PARTICIPANT INFORMATION SUMMARY SHEET

STUDY EMR200621-003

A study assessing the similarity of Neulasta® and the trial drug MSB11455.

Christchurch Clinical Studies Trust Limited is enrolling healthy males and females aged 18 – 55 years into the above study. This summary sheet briefly outlining the study. If you want to know more about the research and think you might like to take part, please read the detailed information sheet before making your decision.

Neulasta is an approved medication used to treat low white blood cells (infection fighting cells). Some people who receive Neulasta® develop antibodies against the drug. Antibodies are special proteins made by the body that recognise foreign substances. Antibodies that form against drugs are called anti-drug antibodies.

Merck is developing an investigational drug designed to be similar to Neulasta®, called MSB11455. **This study aims to test MSB11455 to make sure that it is similar to Neulasta® in terms of the anti-drug antibodies that develop after dosing.** The study will recruit 336 healthy volunteers in 2 locations in New Zealand.

Every person in the study will receive two 6mg doses of either MSB11455 or Neulasta®. The two doses will be given 4 – 5 weeks apart. Each dose will be given as an injection under the skin in the back of the arm.

If you take part, you will be in this study for about 3 months (plus a screening period of up to 5 weeks). This includes two 3-night stays at CCST and 15 scheduled clinic visits. You will be monitored throughout the study for any changes in your health.

There are risks and benefits of this research. In a study like this one, every risk or side effect cannot be predicted. The most common side effects seen with Neulasta® include bone, joint and muscle pain; redness or pain at the drug injection site, headache, reversible changes in certain blood tests, and increased spleen size. It is thought that the side effects of MSB11455 would be similar to Neulasta®.

If you would like to know more about this study and what would be involved, please read the detailed information sheet. This sheet will provide in-depth details about the study, including what you would be required to do during the study, what additional tests would be required, and a full description of the known and potential risks of taking part.

Taking part in this study is voluntary. You are free to say yes or no, or to change your mind and pull out of the study at any time. If you do not wish to know any more information, we thank you for considering your participation.