2014 Vantrela ER

Launch Plan DRAFT

December 23, 2013

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I Executive Summary

Vantrela ER is a single-active ingredient, acetaminophen-free extended release (ER) oral formulation hydrocodone. It utilizes OraGuard™™ an abuse deterrent (AD) technology platform designed to resist common physical methods of tampering such as crushing, along with minimizing dose dumping in the presence of chemical tampering such as mixing with alcohol.

Upon completion of a positive phase III clinical trial (study 3103), Vantrela ER will be 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 for the Long Acting Opioid (LAO) category most commonly used to treat chronic pain (defined as pain lasting > 3-6 months).

Vantrela ER is uniquely positioned to address several unmet needs in the chronic pain market that will provide an unprecedented opportunity for Teva to help physicians and chronic pain patients.

1. **Abuse & Misuse of Opioids:** The prevalence of prescription opioid abuse and misuse has increased in the past decade and poses a serious public health issue. The development of LA opioids formulated to deter abuse is a priority for the FDA. Serious adverse events may occur with the co-administration of alcohol and opioids due to the alcohol induced-excessive exposure to the opioid. It has become standard practice and an FDA expectation to evaluate, both by in vitro and in vivo testing, the potential for opioid dose-dumping in the presence of alcohol.

2. **Teva Pain Care/OraGuard™:** Vantrela ER will be the first new therapeutic entity (NTE) product launch utilizing OraGuard™ technology in the pain care franchise and will set the stage for several additional future NTE launches. It will also present an opportunity to brand OraGuard™ and solidify the technology as a "state of the art" abuse deterrent platform.

3. **Hydrocodone:** In 2012, there were 135 million prescriptions written for immediate release (IR) hydrocodone products (brand names: Vicodin, Lortab, Norco) and there is currently not a marketed formulation that is extended release (ER) abuse deterrent (AD) or APAP free.. The FDA recently announced its intent to reclassify the IR formulations of the molecule to DEA schedule II which will impact the 7.5 million patients take short-acting opioids for chronic pain.

4. **Flexibility:** IR hydrocodone products are only available as combination products containing acetaminophen and may require dosing as frequently as every 4 to 6 hours. Vantrela ER will offer physicians and patients dosing flexibility in a BID, single-active ingredient formulation which may help better manage moderate-to-severe chronic pain because of its potential for a 12 hour duration of action.

II Pain Market Dynamics & OraGuard™ Technology

a) Pain Market overview and background

U.S. Pain Care Market Opportunity

Pain is defined by the International Association for the Study of Pain (IASP) as an unpleasant sensory and emotional experience associated with actual or potential tissue damage. Pain is divided into two distinct categories, acute/subacute and chronic. Since LAOs are prescribed and indicated for chronic pain, which is defined as pain lasting > 3 months, the market overview will focus on this category. Chronic pain falls into one of the following clinical diagnosis:

- Nociceptive – pain that arises from damage or injury to tissue often as a result of a traumatic event(low back pain, soft tissue injury, osteoarthritis)
- Neuropathic - pain arising from a lesion or disease affecting the peripheral nerve (painful diabetic neuropathy, postherpetic neuralgia, post traumatic neuralgia

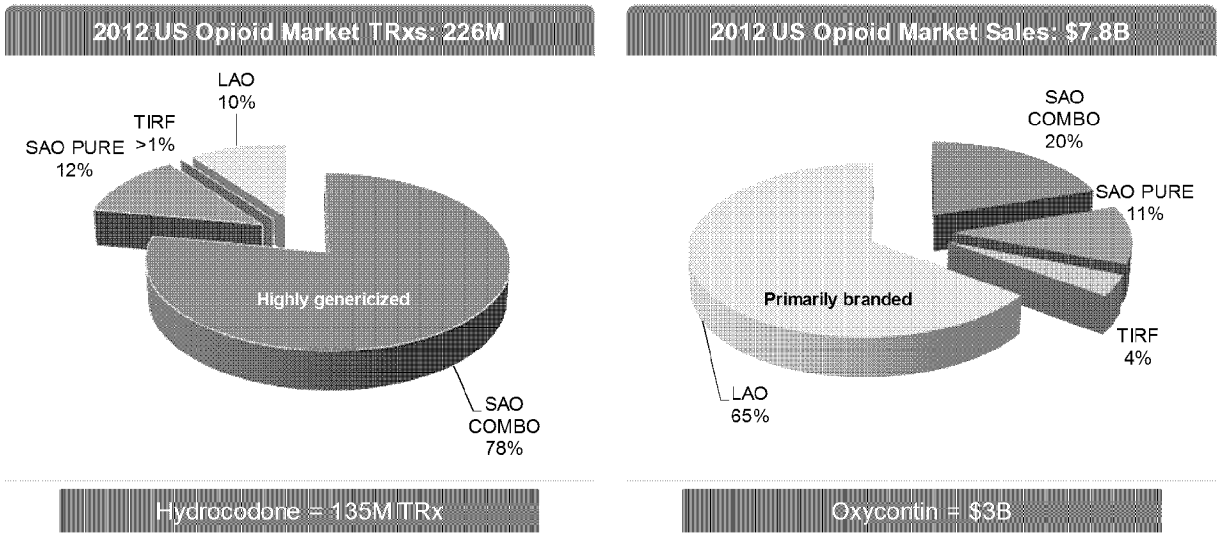
It is well documented that over 100 million Americans suffer from chronic pain. This is more than cancer, diabetes and heart disease combined. The most prevalent forms of chronic pain are osteoarthritis and chronic lower back pain impacting 29.5 million and 26.7 million Americans respectively.

In 2012, the chronic pain marketplace was about $20 billion dollars and consisted of therapies such as opioids, NSAIDs, COX2 Inhibitors and SNRIs. The market is forecasted to grow minimally over the next several years due to the anticipated genericization of several current blockbuster products (Lyrica, Cymbalta, OpanaER, Lidoderm).

(Sources: Decision Resources Pain Reports 2012)

Opioids

Opioids represent nearly half of all pain care prescriptions in the U.S. market. In 2012 there were ≥225M TRx written for opioids, 135M of which were for short acting Hydrocodone combination products. Opioids make up approximately 1/3 of the market ($7.8 billion) and are the most prescribed medications for chronic pain. The LAO market is comprised of more branded product sales than the SAO market and is responsible for nearly 2/3 of all opioid dollar volume as highlighted below.

