

From: Jeffrey Dierks </O=TEVA/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=JDIERKS>
To: Matthew Day; Yousseff Khan
Sent: 2/24/2016 6:56:31 PM
Subject: VANTRELA ER 2016 BP for 2017 updating
Attachments: US MP Vantrela ER 20April2015.docx

TEVA

CNS

Jeffrey Dierks Director, Pain Care Marketing
Tel: +1-610-786-7899
Jeffrey.Dierks@tevapharm.com www.tevapharm.com

IMPROVING HEALTH,
MAKING PEOPLE FEEL BETTER

GETTING
IT DONE
TOGETHER

CREATIVITY
WHERE IT
MATTERS

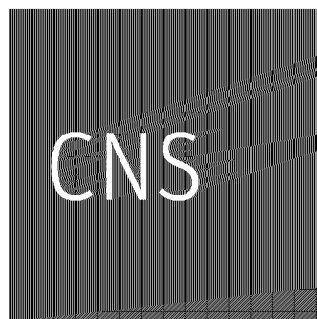
CARING

MAKING OUR
FAMILIES
PROUD

LEADING
THE WAY

OUR PURPOSE & VALUES

PLAINTIFFS TRIAL
EXHIBIT
P-19142_00001



vantrela™ 
(hydrocodone bitartrate) 
extended-release tablets

2016 US REGIONAL BRAND PLAN

March 19, 2015

FOR INTERNAL PURPOSES ONLY – NOT FOR USE IN PROMOTION.

This presentation is a draft for discussion purposes only. It may include information with respect to potential products and/or indications that are not presently approved by the FDA and thus cannot be promoted by Teva. Off-label promotion is against company policy. Sales and marketing promotional activity is strictly limited to the indications currently listed in the products' respective package inserts. Information about non-promoted prescriptions is to be used only for legitimate business planning purposes (e.g., discussions of ongoing or potential clinical development plans, considerations of promotional strategies if and when new indications are approved, production planning, and for budgeting and forecasting revenues). All revenue assumptions or projections assume strict compliance with Teva's policy prohibiting any promotion of off-label uses of Teva products.

This document may also contain forecasts regarding Teva products that have been prepared for confidential business contingency analysis and planning purposes only to consider various business scenarios. Such forecasts and the assumptions used do not reflect or constitute a legal analysis or opinion regarding the merits of pending or anticipated litigation or a legal assessment as to which scenario(s) is/are more likely. Nor do they represent a final agreed course of action and any inference to that effect is not intended and is hereby expressly disclaimed.

Table of Contents – Regional Choices

A.	REGIONAL EXECUTIVE SUMMARY	3
B.	REGIONAL SITUATION ANALYSIS – REGIONAL MARKET INSIGHTS AND IMPLICATIONS.....	4
C.	WHERE TO PLAY	10
C1.	Market definition	10
C2.	Market Prioritized Business Opportunities & Behavioral Objectives.....	11
C3.	Market Stakeholder Prioritization.....	12
C4.	Strategic Imperatives	16
D.	HOW TO WIN	17
D1.	Market Prioritized Value Drivers and Value Proposition.....	17
D2.	Market Communication Platform - Core Messages.....	20
D3.	Critical Success Factors.....	21
D4.	Stakeholder Model / Strategic Spend Guidance	21
D5.	Forecast Assumptions	22

CONFIDENTIAL CONTINGENCY/SCENARIO PLANNING DOCUMENT. FOR INTERNAL DISCUSSION PURPOSES ONLY

INTRODUCTION TO THE VANTRELA™ ER REGIONAL BRAND PLAN**A. REGIONAL EXECUTIVE SUMMARY**

VANTRELA™ ER is a single entity, acetaminophen-free, extended release (ER) oral formulation hydrocodone developed with Teva's proprietary CIMA™ abuse deterrent technology (ADT) platform. VANTRELA ER will play a pivotal role for Teva Pain Care as the company launches its first CIMA™ ADT based product in the U.S and furthers the evolution of the organization into a leader in Pain Care.

The VANTRELA ER brand vision is to position ourselves as the product of choice for patients on short-acting opioids (SAO) who require around-the-clock ER opioids, have responded well to IR hydrocodone and would like to be maintained on the same molecule.

Over 100 million people in the U.S. suffer from chronic pain, of which close to 50 million are considered moderate to severe (*IOM, Decision Group, 2013*). Prescription opioid medication is the most common form of treatment for chronic pain, largely for its strong analgesic effect; however opioid treatment also presents a challenge in the current care pathway for chronic pain patients. Along with their effective analgesia, opioid medications also carry a risk for potential abuse, and/or misuse - although many will acknowledge the issue, few tie the concern to their own role in providing healthcare (Managed care does not want to "pay/cover" AD opioids at a premium price; HCPs do perceive they have "abusers" in their practice). VANTRELA ER is positioned to offer patients, HCPs and payers an LAO that utilizes the most widely used and trusted molecule, hydrocodone, provides effective relief, with the broadest dosing range and most comprehensive abuse deterrent profile.

The key business objectives to win in this market are to educate HCPs, patients and payers about the importance of abuse deterrent opioids and differentiate VANTRELA ER from the competition through our product features and benefits. We have identified three key strategic imperatives aligned to these objectives and include the following: 1. Educate stakeholders about appropriate use, abuse potential and abuse deterrent technology; 2. Develop a differentiated brand (both product and technology); 3. Ensure reimbursement access for appropriate patients and HCPs. Our strategic approach will allow us to successfully launch VANTRELA ER, execute a targeted and efficient promotional effort employing an optimal resourcing approach, driving the brand to achieve over \$1B in cumulative net sales over the life cycle, with peak net sales of over \$400M. Our success will not only prepare the market for the follow-on immediate-release ADT opioid launches that employ CIMA AD technology in 2017 but also elevate Teva as a leader in Pain Care.

CONFIDENTIAL CONTINGENCY/SCENARIO PLANNING DOCUMENT. FOR INTERNAL DISCUSSION PURPOSES ONLY

B. REGIONAL SITUATION ANALYSIS – REGIONAL MARKET INSIGHTS AND IMPLICATIONS

Unmet Needs

Opioid analgesics, the most broadly effective analgesics, are used to treat all types of moderate to severe acute and chronic pain. The unmet needs in chronic pain treatment with opioids center around (1) the ability to better tailor “individualized” pain care through dosing flexibility/broad dosing range, (2) better pain management through consistent analgesia and (3) improved tolerability through enhanced safety profiles.

Due to the complexity with prescribing opioids, Primary care physician comfort in prescribing them is limited and their management of chronic pain often causes frustration by patients, causing them to visit multiple HCPs before finding adequate pain relief.

In addition to the unmet needs mentioned above, the need for enhanced abuse deterrence technologies is significant and the driver behind this developing field. With more than 260 million opioid TRX's written in 2014 and significant societal pressure related to abuse, misuse and diversion, there is a need for a multi-faceted approach, with the goal of mitigating risk to ensure safe and effective pain management. Key stakeholders in this approach include physicians, patients, payers, and the government (policymakers and the FDA), whose behaviors are largely driven by the need for products that exhibit clinical efficacy, quality of life improvements, cost-effectiveness, and abuse deterrence properties.

Addressing Opioid Abuse and Misuse – Abuse Deterrent Technology

The prevalence of prescription opioid abuse and misuse has increased in the past decade and poses a serious public health issue. The statistics are staggering; in 2008, over 36,000 people died from drug overdose, and most of these deaths were caused by prescription drugs. In 2010, 2 million people reported using prescription painkillers nonmedically for this first time within the year. Based on this significant challenge to public health and the continued need for effective pain medications, the development of opioids formulated to deter abuse has become a priority for the FDA. In January 2013, the FDA provided draft guidance to the pharma industry about the different categories of abuse deterrent opioids, the studies that should be conducted to demonstrate that a given product has AD properties, how those studies will be evaluated, and what labeling claims may be approved based on the results of those studies. (Source: Guidance for Industry AD Opioids — Evaluation and Labeling — FDA January 2013)

Opioid analgesics can be abused in a number of ways, with the two most common routes being oral and intranasal. AD technology should target known or expected routes of abuse for the opioid drug substance for that formulation. As a general framework, AD formulations can be categorized as follows:

1. Physical/Chemical barriers – Physical barriers can prevent chewing, crushing, cutting, grating, or grinding/milling. Chemical barriers can resist extraction of the opioid using common solvents like water, alcohol, or other organic solvents. Physical and chemical barriers can change the physical form of an oral drug rendering it less amenable to abuse. (e.g., Oxycontin, Opana)

