

## **XII. Use in Special Populations**

### **A. Efficacy**

Covariate analyses using logistic regression were performed to determine whether age, gender, or race had a significant effect on the *H. pylori* eradication rates. None of these covariates had a significant effect on *H. pylori* eradication status.

### **B. Safety**

Elderly patients who receive HAC may be more likely to report GI side effects compared to younger patients.

Female patients who receive HAC may be more likely to report GI side effects and special senses/other disorders than males, and males may be more likely to have liver and biliary system disorders than females, although the overall incidence was relatively low.

Caucasian patients who receive HAC may be more likely to report GI side effects compared to Black patients.

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**XIII. Conclusions and Recommendations**

Esomeprazole magnesium (formerly H 199/18) when used in combination with amoxicillin and clarithromycin is safe and effective for the treatment of patients with *H. pylori* infection and duodenal ulcer disease (active or history of within the past 5 years) to eradicate *H. pylori*. Eradication of *H. pylori* has been shown to reduce the risk of duodenal ulcer recurrence. The recommendation is for approval of esomeprazole 40 mg, amoxicillin 1 gm, plus clarithromycin 500 mg \_\_\_\_\_ for 10 days for this indication.

Recommended changes have been incorporated into the applicant's draft labeling and can be found in Appendix 4.

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*12/15/00*  
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**Concurrence:**  
HFD-590/TLMO/RocaR */S/ 12.20.00*  
HFD-590/DivDir/GoldbergerM */S/ for 12/22/00*

- cc:**  
HFD-590/Div File/NDA 21-154  
HFD-590/TLMO/RocaR  
HFD-725/TLStat/HigginsK  
HFD-590/DepDivDir/AlbrechtR  
HFD-590/DivDir/GoldbergerM  
HFD-880/Biopharm/MeyerJ  
HFD-590/PM/FritschJ  
HFD-725/DivDir/HuqueM  
HFD-725/Sec/ShoresS

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**APPENDIX 1 – Additional Tables from Study 191**

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**TABLE 1**  
**Number of Patients Entered into Study by Investigator and Treatment Group**  
**Study #191**

Site Number	Investigator	H 40 qd + A 1000 bid + C 500 bid	H 40 qd + C 500 bid	Total
001	Abrahm, Donald	0	0	0
002	Adelglass, Jeffrey	0	0	0
003	Ali, Madad	6	7	13
004	Apter, Jeffrey	0	0	0
005	Arora, Ajit	6	4	10
006	Ashby, Kevin	3	3	6
007	Barnes, Larry	1	1	2
008	Barreiro, Marcelo	2	2	4
009	Bassan, Isaac	12	12	24
010	Bianchi, Thomas	1	0	1
011	Birbara, Charles	2	0	2
012	Bleser, Scott	3	3	6
013	Brandon, Milan	2	1	3
014	Breiter, Jeffrey	8	8	16
015	Chappel, Christopher	6	6	12
016	Chasen, Richard	0	0	0
017	Chiprut, Roberto	12	12	24
018	Chua, David	7	7	14
019	Cirillo, Nicolas	1	1	2
020	Coats, Teresa	1	0	1
021	Cohen, Robert	1	0	1
022	Colip, Charles	1	2	3
023	Dickinson, Douglas	0	0	0
024	Dimitroff, James	0	0	0
025	Dozer, David	3	4	7
026	Eisner, Mark	9	8	17
027	Eskreis, David	2	1	3
028	Fedolin, Michael	0	1	1
029	Fogel, Ronald	5	5	10
030	Foss, Jeffrey	1	1	2

**TABLE 1 (continued)**  
**Number of Patients Entered into Study by Investigator and Treatment Group**  
**Study #191**

Site Number	Investigator	H 40 qd + A 1000 bid + C 500 bid	H 40 qd + C 500 bid	Total
031	Frank, James	0	0	0
032	Gaddam, Syam	5	6	11
033	Dreznick, Elliot	0	0	0
034	Gilderman, Larry	1	0	1
035	Gorsky, Michael	0	2	2
036	Gray, John	0	0	0
038	Gremillion, Daniel	4	4	8
039	Hardi, Robert	1	1	2
040	Jamal, Mazen	3	4	7
041	James, David	0	0	0
042	Jayanty, Vikram	4	4	8
043	Johnson, David	1	1	2
044	Kamyar, Rokay	7	8	15
045	Kassman, Neil	2	2	4
046	Kidao, Jayashri	0	0	0
047	Krause, Richard	3	4	7
048	Krumholz, Steven	0	0	0
049	Lanza, Frank	5	5	10
050	Lepinski, Susan	0	1	1
051	Madan, Manish	0	0	0
052	Maggiacomo, Frank	0	0	0
053	Marcuard, Stefan	4	3	7
054	Martin, William	1	1	2
055	McCluskey, Dennis	1	1	2
056	Milman, Perry	2	0	2
057	Milner, Paul	3	4	7
058	Morton, William	0	0	0
059	Moskovitz, Morry	0	0	0
060	Nett, Robert	0	0	0

**TABLE 1 (continued)**  
**Number of Patients Entered into Study by Investigator and Treatment Group**  
**Study #191**

Site Number	Investigator	H 40 qd + A 1000 bid + C 500 bid	H 40 qd + C 500 bid	Total
062	Novick, James	0	0	0
063	Offenberg, Howard	1	1	2
064	Opipari, Michael	2	1	3
065	Pambianco, Daniel	2	2	4
066	Pardoll, Peter	1	0	1
067	Perakos, Peter	0	0	0
068	Poleski, Martin	0	0	0
069	Rall, Chris	0	1	1
070	Ramirez, Francisco	1	2	3
071	Resnik, Harvey	1	0	1
072	Rhoton, Albert	1	1	2
073	Riff, Dennis	12	12	24
074	Rodriguez, Andres	2	1	3
075	Ross, William	4	4	8
076	Safdi, Michael	2	0	2
077	Schumacher, Douglas	0	0	0
078	Schwartz, Howard	10	9	19
079	Seger, William	1	0	1
080	Shah, Umedchandra	13	12	25
081	Shepherd, Mark	0	1	1
082	Shivakumar, B.N.	4	3	7
083	Siegel, Howard	2	2	4
084	Simmons, Timothy	12	12	24
085	Smith, Thomas	0	0	0
086	Spiota, Jr., Eugene J.	5	4	9
087	Gadallah, Shireen	0	0	0
088	Strong, Lewis	0	0	0
089	Taylor, David	0	0	0
090	Touger, Mitchell	1	1	2
091	Trotman, Bruce	0	0	0
092	Varilek, Gary	1	1	2

