
From: Day, Matthew
Sent: Wednesday, October 24, 2007 1:29 PM
To: Robinson, Dean; Fortescue, Timothy
Subject: ITC
Attachments: PCS ITC November Agenda 2007.doc; Current Market Overview 7-23-07.ppt; Objections and Company Approved Responses 7-23-07.doc

Thanks for talking with me yesterday. Attached is the following:

1. ITC Agenda- for your review
2. Objections- please let me know what you guys think are the top 5 (do not pay attention to the responses; many of them are not consistent with the model call.)
3. Market place slide deck- for Dean

I will set up a dinner for Sunday night. Is around 6pm ok?

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PCS Initial Sales Training Class Agenda

Sunday, November 4th, 2007	
1:00 pm to 9:00 pm	Arrivals / Registration <i>Crowne Plaza Valley Forge, King of Prussia, PA</i>
Monday, November 5th, 2007	
7:00 AM to 7:45 AM	BREAKFAST -
8:00 AM to 8:30 AM	Introductions & Expectations - Dan Scott, Director Sales Training and Development
8:30 AM to 8:45 AM	Welcome to ITC Matt Day, Manager Sales Training
8:45 AM to 9:00 AM	FENTORA- Market Overview Dean Robinson, Atlantic Coast Area Manager
9:00 AM to 10:00 PM	FENTORA- The Path of Pain Matt Day, Manager Sales Training
10:00 AM to 10:15 AM	BREAK -
10:15 AM to 10:45 AM	FENTORA PI- Review Matt Day, Manager Sales Training
10:45 AM to 11:15 AM	FENTORA CVA- OraVescent Technology and Pharmacokinetics Matt Day, Manager Sales Training
11:15 AM to 12:00 PM	FENTORA CVA- Dosing, Titration and Conversion Matt Day, Manager Sales Training
12:00 PM to 1:00 PM	LUNCH -
1:00 PM to 2:00 PM	FENTORA CVA- Efficacy and Safety Tim Fortescue, Southwest Area Trainer
2:00 PM to 2:15 PM	BREAK -
2:15 PM to 3:15 PM	FENTORA – The Model Sales Call Overview and Scenarios Dean Robinson, Atlantic Coast Area Manager Matt Day, Manager Sales Training
3:15 PM to 3:30 PM	BREAK -
3:30 PM to 5:00 PM	Overview of the Risk Management Program (SECURE) Penny Levin, Director Regulatory Affairs
Homework	TBD

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Tuesday, November 6th, 2007	
7:00 AM to 7:45 AM	BREAKFAST -
8:00 AM to 9:30 AM	Utilizing Additional Promotional Material Marketing TBD Matt Day, Manager Sales Training Tim Fortescue, Southwest Area Trainer
9:30 AM to 11:00 AM	FENTORA- Cephalon Speaker Program Slides Dr. Arvind Narayana, Medical Director Fentora
11:00 AM to 11:15 AM	BREAK -
11:15 AM to 12:00 AM	Application Exercise: Off-label scenarios Matt Day, Manager Sales Training
12:00 PM to 1:00 PM	LUNCH -
1:00 PM to 2:00 PM	Objection Handling Workshop Tim Fortescue, Southwest Area Trainer
2:00 PM to 4:00 PM	Application Exercise: Making an Effective and Compliant Call Matt Day, Manager Sales Training
4:00 PM to 5:00 PM	Wrap up Matt Day, Manager Sales Training
6:30 PM	DINNER Magianos <i>Sales Training</i>

