine):
Name: Fluval AB-like influenza vaccine
Active ingredient content: 6 µgHA/strain/0.5ml
Code in the study: FAB-6011
Lot number: FL-K-02/11
Manufacturer: Omninvest Kft. (H-2097 Pilisborosjenö, Fö utca 7.)
Date of manufacturing: June 2011
Date of expiry: 31 August 2012

The investigational vaccine was a trivalent vaccine against seasonal flu. The influenza viruses included in the investigational vaccine were grown in embryonated hen egg, inactivated by formaldehyde, purified and concentrated, and absorbed on aluminum phosphate gel.
The virus strains were chosen according to "EU Recommendations for the Seasonal Influenza Vaccine Composition for the Season 2011/2012" (EMA/CHMP/BWP/156215/2011).</td></tr>
<tr><td>Duration of treatment</td><td colspan="2">Single dose</td></tr>
<tr><td>Reference therapy, dose and mode of administration, batch number</td><td colspan="2">Vaccine B (reference vaccine):
Name: Fluval AB influenza vaccine
Active ingredient content: 15 µgHA/strain/0.5ml
Code in the study: FluvalAB
MA number: OGYI-T-8998 (registered by OGYI /NIP/)
Lot number: FL-K-04/11
Manufacturer: Omninvest Kft. (H-2097 Pilisborosjenö, Fö utca 7.)
Date of manufacturing: June 2011
Date of expiry: 31 August 2012</td></tr>
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<tr><td>Criteria for evaluation:

Safety:</td><td colspan="2">Adverse events, local and systemic reactions, and clinically significant changes in physical status and vital signs were monitored and collected throughout the study.
• Number and percentage of subjects with at least one local reaction between Day 0 and the study termination visit at Day 120.
• Number and percentage of subjects with at least one systemic reaction between Day 0 and the study termination visit at Day 120.
• Number and percentage of subjects with at least one adverse reaction between Day 0 and the study termination visit at Day 120.
• Number and percentage of subjects with at least one adverse event between Day 0 and the study termination visit at Day 120.</td></tr>
<tr><td>Efficacy:</td><td colspan="2">Immunogenicity study objectives were assessed in compliance with CHMP requirements concerning seasonal influenza vaccines as determined in CPMP/BWP/214/96 guideline.
According to this guideline, at least one of the following requirements should be meet as measured by HI test 3 weeks after vaccination:
• Non-elderly adult subjects between 18 and 60 years (i.e. ≥18 and <60):
- number of seroconversions[1] or significant increase in antibody titer[2] >40%,
- increase in geometric mean titres >2.5,
- the proportion of subjects achieving an HI titer ≥40 should be >70%.
• Elderly subjects aged 60 years and over (i.e., ≥60):
- number of seroconversions1 or significant increase in antibody titer2 >30%,
- increase in geometric mean titres >2.0,
- the proportion of subjects achieving an HI titer ≥40 should be >60%.
1) Seroconversion is defined as negative (<10) pre-vaccination serum and post-vaccination titer ≥40.
2) Significant increase in antibody titer is defined as at least a fourfold increase from non-negative (≥10) pre-vaccination serum.