**TABLE 1 (continued)**  
**Number of Patients Entered into Study by Investigator and Treatment Group**  
**Study #191**

Site Number	Investigator	H 40 qd + A 1000 bid + C 500 bid	H 40 qd + C 500 bid	Total
093	Vlahcevic, Zoravko Reno	2	3	5
094	Waring, J. Patrick	0	0	0
095	Wegley, Steven	0	0	0
096	Wiesenhutter, M, Craig	0	0	0
097	Winder, John	0	0	0
098	Witt, Peter	3	4	7
099	Wright, Richard	2	0	2
100	Zarchy, Thomas	0	1	1
101	McElroy, Aubrey	4	4	8
102	Bills, Stephen	0	0	0
103	Godiwala, Tejas	0	0	0
104	Bird, Phillip	0	0	0
105	Bedard, Charles	2	3	5
106	Roth, Sanford	0	0	0
107	Snape, Jr., William J.	2	0	2
108	Aaronson, Richard	1	0	1
109	Rubin, Herbert	6	6	12
110	Galambos, Michael	1	1	2
111	Gaman, Walter	0	0	0
112	Sontag, Stephen	3	3	6
113	Monroe, Paul	1	1	2
114	Mangels, David	2	3	5
115	Mertesdorf, Jim	0	0	0
116	Wadleigh, John	0	0	0
117	Schulman, David S.	0	0	0
118	Sullivan, James	0	0	0
119	Fausel, Craig	0	0	0
120	Cabezas-Mijuste, Maritza	2	1	3
121	Samanta, Arun	2	1	3
122	Axelrad, Andrew	0	0	0
123	Staffetti, Joseph	0	0	0
124	Salzberg, Bruce	0	0	0

**TABLE 1 (continued)**  
**Number of Patients Entered into Study by Investigator and Treatment Group**  
**Study #191**

Site Number	Investigator	H 40 qd + A 1000 bid + C 500 bid	H 40 qd + C 500 bid	Total
125	Fullard, Jasper	0	0	0
126	Benjamin, William	1	1	2
127	Bell, Charles	0	0	0
128	Gupta, Ambrish	5	6	11
129	Phillips, Raymond	0	0	0
130	Provenza, Mark	2	3	5
131	Kruss, Daniel	1	0	1
132	Hatfield, Asa	1	0	1
133	Block, Edward	0	0	0
134	Laine, Loren	1	0	1
135	Hammerman, Kenneth	0	0	0
<b>TOTAL</b>		<b>264</b>	<b>251</b>	<b>515</b>

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**TABLE 2**  
**Patients Excluded from Efficacy Analysis**  
**All Randomized Patients**  
**Study #191**

Site/ Enrollment Number	Patient Allocation Number	Excluded from ITT Analysis	Reason(s) for Exclusion (ITT) <sup>a</sup>	Excluded from PP Analysis	Reason(s) for Exclusion (PP) <sup>a</sup>
<b>HAC</b>					
003/006	1324	Yes	A	Yes	A
003/010	1766	No		Yes	E
003/011	1768	Yes	A	Yes	A
007/001	1009	No		Yes	CE
009/003	1279	Yes	A	Yes	A
009/005	1475	Yes	A	Yes	AC
009/010	1593	Yes	A	Yes	A
009/014	1718	No		Yes	D
009/018	1812	Yes	A	Yes	A
009/021	1877	Yes	A	Yes	A
011/002	1042	No		Yes	F
012/002	1016	Yes	A	Yes	A
015/004	1080	No		Yes	C
017/021	1753	Yes	A	Yes	A
018/003	1400	Yes	A	Yes	A
019/001	1205	Yes	A	Yes	A
020/001	1233	Yes	A	Yes	A
021/001	1173	No		Yes	C
026/003	1126	Yes	A	Yes	A
027/002	1034	No		Yes	D
029/005	1464	No		Yes	B
032/005	1339	Yes	A	Yes	A
032/011	1482	No		Yes	C
038/002	1237	No		Yes	F
038/003	1239	Yes	A	Yes	A
038/007	1855	No		Yes	CE
038/008	1854	Yes	A	Yes	A
040/003	1607	No		Yes	C
042/002	1294	Yes	A	Yes	A

<sup>a</sup> Descriptions of the reason(s) for exclusion are presented in the statistical/evaluability criteria section as well as in Table 6, Clinical and Statistical Review, Study 191

**TABLE 2 (continued)**  
**Patients Excluded from Efficacy Analysis**  
**All Randomized Patients**  
**Study #191**

Site/ Enrollment Number	Patient Allocation Number	Excluded from ITT Analysis	Reason(s) for Exclusion (ITT) <sup>a</sup>	Excluded from PP Analysis	Reason(s) for Exclusion (PP) <sup>a</sup>
<b>HAC (continued)</b>					
042/007	1610	No		Yes	F
045/002	1068	No		Yes	B
053/006	1858	Yes	A	Yes	A
055/002	1230	Yes	A	Yes	A
071/001	1220	No		Yes	E
075/002	1262	Yes	A	Yes	A
078/019	1678	No		Yes	F
080/019	1566	Yes	C	Yes	D
080/020	1565	No		Yes	E
084/008	1444	Yes	A	Yes	A
084/016	1675	No		Yes	CDE
084/019	1790	Yes	A	Yes	AD
084/023	1835	No		Yes	D
084/024	1836	Yes	A	Yes	A
105/003	1449	Yes	A	Yes	A
107/002	1501	Yes	A	Yes	A
109/003	1539	Yes	A	Yes	AB
109/005	1837	Yes	A	Yes	A
112/003	1579	No		Yes	E
113/001	1581	No		Yes	D
128/004	1738	Yes	A	Yes	A
128/006	1818	Yes	A	Yes	A
130/003	1843	No		Yes	D
132/001	1872	Yes	A	Yes	A
<b>HC</b>					
003/001	1001	No		Yes	B
003/013	4009	No		Yes	F
006/006	1829	No		Yes	CE
007/002	1010	Yes	A	Yes	A
009/002	1280	Yes	A	Yes	A

<sup>a</sup> Descriptions of the reason(s) for exclusion are presented in the statistical/evaluability criteria section as well as in Table 6, Clinical and Statistical Review, Study 191

**TABLE 2 (continued)**  
**Patients Excluded from Efficacy Analysis**  
**All Randomized Patients**  
**Study #191**

Site/ Enrollment Number	Patient Allocation Number	Excluded from ITT Analysis	Reason(s) for Exclusion (ITT) <sup>a</sup>	Excluded from PP Analysis	Reason(s) for Exclusion (PP) <sup>a</sup>
<b>HC (continued)</b>					
009/008	1474	Yes	A	Yes	A
012/001	1015	Yes	A	Yes	A
012/003	1013	Yes	A	Yes	A
017/013	1637	Yes	A	Yes	A
017/014	1638	Yes	A	Yes	A
018/009	1561	Yes	A	Yes	A
019/002	1208	Yes	A	Yes	A
025/001	1253	Yes	A	Yes	A
025/003	1255	Yes	A	Yes	AD
025/005	1402	No		Yes	C
040/005	1808	Yes	A	Yes	A
040/007	1805	Yes	A	Yes	A
042/001	1293	No		Yes	C
042/003	1295	No		Yes	E
043/002	1373	Yes	AB	Yes	ABG
047/005	1521	No		Yes	F
047/007	1523	Yes	A	Yes	A
053/002	1378	Yes	A	Yes	A
057/006	1624	Yes	A	Yes	A
064/003	1193	Yes	A	Yes	A
069/001	1372	No		Yes	B
073/003	1135	Yes	A	Yes	AD
075/006	1518	No		Yes	E
075/008	1520	No		Yes	F
078/006	1486	No		Yes	F
078/013	1633	No		Yes	E
080/001	1105	No		Yes	C
084/013	1676	Yes	A	Yes	A
084/015	1674	Yes	A	Yes	A
084/021	1833	Yes	A	Yes	A