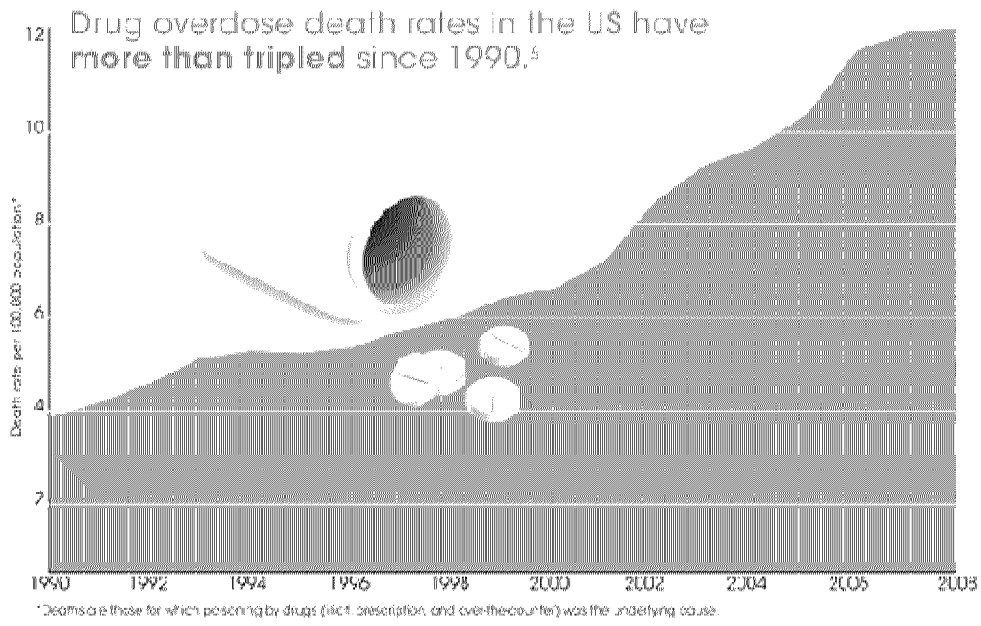


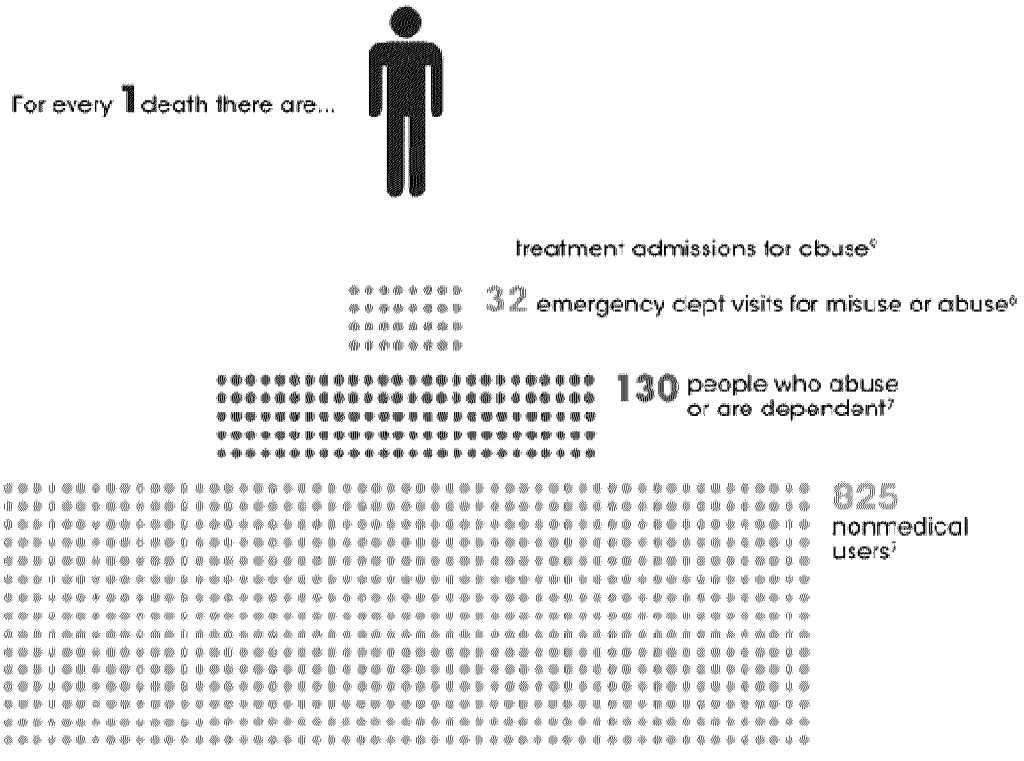
SAO COMBO: Short Acting Opioid combination product (e.g., Vicodin, Percocet, various opioid/ APAP generics)
SAO PURE: Short Acting Opioid pure formulation (e.g., oxycodone HCL)
LAO: Long Acting Opioid (e.g., controlled release oxycodone)
TIRF: Transmucosal Immediate-Release Fentanyl (e.g., Fentora)

Source: IMS National Sales Perspectives and IMS National Prescription Audit

Though opioids can offer substantial pain relief for many patients in need, they also carry a risk for potential addiction and abuse. Abuse is defined as the intentional manipulation of the product for use other than therapeutic effect. 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 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:

- Now nearly 15,000 people die every year of overdoses involving prescription pain medications. This is more than three times the 4,000 pain medication-related deaths reported in 1999.
- Women are increasingly adversely affected by prescription drug abuse. More than five times as many women died from prescription pain medication overdose in 2010 as in 1999.
- In 2010, one in 20 people in the United States age 12 or older reported using prescription painkillers for nonmedical reasons in the past year.
- Nearly half a million emergency department visits in 2009 were due to people misusing or abusing prescription painkillers.
- Nonmedical use of prescription pain medications costs health insurers upwards of $72.5 billion annually in direct health care costs.





Source: Centers for Disease Control and Prevention

b) Teva NTEs & OraGuard™ Technology

Vantrela ER will be the first new therapeutic entity (NTE) product launch utilizing OraGuard™ technology in the pain care franchise and will set the stage for several additional future NTE launches. It will also present an opportunity to brand OraGuard™ and solidify the technology as a "state of the art" abuse deterrent platform that can be applied across a wide variety of opioid medications. See table below for more details on OraGuard™ Technology.

OraGuard	
Technology Description	A novel abuse-deterrent technology featuring coated granulation formed into a compressed tablet that combats various methods of intentional and unintentional extraction
Drug Profile Applications	• Adaptable to a wide variety of molecules • Can be utilized in immediate-release and extended-release drug profiles • Flexibility to provide multiple dosage strengths • Delivers efficacy equal to conventional tablets

Abuse Deterrence Approach	• Multilayer abuse deterrent approach
	• Combines 3 physical/chemical technologies – matrix, barrier, and gelling
	• Maintains the PK profile in extended release drug formulations
	• Provides resistance against various tampering methods, including:
	  • Crushing, ingestion, injection or snorting
	  • Chewing
	  • Aqueous extraction for IV dosing
	  • Alcohol dose dumping

Experience	• Extensive clinical and regulatory experience
	  • Over 10 Phase I studies
	  • Phase III safety and efficacy studies
	  • 2 INDs filed
	  • *In vitro* tampering studies and *in vivo* liking studies conducted
	  • *In vitro* tampering protocol developed in conjunction with the FDA
	  • Obtained regulatory check-ins with the FDA
	  • 5 unique molecules evaluated in various developmental stages

III Launch Plan

a) Launch Team

The Vantrela ER cross-functional launch team is known as CLAD (Core Leadership in Abuse Deterrence) and consists of 55 team members from throughout the organization. The organizational structure of the CLAD team consists of:

- Steering Committee
- Core Team
- Cross-Functional Teams
- Consulting Resources

Steering Committee

The steering committee is a senior team of executives that represent the cross-functional departments supporting the VantrelaER launch. This group will receive regular updates on launch planning progress in 2014 and will provide counsel and input regarding specific situations and decisions.

