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

Volume:

Page:</td><td rowspan="3">For National Authority use only</td></tr>
<tr><td>Name of Finished Product:
Fluval P monovalent influenza vaccine</td></tr>
<tr><td>Name of Active Ingredient:
A/California/07/2009(H1N1)-like NYMC X-179A</td></tr>
<tr><td>Title of Study:</td><td colspan="2">Tolerability and Safety Study of Fluval P Monovalent Influenza Vaccine in Children</td></tr>
<tr><td>Study Number</td><td colspan="2">FLUVAL P-H-08</td></tr>
<tr><td>EudraCT Number</td><td colspan="2">2009-014765-74</td></tr>
<tr><td>Investigators and Study Centres:</td><td colspan="2">Investigator:
Éva Szabó MD.
Head physician, head of department
"Csolnoky Ferenc" Veszprém County Hospital,
Center for Pediatrics</td></tr>
<tr><td>Publication (reference):</td><td colspan="2">None</td></tr>
<tr><td>Phase of development:</td><td colspan="2">Interventional, prevention, open, uncontrolled</td></tr>
<tr><td>Studied period

Date of first enrolment:

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

16.09.2009

20.10.2009</td></tr>
<tr><td>Objectives:</td><td colspan="2">Primary Objective:
• To assess tolerability/safety (incidence of adverse events) of the study drug after Day 28. following the vaccination.
Secondary Objectives:
• To assess the long-term safety of the study drug 180-210 days after immunization.
• To assess the efficacy of the study drug by optional epidemiological follow-up of the participants until the end of the influenza season.</td></tr>
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<tr><td>Methodology:</td><td colspan="2">After physical examinations, children of 6-36 months of age were received 0.25 ml vaccine by deep intramuscular injection into the femoral muscle. The injection was not repeated. The vaccinated persons were observed for 2 hours after the injection. Adverse events and serious adverse events were monitored by telephone follow-up on Days 1., 2., 3., 7., 10., and 28. after vaccination.</td></tr>
<tr><td>Number of patients (planned and analysed):</td><td colspan="2">Ten children aged 6-36 months of age from both sexes were enrolled in one treatment group. Data of all 10 volunteers were available and analysed.</td></tr>
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<tr><td>Diagnosis and main criteria for inclusion:</td><td colspan="2">Inclusion Criteria:
Children aged 6 to 36 months, both sexes;
Are in good health (as determined by vital signs and existing medical condition) or are in stable medical condition. Subjects will not be excluded with known adequately treated clinically significant organ or systemic diseases (e.g. asthma or diabetes), such that, in the opinion of the investigator, the significance of the disease will not compromise the subject's participation in the study;
Capability of the legitimate representative of the volunteer to understand and comply with planned study procedures;
Legitimate representative of the volunteer provide written informed consent prior to initiation of study procedures;
Absence of existence of any exclusion criteria.
Exclusion Criteria:
Known allergy to eggs or other components of the vaccine (in particular mercury);
History of Guillain-Barré syndrome;
Active neoplasm;
Former or on-going immunosuppressive therapy;
Concomitant corticosteroid therapy, including high-dose inhaled corticosteroids;
Immunoglobulin (or similar blood product) therapy within 3 months prior to vaccination;
Documented HIV, HBV or HCV infection;
Chronic illness that, in the opinion of the investigator, may have effect on the participation in the study;
Acute febrile respiratory illness within one week prior to vaccination;
Vaccine therapy within 4 weeks prior to vaccination;
Influenza vaccination within 6 months prior to vaccination;
Experimental drug therapy within 1 month prior to vaccination;
Past or current psychiatric disease of the legitimate representative that upon judgement of the investigator may have effect on the objective decision-making of the legitimate representative;
Alcohol or drug abuse of the legitimate representative.</td></tr>
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<tr><td>Test product, dose and mode of administration, batch number:</td><td colspan="2">Study drug: Fluval P monovalent influenza vaccine
Active ingredient: A/California/07/2009(H1N1)-like NYMC X-179A
Active ingredient content: 6 µgHA / 0.5 ml
Formulated: vaccine, 0,5 dose = 0.25 ml
Manufacturer of the study drug: Omninvest Ltd.
Lot No.: FL-P-K-01/09
The influenza A(H1N1) virus was grown in embryonic hen egg, purified and concentrated, formaldehyde-inactivated and absorbed to aluminum phosphate.</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">-</td></tr>
<tr><td>Criteria for evaluation:

Safety:</td><td colspan="2">In the course of safety/tolerability assessment frequency, severity, mean time of appearance and duration of all local and systemic AEs were calculated by simple descriptive statistics according to CPMP/BWP/214/96: "Note for Guidance on Harmonization of Requirements for Influenza Vaccines", 12 March 1997, Para. 2.4., 2.6., and 3.2.
According to Para. 2.4., 2.6., and 3.2. of CPMP/BWP/214/96, adverse reactions for 3 days following vaccination, either local (induration, erythema, ecchymosis, pain) or general (fever, shivering, malaise, other side-effects) and any other adverse reactions lasting 2 days beyond vaccination should be recorded and assessed.
Adverse events and serious adverse events were monitored by telephone follow-up on Days 1., 2., 3., 7., 10. and 28. after vaccination.</td></tr>
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<tr><td>Statistical methods:</td><td colspan="2">Safety and tolerability have been analysed in all ITT patients vaccinated.
In the course of safety/tolerability assessment frequency, severity, mean time of appearance and duration of all local and systemic AEs were calculated in all groups by simple descriptive statistics according to CPMP/BWP/214/96: "Note for Guidance on Harmonization of Requirements for Influenza Vaccines", 12 March 1997, Para. 2.4., 2.6., and 3.2.</td></tr>
<tr><td>Summary - Conclusions

Safety Results:</td><td colspan="2">Administration of 0.25 ml of Fluval P influenza vaccine with 6 µg HA/0.5 ml proved to be safe and were well tolerated by the participants. No clinically significant changes in the physical condition or vital signs of the volunteers were observed.
Fluval P vaccine related side effects were all mild. No medical intervention was necessary.
No possibly or probably vaccine related moderate and no Serious Adverse Event were observed.</td></tr>
<tr><td>Conclusion</td><td colspan="2">In summary, administration of Fluval P pandemic influenza vaccine is safe in children aged 6 to 36 months.</td></tr>
<tr><td>Date of Report</td><td colspan="2">08 June 2017</td></tr>
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