<sup>a</sup> Descriptions of the reason(s) for exclusion are presented in the statistical/evaluability criteria section as well as in Table 6, Clinical and Statistical Review, Study 191

**TABLE 2 (continued)**  
**Patients Excluded from Efficacy Analysis**  
**All Randomized Patients**  
**Study #191**

Site/ Enrollment Number	Patient Allocation Number	Excluded from ITT Analysis	Reason(s) for Exclusion (ITT) <sup>a</sup>	Excluded from PP Analysis	Reason(s) for Exclusion (PP) <sup>a</sup>
<b>HC (continued)</b>					
084/022	1834	No		Yes	G
086/006	1500	Yes	A	Yes	A
098/001	1349	Yes	A	Yes	A
098/005	1693	No		Yes	E
101/002	1353	Yes	A	Yes	A
105/002	1450	Yes	AB	Yes	AB
105/005	1452	Yes	A	Yes	A
105/006	1700	Yes	A	Yes	AE
109/002	1538	Yes	A	Yes	A
112/004	1580	Yes	A	Yes	A
112/005	1733	No		Yes	C
114/003	1587	Yes	A	Yes	A
120/003	1632	No		Yes	B
121/003	1642	Yes	C	Yes	D
126/002	1726	No		Yes	D
128/002	1739	Yes	A	Yes	A
128/007	1819	Yes	A	Yes	A
128/008	1820	Yes	A	Yes	A
128/010	1890	Yes	A	Yes	A
130/001	1841	No		Yes	CE

<sup>a</sup> Descriptions of the reason(s) for exclusion are presented in the statistical/evaluability criteria section as well as in Table 6, Clinical and Statistical Review, Study 191

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**TABLE 3**  
**Listing of Results for Patients Excluded from Intention-to-Treat Analysis**  
**Study #191**

Site/ Enrollment Number	AN	Discontinued Day	Reason Discontinued	<i>H. pylori</i> Status at Day 38 visit	DU Healed Status by Day 38 visit
<b>HAC</b>					
003/006	1324	44	Completed	Not infected	No DU at Baseline
003/011	1768	43	Completed	Not infected	No DU at Baseline
009/003	1279	36	Completed	Not infected	DU healed
009/005	1475	35	Completed	Not infected	DU healed
009/010	1593	42	Completed	Not infected	DU healed
009/018	1812	42	Completed	Not infected	No DU at Baseline
009/021	1877	39	Completed	Not infected	DU healed
012/002	1016	42	Completed	Not infected	No DU at Baseline
017/021	1753	39	Completed	Not infected	DU healed
018/003	1400	38	Completed	Not infected	No DU at Baseline
019/001	1205	38	Completed	Not infected	DU healed
020/001	1233	42	Completed	Not infected	DU healed
026/003	1126	39	Completed	Not infected	DU not healed
032/005	1339	41	Completed	Not infected	No DU at Baseline
038/003	1239	40	Completed	Not infected	No DU at Baseline
038/008	1854	34	Completed	Infected <sup>a</sup>	DU healed
042/002	1294	40	Completed	Not infected	DU not healed
053/006	1858	37	Completed	Not infected	DU healed
055/002	1230	42	Completed	Not infected	DU healed
075/002	1262	38	Completed	Not infected	No DU at Baseline
080/019	1566	9	Consent withdrawn	Infected <sup>a</sup>	No DU at Baseline
084/008	1444	47	Completed	Not infected	DU healed
084/019	1790	45	AE	Not infected	DU healed

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**TABLE 3 (continued)**  
**Listing of Results for Patients Excluded from Intention-to-Treat Analysis**  
**Study #191**

Site/ Enrollment Number	AN	Discontinued Day	Reason Discontinued	<i>H. pylori</i> Status at Day 38 visit	DU Healed Status by Day 38 visit
<b>HAC (continued)</b>					
084/024	1836	53	Completed	Not infected	DU healed
105/003	1449	42	Completed	Not infected	DU not healed
107/002	1501	42	Completed	Not infected	DU healed
109/003	1539	43	Completed	Not infected	No DU at Baseline
109/005	1837	54	Completed	Not infected	DU healed
128/004	1738	38	Completed	Not infected	DU healed
128/006	1818	40	Completed	Not infected	DU healed
132/001	1872	42	Completed	Not infected	No DU at Baseline
<b>HC</b>					
007/002	1010	40	Completed	Not infected	DU healed
009/002	1280	35	Completed	Not infected	DU healed
009/008	1474	35	Completed	Not infected	DU healed
012/001	1015	42	Completed	Not infected	No DU at Baseline
012/003	1013	42	Completed	Not infected	DU not healed
017/013	1637	42	Completed	Infected	DU healed
017/014	1638	61	Completed	Not infected	No DU at Baseline
018/009	1561	42	Completed	Not infected	DU healed
019/002	1208	38	Completed	Not infected	No DU at Baseline
025/001	1253	37	Completed	Infected	DU not healed
025/003	1255	42	Completed	Not infected	No DU at Baseline
040/005	1808	38	Completed	Not infected	DU healed
040/007	1805	35	Completed	Not infected	DU healed
043/002	1373	43	Completed	Not infected	No DU at Baseline
047/007	1523	40	Completed	Not infected	DU healed
053/002	1378	46	Completed	Not infected	DU not healed

<sup>a</sup> *H. pylori* status at Day 38 visit was not-evaluable, but was estimated as infected for the intention-to-treat analysis.  
<sup>b</sup> Duodenal ulcer healed status by Day 38 visit was not available, but was estimated as not healed for the intention-to-treat analysis for patients with an active duodenal ulcer at Baseline.