Non-inferiority is concluded if the lower limit of the 95% two-sided confidence interval for $\log(GMT_6) - \log(GMT_{15})$ is greater than -0.405.</td></tr>
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Statistical methods:	Definition of populations to be analyzed: Demography: - all vaccinated subjects; Immunogenicity: - all vaccinated subjects, who provide evaluable serum sample both before and after vaccination; Safety population: - all vaccinated subjects with some post-baseline safety data. All analysis was performed using R programming language for statistics. Logarithm stands for natural logarithm. *Analysis of Demographic and Baseline Characteristics* Descriptive statistics (mean, standard deviation, median, minimum and maximum) for age at enrolment were calculated overall and by vaccine group and age group. Distributions of subjects by sex and previous influenza vaccination were summarized overall and by vaccine group and age group. *Analysis of Immunogenicity Criteria* Distributions of the logarithms of 0, 21 and 120 day titers in each subgroup were visualized with normal quantile-quantile plot to ensure normality.Distributions of the logarithms of pre-vaccination titers were summarized and visualized in each subgroup to ensure that they don't vary between Vaccine Groups in the same Age Group. *Primary immunogenicity objective and secondary immunogenicity objective a)* To evaluate immunogenicity of one 0.5 mL IM injection of FAB-6011 influenza vaccine containing 6 μgHA/strain/0.5mL antigen, as measured by HI, in comparison to CHMP requirements as specified in CPMP/BWP/214/96. During the assessment, the following serological indices were considered: (i) seroconversion or significant (i.e. ≥4-fold) increase in HI antibody titer in subjects; (ii) increase in GMTs; and (iii) proportion of subjects achieving an HI titer of ≥40 before and after immunization. The measures of immunogenicity were calculated as: Geometric Mean Titer: GMTs (with 95% confidence interval) will be determined for study day 0, study day 21 28 and study day 110-120. Geometric Mean Titer Ratio: GMTRs (with 95% confidence interval) of the study day 21-28 titers or study day 110 120 titers to the study day 0 titers will be calculated.	

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Statistical methods (cont):	Percentages of Subjects with Seroconversion or Significant Increase in HI Titer: The number and proportion of subjects achieving seroconversion or at least a four-fold increase in HI titers from pre-immunization to 21-28 days and 110-120 days after the immunization will be tabulated. Percentages of Subjects Achieving an HI titer ≥40: The number and proportion of subjects achieving HI titers of at least 40 at study day 0 study day 21-28 and at study day 110-120 will be tabulated. *Secondary immunogenicity objectives b) and c)* The null hypothesis for the secondary immunogenicity objective "b)" stated that the lower limit of the two-sided 95% confidence interval for the ratio of geometric mean titers measured 21 days after vaccination in Group 1 (6µgHA) and Group 2 (15µgHA) was below 1/1.5. H0: GMT6 / GMT15 ≤ 1/1.5 H1: GMT6 / GMT15 > 1/1.5 Instead of using the raw titer values, the log-transformed titers were calculated and the GMT ratio was tested as the difference between the means of the log-transformed titers. The corresponding hypotheses was: H0: log(GMT6) - log(GMT15) ≤ -0.405 H1: log(GMT6) - log(GMT15) > -0.405 The 95 percent two-sided confidence interval for log(GMT6) – log(GMT15) was calculated using the built-in R method which implements Welch-confidence intervals. If the lower limit of the interval is greater than -0.405 non-inferiority is concluded. This calculation was performed for the data from the three different strains and for the two age-groups. For the GMTs measured 120 days after vaccination (secondary immunogenicity objective "c"), the same method was used as for the 21 day-GMTs. *Analysis of Safety Criteria* They included data from the physical examination and observed local and systemic reactions and adverse events. Local reactions include: Pain at injection site, erythema, induration, swelling and ecchymosis. Systemic reactions include: Fever, shivering, headache, malaise, myalgia, arthralgia, headache, sweating, fatigue, and potential indicators of oculo-respiratory syndrome such as: coughing, wheezing, chest tightness, other difficulty breathing, sore throat, facial oedema, and red eye.	

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<tr><td>Statistical methods (cont):</td><td colspan="2">Fever, as a systemic reaction, was programmatically derived from measured axillary temperatures ≥37.0°C.
Any other indications of reactogenicity, all adverse events occurring during the study (study day 0 - study day 110-120), either judged as related or not to vaccination by the investigators, were recorded.
All serious adverse events, adverse events necessitating a physician's visit and/or resulting in premature subject's withdrawal from the study as well as pregnancies were collected throughout the study.
Vaccine-related adverse events causing any permanent damage or a transient damage severe enough to affect normal activities or requiring any treatment were considered as major side effects. Milder vaccine-related adverse events were considered as minor side effects.</td></tr>
<tr><td>Summary - Conclusions