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Wednesday, November 7th, 2007	
7:00 AM to 7:30 AM	BREAKFAST - Conference Center Break Area
8:00 AM to 9:45 AM	Data, Reports and Analysis - Bill Pentz, Sr. Sales Reporting Analyst
9:45 AM to 10:15 AM	BREAK - Conference Center Break Area
10:15 AM to 11:45 AM	Smart Training - Danielle Ruttman
11:45 AM to 1:00 PM	LUNCH - Stirling's Restaurant - Lobby Level
1:00 PM to 2:00 PM	Compliance Session - Stu Kim - Assistant General Counsel
2:00 PM to 2:15 PM	BREAK - Conference Center Break Area
2:15 PM to 3:15 PM	Managed Care Joe Caminiti, VP Addiction Medicine & Healthcare Systems
3:15 to 3:30 PM	BREAK - Conference Center Break Area
3:30 PM to 4:00 PM	Human Resources Gene Sackett, Director of HR
4:00 PM to 5:00 PM	IT & S Overview - Michael Johnson, Client Services Specialist II
6:00 PM -	Meet in Lobby for transportation to Graduation Dinner at General Warren Inne

Thursday, November 8th, 2007	
7:00 AM to 7:30 AM	BREAKFAST - Conference Center Break Area
8:00 AM to 8:30 AM	Fleet Overview Dick Prettyman
8:30 AM to 9:45 AM	Driver Awareness Training Dick Prettyman/ Vendor - ADTS
9:45 AM to 10:00 AM	BREAK - Conference Center Break Area
10:00 AM to 11:00 AM	Executive Presentation Frank Baldino, CEO Cephalon
11:00 AM to 11:30 AM	Adverse Events Reporting - Sam Devonshire, Operations & Compliance Training
11:30 AM to 12:00 PM	Medical Affairs - Danielle Ceccanecchio, Manager Professional Services & Medical Information
12:00 PM to 1:00 PM	Lunch
1:00 PM to 1:15 PM	Sales Administration Jane Hoopes
1:15 PM to 3:15 PM	CSP Overview Dana Luscombe
3:30 PM	Departures

FENTORA™ OBJECTIONS AND COMPANY-APPROVED RESPONSES

OBJECTION #1: Patients like Actiq® better.

PCS/OAS CLARIFYING QUESTION:

“Is there a specific feature the patients like or is it resistance to change?”

COMMON HCP RESPONSE:

“Actually, the patients just don’t want to change. Their BTP is managed with Actiq.”

APPROVED PCS/OAS RESPONSE:

“Doctor, I can appreciate how your patients feel about switching. However, let me share with you why *FENTORA*® may be an appropriate treatment choice for those Actiq patients, as well as new patients that suffer from BTP due to cancer. *FENTORA* provides a pharmacokinetic profile distinct from that of Actiq, based on greater absorption through the buccal mucosa.

- First, the technology of *FENTORA* may optimize the delivery of fentanyl providing fentanyl absorption that is *earlier and more extensive* (approximately 60% higher C_{max}) than Actiq or OTFC.
- Secondly, the efficient delivery of fentanyl across the buccal mucosa allows for approximately a 30%-50% greater bioavailability.

Doctor, while you can clearly see the pharmacokinetic advantages of *FENTORA* over Actiq, *FENTORA* also provides the added benefit of being convenient, discreet and sugar free.

Finally doctor, it is important to remember that due to the higher bioavailability of fentanyl in *FENTORA*, when converting patients from Actiq or OTFC you cannot substitute on a mcg per mcg basis. Your patient’s initial dosing of *FENTORA*, as well as titration of the dose, must be individualized to meet their therapeutic needs and to reach a successful dose of *FENTORA*.”

OBJECTION #2: Packaging difficult to open and the tablets crumble

PCS/OAS CLARIFYING QUESTION:

“Doctor, can I take a few minutes to show you, and any nursing staff that educate patients, the proper way to open the blister pack?”

COMMON HCP RESPONSE:

“You can try, but I still think it will be difficult for my elderly patients.”

APPROVED PCS/OAS RESPONSE:

“Doctor, the *FENTORA* blister pack meets the highest federal standards for child safety and is intended to mitigate the risks of accidental ingestion. However, if the patient

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follows the directions they will be able to access the *FENTORA* tablet intact. Let me demonstrate with a placebo pack:

- For single tablet removal, separate one of the four blister units by tearing apart at the perforations. Bend the unit along the line where indicated. Peel back foil to expose the tablet. The tablet should be taken immediately after the package has been opened, and should not be split.