Steering Committee

- Debra Barrett (Govt. Affairs)
- Jon Congleton (Global CNS)
- Mike Derkacz (GM CNS)
- Susan Franks (Regulatory)
- Denisa Hurtukova (Medical)
- John Jacobs (Marketing)
- Derek Moe (Manufacturing)
- Brendan O'Grady (Mgd Mkts)
- Jim Reilly (Sales)
- Susan Shiff (HEOR)
- Dalton Tomlinson (Global PC)

Core Team

The core team is the leadership group responsible for developing the cross-functional strategies for each sub-team and the core team members are responsible for leading their respective sub-tem. The Core Team meets regularly to ensure the launch plan is progressing toward all timelines and makes decisions around any plan adaptations. Additionally, consulting resources are those team members who possess specific expertise and are relied upon as ad-hoc team members for input. Examples of the departments consisting of consulting resources are: legal, regulatory, compliance, forecasting and finance.

Core Team

- Ryan Daufenbach
- Mara Define
- Christine Baeder
- Deb Bearer
- Kris Cappo
- Chris Doerr
- Kishore Gopu
- Elaine Grotbeck
- Rick Malamut
- Jeff Martini
- Chris Meyer
- Arvind Narayana

Consulting Resources

- Jim Ciciriello
- Doug Harnish
- Yousseff Khan
- Nancy Leone
- Dave Loughery
- Wendy Miller
- Alex Nikas
- Jeff Sipia
- Meredith Taylor

Cross-functional Sub-teams

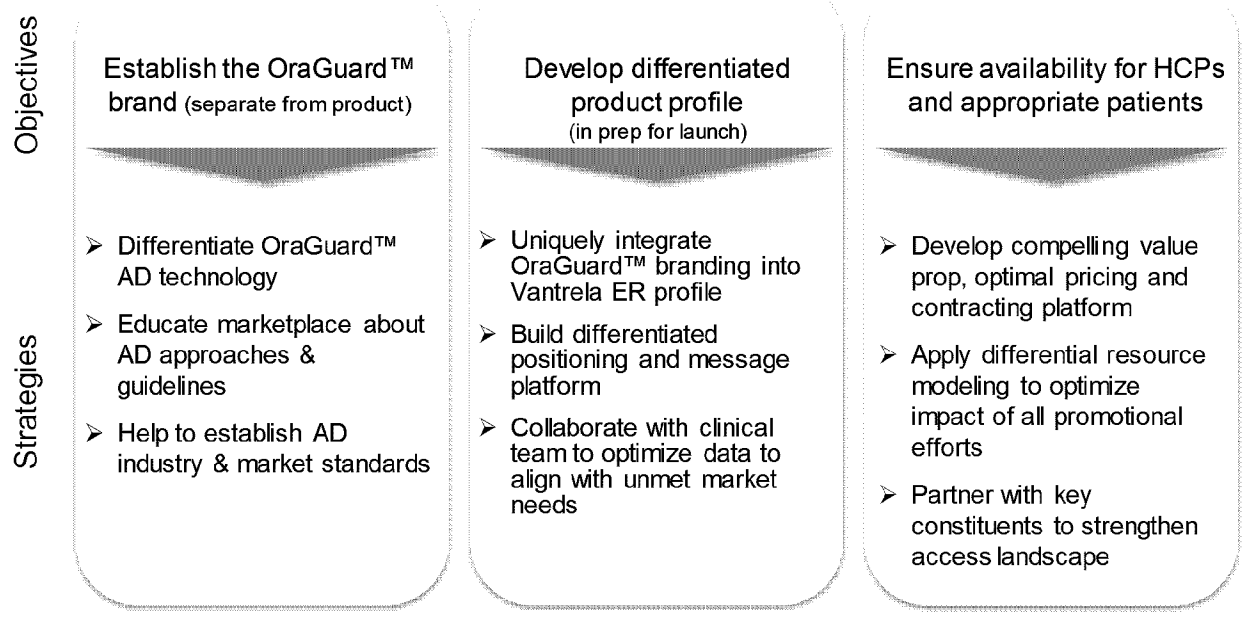
The cross-functional sub- teams are responsible for aligning the strategies, tactics and timelines that support the overall Vantrela ER launch objectives and strategies. More importantly, these are the teams that implement the tactical plans and adhere to the deadlines needed to ensure a successful launch. The 8 cross-functional teams are listed below:

Cross-Functional Teams				
	Medical	Rick Malamut & Arvind Narayana	**Sales Force Readiness**	Chris Meyer
	Marketing	Ryan Daufenbach	**REMS**	Kishore Gopu
	Market Access	Deb Bearer	**Manufacturing**	Elaine Grotbeck
	Gov't Affairs/ Advocacy	Rob Falb	**Trade**	Chris Doerr

b) Pre-Launch Objectives & Strategies

Successful completion of the 2014 Vantrela ER pre-launch strategic objectives will help to ensure the appropriate and successful uptake of the product in the marketplace during the 2015 launch. All launch cross-functional sub-teams have developed strategies and tactics that align with the 3 launch objectives listed below.

The Vantrela ER pre-launch strategies have been developed to achieve the 3 key pre-launch objectives and are aligned as follows:



c) Marketing

Establishing the OraGuard™ brand (separate from Vantrela ER)

A key strategic objective for the launch of Vantrela ER and our other pending NTE products will be to establish OraGuard™ as its own, unique and differentiated brand of AD technology. This initiative is extremely important as the branding will be amortized over the life of all NTE products being developed.

Establishing the OraGuard™ brand is in essence, preparing for the launch of an additional product. To date, the team has developed the brand identity, personality and essence which have led to a creative brief to develop a brand hallmark (color palette, font, logo and icon). In addition, a lexicon document outlining common language for OraGuard™ communications as well as abuse deterrent terminology and messaging is being finalized. In December, a key opinion leader advisory board helped shape this communication and the next steps will include qualitative market research in January 2014. Additionally, the OraGuard™ positioning statement has been developed, tested and finalized.