CONFIDENTIAL CONTINGENCY/SCENARIO PLANNING DOCUMENT. FOR INTERNAL DISCUSSION PURPOSES ONLY

2. Agonist/Antagonist combinations – An opioid antagonist can be added to interfere with, reduce, or defeat the euphoria associated with abuse. The antagonist can be sequestered and released only upon manipulation of the product. For example, a drug product may be formulated such that the substance that acts as an antagonist is not clinically active when the product is swallowed but becomes active if the product is crushed and injected or snorted (e.g., Embeda or Targiniq)
3. Aversion – Substances can be combined to produce an unpleasant effect if the dosage form is manipulated prior to ingestion or a higher dosage than directed is used. (e.g., Oxecta recently renamed Oxaydo as part of Egalet’s rebranding of the product after acquiring it from Acura Pharmaceuticals)
4. Delivery System (including depot injectable formulations and implants) – Certain drug release designs or the method of drug delivery can offer resistance to abuse. For example, a sustained-release depot injectable formulation that is administered intramuscularly or a subcutaneous implant can be more difficult to manipulate
5. Prodrug – A prodrug that lacks opioid activity until transformed in the gastrointestinal tract can be unattractive for intravenous injection or intranasal routes of abuse
6. Combination – Two or more of the above methods can be combined to deter abuse

FDA AD Labeling Claims

The FDA draft guidance document also explains FDA’s current thinking about studies designed to demonstrate AD properties in a given formulation, how studies will be evaluated, and labeling claims that may be approved based on study results. The FDA categorizes potential AD properties of a product in four general tiers of claims:

Tiers	Study Type	Claim
1	Laboratory extraction and manipulation studies	The product is formulated with physiochemical barriers to abuse
2	Pharmacokinetic	The product is expected to reduce or block effect of the opioid when the product is manipulated
3	Clinical abuse potential studies	The product is expected to result in a meaningful reduction abuse
4	Post marketing studies	The product has demonstrated reduced abuse in the community

The FDA tiers generally correlate with three categories of premarketing study data to fully assess the abuse potential of an opioid formulation: manipulation and extraction studies, pharmacokinetic studies, and clinical abuse potential (“liking”) studies.

- In vitro manipulation and extraction studies address the ways an abuser may attempt to overcome AD technologies and the ways a formulation could be altered, either unintentionally or intentionally, that would change the rate or amount of drug released
- Pharmacokinetic studies should compare the pharmacokinetic profiles of manipulated and intact formulations of an opioid, as well as manipulated and intact formulations of comparator drugs. This should include one or more routes of administration, and characterize the effects of food and alcohol, if any, on the pharmacokinetic parameters

CONFIDENTIAL CONTINGENCY/SCENARIO PLANNING DOCUMENT. FOR INTERNAL DISCUSSION PURPOSES ONLY

- Human Abuse Liability (HAL) studies (also known as “liking” studies) are randomized, double-blind, placebo-controlled and positive comparator controlled crossover studies, generally are conducted in a drug-experienced abuser population

Market Access

Overall, Teva will be faced with three issues with respect to their AD opioid franchise in achieving reimbursement access in the U.S.: perception of abuse, perception of AD technology (ADT) and formulary access.

- *Perception of Abuse:* Teva will be faced with payers that have significantly varying viewpoints on opioid abuse and their role in managing that abuse. This ranges from payers that acknowledge the problem and have a desire to act, to payers that do not acknowledge the problem. Under an ideal scenario, payers will be very receptive to abuse deterrence formulations. Under less than ideal scenarios, payers may be unaware of the situation (e.g., not tracking abuse within their covered lives) or non-sensitive to opioid abuse (e.g., few external pressures beyond managing formulary). Therefore, payers often maintain that inappropriate use of opioids is a societal issue; however, a few high-control payers recognize that payers have a role in ensuring appropriate use of opioids.
- *Perception of ADT:* Although payers are not fully convinced of the value of ADT, they did identify cost effective ADT's as an unmet need that may alleviate part of the opioid abuse issue. Payers indicated that a WAC price comparator would be chosen based on clinical similarity, specifically Zohydro ER and Hysingla ER, while a NET price comparator depended almost entirely on price in the competitive LAO space, with OxyContin and Opana ER being the most commonly identified.
- *Formulary Access Implications:* A majority of payers indicate that if ADT were cost-effective, they would widely adopt ADTs in the LAO space. Until that time, the possible access spectrum for ER hydrocodone is in line with the current access spectrum for LAOs. Specifically, the ADTs are expected to be managed largely as non-preferred (Tier 3), with some restrictions including step edits through generic short acting opioids, and in a very small number of instances a double step edit through a generic followed by a branded long acting opioid. Payers indicated that if Product X was cost-neutral relative to preferred LAOs, it has an opportunity to be a first or second line LAO (after generic LAO). Selective contracting with prioritized, targeted commercial payers (ranging from 5% to 30%) in the US will be required to achieve target, unrestricted access goals (i.e., non-preferred with 1 generic step edit allowed).

In conclusion, payers generally recognized the potential benefit of ADTs on reducing overall population risk for abuse, but were unwilling to pay a premium without outcomes/real-world evidence.

Competitive Environment

Abuse deterrent technology continues to evolve while we await our FDA approval. Currently, there are four abuse deterrent products approved by the FDA; based on latest competitive intelligence, there are currently 23 companies associated with the opioid market, developing 61 compounds, utilizing 19 potential AD technologies. Specifically, there are several competitive AD hydrocodone formulations on

CONFIDENTIAL CONTINGENCY/SCENARIO PLANNING DOCUMENT. FOR INTERNAL DISCUSSION PURPOSES ONLY

the market that we will closely monitor as they may be in direct competition to VANTRELA ER for our target appropriate patient population.

- Purdue's Hysingla ER (extended release hydrocodone) – FDA approved in October 2014; launched in late January 2015
- Zogenix's Zohydro ER(extended release hydrocodone) reformulation – FDA approved in January 2015
 - Expectations they will complete AD studies to include AD claims in their label by the end of 2015 (announced their plans for a HAL study regarding gelling properties of their formulation suggesting it would make the product gel once manipulated by crushing, using solvents, etc. thereby making it impossible to snort or inject)
 - Zogenix recently sold Zohydro ER franchise to Pernix – transaction is expect to close in April 2015

A comparative chart of the three ER hydrocodone LAOs demonstrates key differentiation for VANTRELA ER, supporting our value proposition, our positioning and message platform covered later in this document.

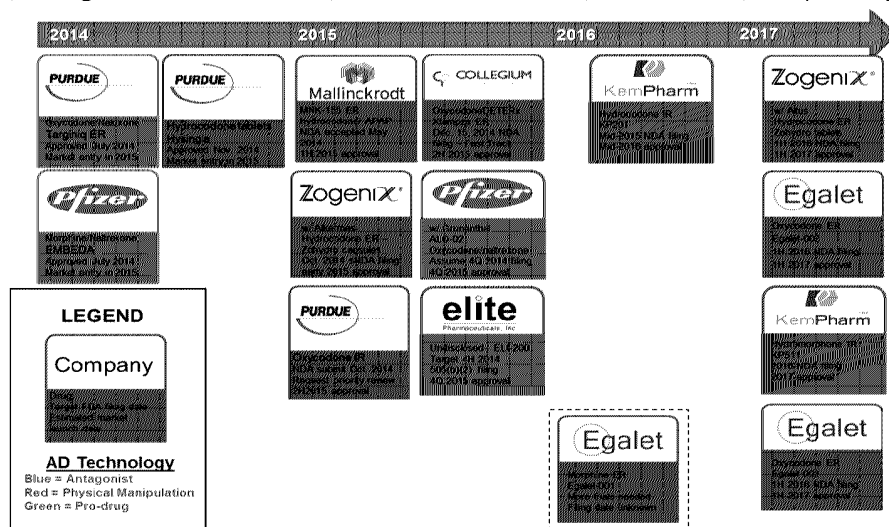
Product	In Vitro IV study	Dosing	Food Restriction	Effect of Alcohol PK	AD- Oral chewed	AD- Crushed/ Milled	AD-Nasal	Anticipated Label Tier
Hysingla • AD properties • Approved 4Q'14	✓	QD	No food restriction	Decreased release with higher alcohol	✓	X	✓	Tier I, III Oral chewed & nasal
Zohydro • Limited AD properties • Approved 2Q'14 • new formulation 2Q2015	Completed Data not available	BID	No food restriction	Increased release in presence of alcohol (dose dumping)	X Study not planned	X Study not planned	Ongoing Expected 2H 2015	Tier I Tier III Nasal pending success
Vantrela-ER • AD properties • NDA submission 4Q'14	✓	BID	Must take on empty stomach	No dose dumping	Not tested	✓	✓	Tier I, III Crushed oral & nasal

In addition to the extended release hydrocodone products, there are also 2 additional AD opioids approved by the FDA:

- Purdue's Targiniq ER (extended release oxycodone/naloxone) - FDA approved in July 2014, but based on competitive intelligence, is not expected to launch in the US. Market Insights believe it did not receive an AD with reduced opioid induced constipation pain indication it does not have any attributes to differentiate itself and with that would cannibalize Purdue's Oxycontin AD product
- Pfizer's AD-EMBEDA (extended release morphine sulfate and naltrexone) – FDA approved in December 2014; expected to be on market early 2015