**TABLE 3 (continued)**  
**Listing of Results for Patients Excluded from Intention-to-Treat Analysis**  
**Study #191**

Site/ Enrollment Number	AN	Discontinued Day	Reason Discontinued	<i>H. pylori</i> Status at Day 38 visit	DU Healed Status by Day 38 visit
<b>HC (continued)</b>					
057/006	1624	35	Completed	Not infected	No DU at Baseline
064/003	1193	42	Completed	Not infected	DU healed
073/003	1135	1	Investigator/ sponsor decision	Infected <sup>a</sup>	DU not healed <sup>b</sup>
084/013	1676	41	Completed	Not infected	No DU at Baseline
084/015	1674	43	Completed	Not infected	DU healed
084/021	1833	49	Completed	Not infected	DU healed
086/006	1500	47	Completed	Not infected	No DU at Baseline
098/001	1349	40	Completed	Not infected	DU healed
101/002	1353	39	Completed	Not infected	DU healed
105/002	1450	48	Completed	Not infected	No DU at Baseline
105/005	1452	49	Completed	Not infected	No DU at Baseline
105/006	1700	36	Completed	Not infected	No DU at Baseline
109/002	1538	42	Completed	Infected <sup>a</sup>	DU not healed <sup>b</sup>
112/004	1580	46	Completed	Not infected	DU healed
114/003	1587	47	Completed	Not infected	DU healed
121/003	1642	41	Lost to follow-up	Infected <sup>a</sup>	DU not healed <sup>b</sup>
128/002	1739	43	Completed	Not infected	No DU at Baseline
128/007	1819	42	Completed	Not infected	DU healed
128/008	1820	40	Completed	Not infected	DU healed
128/010	1890	49	Completed	Not infected	DU healed

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**TABLE 4**  
**Listing of Results for Patients Excluded from Per-Protocol Analysis**  
**Study #191**

Site Number/ Enrollment Number	AN	Discontinued Day	Reason Discontinued	<i>H. pylori</i> Status at Day 38 Visit	Duodenal Ulcer Healed Status by Day 38 Visit
<b>HAC</b>					
003/006	1324	44	Completed	Not infected	No DU at Baseline
003/010	1766	46	Completed	Not infected	DU not healed
003/011	1768	43	Completed	Not infected	No DU at Baseline
007/001	1009	44	Completed	Not infected	DU healed
009/003	1279	36	Completed	Not infected	DU healed
009/005	1475	35	Completed	Not infected	DU healed
009/010	1593	42	Completed	Not infected	DU healed
009/014	1718	6	Investigator/ sponsor decision	Unknown	Unknown
009/018	1812	42	Completed	Not infected	No DU at Baseline
009/021	1877	39	Completed	Not infected	DU healed
011/002	1042	45	Completed	Not infected	DU healed
012/002	1016	42	Completed	Not infected	No DU at Baseline
015/004	1080	42	Completed	Not infected	DU healed
017/021	1753	39	Completed	Not infected	DU healed
018/003	1400	38	Completed	Not infected	No DU at Baseline
019/001	1205	38	Completed	Not infected	DU healed
020/001	1233	42	Completed	Not infected	DU healed
021/001	1173	39	Completed	Not infected	DU healed
026/003	1126	39	Completed	Not infected	DU not healed
027/002	1034	126	Lost to follow-up	Unknown	Unknown
029/005	1464	44	Completed	Not infected	No DU at Baseline
032/005	1339	41	Completed	Not infected	No DU at Baseline
032/011	1482	41	Completed	Not infected	DU healed

**TABLE 4 (continued)**  
**Listing of Results for Patients Excluded from Per-Protocol Analysis**  
**Study #191**

Site Number/ Enrollment Number	AN	Discontinued Day	Reason Discontinued	<i>H. pylori</i> Status at Day 38 Visit	Duodenal Ulcer Healed Status by Day 38 Visit
<b>HAC (continued)</b>					
038/002	1237	49	AE	Not infected	DU healed
038/003	1239	40	Completed	Not infected	No DU at Baseline
038/007	1855	42	Completed	Infected	No DU at Baseline
038/008	1854	34	Completed	Unknown	DU healed
040/003	1607	134	Consent withdrawn	Unknown	Unknown
042/002	1294	40	Completed	Not infected	DU not healed
042/007	1610	45	Completed	Not infected	DU not healed
045/002	1068	36	Completed	Not infected	No DU at Baseline
053/006	1858	37	Completed	Not infected	DU healed
055/002	1230	42	Completed	Not infected	DU healed
071/001	1220	38	Completed	Not infected	No DU at Baseline
075/002	1262	38	Completed	Not infected	No DU at Baseline
078/019	1678	23	Lack of therapeutic response	Unknown	Unknown
080/019	1566	9	Consent withdrawn	Unknown	No DU at Baseline
080/020	1565	39	Completed	Infected	No DU at Baseline
084/008	1444	47	Completed	Not infected	DU healed
084/016	1675	3	Consent withdrawn	Unknown	Unknown
084/019	1790	45	AE	Not infected	DU healed
084/023	1835	46	Completed	Not infected	DU healed
084/024	1836	53	Completed	Not infected	DU healed
105/003	1449	42	Completed	Not infected	DU not healed
107/002	1501	42	Completed	Not infected	DU healed

**TABLE 4 (continued)**  
**Listing of Results for Patients Excluded from Per-Protocol Analysis**  
**Study #191**

Site Number/ Enrollment Number	AN	Discontinued Day	Reason Discontinued	<i>H. pylori</i> Status at Day 38 Visit	Duodenal Ulcer Healed Status by Day 38 Visit
<b>HAC</b>					
109/003	1539	43	Completed	Not infected	No DU at Baseline
109/005	1837	54	Completed	Not infected	DU healed
112/003	1579	72	Completed	Infected	DU healed
113/001	1581	1	Lost to follow-up	Unknown	Unknown
128/004	1738	38	Completed	Not infected	DU healed
128/006	1818	40	Completed	Not infected	DU healed
130/003	1843	43	Completed	Infected	DU not healed
132/001	1872	42	Completed	Not infected	No DU at Baseline
<b>HC</b>					
003/001	1001	39	Completed	Not infected	No DU at Baseline
003/013	4009	41	Completed	Not infected	DU not healed
006/006	1829	39	Completed	Not infected	DU healed
007/002	1010	40	Completed	Not infected	DU healed
009/002	1280	35	Completed	Not infected	DU healed
009/008	1474	35	Completed	Not infected	DU healed
012/001	1015	42	Completed	Not infected	No DU at Baseline
012/003	1013	42	Completed	Not infected	DU not healed
017/013	1637	42	Completed	Infected	DU healed
017/014	1638	61	Completed	Not infected	No DU at Baseline
018/009	1561	42	Completed	Not infected	DU healed
019/002	1208	38	Completed	Not infected	No DU at Baseline
025/001	1253	37	Completed	Infected	DU not healed
025/003	1255	42	Completed	Not infected	No DU at Baseline
025/005	1402	43	Completed	Not infected	DU healed

