Clinical Trial Protocol

Project No:	TMC120	**Non-Proprietary name:**	
Department:	Clinical R&D	**Document ID:**	
Version:	1.0	**Date:** 16 APRIL 2004	**Status:** Final
Title:	Phase I Study of a Vaginal Ring for Delivery of TMC120 as a Vaginal Microbicide		
Trial No:	TMC120-C130/IPM001	**Clinical Phase:**	I
Summary:	This Phase I trial will assess the feasibility of using a silicone elastomer vaginal ring to deliver the candidate microbicide TMC120. The study population consists of 12 healthy sexually abstinent women. Safety and tolerability will be assessed through clinical and laboratory assessments. Feasibility of drug delivery will be assessed by measuring TMC120 concentrations in vaginal fluids, vaginal and cervical tissue, and plasma.		
Trial Location:	Ghent, Belgium		
Investigators:	Dr. Luc Van Bortel, Drug Research Unit, UZ Ghent (principle investigator) Dr. Marleen Temmerman, Department of Gynecology, UZ Ghent (sub-investigator)		
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Sponsor:	Tibotec Pharmaceuticals Ltd., Blanchardstown Corp. Park, Dublin 15, IRELAND		
Co-Sponsor:	International Partnership for Microbicides (IPM), Silver Spring, Maryland, USA		
Trial Coordinator:	Greet Beets, Tibotec Pharmaceuticals Ltd., Tel.: +32 (0)15 401205		
Treatment:	Seven-day exposure to a placebo vaginal ring (containing no investigational agent) followed by seven-day exposure to a ring containing 120 mg of TMC120 (excluding screening and post-exposure follow-up).		

GCP Statement:	This trial will be conducted in accordance with this protocol, Good Clinical Practices, and applicable regulatory requirements.
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