CONFIDENTIAL CONTINGENCY/SCENARIO PLANNING DOCUMENT. FOR INTERNAL DISCUSSION PURPOSES ONLY

- Several oxycodone, morphine and hydrocodone products are nearing regulatory filing and decisions for Pfizer, Collegium Pharmaceuticals, Elite Pharmaceuticals, Mallinckrodt, and possibly Egalet



SWOT Analysis

Below you will find a detailed SWOT which outlines the collective thoughts of the VANTRELA ER cross functional team about the product and market landscape:

Strengths	Weakness
<ul style="list-style-type: none"> Unique CIMA AD technology platform properties (3 layers of abuse deterrence technology) Broad dosing range (30-180 mg/day) Consistent 12 hr. dosing for around the clock pain control through unique delivery system Absence of dose dumping in presence of alcohol Delivers the safety and tolerability profile as expected with hydrocodone 	<ul style="list-style-type: none"> Take without food dosing instructions Late entry into market (Hysingla and Zohydro already in market) Pharmacy stocking will be driven by patient demand
Opportunities	Threats
<ul style="list-style-type: none"> FDA recognition of importance of abuse deterrence and opioid safety Limited education on Abuse Deterrence technology, FDA guidelines, label tiering Policymakers mission to address societal impact of opioid abuse, raise awareness of chronic pain and AD opioids 	<ul style="list-style-type: none"> Legal and regulatory uncertainties around launch timing Perception that opioid abuse is not the issue Payer unwillingness to pay premiums for AD technology Rescheduling of hydrocodone as CII may impact pharmacy stocking

Strengths

- A key strength is our differentiated, unique CIMA AD technology platform that serves as the foundation of the entire Teva ADT Opioid franchise. This platform is not only built with 3 layers to deter abuse (gelling, matrix and barrier mechanisms), but it also allows for the delivery of hydrocodone as polymer granules in a tablet matrix which allows for consistent 12-hour analgesia

CONFIDENTIAL CONTINGENCY/SCENARIO PLANNING DOCUMENT. FOR INTERNAL DISCUSSION PURPOSES ONLY

for around-the-clock pain relief. The absence of dose dumping with alcohol is a strength, especially since direct competitors either show a decreased (Hysingla) or increased (Zohydro) release with alcohol. VANTRELA ER also has the broadest dosing range of any extended release hydrocodone product (30mg-180mg per 24 hours) and delivers the safety and tolerability profile as expected with a hydrocodone.

Weakness

- VANTRELA ER will likely be approved with the dosing instructions “take without food”, but research has shown that this will have a minimal impact on HCP prescribing. Our late entry into the extended release hydrocodone market (Hysingla and Zohydro already available and working to establish their position in the marketplace) places competitive pressure on us, not only for promotion, but also pharmacy stocking due to the limited space for controlled substances (at launch, VANTRELA ER may only be ordered when a patient presents a prescription). Pharmacies/retailers face pressures from the DEA who is responsible for enforcing inappropriate use/distribution of opioids. The 3 major wholesalers have also put in place SOM (suspicious order monitoring) processes to help control the distribution of all controlled substances which puts ordering thresholds on pharmacies which can make it difficult to get product.

Opportunities

- There is a large opportunity in offering an AD opioid solution for chronic pain patients, but work must be done in educating stakeholders on the benefits and relative value of AD technology as little is understood in this area. Through outreach, we can not only help to educate, but also establish CIMA® ADT as a “state of the art” AD technology platform. The recognition of, and resulting government focus on, opioid abuse deterrence and safety is an additional supporting opportunity. Policymakers are working to address the societal impact of the opioid abuse and as a result, there are 13 states with proposed legislation to require AD formulations to be dispensed at written.

Threats

- The impact of currently unresolved legal and regulatory uncertainties surrounding the Zogenix/Purdue issue poses a threat to the launch timeline of VANTRELA ER as our NDA application with the FDA for review. There is the concern that the perception amongst stakeholders is that opioid abuse and/or safety is an issue, but not “their” issue (HCPs don’t have abusers in their practice and payers are likely to be reluctant to reimburse at premium prices for ADT vs. generics). The rescheduling of hydrocodone as a CII may also impact pharmacy stocking and should be considered a threat to our launch stocking while demand for the product is being created.

C. WHERE TO PLAY

C1. Market definition

VANTRELA ER will be entering a highly competitive market? with other long acting schedule II opioids indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment, and for which alternative treatment options are inadequate. This is a class indication

CONFIDENTIAL CONTINGENCY/SCENARIO PLANNING DOCUMENT. FOR INTERNAL DISCUSSION PURPOSES ONLY

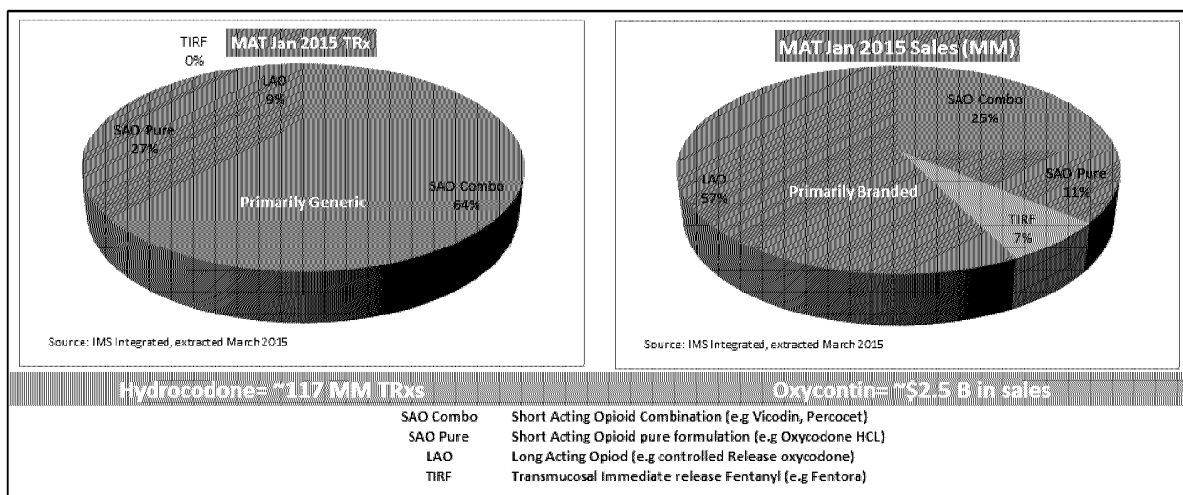
for the Long Acting Opioid (LAO) category most commonly used to treat chronic pain lasting at least 3-6 months. The Institute of Medicine reports over 100 million Americans are impacted by chronic pain and chronic pain results in up to \$635 billion annually in direct medical costs and lost productivity. The most prevalent forms of chronic pain are osteoarthritis and chronic lower back pain (CLBP), impacting 29.5 million and 26.7 million Americans, respectively¹. CLBP is treated with analgesic narcotics 31.5% of the time, while osteoarthritis is treated with analgesic narcotics in 15.4% of cases. The figures below highlight the opportunity for the Teva Pain Care Franchise in the chronic pain market:

Chronic Pain Diagnosis	U.S. Prevalence	% of Opioid Prescriptions
Osteoarthritis	29.5 million	31.5%
Chronic Lower Back Pain	26.7 million	15.4%

The U.S. Opioid market is the largest in the world generating 260M prescriptions and over \$8.6B in revenue in 2014. IR Hydrocodone based products were responsible for 45% of all opioid TRxs (116M, primarily generic). Although long-acting opioids (LAO), only make up 6% of the TRx's, they account for 57% of the market sales and has been a focus of innovation in the US with respect to abuse deterrent technology

Figure 1 provides a further illustration of the market:

Figure 1. US Opioid Market



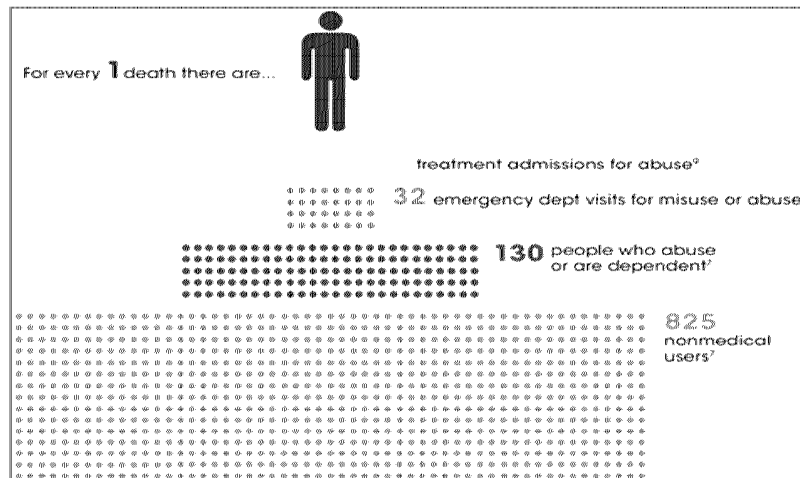
Though opioids can offer substantial pain relief for many patients in need, they also carry a risk for potential abuse and misuse. Abuse is defined as taking the product for purposes other than therapeutic effect, with or without manipulating it. Misuse is defined as intentionally or unintentionally taking a product other than how it was prescribed, but to still achieve therapeutic benefit. An example of this would be having a glass of wine at dinner after having taken a prescription opioid (there are warnings and precautions about this in the labels of all opioid products). The societal impact of abuse and misuse

CONFIDENTIAL CONTINGENCY/SCENARIO PLANNING DOCUMENT. FOR INTERNAL DISCUSSION PURPOSES ONLY

has led to numerous detrimental health outcomes, creating the search for answers on how to minimize this issue.