TO	*healthcare professionals treating pain*
WHO	*value the extra assurance of safety to minimize concerns over abuse, misuse, and diversion*
OraGuard IS	*a first-in-class, multi-mechanism physical/chemical abuse deterrent technology*
THAT	*allows HCPs to focus on treating their patients' pain appropriately*

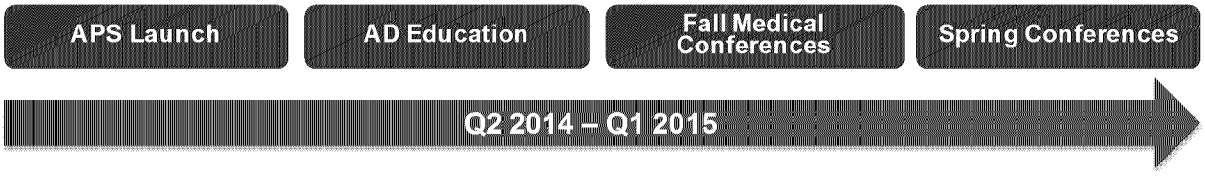
BECAUSE	– *Provides resistance against unintentional/intentional abuse and various tampering methods, including:*
	  – *Crushing, ingestion, injection, or snorting*
	  – *Chewing*
	  – *Aqueous extraction for IV dosing*
	  – *Alcohol dose dumping*
	– *Allows for consistent drug delivery*
	– *Available for a broad patient population: IR, QD, and BID dosing*

SO THAT	*HCPs have the confidence to freely treat their patients' pain*

OraGuard allows HCPs to focus on treating their patients' pain appropriately

Upon completion of the OraGuard™ messaging in 2014, a full-scale, comprehensive rollout will occur that will include educating HCPs about AD approaches and guidelines along with how OraGuard™ will help set industry standards for AD technology. Pain Week 2014 is the ideal launch for OraGuard™ because of the high media exposure and attendance by KOLs and prescribers alike. Examples of the tactical roll out that are in development for launch in 2014 include:

- Convention strategy rollout
- Non-cme educational programs
- PR campaign
- Digital strategy



The metrics for these initiatives will be to raise OraGuard™ awareness among target physicians to 30% from a baseline of 0% awareness. The team is also planning to reach approximately 80% of all targeted physicians with at least one touch point.

Develop Differentiated Vantrela ER Product Profile (in preparation for launch)

During 2013 we completed the Vantrela ER product positioning utilizing an innovative decision heuristics science approach. This model allowed us to map the impact of heuristics on treatment decisions made in chronic pain management and develop positioning concepts based on dominant heuristics. During this process, the concept of flexibility consistently rose to the top in the quantitative algorithm research. Additional qualitative and quantitative market research with pain care specialists and primary care physicians consistently supported the product's ability to deliver the flexibility needed to tailor treatment to meet the needs of their chronic pain patients. This led to the creation of the following positioning statement for Ventrela ER:

TO	*healthcare professionals treating chronic pain*
WHO	*are looking to ease their patients' transition from short-acting opioids to long-acting opioids*
VantrelaER IS	*the only long-acting, APAP-free hydrocodone*
THAT	*delivers the flexibility to tailor around-the-clock pain relief to meet individual patient needs*

BECAUSE	• *BID dosing offers 12-hour sustained, smooth pain relief*
	• *Available in 5 dosage strengths for optimal ability to individualize pain management*
	• *OraGuard Technology lowers potential for intentional and accidental abuse*
	  • *Crushing*
	  • *IV dosing*
	  • *Alcohol dose dumping*

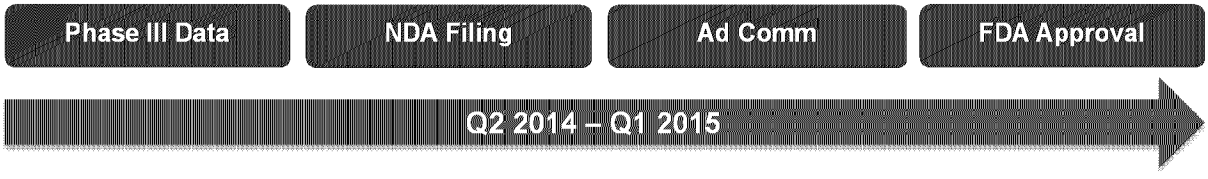
SO THAT	*HCPs feel greater assurance that they can effectively manage their patients' pain in a way that fits their patients' lives*

Vantrela ER delivers the flexibility to tailor around-the-clock pain relief to meet individual patient needs

Once the OraGuard™ branding has been completed, it will be uniquely and appropriately integrated into the Vantrela ER profile. WE will complete the Vantrela ER creative and branding elements during the first half of 2014. Also, upon completion of the pivotal phase III trial in March 2014, we will have the data necessary to being message development and testing.

Public Relations

The 2014 tactical public relations plan is currently being finalized. There are numerous opportunities to support the pre-launch objectives and specifically, raise the awareness of OraGuard™. Public Relations will also offer the first opportunity to report key clinical and regulatory milestones for Vantrela ER and will include appropriate announcements to correspond with the below significant events:

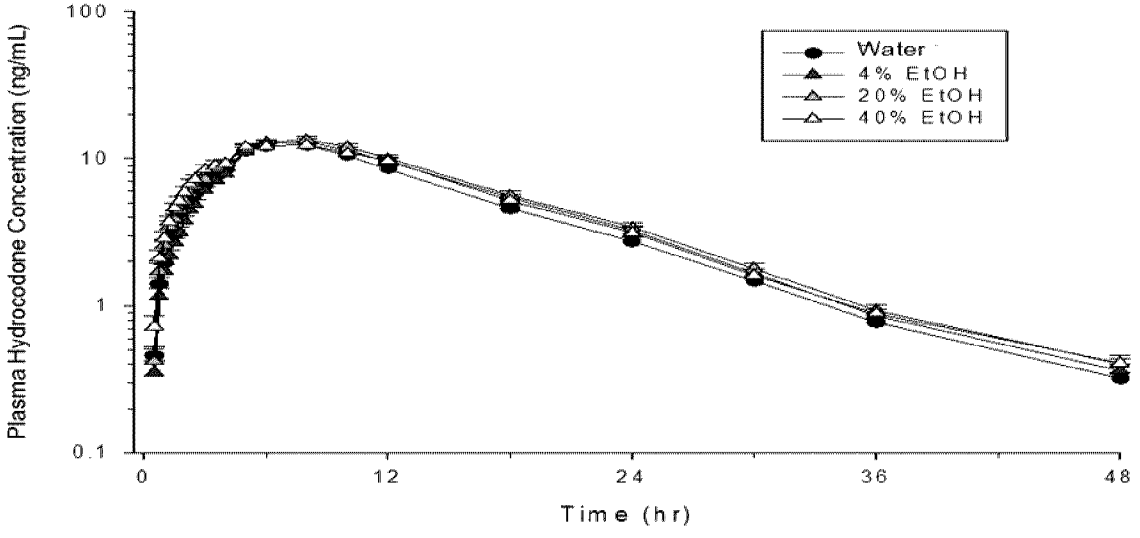


d) Medical & Clinical

Establishing the OraGuard™ brand (separate from Vantrela ER)

