**Clinical Trial – Recruiting Now**

Re: V114-017 (PNEU-DAY) A Phase 3, Multicentre, Randomised, Double-Blind, Active Comparator-Controlled Study to Evaluate the Safety, Tolerability and Immunogenicity of V114 Followed by Administration of Pneumovax™ 23 Six Months Later in Immunocompetent Adults Between 18 and 49 Years of Age at Increased Risk of Pneumococcal Disease.

Dear Colleague,

I am an investigator for the V114-017 (PNEU-DAY) clinical research study, which will evaluate an investigational 15-valent pneumococcal conjugate vaccine (V114) to protect against pneumococcal disease.

**Patients will be randomised in a 3:1 ratio into one of two groups:**

* + - * Group 1: V114 followed by Pneumovax™ 23 given 6 months later
			* Group 2: Prevnar™ 13 followed by Pneumovax™ 23 given 6 months later

This clinical study is designed to evaluate the safety, tolerability and immunogenicity of a single-dose of V114 compared with Prevnar™ 13 in immunocompetent, at-risk individuals, followed by sequential administration of Pneumovax™ 23, 6 months later.

Approximately 1500 individuals will be randomly assigned in a 3:1 ratio to receive either V114 (1125 participants) or Prevnar™ 13 (375 participants) at Day 1.

**Key Inclusion Criteria**

* Pneumococcal vaccine-naïve adults 18 to 49 years of age
* At least one chronic medical condition such as diabetes, heart, liver or lung disease
* And/or a current cigarette smoker

**Key Exclusion Criteria**

* Active hepatitis – within the last 3 months
* History of diabetic retinopathy - within the last 3 months
* Myocardial infarction - within the last 3 months
* Impaired immunology

Additional inclusion and exclusion criteria apply.

Participants can expect to be part of the study for seven months, visit the clinic five times, and be contacted by telephone twice.

To learn more about this study, or to refer a patient, please contact the Research Nurses at the BOP Clinical Trials Unit, Tauranga Hospital:

Michelle Raitak – 07 5575242 / michelle.raitak@bopdhb.govt.nz

Sincerely,

Dr Diane Hanfelt-Goade

V114-017\_Physician Referral Letter\_V2.0\_English-NZ

Consultant Physician Infectious Diseases Tauranga Hospital