**TABLE 4 (continued)**  
**Listing of Results for Patients Excluded from Per-Protocol Analysis**  
**Study #191**

Site Number/ Enrollment Number	AN	Discontinued Day	Reason Discontinued	<i>H. pylori</i> Status at Day 38 Visit	Duodenal Ulcer Healed Status by Day 38 Visit
<b>HC (continued)</b>					
040/005	1808	38	Completed	Not infected	DU healed
040/007	1805	35	Completed	Not infected	DU healed
042/001	1293	41	Completed	Infected	DU healed
042/003	1295	42	Completed	Infected	DU not healed
043/002	1373	43	Completed	Not infected	No DU at Baseline
047/005	1521	40	Completed	Infected	DU not healed
047/007	1523	40	Completed	Not infected	DU healed
053/002	1378	46	Completed	Not infected	DU not healed
057/006	1624	35	Completed	Not infected	No DU at Baseline
064/003	1193	42	Completed	Not infected	DU healed
069/001	1372	39	Completed	Infected	No DU at Baseline
073/003	1135	1	Investigator/ sponsor decision	Unknown	Unknown
075/006	1518	41	Completed	Not infected	DU not healed
075/008	1520	37	Completed	Infected	DU healed
078/006	1486	24	AE	Infected	DU healed
078/013	1633	51	Completed	Infected	DU healed
080/001	1105	41	Completed	Not infected	DU healed
084/013	1676	41	Completed	Not infected	No DU at Baseline
084/015	1674	43	Completed	Not infected	DU healed
084/021	1833	49	Completed	Not infected	DU healed
084/022	1834	45	Completed	Not infected	DU healed
086/006	1500	47	Completed	Not infected	No DU at Baseline
098/001	1349	40	Completed	Not infected	DU healed
098/005	1693	39	Completed	Infected	DU not healed

**TABLE 4 (continued)**  
**Listing of Results for Patients Excluded from Per-Protocol Analysis**  
**Study #191**

Site Number/ Enrollment Number	AN	Discontinued Day	Reason Discontinued	<i>H. pylori</i> Status at Day 38 Visit	Duodenal Ulcer Healed Status by Day 38 Visit
<b>HC (continued)</b>					
101/002	1353	39	Completed	Not infected	DU healed
105/002	1450	48	Completed	Not infected	No DU at Baseline
105/005	1452	49	Completed	Not infected	No DU at Baseline
105/006	1700	36	Completed	Not infected	No DU at Baseline
109/002	1538	42	Completed	Unknown	Unknown
112/004	1580	46	Completed	Not infected	DU healed
112/005	1733	39	Completed	Not infected	DU not healed
114/003	1587	47	Completed	Not infected	DU healed
120/003	1632	48	Completed	Infected	No DU at Baseline
121/003	1642	41	Lost to follow-up	Unknown	Unknown
126/002	1726	-1	Lost to follow-up	Unknown	Unknown
128/002	1739	43	Completed	Not infected	No DU at Baseline
128/007	1819	42	Completed	Not infected	DU healed
128/008	1820	40	Completed	Not infected	DU healed
128/010	1890	49	Completed	Not infected	DU healed
130/001	1841	41	Completed	Not infected	DU healed

**APPEARS THIS WAY  
ON ORIGINAL**

**TABLE 5**  
**Distributions of Study Medication Taken**  
**Number (%) of Patients**  
**All Randomized Patients**  
**Study #191**

	H 40 qd + A 1000 bid + C 500 bid  (N=264)	H 40 qd + C 500 bid  (N=251)
	n (%)	n (%)
<b>Total Number of H 199/18 40 mg Capsules Taken</b>		
Unknown	2 (< 1%)	1 (< 1%)
0 - 2	3 (1%)	6 (2%)
3 - 4	4 (2%)	0 (0%)
5 - 6	4 (2%)	1 (< 1%)
7 - 8	3 (1%)	2 (< 1%)
9 - 10	248 (94%)	241 (96%)
<b>Total Number of Clarithromycin 250 mg Tablets Taken</b>		
Unknown	2 (< 1%)	1 (< 1%)
0 - 8	2 (< 1%)	6 (2%)
9 - 16	4 (2%)	0 (0%)
17 - 24	5 (2%)	1 (< 1%)
25 - 32	3 (1%)	2 (< 1%)
33 - 40	248 (94%)	241 (96%)
<b>Total Number of Amoxicillin 500 mg Tablets / Placebo Tablets Taken</b>		
Unknown	2 (< 1%)	1 (< 1%)
0 - 8	2 (< 1%)	6 (2%)
9 - 16	4 (2%)	0 (0%)
17 - 24	5 (2%)	1 (< 1%)
25 - 32	3 (1%)	2 (< 1%)
33 - 40	248 (94%)	241 (96%)

**TABLE 6**  
**Classification of *H. pylori* Infection, Evaluability, and Eradication**  
**Based on Endoscopic Tests for *H. pylori* at Baseline**  
**All Randomized Patients**  
**Study #191**

Pre-therapy (Baseline) Diagnosis					
Culture	Histology	CLOtest <sup>®a</sup>	Patient Status	H 40 qd + A 1000 bid + C 500 bid (N=264)	H 40 qd + C 500 bid (N=251)
Three tests available					
+	+	+	Infected	161	146
+	+	-	Infected	---	---
+	-	+	Infected	3	1
+	-	-	Infected	---	---
-	+	+	Infected	43	44
-	-	+	Not infected	24	24
-	+	-	Not infected	---	---
-	-	-	Not infected	1 <sup>b</sup>	1 <sup>b</sup>
Two tests available					
+	+	N/A	Infected	---	---
+	-	N/A	Infected	---	---
-	+	N/A	Not evaluable	---	---
-	-	N/A	Not infected	---	---
+	N/A	+	Infected	1	1
+	N/A	-	Infected	---	---
-	NA	+	Not evaluable	1	0
-	NA	-	Not infected	---	---
N/A	+	+	Infected	26	24
N/A	+	-	Not evaluable	---	---
N/A	-	+	Not evaluable	4	7
N/A	-	-	Not infected	---	---
Zero or one test available					
+	N/A	N/A	Infected	---	---
-	N/A	N/A	Not evaluable	---	---
N/A	N/A	+	Not evaluable	0	1
N/A	N/A	-	Not evaluable	---	---
N/A	+	N/A	Not evaluable	---	---
N/A	-	N/A	Not evaluable	---	---
N/A	N/A	N/A	Not evaluable	0	2 <sup>b</sup>

<sup>a</sup> Patient must have had a positive CLOtest<sup>®</sup> to receive study medication and to be included in the study.

<sup>b</sup> Four patients were entered into this study even though the baseline CLOtest<sup>®</sup> was negative or not available.

