Pandemic Influenza Vaccine Clinical Trial Abstract Minimum information:

Title of Trial: A Phase 1 study on the safety and immunogenicity of H5N1 vaccine (BK-PIFA).
Clinical Trial registration site if applicable (e.g. ClinicalTrials.gov):  
Authors/participants/sponsors: Shigeharu Ueda.

Study Design: Clinical Center, phase I open-label clinical trial
2 doses of vaccine were administered by the subcutaneous or intramuscular routes. The 1 and 2 doses were given with 21 days interval.

Vaccine: H5N1
Manufacturer: The Research Foundation for Microbial Diseases of Osaka University (BIKEN), Japan
Type (whole virus/subvirus/subunit/live/recombinant/DNA/vector): formaldehyde inactivated whole virus vaccine, strain: A/Viet Nam/1194/2004 NIBRG-14
Adjuvant: aluminum hydroxide
Delivery system/site: Subcutaneously, intramuscularly
Doses (antigen and adjuvant): 5.0 and 15 µg of viral HA protein, 0.15mg (Al) of Al(OH)₃

Study population: Age range: 20-40 years old, 20 healthy male adults in a group, total 120 subjects
Health status: healthy
Special exclusion criteria: prior infection with H5N1 virus

Clinical Endpoints Assessed:
Safety assessments: Safety clinical laboratory tests (blood, urine), clinical signs and symptoms, physical checkup (body temperature, blood pressure, pulse rate, ECG)

Immunogenicity assessments: antibody responses were measured at day 0, 21 and 42
immunoassay type: hemagglutination inhibition (HI) and neutralization (NT)
HI (type of RBC used): Horse RBCs
Neutralization (type of neutralization assay): micro-neutralization (NIID method)

Results
Safety: Vaccines are safe and well tolerated.
Reactogenicity:  
AEs:  
Local reactions:  
Redness  55.0(%)  30.0(%)  
Swelling  20.0  20.0  
Pain  45.0  65.0  
Systemic reactions  
Fever:  20.0  0.0  
SAEs: None

Immunogenicity: Results are presented after 2 doses
GMTs:  
NT  SC injection (15 µg)  IM injection (15 µg)  
123.9  130.0
GMT Ratios (post:pre):

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<thead>
<tr>
<th></th>
<th>SC</th>
<th>IM</th>
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<tbody>
<tr>
<td>3.4x (1.7µg)</td>
<td>2.9x (1.7µg)</td>
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<tr>
<td>5.7x (5µg)</td>
<td>7.0x (5µg)</td>
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<tr>
<td>13.3x (15µg)</td>
<td>14.0x (15µg)</td>
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Percent responding (4 fold or greater rise and definition for reporting):

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<th>NT≥40 and NT≥4 fold rise:</th>
<th>SC</th>
<th>IM</th>
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<tr>
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<td>47.4% (1.7µg)</td>
<td>40.0% (1.7µg)</td>
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<td>750% (5µg)</td>
<td>65.0% (5µg)</td>
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<td>78.9% (15µg)</td>
<td>95.0% (15µg)</td>
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Current status of the clinical trial (completed, ongoing, in preparation): completed.

Date envisaged for availability of results if not yet available

Planned time schedule for next phase of development: Phase II/III was completed