STATUS REPORTS OF OTHER POST MARKETING STUDIES – ONGOING STUDIES

STUDY STATUS SUMMARY (II) – September 28, 2001

Study Title: Comparison of abortions induced by mifepristone followed by vaginal versus oral misoprostol up to 56 days gestation

Protocol Number: 298

Study Phase:

Date of Study Initiation: February 27, 2001

Date of IND Submission: June 19, 2001 (Submission Serial Number: 216)

Study Status (Ongoing/Completed/Discontinued): Suspended

Investigator(s)/Study Center(s):

1. Ellen Wiebe, University of British Columbia, Vancouver, British Columbia, Canada
2. Francis Jacot, Clinique de Planification des Naissances de l'Éstrie, Centre Universitaire de Santé de l'Éstrie, Sherbrooke, Quebec
3. Edith Guilbert, The Family Planning Clinic of Le Center Hospitalier Universitaire de Quebec, Quebec City, Quebec
4. Sheila Dunn, Bay Center for Birth Control, University of Toronto, Toronto, Ontario
5. Lisa Lugtig, Klinic Community Health Centre, Inc., Winnipeg, Canada

Objective: To compare the use of vaginal misoprostol (800 µg) and oral misoprostol (400 µg or 600 µg) in combination with mifepristone (200 mg) to terminate pregnancies of up to 56 days gestation.

Study Design: Randomized, non-placebo controlled trial

Drugs:

Investigational Drug: Mifepristone + Misoprostol
Control Drug: None

Dosage: 200 mg oral mifepristone, 400 µg oral misoprostol or 600 mcg oral misoprostol or 800 mcg vaginal misoprostol (2 days later)

Description of Patients: Pregnant women with gestations ≤ 56 days gestation

Number of Patients

Planned:	1500
Enrolled:	940
Age Range:	18 - 45
Gender:	female
Race:	n/a
Dropped:	0
Completed:	940

Safety Variables: Frequency of blood transfusion, administration of IV fluids and hospitalization

Efficacy Variables: Success, complete abortion without a surgical intervention

Safety Results:

Blood transfusion	= 1
Administration IV fluids	= 2
Hospitalization	= 1*
Death	= 1*

Efficacy Results: Success (interim analysis of 817 cases)

Overall =		97.8%
400 µg oral misoprostol =		97.1%
600 µg oral misoprostol =		98.5%
800 µg vaginal misoprostol	=	97.8%

*IND Safety Reports were submitted to IND 22,047 (Initial Report, Submission Serial Number 218, September 5, 2001 and Follow-up Report, Submission Serial Number 219, September 19, 2001).