The societal impact of abuse and misuse has led to numerous detrimental health outcomes, creating the search for answers on how to minimize this issue. Over the past several years, statistics prove the damaging effects of opioid abuse and misuse. US statistics are most widely documented and available:

- Over 2 million Americans are addicted to prescription opioids
- 1 in 20 over the age of 12 have abused opioids
- Estimated 15,000 overdose deaths per year
- Increase in deaths: +415% from 1999-2009
- 943,365 Emergency Room visits in 2010
- Nonmedical use of prescription pain medications costs health insurers upwards of \$72.5 billion annually in direct health care costs.



C2. Market Prioritized Business Opportunities & Behavioral Objectives

Treatment Patterns and Patient Flow for Chronic Pain

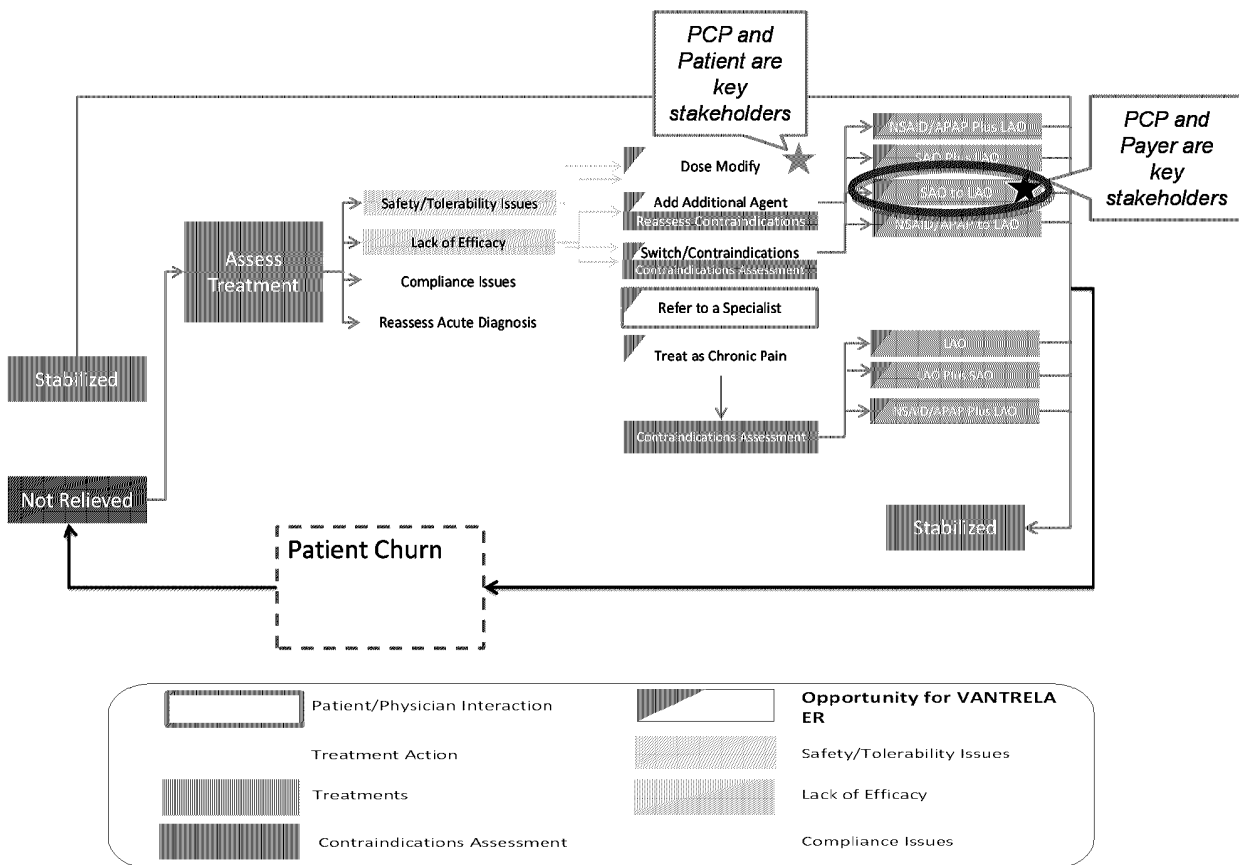
Because chronic pain patients have differing response rates to current therapies, and because there are a multitude of conditions that lead to the development of chronic pain, the majority of chronic pain patients are prescribed more than one analgesic drug.

In general, patients present to their primary care physician or generalist, who will then decide whether to manage the chronic pain with first-line agents (e.g. NSAIDs) or to refer the patient to a specialist—which could include a pain specialist, rheumatologist, orthopedic surgeon, anesthesiologist, or neurologist—depending on the underlying cause (e.g. PDN vs. LBP), region and local referral patterns. (Decision Resources 2013/2014)

CONFIDENTIAL CONTINGENCY/SCENARIO PLANNING DOCUMENT. FOR INTERNAL DISCUSSION PURPOSES ONLY

According to IMS data, 99% of all chronic pain patients begin therapy on medication other than an LAO. As a result, the journey for the potential VANTRELA ER patient begins with 2nd line usage. At this point along the pain management journey, the patient has already been diagnosed by an HCP with acute/chronic pain and treated accordingly, prior to moving into 2nd line treatment. The patient typically receives a short acting product and takes it multiple times per day. As the pain continues past 3 months, the diagnosis may change from acute to chronic, resulting in a potential medication change. Standard treatment is to either leave the patient on an IR product (requiring pills 4-6 times per day) or switch them to an ER product. This is an important opportunity for the VANTRELA ER brand, as it can leverage the significant IR hydrocodone usage along with providing abuse deterrent features.

The patient pathway is further illustrated below.

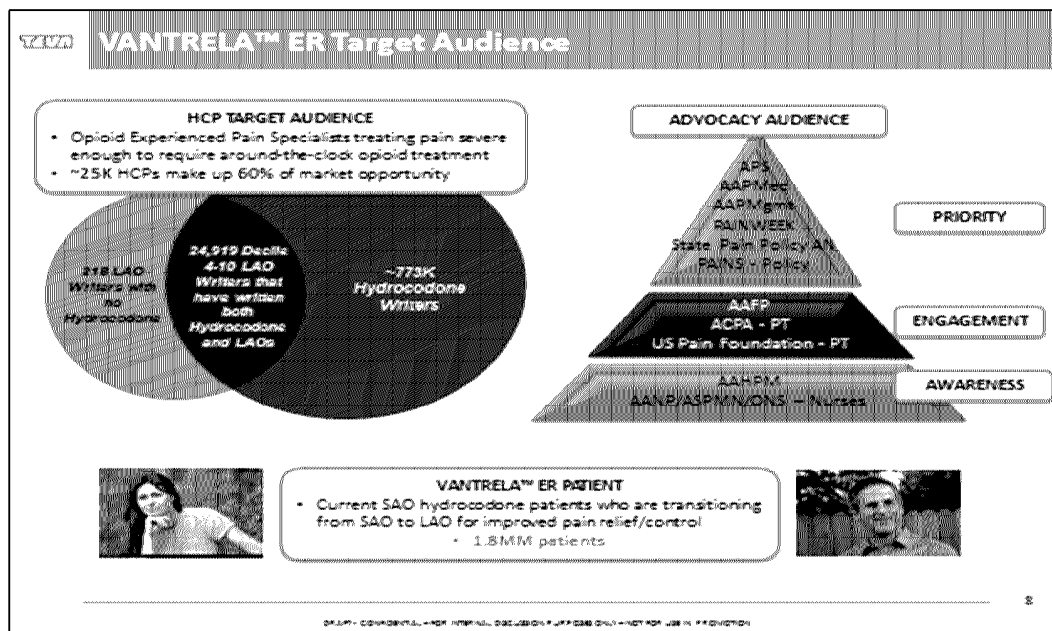


C3. Market Stakeholder Prioritization

As part of our launch planning, investment was made to better understand the key stakeholders in the treatment of chronic pain to better understand their role/influence and how best to prioritize into actionable segments to guide resource investments accordingly. Key stakeholders identified in the

CONFIDENTIAL CONTINGENCY/SCENARIO PLANNING DOCUMENT. FOR INTERNAL DISCUSSION PURPOSES ONLY

treatment decision pathway include HCPs, payers and patients, with government and advocacy growing in importance.