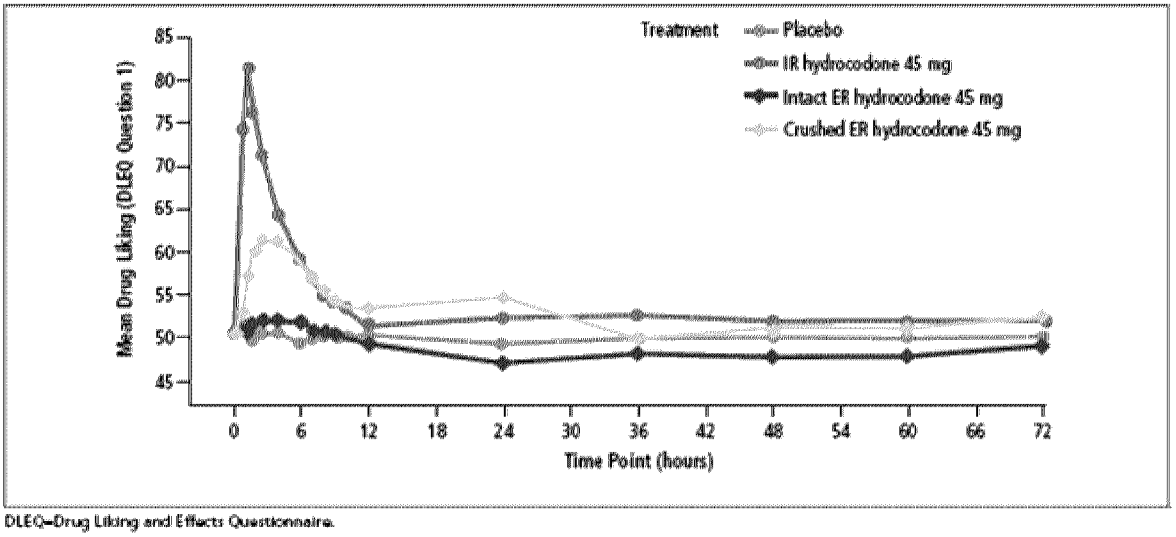
The clinical pharmacology program has completed studies that have yielded results that support the branding of OraGuard™ abuse deterrent technology. These consist of:

- 1076 Food Effect/Alcohol - the PK profile does not change in the presence of alcohol (ie. No dose dumping). These data are quite important as the FDA requires these studies prior to the approval of any LAO. The graph below highlights the fact that the PK profile is not altered in the presence of alcohol at various concentrations simulated to reflect possible real world consumption of alcohol with a LAO (4% - beer, 20% - wine, 40% - vodka). While all opioids should never be consumed with alcohol (this will be reflective in all opioid product labels), it will be important for clinicians to understand the OraGuard™ technology prevents doe dose dumping under these conditions.



- 1079 Crushing Effect on PK Profile

- 1085 Liking Study – Vantrela ER was preferred less when crushed compared to crushed IR hydrocodone (do you want to add a bit more description here? E.g. this study was positive, very strong results…we anticipate this will help to lead to Tier 3 label and be in the label etc.? The success of this study is extremely important for being able to differentiate OraGuard™ technology. While the study was performed utilizing Vantrela ER, it has provided the clinical team guidance for developing future liking studies utilizing OraGuard™ technology in the other NTEs that are being developed.



DLEQ=Drug Liking and Effects Questionnaire.

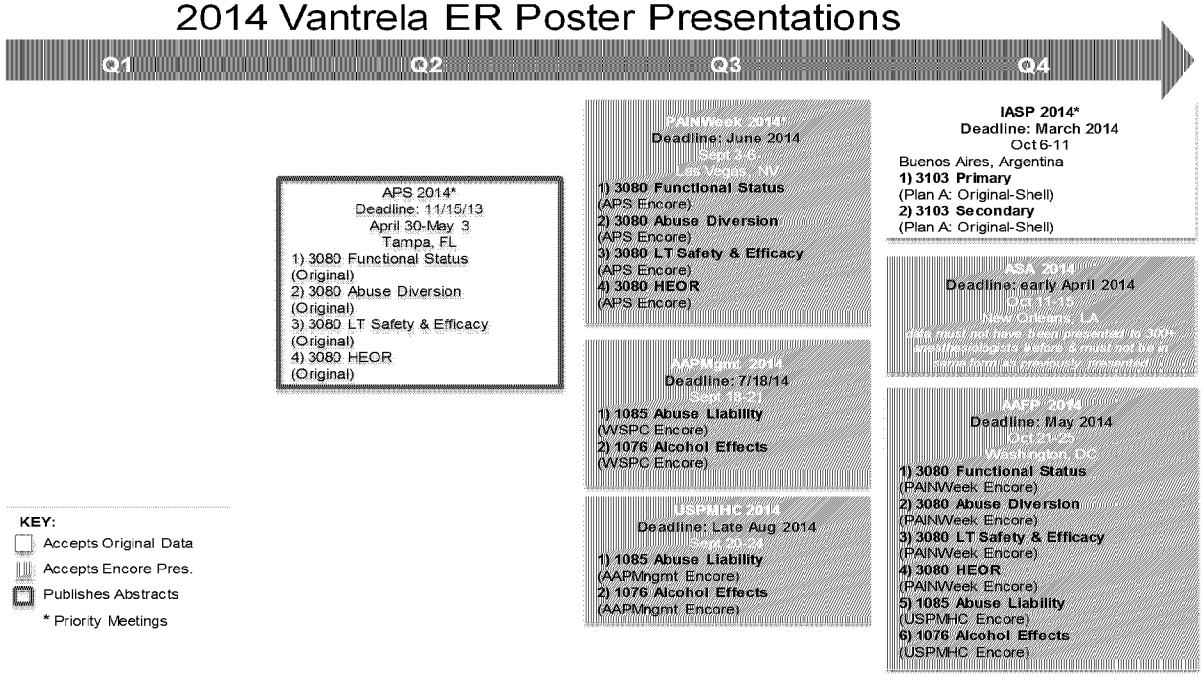
Variable	Placebo (N=43)	45-mg IR (N=41)	45-mg ER crushed (N=43)	45-mg ER intact (N=42)
Primary variable				
Peak drug liking (E_{max} DLEQQ1)	53.2 (9.80)*	85.2 (12.45)	66.9 (15.08)*	53.9 (5.77)*†

*=p≤0.0022 in comparison with 45-mg hydrocodone bitartrate immediate-release product.
†=p≤0.0022 in comparison with 45-mg hydrocodone bitartrate extended-release tablet administered crushed.