**TABLE 7**  
**Classification of *H. pylori* Infection, Evaluability, and Eradication**  
**Based on Endoscopic Tests for *H. pylori* at Day 38 Visit**  
**All Randomized Patients**  
**Study #191**

Post-therapy (Day 38 Visit) Diagnosis					
Culture	Histology	CLOtest®	Patient Status	H 40 qd + A 1000 bid + C 500 bid (N=264)	H 40 qd + C 500 bid (N=251)
Three tests available					
+	+	+	Infected	10	36
+	+	-	Infected	2	5
+	-	+	Infected	0	0
+	-	-	Infected	1	2
-	+	+	Infected	8	31
-	-	+	Infected	5	4
-	+	-	Infected	1	4
-	-	-	Eradicated	179	121
Two tests available					
+	+	N/A	Infected	0	0
+	-	N/A	Infected	0	0
-	+	N/A	Infected	0	0
-	-	N/A	Eradicated	0	0
+	N/A	+	Infected	1	1
+	N/A	-	Infected	0	0
-	N/A	+	Infected	1	1
-	N/A	-	Eradicated	3	2
N/A	+	+	Infected	0	5
N/A	+	-	Infected	0	1
N/A	-	+	Infected	0	0
N/A	-	-	Eradicated	26	20
One test available					
+	N/A	N/A	Infected	0	0
-	N/A	N/A	Not evaluable	0	0
N/A	N/A	+	Infected	0	0
N/A	N/A	-	Not evaluable	0	0
N/A	+	N/A	Infected	0	0
N/A	-	N/A	Not evaluable	0	0
Zero tests available					
N/A	N/A	N/A	Not evaluable	27	18

**APPENDIX 2 – Additional Tables from Study 192**

**APPEARS THIS WAY  
ON ORIGINAL**

**TABLE 1**  
**Number of Patients Entered into Study by Investigator and Treatment Group**  
**Study #192**

Site Number	Investigator	H 40 qd + C 500 bid	H 40 qd	Total
200	Baz, Malik	1	0	1
201	Beckwith, Jay	2	0	2
202	Caos, Antonio	6	2	8
203	Groisser, Victor	----	----	----
204	Gulden, Peter	1	0	1
205	Hassman, David	----	----	----
206	Hirsh, Eugene	1	0	1
207	Johnson, Bruce	1	0	1
208	Kiyasu, Phillip Kunisada	----	----	----
209	Kogut, David	6	2	8
210	Kucer, Frank T.	----	----	----
211	Libster, Boris	----	----	----
212	Luxon, Bruce	----	----	----
213	Magier, David	1	0	1
214	Maton, Paul	----	----	----
215	Metz, David	1	1	2
216	Mitchell, Sue	1	1	2
217	Noss, Michael	1	1	2
218	Provenza, Mark	10	4	14
219	Shaker, Reza	----	----	----
220	Silvers, David	2	0	2
221	Stanton, David	3	1	4
222	Tonkon, Melvin	----	----	----
223	Winston, Barry	3	1	4
224	Wohlman, Robert	----	----	----
225	Goldstein, Jack	3	1	4
226	Mula, Gregory	----	----	----
227	Gringeri, Louis	----	----	----
228	Donachie, Robert	----	----	----
229	Isbell, Gerald	2	1	3
230	Johnson, Robert M.	----	----	----
231	Shah, Atul	6	2	8
TOTAL		51	17	68

**TABLE 2**  
**Listing of Results for Patients Excluded from Intention-to-Treat Analysis**  
**Study #192**

Treatment Group	Site Number/ Enrollment Number	AN	Discontinued Day	Reason Discontinued	<i>H. pylori</i> Status at Day 38 Visit	DU Healed Status by Day 38 Visit
H 40 qd + C 500 bid	218/007	2091	43	Completed	Not infected	No DU at Baseline
H 40 qd	209/006	2110	40	Completed	Not infected	DU not healed

**TABLE 3**  
**Listing of Results for Patients Excluded from Per-Protocol Analysis**  
**Study #192**

Treatment Group	Site Number/ Enrollment Number	AN	Discontinue d Day	Reason Discontinued	<i>H. pylori</i> Status at Day 38 Visit	DU Healed Status by Day 38 Visit
H 40 qd + C 500 bid	200/001	2045	8	AE	Unknown	Unknown
H 40 qd + C 500 bid	209/008	2112	73	Lost to Follow-up	Unknown	Unknown
H 40 qd + C 500 bid	218/007	2091	43	Completed	Not infected	No DU at Baseline
H 40 qd + C 500 bid	221/001	2088	43	Completed	Not infected	No DU at Baseline
H 40 qd	209/006	2110	40	Completed	Not infected	DU not healed
H 40 qd	229/003	2161	49	Completed	Infected	DU healed

**TABLE 4**  
**Distributions of Study Medication Taken**  
**Number (%) of Patients**  
**All Randomized Patients**  
**Study #192**

	H 40 qd + C 500 bid (N = 51)	H 40 qd (N = 17)
	n (%)	n (%)
<b>Total Number of H 199/18 40 mg Capsules Taken</b>		
Unknown	1 (2%)	0 (0%)
0-2	0 (0%)	0 (0%)
3-4	1 (2%)	0 (0%)
5-6	1 (2%)	0 (0%)
7-8	0 (0%)	0 (0%)
9-10	48 (94%)	17 (100%)
<b>Total Number of Clarithromycin 250 mg Tablets / Placebo Tablets Taken</b>		
Unknown	1 (2%)	0 (0%)
0-8	0 (0%)	0 (0%)
9-16	0 (0%)	0 (0%)
17-24	0 (0%)	0 (0%)
25-32	2 (4%)	0 (0%)
33-40	48 (94%)	17 (100%)

**APPEARS THIS WAY  
ON ORIGINAL**

**TABLE 5**  
**Classification of *H. pylori* Infection, Evaluability, and Eradication**  
**Based on Endoscopic Tests for *H. pylori* at Baseline**  
**All Randomized Patients**  
**Study #192**

Pre-therapy (Baseline) Diagnosis					
Culture	Histology	CLOtest <sup>®a</sup>	Patient Status	H 40 qd + C 500 bid (N=51)	H 40 qd (N=17)
Three tests available					
+	+	+	Infected	35	14
+	+	-	Infected	---	---
+	-	+	Infected	0	0
+	-	-	Infected	---	---
-	+	+	Infected	9	2
-	-	+	Not infected	1	1
-	+	-	Not infected	---	---
-	-	-	Not infected	---	---
Two tests available					
+	+	N/A	Infected	---	---
+	-	N/A	Infected	---	---
-	+	N/A	Not evaluable	---	---
-	-	N/A	Not infected	---	---
+	N/A	+	Infected	1	0
+	N/A	-	Infected	---	---
-	NA	+	Not evaluable	0	0
-	NA	-	Not infected	---	---
N/A	+	+	Infected	5	0
N/A	+	-	Not evaluable	---	---
N/A	-	+	Not evaluable	0	0
N/A	-	-	Not infected	---	---
One test available					
+	N/A	N/A	Infected	---	---
-	N/A	N/A	Not evaluable	---	---
N/A	N/A	+	Not evaluable	0	0
N/A	N/A	-	Not evaluable	---	---
N/A	+	N/A	Not evaluable	---	---
N/A	-	N/A	Not evaluable	---	---

<sup>a</sup> Patient must have had a positive CLOtest<sup>®</sup> to receive study medication and to be included in

the study.