A detailed assessment of each prioritized stakeholder is found below.

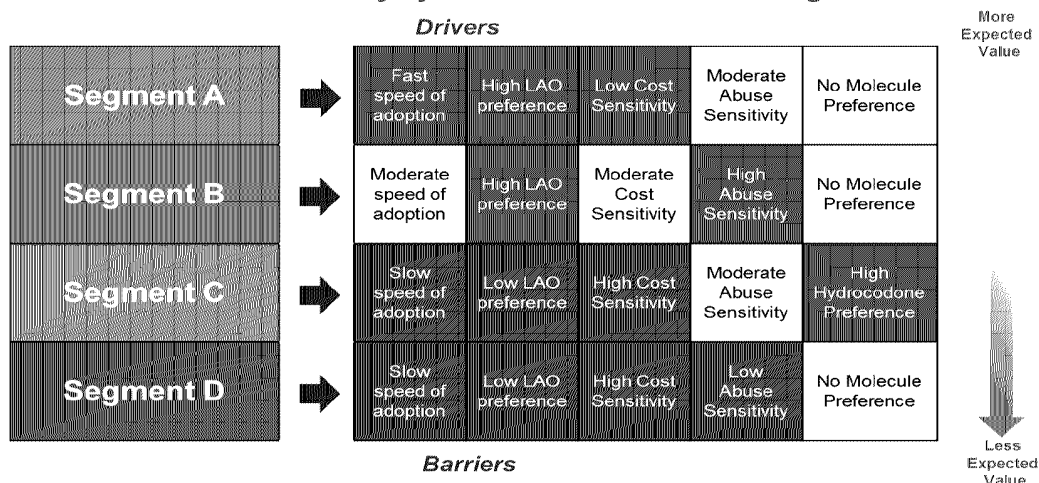
Health Care Professionals (HCP)

The HCP is the key stakeholder who is largely motivated by clinical data to guide treatment decisions with the goal of providing optimal care. The most frequent opioid prescribers are Pain specialists, PCPs, and NP/PAs. Opioids are a critical, if not essential, treatment option for patients with chronic pain and most HCPs treating chronic pain have confidence in their effectiveness for providing analgesia. HCPs are seeking long-acting opioids that can provide consistent 24-hour analgesia (round-the-clock pain relief), a broad dosing range to allow for the ability to better “individualize” pain care to each patient and an improved safety/tolerability profile. Attitudes and behaviors about opioids and their role in chronic pain vary across these specialties, requiring us to segment our customers to ensure we deploy resources only against our most appropriate targets.

Behavioral and attitudinal HCP segmentation was conducted in late 2014 amongst 375 PCPs, Pain Specialists and NP/PAs, that identified key drivers and barriers to prescribing in the chronic pain market. The research culminated in identifying four specific actionable segments of HCPs with each segment being assigned a potential “value” to the brand derived from the analysis (factors includes HCP’s current LAO prescribing volume, time to switch from SAO to LAO, preference for hydrocodone as a molecule, HCP attitude toward new treatments, and HCP concern for abuse-deterrence. The value derived from the segmentation allows for the prioritization of each segment and subsequent development of strategies and tactics to meet our customers’ needs. An overview can be seen in the table below.

CONFIDENTIAL CONTINGENCY/SCENARIO PLANNING DOCUMENT. FOR INTERNAL DISCUSSION PURPOSES ONLY

Drivers and Barriers by hydrocodone ER Customer Segment



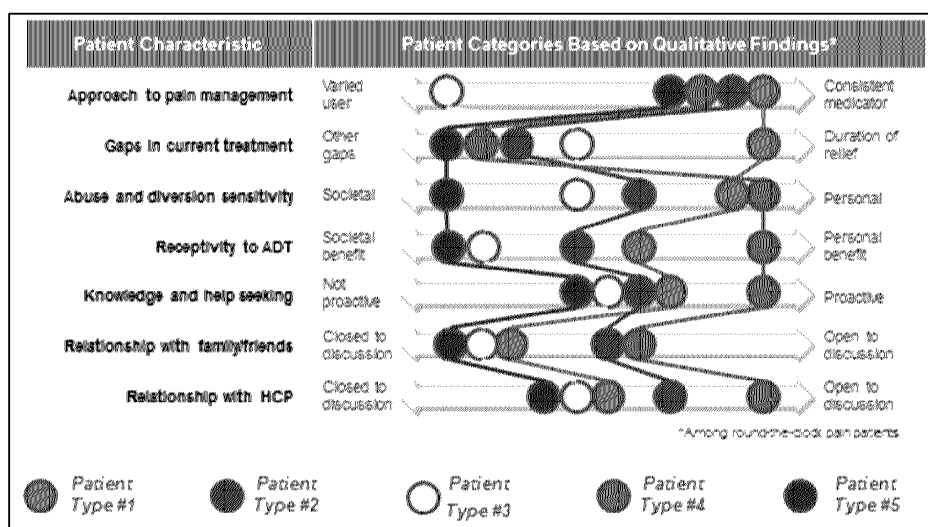
The segmentation will be refreshed later in 2015 as data becomes available for the launches of Zohydro™ ER and Hysingla™ ER to assist in the finalization of the HCP target list for hydrocodone ER.

Patient

The patient is primarily motivated to seek the most appropriate medication that will provide consistent analgesic relief with manageable side effects. A barrier to optimal pain care is the current perception of opioids; many patients are aware of the abuse and misuse of opioids and are hesitant to use those products because of the stigma associated with opioid use. With over 1MM chronic pain patients seeking to transition from a short-acting opioid to a long-acting opioid for effective pain management, we have identified opportunities through the patient journey and segmentation to engage patients to have more productive discussions with their HCPs.

The key promotional opportunities for VANTRELA ER to patients are the points at which the dosage or frequency of administration is modified, as well as when the patient reports dissatisfaction with the pain relief associated with IR treatments (see patient journey earlier in Section C2 of marketing plan). Initial patient segmentation work has been done to identify what are the drivers of change and the size of actionable patient segments to reach through promotion and we have identified 2 segments of patients (Type #1 and Type #2) that will be a focus for the brand with communications to mobilize and proactively discuss AD opioids and VANTRELA ER as an appropriate option with their HCPs.

CONFIDENTIAL CONTINGENCY/SCENARIO PLANNING DOCUMENT. FOR INTERNAL DISCUSSION PURPOSES ONLY



Payer

Payers are critical in providing reimbursement access and evaluating available treatments based on a variety of factors such as cost, safety and efficacy, quality of life, ease of administration, and comparable treatments. With the majority of prescription volume driven by generic options in the larger markets and opioids not having a large impact on budgets, payers generally do not currently manage the opioid products as tightly as they do other categories. This may change as new, branded AD formulations enter the market in the next few years. Payers can implement a variety of strategies to mitigate financial risks associated with opioid (ab)use (e.g. formulary controls, claims data surveillance, etc.). Payer landscape research indicates that payers' approaches to chronic pain management varies regionally and can potentially be affected by state government policy as AD technology becomes available. The objective is to ensure unimpeded coverage at the point where the patient is being switched from SAO to LAO treatment. This will be accomplished by profiling payers and engaging them with a differentiated payer value proposition that addresses the cost of opioid abuse and the costs associated with the use of IR products for a chronic pain condition (budgetary impact versus cost effectiveness).

Government

The wide-spread societal impact of abuse/misuse of opioids has created an environment that has the government looking for answers on how to cope with this epidemic. A number of states (13) have put forward legislation around AD opioids and additional measures are being reviewed at the federal level as well. As a company focused on appropriate prescribing and developing AD formulations of opioids, Teva has an opportunity to work with policymakers and appropriately affect the discussion around the need for AD products. Teva is becoming a recognized expert and is often asked by key legislators including FDA to comment on the effectiveness of proposed legislation.

