

**ERRATA  
to the FDA Briefing Information**

**Cardiovascular and Renal Drugs Advisory Committee  
December 10, 2008**

This erratum corrects typographical errors, provides better illustration for a figure and clarifies subject distribution in Study 04.

**1) Page 10, footnote 10, corrects the typographical error in the footnote to Table 2:**

"mITT = received AI-700 (any part of a dose for Study 33; all of a dose for Study 33)..."

Corrected to read:

"mITT = received AI-700 (any part of a dose for Study 32; all of a dose for Study 33)..."

**2) Page 11, corrects the typographical error in Table 3. The second header should be labeled "Study 33."**

**Table 3. Performance Characteristics, by Echocardiography Reader**

Diagnostic Statistic	Study 32				Study 32			
	SPECT	ECHO #1	ECHO #2	ECHO #3	SPECT	ECHO #1	ECHO #2	ECHO #3
Accuracy	70 %	66 %	67 %	71 %	67 %	66 %	70 %	70 %
Ratio		0.94	0.96	1.0		0.98	1.0	1.0
Ratio CI limit		0.86	0.87	0.93		0.89	0.96	0.96
Sensitivity	78 %	77 %	57 %	50 %	61 %	73 %	68 %	73 %
Ratio		0.99	0.73	0.64		1.2	1.1	1.2
Ratio CI limit		0.88	0.63	0.54		1.08	1.01	1.09
Specificity	64 %	58 %	75 %	88 %	76 %	55 %	72 %	66 %
Ratio		0.91	1.2	1.4		0.73	0.95	0.87
Ratio CI limit		0.78	1.04	1.24		0.62	0.84	0.76

Corrected to read:

**Table 3. Performance Characteristics, by Echocardiography Reader**

Diagnostic Statistic	Study 32				Study 33			
	SPECT	ECHO #1	ECHO #2	ECHO #3	SPECT	ECHO #1	ECHO #2	ECHO #3
Accuracy	70 %	66 %	67 %	71 %	67 %	66 %	70 %	70 %
Ratio		0.94	0.96	1.0		0.98	1.0	1.0

Ratio CI limit		<b>0.86</b>	<b>0.87</b>	<b>0.93</b>		<b>0.89</b>	<b>0.96</b>	<b>0.96</b>
<b>Sensitivity</b>	78 %	77 %	57 %	50 %	61 %	73 %	68 %	73 %
Ratio		<b>0.99</b>	<b>0.73</b>	<b>0.64</b>		<b>1.2</b>	<b>1.1</b>	<b>1.2</b>
Ratio CI limit		<b>0.88</b>	<b>0.63</b>	<b>0.54</b>		<b>1.08</b>	<b>1.01</b>	<b>1.09</b>
<b>Specificity</b>	64 %	58 %	75 %	88 %	76 %	55 %	72 %	66 %
Ratio		<b>0.91</b>	<b>1.2</b>	<b>1.4</b>		<b>0.73</b>	<b>0.95</b>	<b>0.87</b>
Ratio CI limit		<b>0.78</b>	<b>1.04</b>	<b>1.24</b>		<b>0.62</b>	<b>0.84</b>	<b>0.76</b>

**3. Page 11, corrects the subject distribution in Table 4.**

**Table 4. AI-700 Exposure**

n	Subjects
1,194	Total population
911	Suspected or known CAD/proposed dose regimen
167	Co-morbidities and/or alternate dose regimens
116	Healthy volunteers

Corrected to read:

**Table 4. AI-700 Exposure**

n	Subjects
1,194	Total population
911	Suspected or known CAD/proposed dose regimen
153	Co-morbidities and/or alternate dose regimens
130	Healthy volunteers

**4. Page 12, corrects the subject distribution and exposure history cited in Study 04.**

"Overall, 21 subjects received AI-700 in the study."

Corrected to read:

"Overall, 12 subjects were enrolled, 10 received AI-700 and 2 received placebo during Stage 1. During Stage 2, the same subjects were rechallenged (with either AI-700 or placebo, depending on which test article was administered during Stage 1). During Stage 2, 7 subjects received AI-700 and 2 received placebo."

and

"Stage 2 began one year following Stage 1..."

Corrected to read:

"Stage 2 began more than one year following Stage 1..."

**5. Page 13, to correct the typographical error.**

"Of the 1870 adverse events..."

