

DATE: May 18, 2009

TO: Participants at the Meeting of the Gastrointestinal Advisory Committee (GIDAC)

FR: Debiovision, Inc.

SUBJECT: Errata to Debiovision Background document for the Sanvar

Please accept the following corrections to the original Debiovision background package submitted for the Sanvar (vapreotide) advisory committee meeting scheduled for May 19, 2009

Page	Table	Item	Correction
Pg 64	Table 26	# Vapreotide patients in Non-EVB Studies	N=258 correct to N=259
Pg 67	Table 29	Last 2 columns provide Safety Outcome for 9-Study Database; not 4 Non-EVB Studies	<i>4 Non-EVB Studies Vapreotide N=259; Placebo N=189</i> correct to <i>9-Study Database Vapreotide N=728; Placebo N=536</i>

Pg 77 & Pg 89	Text	Number of HIV/AIDS patients who died in VAP-301	All 6 HIV/AIDS patients died on study correct to 5 of 6 HIV/AIDS patients died on study
Pg 79	Table 36	Footnote (a)	Should read: Patients who recovered or died from the rebleeding.

Page 78 Table 35 Deaths Occurring in Vapreotide EVB Studies

Cause of Death	Days 1-42, n (%)			Days 1-5 (drug infusion), n (%)			Days 6-42 (Follow-up), n (%)		
	4 EVB RCTs		VAP-301	4 EVB RCTs		VAP-301	4 EVB RCTs		VAP-301
	Vapreotide N=366	Placebo N=347	Vapreotide N=103	Vapreotide N=366	Placebo N=347	Vapreotide N=103	Vapreotide N=366	Placebo N=347	Vapreotide N=103
Total deaths	55 (15.0%)	57 (16.4%)	26 (25.2%)	24 (6.6%)	24 (6.9%)	9 (8.7%)	31 (8.5%)	33 (9.5%)	17 (16.5%)
Uncontrolled bleeding/ recurrence of bleeding leading to hemorrhagic shock ^a	27 (7.4%)	30 (8.6%)	5 (4.9%)	15 (4.1%)	16 (4.6%)	2 (1.9%)	12 (3.3%)	14 (4.0%)	3 (2.9%)
Worsening of liver disease ^b	18 (4.9%)	15 (4.3%)	7 (6.8%)	7 (1.9%)	5 (1.4%)	1 (1.0%)	11 (3.0%)	10 (2.9%)	6 (5.8%)

Infection/multiorgan failure ^c	3 (0.8%)	5 (1.4%)	9 (8.7%)	---	---	4 (4.8%)	3 (0.8%)	5 (1.4%)	5 (4.9%)
Cardiac/cardiorespiratory arrest ^d	2 (0.5%)	4 (1.2%)	2 (1.9%)	1 (0.3%)	2 (0.6%)	1 (1.0%)	1 (0.3%)	2 (0.6%)	1 (1.0%)
Cerebrovascular accident	2 (0.5%)	---	---	1 (0.3%)	---	---	1 (0.3%)	---	---
Renal failure	1 (0.3%)	---	---	---	---	---	1 (0.3%)	---	---
Respiratory distress/acute respiratory distress syndrome/ respiratory failure	1 (0.3%)	2 (0.6%)	2 (1.9%)	---	1 (0.3%)	1 (1.0%)	1 (0.3%)	1 (0.3%)	1 (1.0%)
Death (not otherwise specified)	1 (0.3%)	1 (0.3%)	1 (1.0%)	---	---	---	1 (0.3%)	1 (0.3%)	1 (1.0%)

^a Includes upper gastrointestinal hemorrhage, melena, duodenal ulcer hemorrhage, rectal hemorrhage, hemorrhagic shock, hypovolemic shock, shock.

^b Includes hepatic encephalopathy, hepatorenal syndrome, hepatic neoplasm, hepatic cirrhosis hepatic failure, hepatic coma.

^c Includes peritonitis/ascites infection, pneumonia, fungemia, sepsis/septic shock, multiorgan failure (included because cases of multiorgan failure also had infection/sepsis).

^d Cardiac/cardiorespiratory arrest resulting from severe bleeding and hemorrhagic shock included in the uncontrolled bleeding category, not herein.

-- : no events reported