Advocacy

Advocacy groups seek to protect the interests of people who suffer from chronic pain. They advocate for access to appropriate medications and are a key stakeholder with the potential to influence pain

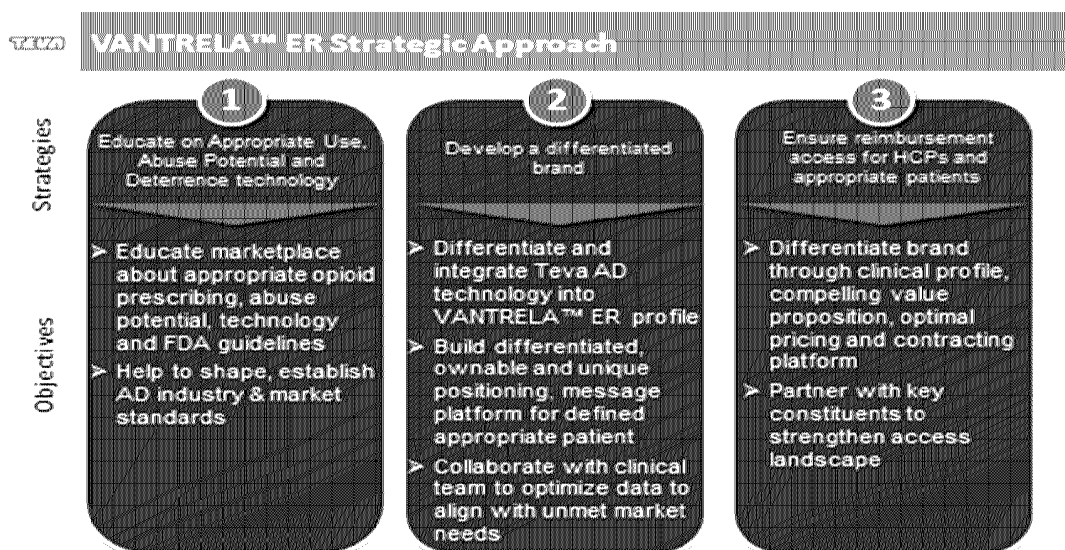
CONFIDENTIAL CONTINGENCY/SCENARIO PLANNING DOCUMENT. FOR INTERNAL DISCUSSION PURPOSES ONLY

management therapies and policies. Teva, as a leader in the field has the opportunity to engage with advocacy groups in a variety of ways, such as supporting programs that foster mitigation of risks associated with opioids programs that enhance patient education about pain management and improve HCP and Care Team interactions with patients.

C4. Strategic Imperatives

We have identified three strategic imperatives to be achieved to maximize the success of VANTRELA ER.

1. Educate stakeholders about appropriate use, abuse potential and abuse deterrent technology
 - We will accomplish this through our unbranded campaign, PAIN MATTERS, seeking to establish Teva as the responsible partner in pain care by providing best-in-class information, support and resources that help navigate evolving pain care landscape
 - The program will build on 4 communication pillars:
 - I. Chronic pain is a serious medical condition
 - II. Prescription opioids are an important part of a comprehensive treatment plan for some patients with chronic pain, but opioids also carry a risk of abuse
 - III. Reducing opioid abuse requires a multi-faceted approach
 - IV. Teva is committed to developing innovative approaches to deterring abuse
2. Develop a differentiated brand (both product and technology)
 - We will accomplish this through product positioning (Intelligent Design), branding and messaging to create a ownable and sustainable place in the market
3. Ensure reimbursement access for appropriate patients and HCPs.
 - We will accomplish this with a compelling value proposition & optimal market access plan



11

DRAFT - CONFIDENTIAL - NOT FOR INTERNAL DISCUSSION - PURPOSED ONLY - NOT FOR USE IN PROMOTION

CONFIDENTIAL CONTINGENCY/SCENARIO PLANNING DOCUMENT. FOR INTERNAL DISCUSSION PURPOSES ONLY

D. HOW TO WIN

D1. Market Prioritized Value Drivers and Value Proposition

Value Proposition of AD Opioids

The key elements that encompass the value proposition include: 1) Unmet medical needs that currently exist from a patient, physician and payer perspective and which will be addressed by VANTRELA ER. 2) The target patient population for who the AD opioids are intended. 3) Competitive differentiation highlights attributes of AD opioids and which differentiate it from its competitors. 4) Patient centric arguments highlights attributes of AD opioids that would be of importance to both physicians and patients and, will therefore encourage its adoption by them. 5) Economic value arguments discuss attributes/ arguments that are important to gain reimbursement from a payer perspective.

A discussion of the key value proposition elements is provided below.

Unmet Medical Needs:

Opioid related abuse: Opioids are an important component and serve as the mainstay therapeutic option for treating acute and chronic cancer and non-cancer pain (Raffa 2014, Gudin 2013). Despite their therapeutic benefits, abuse and misuse of opioids have created a serious and growing public health problem and one that has increased substantially from 2002-2010 with a slight decrease from 2011-2013 (FDA guidelines 2013, Katz 2014, Dart 2015). Payers perceive opioid abuse as a societal issue versus an issue that directly impacts them and has consequences in terms of high health care costs. In addition to demonstrating burden of opioid abuse, Teva's AD opioid formulations are expected to limit abuse potential and save overall direct and societal costs associated with opioid abuse.

Treatment Response

Chronic pain patients vary in their treatment response and no one single agent has consistent level of efficacy across all patients (Decision Resources, 2013). The availability of AD opioid formulations will add to the treatment options available to physicians to treat chronic pain. In addition, the availability of wide dose range with ER AD single entity hydrocodone coupled with q12 hour dosing will offer physicians dosing flexibility in individualizing patient treatment for optimal treatment response.

Complexity of opioid conversion

In clinical practice, chronic patients often start off on an immediate release opioid for pain relief and then require extended release opioids for longer duration of effect. As the IR and ER versions are likely not the same chemical entity, this requires a conversion of the IR opioid formulation to morphine equivalents to determine a dose for the extended release opioid. Teva will have both IR and ER AD versions of hydrocodone available which will help reduce the need for opioid conversion to morphine equivalents.

Target patient population for VANTRELA ER

CONFIDENTIAL CONTINGENCY/SCENARIO PLANNING DOCUMENT. FOR INTERNAL DISCUSSION PURPOSES ONLY

Patients on SAO's who require around-the-clock ER opioids, have responded well to IR hydrocodone and would like to be maintained on the same molecule

Competitive Differentiation for Brand Planning Purposes (not to be used in promotion)

The key AD competitors for VANTRELA ER are Hysingla and Zohydro. As different attributes are relevant for different competitors, competitive differentiation of VANTRELA ER has been parsed by the different competitors and can be summarized as follows:

VANTRELA ER vs Hysingla

- Q12hr vs QD- Q12 dosing could offer the ability for ease of titration and ease of taper off compared with qd dosing for Hysingla
- Broad dose range up to 180mg/day with VANTRELA ER vs. up to 120mg/day with Hysingla allows for optimal individual titration
- Smaller tablet size of VANTRELA ER allows for ease of administration (aspirational TBD)
- More robust Tier III AD label claim through demonstration of milling abuse deterrence with VANTRELA ER will be demonstrated. The same has not been shown with Hysingla.

VANTRELA ER vs. Zohydro

- Tier I and tier III abuse deterrence claims with VANTRELA ER will be demonstrated compared with limited AD properties with the Zohydro AD formulation currently being developed
- VANTRELA ER will offer a broad dose range (up to 180 mg/day) compared with 100mg for Zohydro. This will allow for optimal individual titration and dosing flexibility with ER AD hydrocodone
- There is no dose dumping in presence of alcohol with VANTRELA ER AD. On the other hand, dose dumping occurs in presence alcohol with Zohydro resulting in increased abuse potential with Zohydro

Patient centric arguments

VANTRELA ER will offer patients several benefits which can be summarized as follows:

- Broad single entity dose range coupled BID dosing offers great flexibility in terms of ease of titration and ease of tapering off and the ability to customize pain relief treatment based on individual patient needs
- Patients demonstrate improved functional outcomes with Teva's VANTRELA ER in the long term

The Competitive Assessment is illustrated in Figures X below.

CONFIDENTIAL CONTINGENCY/SCENARIO PLANNING DOCUMENT. FOR INTERNAL DISCUSSION PURPOSES ONLY

Product	Dosing	Total Daily Dose	Food Restriction	In Vitro IV study	Effect of Alcohol on PK	Oral Crushed/ Milled Liking	Nasal Liking
Hydro ER • Q2 2015 • Teva	q12h 15-90mg	30-180mg	Must take on empty stomach	✓	No dose dumping (in vivo)	✓	✓
Hysingla™ ER • Approved • Purdue	q24h 20-120mg	20-120mg	No food restriction	✓	Decreased release with higher alcohol (in vitro)	✓ Chewing only	✓
Zohydro® ER • Approved (reformulation) • Zogenix	q12h 10-50mg	20-100mg	No food restriction	Completed Data not available	X	X	Ongoing Expected 2H 2015

Payer Economic Value Argument

Teva's AD opioid formulations will offer several economic benefits to payers which can be described as follows:

- Reduced risk of abuse potential with Teva's AD opioid formulations compared with non-AD opioid formulations also offers the potential to save health care costs in addition to societal/indirect costs
- DACON of once daily may be challenged for Hysingla which may not render Hysingla as cost effective treatment with minimal/ no budgetary impact (TBD)
- In the US, ER ADF hydrocodone costs are partly offset by cost savings achieved with reduced abuse deterrence

In conclusion, the overall value proposition can be summarized as: VANTRELA ER (1) reduce the abuse risk in the target patient population (2) with manageable impact to payer budgets (3) without Zohydro (vs ER AD hydrocodone only) and extended release opioids abuse risk.