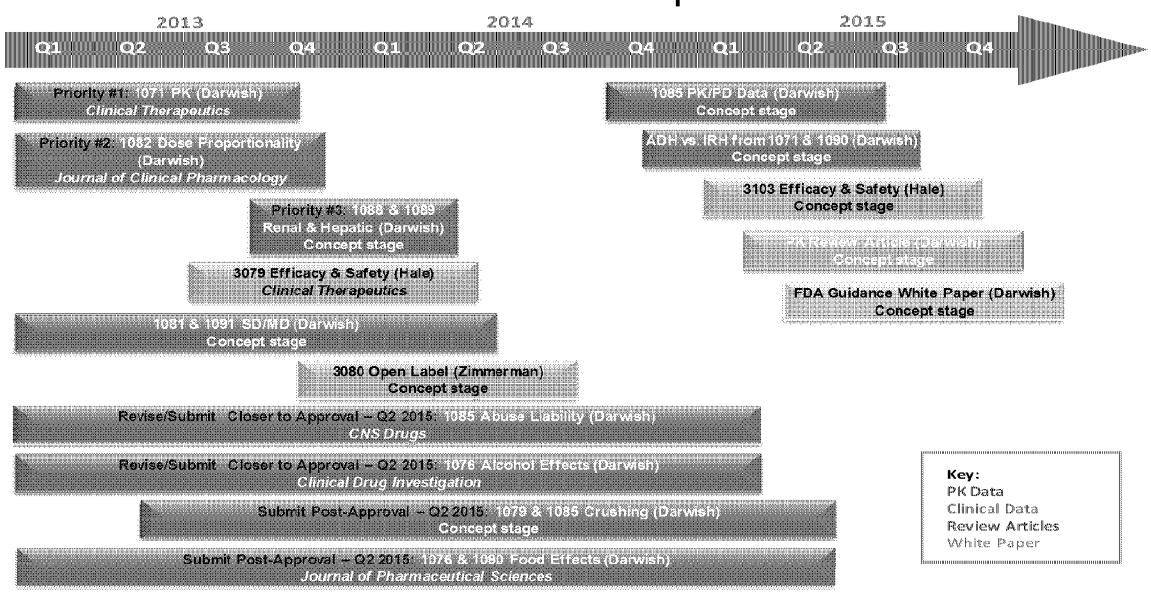
Scientific Communications

Additionally, the scientific communications team has developed a platform to present OraGuard™ & Vantrela ER study results via abstracts, posters & manuscripts during 2014 at various scientific venues. This plan supports the strategy of ensuring all data is disseminated to target stakeholders in a timely manner and that we create appropriate awareness about OraGuard™ and Vantrela ER.

2014 Vantrela ER Poster Presentations



2013-2015 Vantrela ER Manuscript Activities



Medical & Clinical (cont'd)

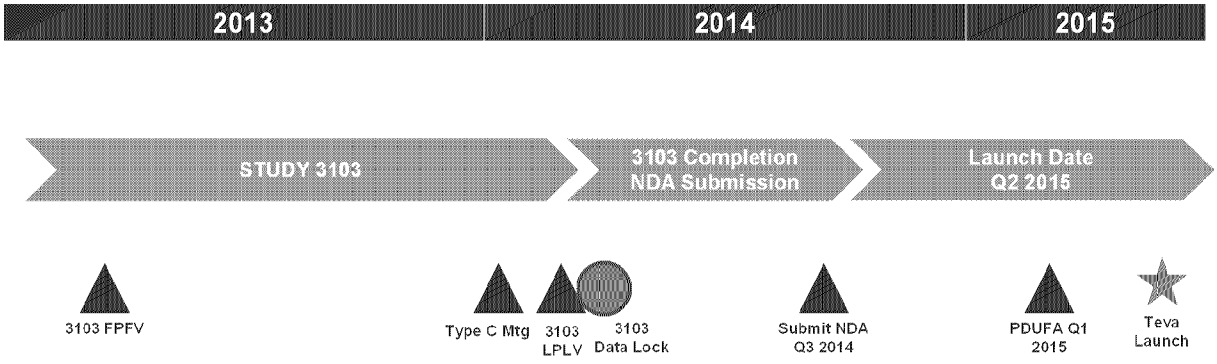
Develop Differentiated Vantrela ER Product Profile (in preparation for launch)

2

Develop differentiated product profile
(in prep for launch)

- Mitigate a potential competitive disadvantage by understanding the clinical effects when Vantrela ER is taken with food
- Ensure product information is disseminated to all target stakeholders
- Generate safety and efficacy data (e.g., SAO-LAO conversion, ATC pain relief, etc.) to address unmet market needs and differentiate from competitors beyond OraGuard™ technology

Upon completion of study 3103, data will be analyzed and interpreted. The study is currently on track for LPLV in February 25, 2014 and a potential database lock in March 2014.

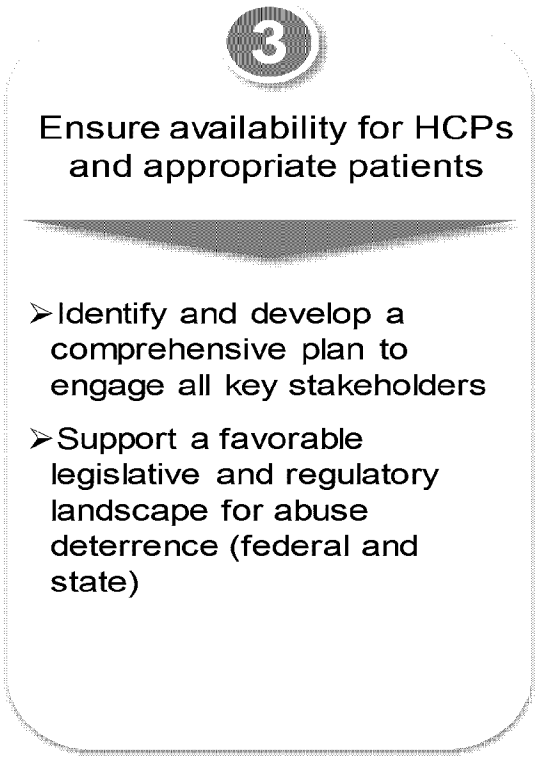


One key strategy the medical team will complete in 2014 is finalizing a clinical trial to better understand the impact of taking Vantrela ER with food. Based upon the results of a single dose study, subsequent phase 3 studies have required patients take each dose of Vantrela ER on an empty stomach (one hour prior and 2 hours after eating). It is anticipated upon the launch of Vantrela ER, the product label would include these same dosing instructions. This would be different than other ER Hydrocodone competitors entering the market and based on qualitative market research and physician advisory board feedback, potentially create a disadvantage in the minds of our customers due to more complex dosing instructions. Current simulation data suggest the food effect may be less pronounced at steady state (~20-25% difference in Cmax). There may be an opportunity to demonstrate clinically the food effect is not as pronounced as originally thought and potentially change the dosing instructions accordingly. The steps to further investigate this include:

- Perform a multiple dose PK study (naltrexone-blocked healthy subjects)
- If the food effect at steady state confirms the modeling and simulation prediction, allow patients in study 3104 (open label safety study) to take doses without respect to food
- Submit safety data when doses were taken without food restriction in study 3104 to FDA in the 4 month safety update
- If no safety signal is observed when doses are taken without food restriction in the 3104 study, then discussion with the FDA will take place about removing requirements to take the product on an empty stomach

e) Government/Advocacy

Ensure availability for HCPs and appropriate patients



Advocacy

During 2013 the advocacy team completed an analysis to determine what professional societies and advocacy groups we should work with to develop partnerships that could help patients who suffer from chronic pain . The analysis focused on the prominence of the groups, unmet market needs and the opportunity to engage them in partnerships. The team has decided to focus on a core of approximately 10 societies and advocacy groups as highlighted in the graphic below.

