# Clinical Trial Protocol

<table>
<thead>
<tr>
<th>Project No:</th>
<th>TMC120</th>
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<tbody>
<tr>
<td>Department:</td>
<td>Clinical R&amp;D</td>
</tr>
<tr>
<td>Version:</td>
<td>1.0</td>
</tr>
<tr>
<td>Date:</td>
<td>16 APRIL 2004</td>
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<tr>
<td>Status:</td>
<td>Final</td>
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## 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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Tel.: +32 (0)9 240 55 44 / fax: +32 (0)9 240 56 50

## 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).
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<tr>
<th><strong>GCP Statement:</strong></th>
<th>This trial will be conducted in accordance with this protocol, Good Clinical Practices, and applicable regulatory requirements.</th>
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<tbody>
<tr>
<td><strong>Confidentiality Statement:</strong></td>
<td>The information in this document contains trade secrets and commercial information that are privileged or confidential and may not be disclosed unless such disclosure is required by law. In any event, persons to whom the information is disclosed must be informed that the information is privileged or confidential and may not be further disclosed by them. These restrictions apply to all future information supplied to you which is indicated as privileged or confidential.</td>
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