For	Opioid prescribing Healthcare Professionals
Who	Are looking to effectively transition chronic pain patients from SAO hydrocodone to an LAO
VANTRELA ER is	The only q12 AD hydrocodone
That	Is intelligently designed to make a real difference in the life of chronic pain patients
Because	<ul style="list-style-type: none"> • Utilizes the most widely used and trusted opioid molecule, hydrocodone • Offers consistent round-the-clock pain relief with q12hr dosing through polymer granulated matrix manufacturing delivery system • Designed responsibly to deter the risk of abuse in three ways: crushing, snorting and alcohol dose dumping • Available in 5-dosage strengths to better meet individual patient pain control needs • Offers broadest dosing range (30mg-180mg per 24 hours) of any long-acting hydrocodone • Formulated to avoid toxicities that acetaminophen may cause with long term use
So That	Patients have ability to do more in their daily lives

(note: value proposition positioning statements are aspirational and do not represent messaging)

CONFIDENTIAL CONTINGENCY/SCENARIO PLANNING DOCUMENT. FOR INTERNAL DISCUSSION PURPOSES ONLY

References supporting Value Proposition section

- *Chronic Pain. 2013. Decision Resources report.*
- *Dart RC, Surratt HL, Cicero TJ, Parrino MW, Severtson G, Bucher-Bartelson B, Green JL Trends in Opioid Analgesic Abuse and Mortality in the United States. N Engl J Med 2015;372:241-8.*
- *FDA - Guidance for industry AD Opioids-Evaluation and Labeling Jan 2013*
- *Gudin J. Assessment of Extended-Release Opioid Analgesics for the Treatment of Chronic Pain. Journal of Pain & Palliative Care pharmacotherapy 2013;27:49-61*
- *Katz N, Dart R, Bailey E, et al. Tampering with Prescription Opioids: Nature and Extent of the Problem, Health Consequences, and Solutions. The American Journal of Drug and Alcohol Abuse, 2011; 37:205-217*
- *Raffa R, Taylor R, Pergolizzi J. Sequestered naltrexone in sustained release morphine or oxycodone -a way to inhibit illicit use? Expert Opin. Drug Saf. 2014;13(2):181-190*

D2. Market Communication Platform - Core Messages

The VANTRELA ER communication platform will pull through the abuse deterrent elements of CIMA™ AD technology and support the brand positioning of Intelligent Design. The communication platform will be implemented through a variety of tactics such as promotional speaker programs, non-personal promotion programs (direct mail, banner ads etc...), and direct promotion via the sales force to build a brand position that is competitive, differentiated, sustainable and accretive.

Positioning: VANTRELA ER will be uniquely and competitively positioned as the “Intelligent Designed” LAO, built upon a strong foundation of differentiation to the key stakeholders in the chronic pain continuum, helping to address the unmet needs of abuse & misuse of opioids and the individuality of pain management for our customers. VANTRELA ER:

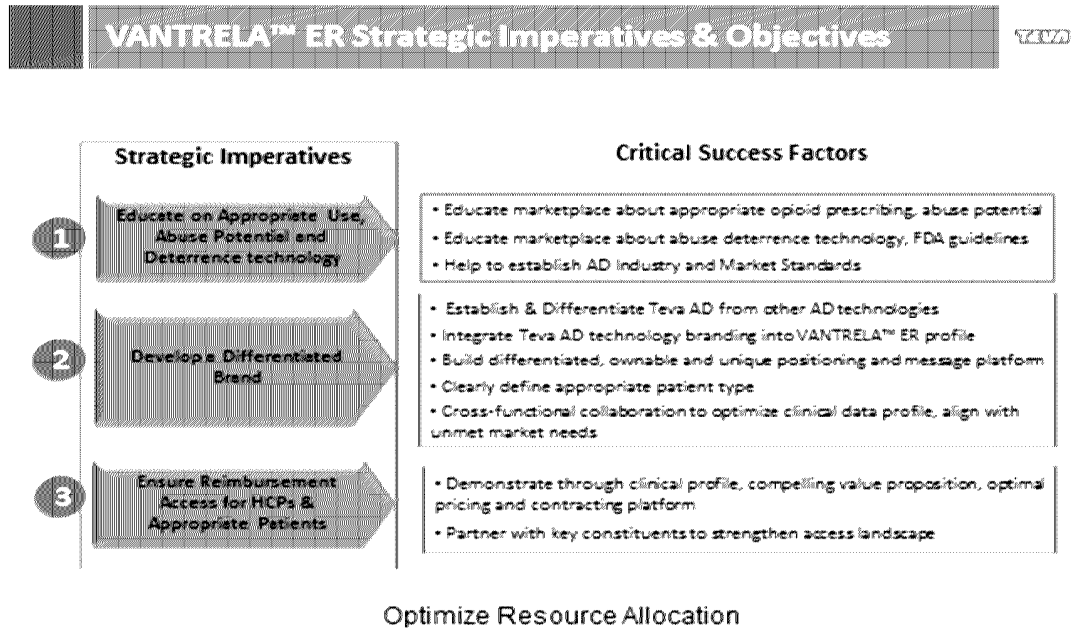
VANTRELA™ ER Positioning	
Premise	Treating patients with a long-acting opioid gives them the round-the-clock pain relief that enables them to re-engage in life. Yet, not all long-acting opioids are built with the patients' needs in mind
Promise	VANTRELA™ ER is intelligently designed to make a real difference in the life of chronic pain patients
Reasons To Believe	Because VANTRELA™ER: <ul style="list-style-type: none"> • Utilizes the most widely used and trusted opioid molecule, hydrocodone • Offers consistent round-the-clock pain relief with q12hr dosing through polymer granulated matrix manufacturing delivery system • Designed responsibly to deter the risk of abuse in three ways: crushing, snorting and alcohol dose dumping • Available in 5-dosage strengths to better meet individual patient pain control needs • Offers broadest dosing range (30mg-180mg per 24 hours) of any long-acting hydrocodone • Formulated to avoid toxicities that acetaminophen may cause with long term use

***Positioning statements are aspirational in nature and do not represent messaging.**

The messaging platform to support hydrocodone ER's positioning will be built on the reasons to believe.

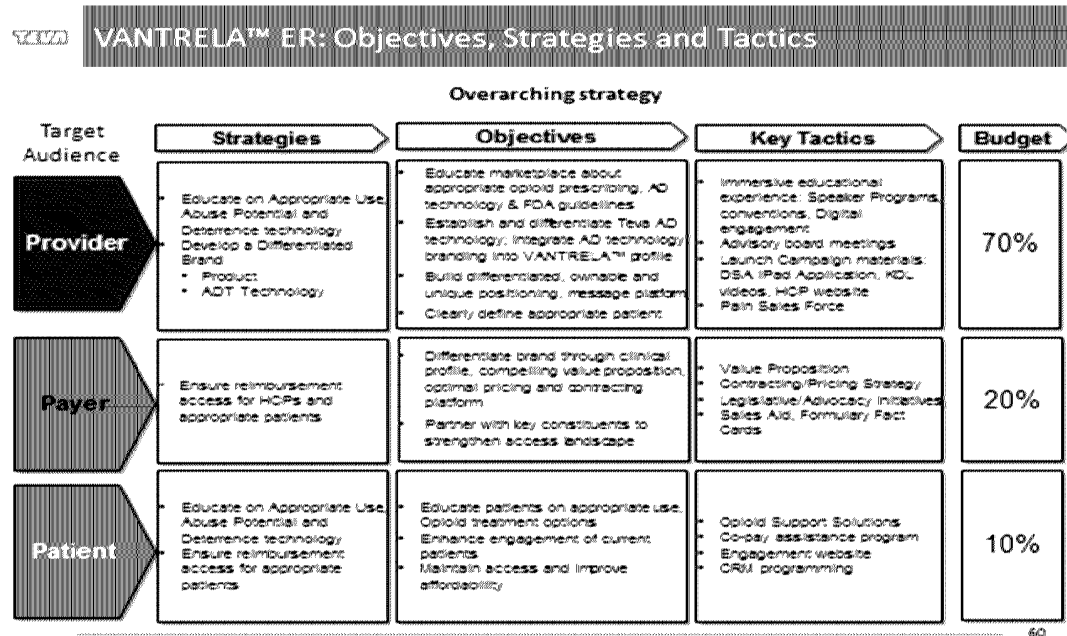
CONFIDENTIAL CONTINGENCY/SCENARIO PLANNING DOCUMENT. FOR INTERNAL DISCUSSION PURPOSES ONLY