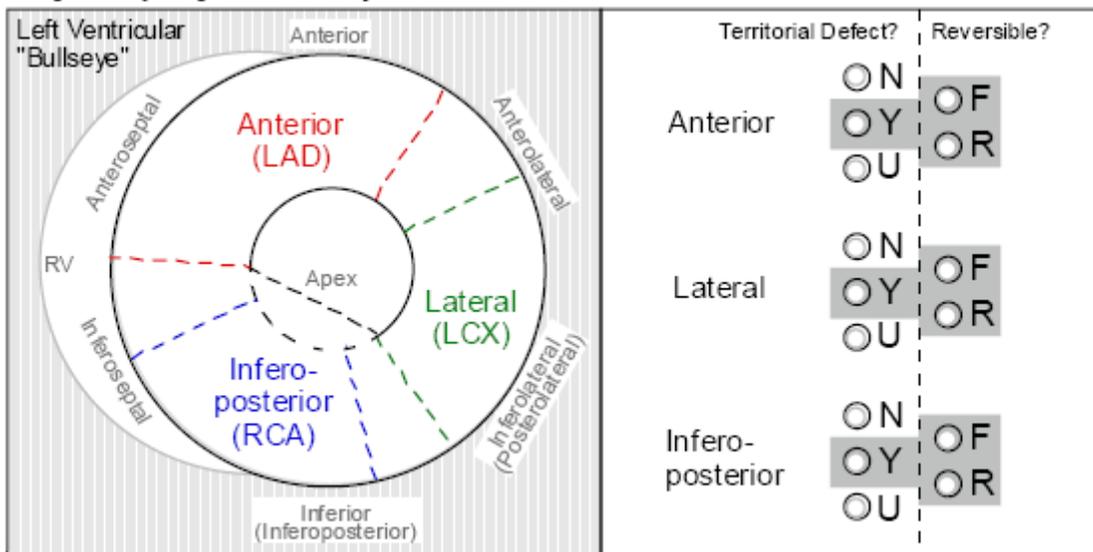
Corrected to read:

"Of the 1879 adverse events..."

**6. Page 9, to provide a more explicit description of the image assessment figure.**

Specifically to provide a clearer picture and to note that "unevaluable" was not an assessment for echocardiography (instead, "unvisualizable" was to be noted). "Unevaluable" was an option for SPECT.

**Figure 2: Global Outcome Scoring Report**

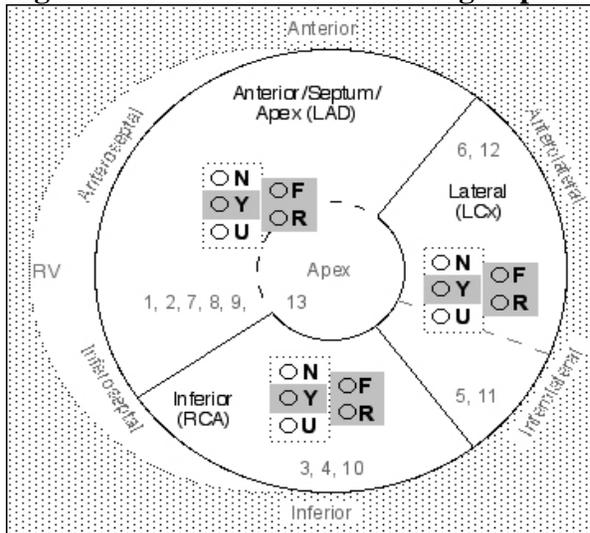


All study echocardiograms were assessed for defects (disease) by providing the following Global Outcome scores:

- |  |  |
|--|--|
| Y = defect                                     | N = no defect                                    |
| U = unevaluable                                | U = Unvisualizable                               |
| F = little or no evidence of reversible defect | R = partially or predominantly reversible defect |

Corrected and clarified as:

**Figure 2: Global Outcome Scoring Report**



**LEGEND**

Primary Defect/ No Defect Scoring

“N” = No, probably has no myocardial defect;

“Y” = Yes, probably has a myocardial defect;

“U” = Unvisualizable, available views do not permit visualization of the region.

Secondary Scoring (Defects Only)

“F” = little or no evidence of a reversible defect (i.e., ”Fixed”);

“R” = partially or predominantly Reversible defect.