Remember doctor, when prescribing *FENTORA* for either a new opioid-tolerant patient or when converting from OTFC, dosing must be individualized and not switched on a mcg per mcg basis.”

OBJECTION #3: *FENTORA* causes ulceration or irritation in the mouth.

PCS/OAS CLARIFYING QUESTION:

“Doctor, what percentage of the time do you actually see this ulceration in the patient’s mouth?”

COMMON HCP RESPONSE

“I have seen it a few times, so I just switch the patient back to Actiq or another SAO.”

APPROVED PCS/OAS RESPONSE:

“Doctor, while there were reports of application site reactions during clinical trials, they tended to occur early in treatment and were transient and self-limited, resolving over continued use. You may also direct the patient to alternate tablet placement to the opposite side of the mouth above a rear molar.”

OBJECTION #4: I used the conversion chart, but *FENTORA* is not providing adequate pain relief.

PCS/OAS CLARIFYING QUESTION:

“Doctor, it may be possible that the patient was not receiving adequate pain relief *prior* to being prescribed *FENTORA*, there are those patients that may be reluctant to discuss their BTP episodes as it may be a sign of their worsening condition. Using the conversion chart is a suitable guideline. However, did you individualize the titration of *FENTORA* for your patient?”

COMMON HCP RESPONSE:

“No, I assumed the conversion chart provided the appropriate dose adjustment.”

APPROVED PCS/OAS RESPONSE:

“Doctor, the recommended conversion chart for *FENTORA* may be appropriate for the patients you are upgrading to *FENTORA* from Actiq. However, it is

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conservative. That is why it is important that your patient's dose of *FENTORA* be individualized during the titration phase in order to find the successful dose that will provide appropriate analgesia and acceptable side effects."

OBJECTION #5: Breakthrough pain is not intense enough to use that potent of a drug.

PCS/OAS CLARIFYING QUESTION:

"Doctor, why do you feel *FENTORA* is more potent than the other opioids?"

COMMON HCP RESPONSE:

"Because it works faster and it must have a greater abuse potential than the other opioids."

APPROVED PCS/OAS RESPONSE:

"Doctor, in terms of "working faster" *FENTORA* does provide pain relief within 15 minutes in some patients, with duration of pain relief up to 60 minutes (last time point measured). *FENTORA* may be an appropriate treatment choice to match the onset and duration of a typical episode of BTP in patients with cancer. As for the potential for abuse; like other CII opioids (morphine, oxycodone, hydromorphone, oxymorphone, and methadone) *FENTORA* has a similar abuse liability. This should be considered in situations that you may be concerned about abuse, as you would with any other opioid you were prescribing. Also doctor, Cephalon has developed the SECURE Program which is the *FENTORA* Risk MAP that focuses on minimizing risk, inclusive of abuse."

OBJECTION #6: My patients liked that they could re-use Actiq. They can't re-use *FENTORA*.

PCS/OAS CLARIFYING QUESTION:

"Doctor you may recall that within five minutes over 60% of the OTFC matrix is dissolved. Taking the unit out of the mouth to re-use, would not deliver enough fentanyl to provide adequate analgesia to treat your patient's next BTP episode after partial use. What would you advise the patient to do if their BTP was not covered?"

COMMON HCP RESPONSE:

"Take an additional unit to control their BTP."

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APPROVED PCS/OAS RESPONSE:

“Doctor the OTFC unit should not be re-used for obvious safety reasons. Having a partially consumed unit has a greater risk of accidental exposure; even a small amount of fentanyl left on the handle may be fatal to a child. Since *FENTORA* is a discreet tablet contained in packaging that meets the highest FDA packaging safety standards, this is not an issue. Furthermore a *FENTORA* tablet should be used immediately upon opening of the blister package.”

(Transition to efficacy)

“*FENTORA* provides a profile distinct from that of Actiq (OTFC) based on greater absorption of fentanyl through the buccal mucosa. Because of the breakthrough technology of *FENTORA*, fentanyl is readily absorbed providing earlier and greater exposure of fentanyl through the buccal mucosa.”