**APPEARS THIS WAY  
ON ORIGINAL**

**TABLE 6**  
**Classification of *H. pylori* Infection, Evaluability, and Eradication**  
**Based on Endoscopic Tests for *H. pylori* at Day 38 Visit**  
**All Randomized Patients**  
**Study #192**

Post-therapy (Day 38 Visit) Diagnosis					
Culture	Histology	CLOtest®	Patient Status	H 40 qd + C 500 bid (N=51)	H 40 qd (N=17)
Three tests available					
+	+	+	Infected	14	12
+	+	-	Infected	0	0
+	-	+	Infected	0	0
+	-	-	Infected	0	0
-	+	+	Infected	5	3
-	-	+	Infected	1	0
-	+	-	Infected	0	1
-	-	-	Eradicated	21	1
Two tests available					
+	+	N/A	Infected	0	0
+	-	N/A	Infected	0	0
-	+	N/A	Infected	0	0
-	-	N/A	Eradicated	0	0
+	N/A	+	Infected	0	0
+	N/A	-	Infected	0	0
-	NA	+	Infected	0	0
-	NA	-	Eradicated	1	0
N/A	+	+	Infected	1	0
N/A	+	-	Infected	0	0
N/A	-	+	Infected	0	0
N/A	-	-	Eradicated	2	0
One test available					
+	N/A	N/A	Infected	0	0
-	N/A	N/A	Not evaluable	0	0
N/A	N/A	+	Infected	0	0
N/A	N/A	-	Not evaluable	2	0
N/A	+	N/A	Infected	0	0
N/A	-	N/A	Not evaluable	0	0
Zero tests available					
N/A	N/A	N/A	Not evaluable	4	0

**APPENDIX 3 – Additional Tables from Study 193**

**APPEARS THIS WAY  
ON ORIGINAL**

**TABLE 1**  
**Number of Patients Entered into Study by Investigator and Treatment Group**  
**Study #193**

Site Number	Investigator	H 40 qd + A 1000 bid + C 500 bid	H 40 qd	Total
300	Baird, Ian	0	0	0
301	Bills, Stephen	0	0	0
302	Botoman, Alin	0	0	0
303	Chen, Yang	3	2	5
304	DeAbate, Carl	12	4	16
305	Ertan, Atilla	4	1	5
306	Esposito, Stephen	0	0	0
307	Fidelholtz, James	1	0	1
308	Fitch, Duane	1	1	2
309	Grossman, Michael	2	1	3
310	Hagan, Robert	2	1	3
311	Harris, Arthur	1	0	1
312	Herbst, Jeffrey R.	3	1	4
313	Ricci, Donato	0	0	0
314	Kovacs, Thomas	0	0	0
315	Ladenheim, Jay	1	0	1
316	Linne, James	1	0	1
317	McCarty, James	3	0	3
318	Medoff, Jeffrey	5	1	6
319	Miskin, Barry	0	0	0
320	Movva, Rao	4	1	5
321	Nichols, Trent	2	0	2
322	Rosman, Gary	1	1	2
323	Safavi, Shahriar	8	3	11
324	Duckor, Steven	13	4	17
325	Sievers, Richard	0	0	0
326	Sturgeon, John	0	0	0
327	Miller, Stephen	1	1	2
328	Pruitt, Ronald E.	7	3	10
329	Moster, Susan	0	0	0
330	Fromm, Hans	0	0	0

**TABLE 1 (continued)**  
**Number of Patients Entered into Study by Investigator and Treatment Group**  
**Study #193**

Site Number	Investigator	H 40 qd + A 1000 bid + C 500 bid	H 40 qd	Total
331	Reddy, Joseph	4	1	5
332	Wiener, Gregory	0	0	0
333	Dalgin, Paul	0	0	0
334	Chiprut, Roberto	6	2	8
TOTAL		85	28	113

**APPEARS THIS WAY  
ON ORIGINAL**

**TABLE 2**  
**Patients Excluded from Efficacy Analysis**  
**All Randomized Patients**  
**Study #193**

Site/ Enrollment Number	Patient Allocation Number	Excluded from ITT Analysis	Reason(s) for Exclusion (ITT) <sup>a</sup>	Excluded from PP Analysis	Reason(s) for Exclusion (PP) <sup>a</sup>
<b>HAC</b>					
304/001	3049	Yes	A	Yes	A
304/003	3051	Yes	A	Yes	A
307/001	3008	Yes	A	Yes	A
310/001	3048	Yes	A	Yes	AD
312/013	3032	Yes	A	Yes	A
318/006	3142	No	---	Yes	C
321/001	3017	Yes	A	Yes	A
321/002	3018	Yes	A	Yes	AD
322/001	3021	No	---	Yes	C
324/001	3085	Yes	A	Yes	A
331/004	3185	Yes	AB	Yes	AB
331/003	3186	Yes	AB	Yes	AB
331/005	3221	Yes	A	Yes	AC
334/007	3231	No	---	Yes	D
<b>H</b>					
304/005	3137	Yes	A	Yes	A
310/003	3046	No	---	Yes	C
328/009	3213	Yes	A	Yes	A
331/001	3188	Yes	A	Yes	A
334/004	3228	Yes	A	Yes	A

**Table 3**  
**Listing of Results for Patients Excluded from Intention-to-Treat Analysis**  
**Study #193**

Site Number/ Enrollment Number	AN	Discontinued Day	Reason Discontinued	<i>H. pylori</i> Status at Day 38 Visit	Duodenal Ulcer Healed Status by Day 38 Visit
<b>HAC</b>					
304/001	3049	52	Completed	Not infected	DU healed
304/003	3051	40	Completed	Not infected	DU not healed
307/001	3008	38	Completed	Not infected	No DU at Baseline
310/001	3048	4	Investigator/ Sponsor decision	Infected <sup>a</sup>	No DU at Baseline
312/013	3032	35	Completed	Not infected	DU healed
321/001	3017	39	Completed	Not infected	DU healed
321/002	3018	4	AE	Infected <sup>a</sup>	DU not healed <sup>b</sup>
324/001	3085	40	Completed	Infected	DU healed
331/003	3186	38	Completed	Not infected	No DU at Baseline
331/004	3185	43	Completed	Not infected	No DU at Baseline
331/005	3221	40	Completed	Not infected	DU healed
<b>H</b>					
304/005	3137	39	Completed	Not infected	DU not healed
328/009	3213	47	Completed	Infected	DU not healed
331/001	3188	37	Completed	Not infected	No DU at Baseline
334/004	3228	40	Completed	Not infected	DU healed

<sup>a</sup> *H. pylori* status at Day 38 visit was not-evaluable, but was estimated as infected for the intention-to-treat analysis.

<sup>b</sup> Duodenal ulcer healed status by Day 38 visit was not available, but was estimated as not healed for the intention-to-treat analysis for patients with an active duodenal ulcer at Baseline.

