Phase IV OxyContin® Tablets Team

To: Distribution

From: E. Chickering/L. Harrison
Reviewed By: E. Lockhart

Subject: Phase IV OxyContin□ Tablets
Team Meeting
Minutes - June 13, 1997

Date: June 16, 1997

S. Aron*, E. Chickering, M. Cullen, R. Davis*, L. Harrison, E. Ingber*, B. Kennedy, M. Laszek*, H. Lazarus, E. Lockhart, M. Shi

*absent

Marketing and Sales Update

Mike Cullen discussed in detail Marketing's positioning of OxyContin. He explained that we want to expand extensively in the noncancer market segment, while promoting OxyContin as "the one to start with" in cancer pain (instead of Percocet/Vicodin, etc.) and "the one to stay with" through proper titration.

We can show that we are as "effective" as morphine, but do not want to say OxyContin is as "powerful" as morphine. Words such as "powerful" may make some people think the drug is dangerous and should be reserved for the more severe pain. This could have a negative effect in the much larger noncancer pain market. Mike reminded the team that we should keep this positioning in mind as we develop future marketing programs, symposia, clinical study manuscripts, and any other items that discuss the use of OxyContin.

Mike also reviewed the recent attribute grid market research that was conducted at the Purdue "Train the Trainer" Symposium held in San Antonio with physicians from the South Central Region. The grid results show us which attributes are important to physicians for treating cancer pain as well as noncancer pain and how OxyContin is perceived versus the competitive products in meeting these attributes.

Medical Education Program Update

H. Lazarus reported on the Purdue-sponsored pain management symposia in May/June.

- **CME Regional Meeting - Dallas, TX - 5/31-6/1**

  Attendees: 90 primary care physicians
  Drs. R. Scott, M. Cone, S. Nadler, and D. Manning, spoke on "Meeting the Chronic Pain Challenge"

ξ **North Central Region Pain Management/Speakers' Bureau Mtg. - New Orleans, LA - 5/30-6/1**

Attendees: 150 physicians
- Speakers included Drs. M. Levy, E. Narcessian, N. Irick, A. Lipman, A. Spanos, and two of patients of Dr. Spanos
- Surveys were distributed and are being analyzed.

Scientific Writing Update

ξ Double-Blind Trial vs. IR Oxycodone in Low Back Pain (OC92-1201) manuscript is in internal review.

ξ Double-Blind Trial vs. Placebo in Osteoarthritis (OC92-1102 - Roth) manuscript is expected to be in internal review by week of 6/16.

ξ Study report OC95-0103 (vs. Percocet and Placebo in Osteoarthritis) comments have been incorporated and draft report will begin peer review during week of 6/16; final signoff expected 7/15.

ξ OC93-1104 (Relative Potency Study vs. MS Contin) - draft manuscript is being written by a contract writer; expect first draft in-house by end of June.

OxyContin Clinical Program Update

Completed

1) **OC95-0103 - Placebo-Controlled vs. Percocet in Osteoarthritis - n = 167**
Status: Data has been preliminarily analyzed. Both actives separate from placebo for pain relief. OxyContin has superior sleep quality over Percocet.
Timeline: Final study report preparation and sign off by 7/15

2) **OC92-1101 - Open Label Clinical Testing - n = 247**
Status: All outside data clarification forms have been answered.
Timeline: BCDM stat tables to Sci Comm by 7/30

3) **OC93-0506 - Opioid Naive / Fixed Combo Dosing Guidelines - n = 68**
Status: Data clarification forms have been answered and will be sent to outside data entry.
Timeline: BCDM stat tables to Sci Comm - end of 3rd Q

4) **OC93-0704 - Open Label Dosing Guidelines - n = 131**
Status: Data analysis will be hand tallied
Timeline: To be determined

5) **OC95-0203 - Cancer Efficacy in Mexico - n = 41**
Status: DCFs to be completed at the end of June
Timeline: Stat report due by 7/15

Ongoing

1) **OC96-0204 - Postop Within Labeling Conversion from PCA - n = 200 (planned)**
Status: Enrollment: 180. Preliminary report shows that conversion of 1 to 1.5 from IV morphine OxyContin has very good efficacy and good side effect profile. Abstract to be submitted to APS Annual Meeting.
Timeline: Study completion in field 6/15

2) **OC95-0304 - vs. Percocet in Opioid-Naive Cancer Patients - n = 100 (planned)**
Status: Enrollment: 78.
Timeline: Study will end in the field in August

3) **OC96-0502 - Postop Inpatient Safety/Dose Finding Study to Expand Indications - n = 120 (planned)**
Status: Twenty-one patients completed. All sites are initiated. Anticipate 12 patients per month.
Timeline: Study completion 1st Q/98

4) **OC96-0602 - Pharmacokinetic Study in Children - n = 25 FDA required**
Status: Three patients have completed. Dr. Peter Davis of the University of Pittsburgh is submitting budget. Protocol sent to University of Utah.
Timeline: Completion 3rd Q/98

5) **OC96-0703 - Postop Within Labeling Conversion from Epidural - n = 120 (planned)**
Status: Study initiated.
Timeline: Study completion 4th Q/97

6) **OC96-0302 - Postop Ambulatory Study to Expand Indications - n = 120 (planned)**
Status: Study initiated at three sites in Salt Lake City area.
Timeline: Completion by 1st Q/98 is anticipated

7) **OC96-1003 - Placebo Controlled / Osteoarthritis - n = 100 (planned)**
Status: Two sites initiated; other 8 sites to follow over the next few weeks.
Timeline: Completion 3rd Q/98

Protocols Under Development or for Second and Third Quarter 1997 Initiation

1) **OC96-0701 - Postop 60-Center Surgeon Study - n = 300 (planned)**
Status: First teleconference has taken place. Abbott has sent out its sales force to continue to recruit surgeons.
Timeline: Next teleconference with surgeons scheduled for June 18. Completion in the field 4th Q/97

2) **OC96-1002 - Placebo Controlled / Back Pain - n = 100 (planned)**
Status: Protocol to be signed off. Plan to use Pharmacy Gold HMO as site.
Timeline: Initiation end of 3rd Q; Completion in field 4th Q/98

3) **OC95-0202 - Open Label Outcomes vs. IR Oxycodone/APAP in Osteoarthritis - n=200 (planned)**
Status: Protocol being developed.
Timeline: Initiation 3rd Q; Completion in the field 4th Q/98

4) **OC95-0202A - Pharmacoeconomic Cost-Effectiveness Analysis (associated with OC95-0202)**
Status: Developing timelines for pilot and main study.
Timeline: Pilot study to start with OC96-1003. Report at end of OC96-0202.

5) **OC97-0302 - Long Term Open Log of Noncancer Patients**
Status: Synopsis submitted for executive review.
Timeline: Initiate in 3rd Q

6) **OC97-0301 - PK 160 mg vs. 2 x 80 mg vs. 4 x 40 mg**
Status: Protocol is in final review, awaiting FDA response.
Timeline: Initiation is projected for July.

Miscellaneous

- Presentation to IPS scheduled for June 24.
- A. Labrosciano joined the team as CRA.

cc: Team, M. Alfonso, R. Burch, J. Conover, R. Fitzmartin, M. Friedman, P. Goldenheim, W. Herlihy, R. Kaiko, J. Komorowski, J. Lang, W. Mallin, R. Reder, K. Sackler, R. Sackler