



PRESS RELEASE

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POSITIVE OUTCOME OF PHASE I DNA INFLUENZA STUDY

PowderMed announces first clinical trial results

Oxford, UK, 18th November 2004 – PowderMed Ltd (PowderMed), a company focusing on the development of therapeutic DNA vaccines has announced positive results in a Phase I clinical trial of a proprietary prophylactic DNA influenza vaccine.

The trial examined three doses of the DNA influenza vaccine (1, 2 and 4 micrograms), in 12 volunteers per arm, making 36 volunteers in total. Each was administered as a single dose to healthy adult volunteers. The immune response was assessed according to the criteria laid down by the Committee for Proprietary Medicinal Products (CPMP) for the approval of annual flu vaccines in the European Union. All three doses passed the CPMP criteria at 56 days and the maximum dose (4 micrograms) passed the criteria at 21 days and was well tolerated. At the maximum dose (4 micrograms) 100% of the subjects achieved a seroprotective level of antibodies demonstrating that this DNA vaccine is a viable candidate for further trials to develop a vaccine against influenza or pandemic flu.

Dr Clive Dix, CEO of PowderMed commented:

“We are very encouraged by this positive clinical data generated with PowderMed technology. I am convinced that a PowderMed DNA flu vaccine could become a viable solution for the current threat from pandemic flu”

This DNA influenza vaccine can be readily commercialised using PowderMed’s proprietary PowderJect™ Particle Mediated Epidermal Delivery (PMED™) technology. DNA vaccines using PMED are highly versatile in that they rely on powdered DNA and can be stored at room temperature and have much longer shelf-lives than traditional vaccines.

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NOTES FOR EDITORS

About PowderMed Ltd – www.powdermed.com

PowderMed Ltd, based in Oxford, United Kingdom, is a leader in the development of therapeutic DNA Vaccines. The Company was created through a spin-out of the powder injection DNA Vaccines technology from Chiron Vaccines, a business unit of Chiron Corporation (NASDAQ: CHIR). PowderMed has acquired the rights to the PowderJect™ Particle Mediated Epidermal Delivery (PMED™) technology which it plans to use, in the first instance, in the development of therapeutic DNA vaccines targeting chronic viral diseases and cancer. PowderMed has a proprietary therapeutic vaccine for the treatment of genital herpes in Phase I trials and also two partnered Phase I programmes in Cancer (Ludwig Institute) and HIV/AIDS (GlaxoSmithKline). In addition the Company has two proprietary preclinical lead programmes targeting genital warts and, hepatitis B. The Company will seek to further its technology in areas outside of its strategic focus through partnerships and collaborations.

Influenza

Influenza is an acute viral infection involving the respiratory tract. It is marked by inflammation of the nasal mucosa, the pharynx, and conjunctiva, and by headache and severe, often generalized, myalgia. Worldwide, an estimated 100,000 hospitalisations and about 20,000 deaths occur each year from the flu or its complications (source: *The National Institute of Allergy and Infectious Diseases*).

Phase I Clinical trial

Phase I clinical trials are the first trials of a drug in humans. They are usually short term trials in a small number of individuals designed to evaluate preliminary safety of a compound in humans.

Committee for Proprietary Medicinal Products (CPMP) Guidance on Flu Vaccines

Before a licence is given to market an influenza vaccine, each formulation must be tested in accordance with the Committee for Proprietary Medicinal Products (CPMP) Note for Guidance on Harmonisation of Requirements for Influenza Vaccines published in March 1997 (ref. CPMP/BWP/214/96) to observe whether or not they are able to provide adequate immunological protection.

The CPMP guideline requires that only one of three serological assessments be met for each influenza strain in both a 'non-elderly' (18-59 years) and 'elderly' (60-79 years) age groups. To fulfil this guideline, at least one of the following criteria must be met for each of the strains contained in the vaccine:

- >70% of 'non-elderly' subjects (>60% 'elderly' subjects) achieve a post-vaccination anti-HA titre of ≥ 40 .
- the geometric mean increase in anti-HA titre is >2.5 for 'non-elderly' subjects and >2.0 for 'elderly' subjects.
- >40% of 'non-elderly' subjects (>30% of 'elderly' subjects) must seroconvert or demonstrate a significant increase in anti-HA titre.

NB: Seroconversion with regard to the anti-HA antibodies is defined as either:

- a negative pre-vaccination titre (<10) with a post-vaccination titre of ≥ 40 .
- a significant increase in antibody titre, i.e., at least a 4-fold increase between pre-and post-vaccination titres (where the pre-vaccination titre was ≥ 10).

PowderJect® Particle Mediated Epidermal Delivery (PMED) technology

Using the PowderJect device, DNA precipitated onto microscopic gold particles, is propelled by pressurised helium gas at near supersonic speeds into the epidermis. The microscopic gold particles (mean particle diameter 1 - 3 microns) are used as the carrier because they have the appropriate size and density needed to deliver the DNA directly into the immunologically active antigen presenting cells (APCs) of the epidermis. These cells have a mean diameter 20 microns and thus the microscopic gold can easily enter the cell. Studies have shown that once inside the nuclei of APCs, the DNA elutes off the gold and becomes transcriptionally active, producing the encoded protein that when presented by the APCs to lymphocytes, triggers strong T-cell mediated immune responses. It is this ability of PMED to produce a robust and reproducible T-cell mediated immune response to a broad range of viral and cancer antigens, that provides PowderMed with its unique competitive advantage in the field of therapeutic vaccines.