D3. Critical Success Factors



CONFIDENTIAL CONTINGENCY/SCENARIO PLANNING DOCUMENT FOR INTERNAL DISCUSSION PURPOSES ONLY

D4. Stakeholder Model / Strategic Spend Guidance



CONFIDENTIAL CONTINGENCY/SCENARIO PLANNING DOCUMENT FOR INTERNAL DISCUSSION PURPOSES ONLY

CONFIDENTIAL CONTINGENCY/SCENARIO PLANNING DOCUMENT. FOR INTERNAL DISCUSSION PURPOSES ONLY

D5. Forecast Assumptions & Contingencies

Forecast Assumptions

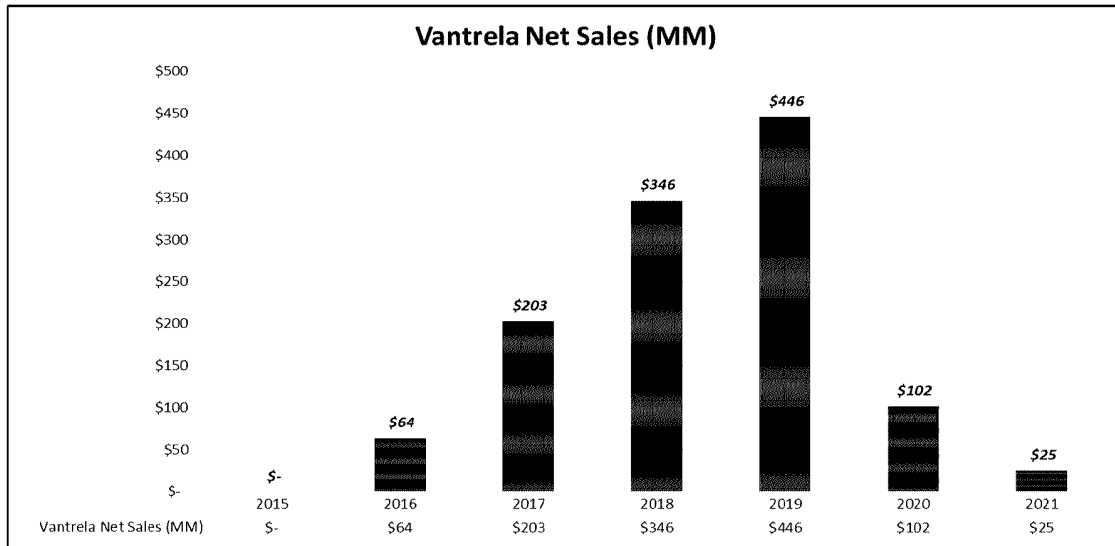
Assumption	2014 LRP	2015 LRP	Source
Launch Date	May 2015	February 2016	
Market Size	220K TRx's Opioids	260K/23.4k TRx's	<ul style="list-style-type: none"> IMS 2014 Data Inclusion of tramadol and tapentadol in market definition
Market Growth	Flat Market	Flat Market	IMS
LOE	48 months	48 months	<ul style="list-style-type: none"> PRIVILEGED AND CONFIDENTIAL DRAFT Possible Alternative legal and business planning scenario options and related analysis <i>Oxycontin FDA ruling on AD extension</i>
Peak Market Share	Total SAO Hydro \approx 4.5% Total Opioid Market \approx 1.47% Total SAO Market \approx 2.35% Total LAO Market \approx 4.10%	Total SAO Hydro Market - 4.9% Total Opioid Market \approx 1.71% Total SAO Market \approx 2.74% Total LAO Market \approx 5.58%	<ul style="list-style-type: none"> Increase share capture due to MLK-155 not launching
Time to Peak Share	3 years	3 years	
Launch Price	<ul style="list-style-type: none"> \$8.52/tablet; \$511/TRx (benchmark to Oxycontin) 5% Price increase in 2016-2018; 2% in 2019 	<ul style="list-style-type: none"> \$8.14/tablet; \$488/TRx 5% Price increase in 2017-2018; 2% in 2019 	<ul style="list-style-type: none"> ISA Payer Research, 2015
Peak Year Net Sales	\$430MM in 2018	\$445MM in 2019	<ul style="list-style-type: none"> Increase share capture due to MLK-155 not launching
Sales Force	416 Reps (276 PDEs)	416 Reps (240K PDEs)	<ul style="list-style-type: none"> ZS & Associates Optimization
Competition	Hysingla - Nov 2014 Mallinkrodt - Q1 2015 Launch (March) AD Zohydro - Q1 2015 Launch (January)	Hysingla ER – Feb 2015 Launch Mallinckrodt MLK-155 – Does not launch Zohydro ER ADT – Q2 2015 Launch Zohydro ER – LOE Q1 2017	Market research / CI <ul style="list-style-type: none"> 3rd entry into market due to MLK-155 not launching
Units Per TRX	60	60	Rx size

Differences between 2014 LRP and 2015 LRP noted in red

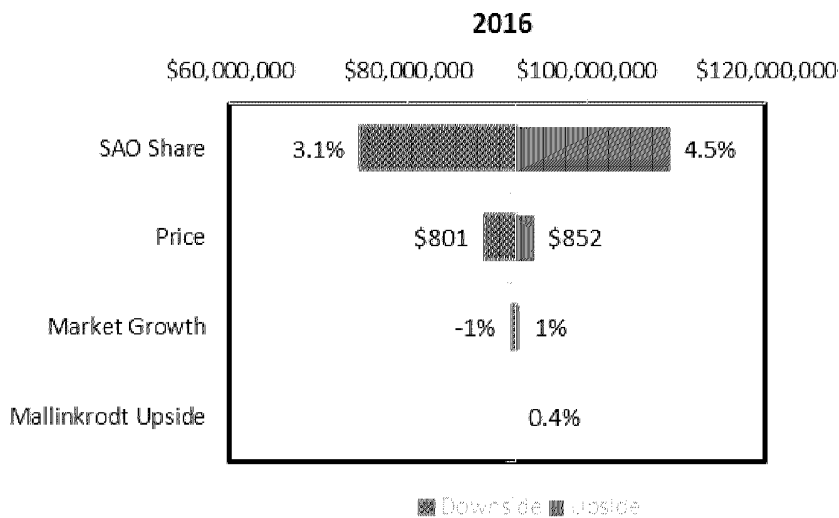
CONFIDENTIAL CONTINGENCY/SCENARIO PLANNING DOCUMENT. FOR INTERNAL DISCUSSION PURPOSES ONLY

Forecast

Non-Risk Adjusted VANTRELA™ ER Net Sales (\$M) Forecasts 2015-2021



Upside/Downside Forecast Planning



Variable	2016			Input		
	Downside	Upside	Range	Downside	Upside	Base Case
SAO Share	\$75	\$109	\$35	3.1%	4.5%	3.8%
Price	\$88	\$94	\$6	\$801	\$852	\$832
Market Growth	\$91	\$92	\$1	-1%	1%	0%
Mallinkrodt Upside	\$92	\$92	\$0	0.2%	0.6%	0.4%

CONFIDENTIAL CONTINGENCY/SCENARIO PLANNING DOCUMENT. FOR INTERNAL DISCUSSION PURPOSES ONLY

Contingency Planning

Contingencies & Key Considerations					
Key Uncertainty	Timing Resolution	Probability H/M/L	Potential Impact	Contingency Plan	Barriers to Implementation
Regulatory Exclusivity impact on 505b2 NDA submission	Q2 2015	L	<i>Could prohibit entrance into market until October 2016</i>	Convert NDA submission to a 505b1 application through right of reference waiver purchase from AbbVie	Agreement of terms with AbbVie completed 5/8
COMET Assay results from API	Q2 2015	L	Delay launch until Feb 2016	Working to accelerate conversion to secondary supplier of API (NORAMCO)	Initial results from COMET Assay test negative
Launch Timing Accelerated to November '15	Q3 2015	M	Additional net sales in '15	Ongoing assessment of launch timing, sales force sizing /timing	Current Infrastructure vs. expanded sales team; coinciding launch with Zecuity; packaging risks; training timeline
Generic Zohydro	Q3 2016	L	Erosion of branded ER hydro market	Gov't Affairs/professional relations efforts to remove original Zohydro from market upon AD approval	

Regional Brand Team members

Lead	Name
Regional Brand Lead	Jeffrey Dierks
Regional Medical Affairs Lead	Matt Wieman
Regional Medicines Insights Lead	Yousseff Khan
Regional Market Access Lead	Deb Bearer
Regional Finance Lead	Robert Pfeifer
Regional Project Team Lead	Jeff Martini
Regional Launch Lead	Jorge Vasquez
Regional RA Lead	Doug Harnish
Regional Operations Lead	Elaine Grotbeck
Regional Legal Lead	Alexander Nikas
Patient solutions lead (<i>where applicable</i>)	TBD
Patient technologies lead	Jeannine Andronowitz

Membership to be adapted to the structure of the region & lifecycle stage of the brand

CONFIDENTIAL CONTINGENCY/SCENARIO PLANNING DOCUMENT. FOR INTERNAL DISCUSSION PURPOSES ONLY