# Clinical Trial Protocol

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| **Project No:** | TMC120 | **Non-Proprietary name:** | - |
| **Department:** | Clinical R&D | **Document ID:** | |
| **Version:** | 1.0 | **Date:** 27 May 2005 | **Status:** Final |
| **Title:** | Double-blind, randomized, placebo controlled trial to study safety, local and systemic availability of TMC120 from a vaginal ring. | | |
| **Trial No:** | IPM 008/ TMC120-C131 | **Clinical Phase:** | I |
| **Summary:** | This Phase I trial will assess the feasibility of using a vaginal ring to deliver the candidate microbicide TMC120 for 7 days. The study population will consist of 13 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 epithelial tissue, and plasma. | | |
| **Trial Location:** | Gent, Belgium | | |
| **Investigators:** | Dr. Luc Van Bortel, Drug Research Unit Gent, UZ Gent (principle investigator)<br>Dr. Marleen Temmerman, Department of Gynecology, UZ Gent (sub-investigator) | | |
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| **Sponsor:** | International Partnership for Microbicides (IPM), Silver Spring, Maryland, USA | | |
| **Co-Sponsor:** | Tibotec Pharmaceuticals Ltd., Little Island, Co Cork; IRELAND | | |
| **Trial Coordinator:** | Richard M. Erwin, Director Clinical Operations IPM,<br>1010 Wayne Avenue, Suite 1450<br>Silver Springs, Maryland, USA, 20910<br>Tel.: (301) 608-2221 / fax: (301) 608-2241 | | |
| **Treatment:** | Seven-day exposure to a TMC120 vaginal ring in 10 subjects; seven-day exposure to a placebo vaginal ring in 3 subjects. | | |

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