**APPEARS THIS WAY  
ON ORIGINAL**

**TABLE 4**  
**Listing of Results for Patients Excluded from Per-Protocol Analysis**  
**Study #193**

Site Number/ Enrollment Number	AN	Discontinued Day	Reason Discontinued	<i>H. pylori</i> Status at Day 38 Visit	Duodenal Ulcer Healed Status by Day 38 Visit
<b>HAC</b>					
304/001	3049	52	Completed	Not infected	DU healed
304/003	3051	40	Completed	Not infected	DU not healed
307/001	3008	38	Completed	Not infected	No DU at Baseline
310/001	3048	4	Investigator/ Sponsor decision	Unknown	No DU at Baseline
312/013	3032	35	Completed	Not infected	DU healed
318/006	3142	41	Completed	Infected	DU healed
321/001	3017	39	Completed	Not infected	DU healed
321/002	3018	4	AE	Unknown	Unknown
322/001	3021	41	Completed	Not infected	DU not healed
324/001	3085	40	Completed	Infected	DU healed
331/003	3186	38	Completed	Not infected	No DU at Baseline
331/004	3185	43	Completed	Not infected	No DU at Baseline
331/005	3221	40	Completed	Not infected	DU healed
334/007	3231	9	Investigator/ Sponsor decision	Unknown	Unknown
<b>H</b>					
304/005	3137	39	Completed	Not infected	DU not healed
310/003	3046	40	Completed	Infected	DU healed
328/009	3213	47	Completed	Infected	DU not healed
331/001	3188	37	Completed	Not infected	No DU at Baseline
334/004	3228	40	Completed	Not infected	DU healed

**APPEARS THIS WAY  
ON ORIGINAL**

**TABLE 5**  
**Distributions of Study Medication Taken**  
**Number (%) of Patients**  
**All Randomized Patients**  
**Study #193**

	H 40 qd + A 1000 bid + C 500 bid	H 40 qd
	(N=85)	(N=28)
	n (%)	n (%)
<b>Total Number of H 199/18 40 mg Capsules Taken</b>		
0 - 2	2 (2%)	0 (0%)
3 - 4	0 (0%)	0 (0%)
5 - 6	1 (1%)	0 (0%)
7 - 8	1 (1%)	1 (4%)
9 - 10	81 (95%)	27 (96%)
<b>Total Number of Clarithromycin 250 mg Tablets/ Placebo Tablets Taken</b>		
0 - 8	2 (2%)	0 (0%)
9 - 16	0 (0%)	0 (0%)
17 - 24	1 (1%)	0 (0%)
25 - 32	0 (0%)	1 (4%)
33 - 40	82 (96%)	27 (96%)
<b>Total Number of Amoxicillin 500 mg Tablets / Placebo Tablets Taken</b>		
0 - 8	2 (2%)	0 (0%)
9 - 16	0 (0%)	0 (0%)
17 - 24	1 (1%)	0 (0%)
25 - 32	0 (0%)	1 (4%)
33 - 40	82 (96%)	27 (96%)

**APPEARS THIS WAY  
ON ORIGINAL**

**TABLE 6**  
**Classification of *H. pylori* Infection, Evaluability, and Eradication**  
**Based on Endoscopic Tests for *H. pylori* at Baseline**  
**All Randomized Patients**  
**Study #193**

Pre-therapy (Baseline) Diagnosis					
Culture	Histology	CLOtest <sup>®a</sup>	Patient Status	H 40 qd + A 1000 bid + C 500 bid (N=85)	H 40 qd (N=28)
Three tests available					
+	+	+	Infected	62	18
+	+	-	Infected	----	----
+	-	+	Infected	2	0
+	-	-	Infected	----	----
-	+	+	Infected	9	6
-	-	+	Not infected	10	3
-	+	-	Not infected	----	----
-	-	-	Not infected	1 <sup>b</sup>	0
Two tests available					
+	+	N/A	Infected	----	----
+	-	N/A	Infected	----	----
-	+	N/A	Not evaluable	----	----
-	-	N/A	Not infected	----	----
+	N/A	+	Infected	0	0
+	N/A	-	Infected	----	----
-	NA	+	Not evaluable	0	0
-	NA	-	Not infected	----	----
N/A	+	+	Infected	1	0
N/A	+	-	Not evaluable	----	----
N/A	-	+	Not evaluable	0	1
N/A	-	-	Not infected	----	----
Zero or one test available					
+	N/A	N/A	Infected	----	----
-	N/A	N/A	Not evaluable	----	----
N/A	N/A	+	Not evaluable	0	0
N/A	N/A	-	Not evaluable	----	----
N/A	+	N/A	Not evaluable	----	----
N/A	-	N/A	Not evaluable	----	----
N/A	N/A	N/A	Not evaluable	----	----

<sup>a</sup> Patient must have had a positive CLOtest<sup>®</sup> to receive study medication and to be included in the study.  
<sup>b</sup> One patient was entered into this study even though the baseline CLOtest<sup>®</sup> was negative or not available.

**TABLE 7**  
**Classification of *H. pylori* Infection, Evaluability, and Eradication**  
**Based on Endoscopic Tests for *H. pylori* at Day 38 Visit**  
**All Randomized Patients**  
**Study #193**

Post-therapy (Day 38 Visit) Diagnosis					
Culture	Histology	CLOtest®	Patient Status	H 40 qd + A 1000 bid + C 500 bid (N=85)	H 40 qd (N=28)
Three tests available					
+	+	+	Infected	7	13
+	+	-	Infected	0	1
+	-	+	Infected	0	1
+	-	-	Infected	2	0
-	+	+	Infected	1	7
-	-	+	Infected	1	1
-	+	-	Infected	1	0
-	-	-	Eradicated	61	4
Two tests available					
+	+	N/A	Infected	0	0
+	-	N/A	Infected	0	0
-	+	N/A	Infected	0	0
-	-	N/A	Eradicated	0	0
+	N/A	+	Infected	0	0
+	N/A	-	Infected	0	0
-	N/A	+	Infected	0	0
-	N/A	-	Eradicated	1	0
N/A	+	+	Infected	0	0
N/A	+	-	Infected	0	0
N/A	-	+	Infected	0	0
N/A	-	-	Eradicated	4	0
One test available					
+	N/A	N/A	Infected	0	0
-	N/A	N/A	Not evaluable	0	0
N/A	N/A	+	Infected	0	0
N/A	N/A	-	Not evaluable	0	0
N/A	+	N/A	Infected	0	0
N/A	-	N/A	Not evaluable	0	0
Zero tests available					
N/A	N/A	N/A	Not evaluable	7	1

## **APPENDIX 4 – Proposed Labeling Changes**

*Note: Hard copy has proposed label (12/14/00)*

**APPEARS THIS WAY  
ON ORIGINAL**

WITHHOLD 32 PAGES

DRAFT

Labeling