Safety Results:</td><td colspan="2">Administration of both the investigational and the reference vaccines was well tolerated by the study subjects. No serious and no severe possibly or probably related adverse event was observed. Both the investigational and the reference vaccines proved to be safe, no vaccine-related clinically significant changes in the physical condition or vital signs of the volunteers were observed. Significant difference between safety profiles of the investigational and the reference vaccines could not be established.</td></tr>
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Summary – Conclusions (cont)
Efficacy Results:

Summary of results according to CPMP/BWP/214/96 criteria							
A.G.	**Strain**	**CPMP criteria**		**Vaccine Group 6µgHA**		**Vaccine Group 15µgHA**	
				Day 21	**Day 120**	**Day 21**	**Day 120**
18-60	**A/H1N1**	**SC**	≥ 40 %	66 %	47 %	69 %	51 %
		GMTR	≥ 2.5	5.4	3.7	6.1	4.1
		SP	≥ 70 %	93 %	83 %	95 %	87 %
	A/H3N2	**SC**	≥ 40 %	65 %	51 %	69 %	54 %
		GMTR	≥ 2.5	5.4	3.8	5.5	3.8
		SP	≥ 70 %	99 %	95 %	99 %	96 %
	B	**SC**	≥ 40 %	67 %	50 %	75 %	56 %
		GMTR	≥ 2.5	5.2	3.4	5.5	3.4
		SP	≥ 70 %	90 %	75 %	90 %	79 %
60+	**A/H1N1**	**SC**	≥ 30 %	68 %	51 %	68 %	51 %
		GMTR	≥ 2.0	5.5	3.8	5.2	3.8
		SP	≥ 60 %	83 %	72 %	83 %	72 %
	A/H3N2	**SC**	≥ 30 %	60 %	38 %	58 %	40 %
		GMTR	≥ 2.0	4.5	3.0	4.4	2.9
		SP	≥ 60 %	95 %	92 %	97 %	94 %
	B	**SC**	≥ 30 %	56 %	42 %	64 %	50 %
		GMTR	≥ 2.0	4.0	2.7	4.2	3.0
		SP	≥ 60 %	76 %	66 %	82 %	74 %

Furthermore, a non-inferiority analysis demonstrated that on the basis of Para. III.B.1.a. of Guidance for Industry of U.S. Department of Health and Human Services, Food and Drug Administration on Clinical Data Needed to Support the Licensure of Seasonal Inactivated Influenza Vaccines (May 2007) FAB-6011 trivalent seasonal influenza vaccine containing 6 µgHA/strain/0.5mL antigen is non inferior in terms of HI titers and seroconversion rates at post-immunisation days 21-28 and 110-120 to FluvalAB 15 µgHA/strain/0.5mL vaccine.

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<tr><td>Conclusion</td><td colspan="2">Both the investigational vaccine and the reference vaccine were well tolerated by the participants. No serious and no severe possibly or probably related adverse event was observed.
No statistically significant difference was found in frequency of adverse reactions occurred in Group 1, where Fluval AB-like influenza vaccines of 6 µgHA/strain/0.5mL antigen content was administered compared to Group 2, where Fluval AB influenza vaccine of 15 µgHA/strain/0.5mL antigen content was administered.
Both vaccines of 6 and 15µgHA/strain/0.5mL active ingredient content fulfilled all three CHMP immunogenicity criteria for the evaluation of seasonal influenza vaccines as determined in CPMP/BWP/214/96 guideline in terms of all three virus strains and both age groups in case of both 21 days and 120 days after vaccination.
Furthermore, a non-inferiority analysis demonstrated that Fluval AB-like trivalent seasonal influenza vaccine containing 6 µgHA/strain/0.5mL antigen is non inferior to FluvalAB 15 µgHA/strain/0.5mL vaccine.
In summary, on the basis of the results of the present clinical study the Fluval AB-like influenza vaccine of 6 µgHA/strain/0.5mL antigen content is safe and effective, and non inferior to FluvalAB seasonal influenza vaccine of 15 µgHA/strain/0.5mL antigen content.</td></tr>
<tr><td>Date of Report</td><td colspan="2">08 June 2017</td></tr>
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