# STATUS REPORT OF OTHER POST MARKETING STUDIES – COMPLETED STUDIES

## STUDY STATUS SUMMARY (II) – SEPTEMBER 27, 2002

***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): Completed***

***Investigator(s)/Study Center(s):***

(b) (4), (b) (6)

1)
2)
3)
4)
5)

***Objective:*** To compare the safety, efficacy and acceptability of three regimens of mifepristone-misoprostol medical abortion, 400 µg oral misoprostol, 600 µg oral misoprostol and 800 µg vaginal misoprostol given 24 to 48 hours following administration of 200 mg mifepristone.

***Study Design:*** Randomized, comparative trial

***Drugs:***

*Investigational Drug:* Mifepristone + Misoprostol

*Control Drug:* None

***Dosage:*** 200 mg oral mifepristone, 400 µg oral misoprostol or 600 µg oral misoprostol or 800 µg vaginal misoprostol (1 to 2 days later)

***Description of Patients:*** Pregnant women with gestations under 56 days LMP

## STUDY STATUS SUMMARY (II) – SEPTEMBER 27, 2002 (CONT.)

***Number of Patients***

| | |
|---|---|
| *Planned:* | 1500 |
| *Enrolled:* | 971* |
| *Age Range:* | 18 - 45 |
| *Gender:* | female |
| *Race:* | n/a |
| *Dropped:* | 0 |
| *Completed:* | 971 |

***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 =

94.7 ± 2.5 (400 µg oral misoprostol, n =302)

92.7 ± 3.0 (600 µg oral misoprostol, n=294)

94.1 ± 2.6 (800 µg vaginal misoprostol, n=301)

Results still preliminary.

* Please note the enrollment figure of 940 as reported in the last annual report for NDA 20-687 dated December 14, 2001 was a preliminary enrollment figure.