OBJECTION #7: If it works that fast, it must have a high abuse potential.

PCS/OAS CLARIFYING QUESTION:

“Doctor, how great of a concern do you have for your opioid-tolerant patients suffering with BTP due to cancer abusing their opioid prescriptions?”

COMMON HCP RESPONSE:

“I generally, don’t have a great concern. However, this drug worries me because it works fast and I don’t want it to get into the wrong hands.”

APPROVED PCS/OAS RESPONSE:

“I can understand your concern. Currently, there is no data that says fentanyl is more abusable than other opioids. You should manage this as you would for any opioid you were prescribing for a patient you had concerns over. In addition, Cephalon has developed the SECURE Program which is the *FENTORA* Risk MAP that focuses on minimizing risk.”

(Transition to efficacy)

“Doctor, *FENTORA* delivers the same amount of fentanyl using approximately two-thirds the dose of OTFC. The efficient delivery of fentanyl across the buccal mucosa allows for greater bioavailability.”

OBJECTION #8: The tablet won’t dissolve and then patients think that it isn’t working.

PCS/OAS CLARIFYING QUESTION:

“Doctor, is your patient experiencing pain relief with *FENTORA*, even when the tablet is still dissolving?”

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COMMON HCP RESPONSE:

“I assumed that they were not because the tablet was not dissolving, therefore not having an effect on pain relief.”

APPROVED PCS/OAS RESPONSE

“Doctor, *FENTORA* is the first and only fentanyl tablet that utilizes OraVescent Technology. Like any new technology, there is a need for appropriate education on proper use and product expectations. The tablet dwell time (the length of time that the tablet takes to fully dissolve following buccal administration) does not affect early systemic exposure to fentanyl.”

(Transition to efficacy)

“The OraVescent technology may optimize delivery of fentanyl across the buccal mucosa. Fentanyl absorption is earlier and more extensive with *FENTORA*. The efficient delivery of fentanyl allows for 65% bioavailability.”

OBJECTION #9: *FENTORA* tastes terrible!

PCS/OAS CLARIFYING QUESTION:

“Doctor, how frequently does the issue of taste outweigh the benefit of pain relief the patient experiences with *FENTORA*?”

COMMON HCP RESPONSE:

“Some continue to use *FENTORA*, others request Actiq or another alternative.”

APPROVED PCS/OAS RESPONSE

“Doctor, the *FENTORA* tablet is sugar free, and for safety purposes intended to not be appealing (i.e., for children). Nevertheless, taste is subjective and I can appreciate that some patients may find the flavor unfavorable. However, in clinical trials the issue of an unpleasant taste (dysgeusia, parageusia) was minimal among patients and was not a cause for discontinuation. Remember, the patient should place the tablet in the back of the mouth above a rear molar. Additionally, you can suggest the patient rinse their mouth after tablet dissolution.”

(Transition to efficacy)

“Doctor, patients may experience rapid onset of relief. Onset of pain relief with *FENTORA* was seen within 15 minutes in some patients.”

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OBJECTION #10: I don't use big drugs like fentanyl.

PCS/OAS CLARIFYING QUESTION:

“Doctor, what makes you characterize fentanyl as a “big drug?”

COMMON HCP RESPONSE:

“Because it's more potent and works faster, it has a greater potential to be abused.”

APPROVED PCS/OAS RESPONSE:

“Doctor, currently, there is no data that says fentanyl is more abusable than other opioids. You should manage the risk for abuse the same as you would for any opioid you were prescribing. However, let me provide you with the Emerging Solutions in Pain website. This website is dedicated to educating physicians on pain management, as well as providing tools to help minimize risk of abuse yet maximize therapeutic benefit when prescribing opioids.”

(Transition to efficacy)

“Doctor, *FENTORA* may be an appropriate treatment choice to match the onset and duration of a typical episode of BTP in patients with cancer because *FENTORA* provides pain relief within 15 minutes in some patients, with duration of pain relief up to 60 minutes (last time point measured).”

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