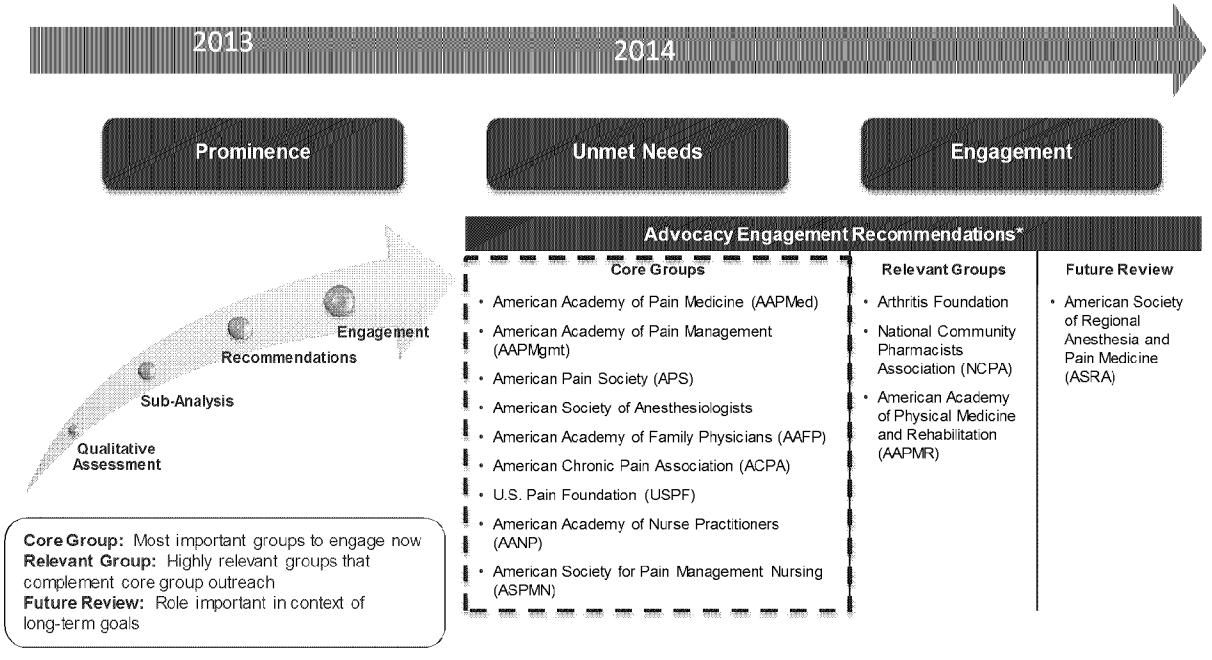


*Table represents advocacy groups prioritized to date.

Teva does not have any prior experiences or relationships with many of these groups, emphasizing the importance to establish relationships and build credibility prior to initiating partnership level discussions. A first step toward this was achieved during the November 2013 Teva Advocacy Summit.

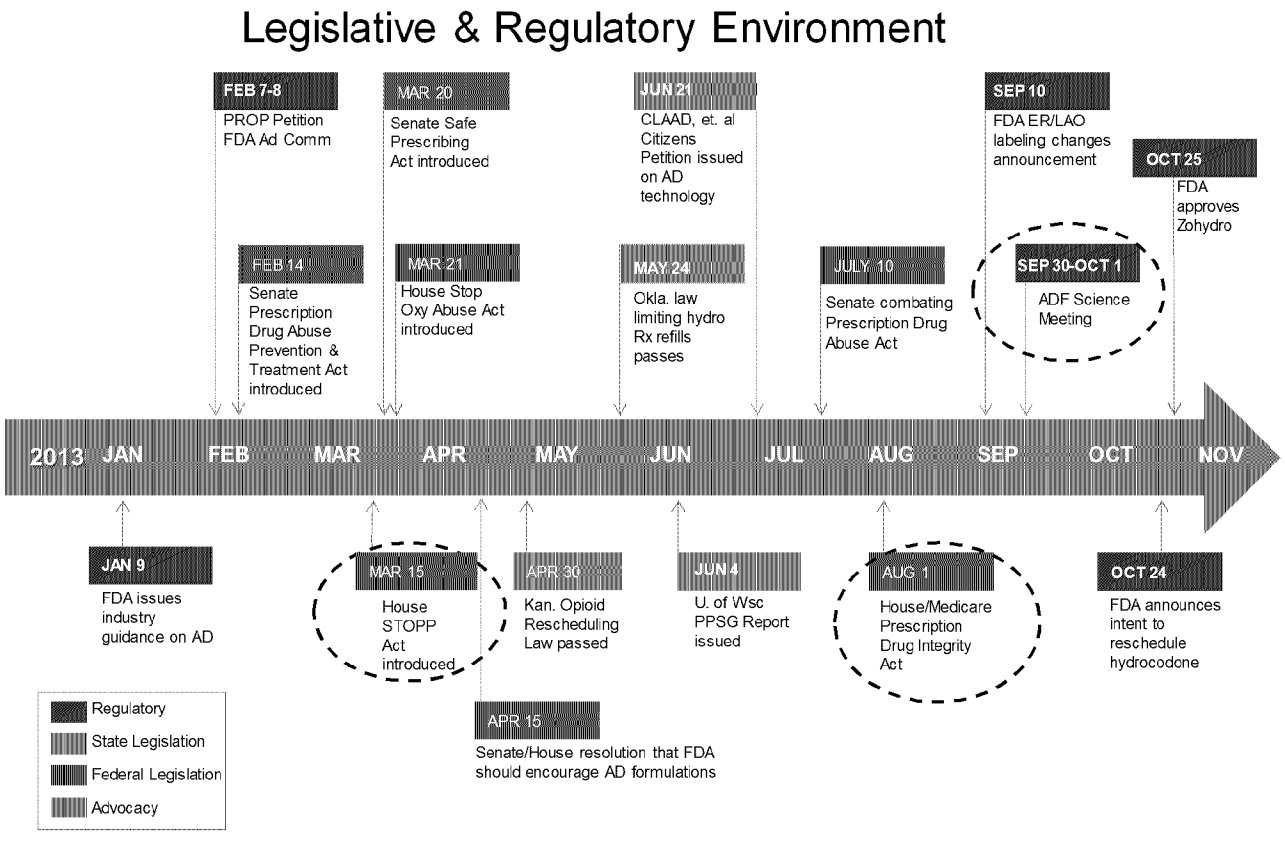
In 2014, the advocacy team plans to further these relationships by:

- Engage summit attendees and follow-up on 2014 opportunities
- Further develop relationships with frequent touch points

- Uncover gaps in communications between patients, HCPs and industry
- Align advocacy groups and shape dialog around the need for abuse deterrent formulations

Government Affairs:

A key strategy for the government affairs team in 2014 will be to help support the legislative environment around abuse deterrence. This has already occurred in numerous instances, helping establish Teva as a leader in this category which is extremely important. Some of the significant state, federal and regulatory initiatives regarding opioids are highlighted below.



