

**Study Title**

A randomized, controlled, open label trial to compare the efficacy, safety and tolerability of TMC114/RTV versus LPV/RTV in treatment experienced HIV-1 infected subjects.

**Status**

Enrolment complete

**Primary Investigator at TGH**

Dr. Sharon Walmsley

**Sponsor**

Tibotec Pharmaceuticals

**Brief Description of the Study**

This is a randomized controlled, open label, Phase III trial to determine the efficacy, safety and tolerability of TMC114 administered with a low dose of ritonavir(RTV) over a 96 week treatment period. Subjects must be on their current Highly Active Antiretroviral Treatment (HAART) regimen for at least 12 weeks. At baseline subjects will change their screening regimen. An optimized background regimen (OBR) will be initiated and will consist of at least 2 antiretrovirals (ARV's). Additionally, subjects will be randomized at baseline in a 1:1 ratio to receive a new PI regimen (along with the selected OBR) consisting of either TMC114/RTV or LPV/RTV. Subjects who meet the specifically defined criteria for virologic failure (TMC114/RTV or LPV/RTV) or who experience a grade 4 adverse event or confirmed grade 4 (or specific grade 3) laboratory abnormality (LPV/RTV group only), may roll over to a rollover phase.

**Study Arms**

- TMC114/RTV plus the investigator selected optimized background regimen consisting of at least 2 antiretrovirals (NRTI's with or without NNRTI's).
- LPV/RTV plus the investigator selected optimized background regimen consisting of at least 2 antiretrovirals (NRTI's with or without NNRTI's).

**Contact**

For more information contact Adriana D'Aquila, RN @ 416-340-4800 ext: 8170,  
Email: adri.d'aquila@uhn.on.ca