

Appendix J

Table 8.2.5 **OPTIONS - Serious or Potentially Serious Adverse Events
(Treated Population)**

| Site/Subject # | Age | Gender | Treatment duration (Days) | Relationship | Serious Event |
|----------------|-----|--------|---------------------------|--------------|---------------------------------|
| 0007/0022 | 54 | M | 50 | Unrelated | Pancreatitis |
| 0017/0017 | 64 | M | 84 | Unrelated | Squamous cell cancer |
| 0019/0028 | 43 | M | 9 | Unrelated | Pericardial cyst |
| 0019/0091 | 60 | M | 24 | Unrelated | Gastroesophageal reflux disease |

Subject 0007/0022, was a 54 year-old black male with a past medical history of hyperlipidemia, hypertension, alcohol abuse, and pancreatitis whose concomitant medications included Accupril and Adalat. The subject reported the acute onset of abdominal pain, nausea, and vomiting 50 days after starting Pravachol 10 mg and was admitted to the hospital. These symptoms were described as similar to his previous episodes of pancreatitis. The last available laboratory values for SGPT (52 U/L), SGOT (49 U/L), and amylase (284 U/L) were collected approximately 7 months prior to the subject taking Pravachol 10 mg. The laboratory values on the day of admission were: SGPT (41 U/L), SGOT (40 U/L), and amylase (227 U/L). While in the hospital, he was treated with medication for pain, and intravenous fluids and was discharged the next day. The investigator did not attribute the event to use of Pravachol 10 mg, and the subject continued to take the medication.

Subject 0017/0017, was a 64 year-old white male with a previous history of basal cell carcinoma reported to his physician for an evaluation of a suspicious lesion on his right arm 60 days after starting Pravachol 10 mg and continued on Pravachol 10 mg for another 24 days and completed the study. Sixteen days after completing the study the lesion was excised and a squamous cell carcinoma was confirmed by biopsy. The event was considered unrelated to the study medication.

Subject 0019/0028, was a 43 year-old white male with a known, asymptomatic right-sided pericardial cyst, developed shortness of breath at rest and during exertion, and chest "fullness" 9 days after starting Pravachol 10 mg. Because of these symptoms the subject

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elected to undergo thoroscopic resection of the cyst. The subject tolerated the surgery well and was discharged 2 days later. The subject continued to take Pravachol 10 mg and completed 1 month of treatment. The investigator considered this event unrelated to use of Pravachol 10 mg.

Subject 0019/0091, was a 60 year-old white male with a history of gastroesophageal reflux disease treated with Prilosec, and migraine headaches, reported to the emergency room complaining of chest pain radiating to his back 24 days after starting Pravachol 10 mg. The pain was not relieved with Maalox, Alka-Seltzer or Gas-X. The subject had run out of his Prilosec 2 days prior to the onset of the symptoms. He was given nitroglycerin and morphine which provided mild relief. There were no ECG changes and laboratory data revealed a creatine kinase of 63 U/L with a normal MB fraction. The subject was kept overnight for observation, underwent a thallium treadmill test the next morning (which was normal), and was discharged with a diagnosis of gastroesophageal reflux disease. The investigator did not attribute the event to Pravachol 10 mg and the subject continued with the study.