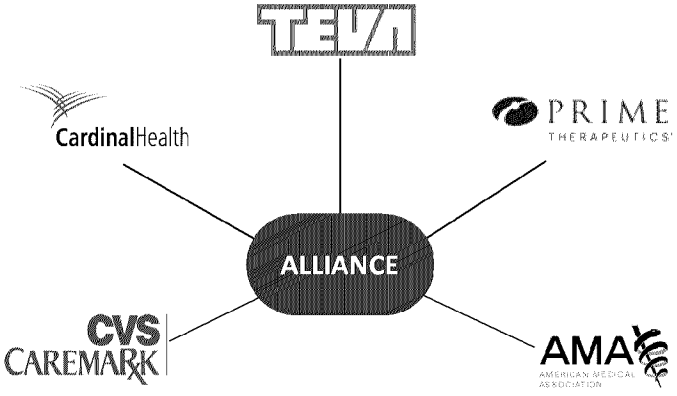
An excellent example of this approach is the Alliance. In 2013 the government affairs team was instrumental in creating the Alliance, a partnership of key stakeholders in the drug supply chain with a mission to:

- Raise awareness of the issue of prescription drug abuse
- Partner with legislators to craft achievable solutions.
- Serve as a resource for policymakers and the media

This group will meet more frequently and gain more prominence in 2014.

The Alliance Mission:

- Raise awareness of the issue of prescription drug abuse
- Partner with legislators to craft achievable solutions
- Serve as a resource for policymakers and the media



f) Market Access

Prior to beginning the market access launch plan development, the team engaged in a process to fully understand the payer environment regarding the management of chronic pain and opioids, followed by their perceptions of opioid abuse/misuse and the role of abuse deterrent opioid formulations.
The insights gathered are summarized into the following categories:

a. Management of chronic pain

Chronic pain is generally labeled by payers as a broad category with little distinction between pain types

- Payers generally do not parse out different types of chronic pain
- Payers do not have specific guidelines for treating different types of pain

Payer management of chronic pain patients is lacking due to poor patient identification and weak intervention strategies

- Payers are not easily able to track chronic pain patients
- Payers do not typically intervene early in the course of chronic pain

b. Management of opioids

Advisors acknowledged that many different treatment modalities are used to treat chronic nociceptive pain

- Current treatments for chronic nociceptive pain include medications, surgery, physical therapy, and behavioral therapy
- A multi-modal approach to treatment was considered by advisors to be ideal

Current opioid treatment options received poor reviews from advisors on both safety and efficacy

- Advisors had a generally negative viewpoint of current treatment options
- Advisors described major safety concerns with current opioid treatments

"Definitions of opioid "superiority" are varied and unclear, while unmet needs are clearly defined based on common challenges

- 2 advisors stated that some opioids are superior to others in some ways (eg, efficacy or patient preference)
- Unmet needs were congruent with the known adverse event profile of long-acting opioids

c. Abuse deterrent opioids

Abuse/misuse regarded as an inseparable part of opioid use for chronic pain, but plans are not sure how to address it

- Opioid abuse is a topic of moderate concern for most advisors
- Plans appear to be unsure of what impact they can have in combating abuse

Plans are unsure who should receive AD formulations without federal mandates requiring their use in all patients

- Plans struggle with requirement of AD formulations for specifically identified patient populations
- Without federal AD formulation requirements, price point may dictate utilization and coverage of the drug

Advisors considered AD formulations to be positive from a societal point of view if they are truly tamper-resistant

- Abuse deterrent formulations considered a step in the right direction from a societal perspective
- Advisors see value in an AD opioid formulation that is proven tamper-resistant in the real world

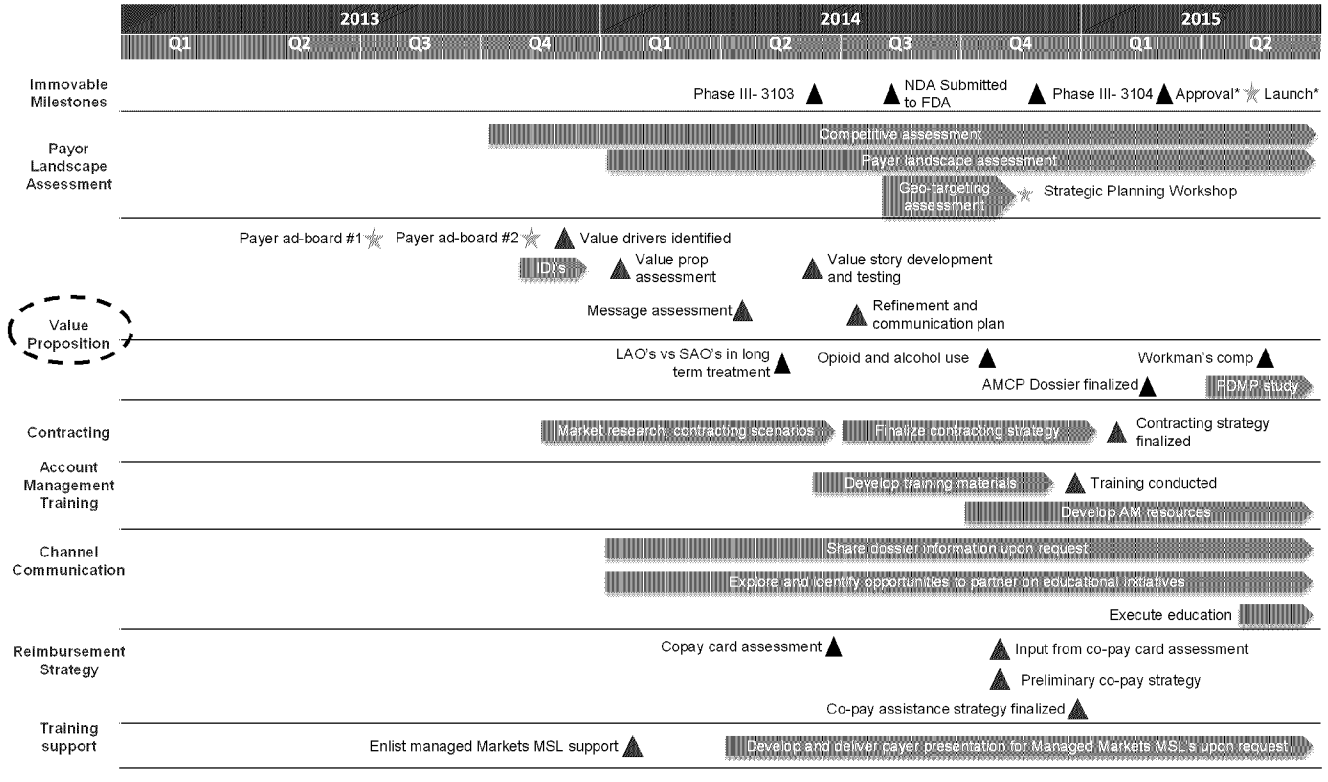
These insights will help to better inform the detailed plans and tactics that will support each of the following strategies:

Ensure availability for HCPs and appropriate patients

- Create compelling value/economic story
- Develop optimal pricing and contracting strategy to secure favorable payer positioning
- Segment payers and identify appropriate channels to optimize access

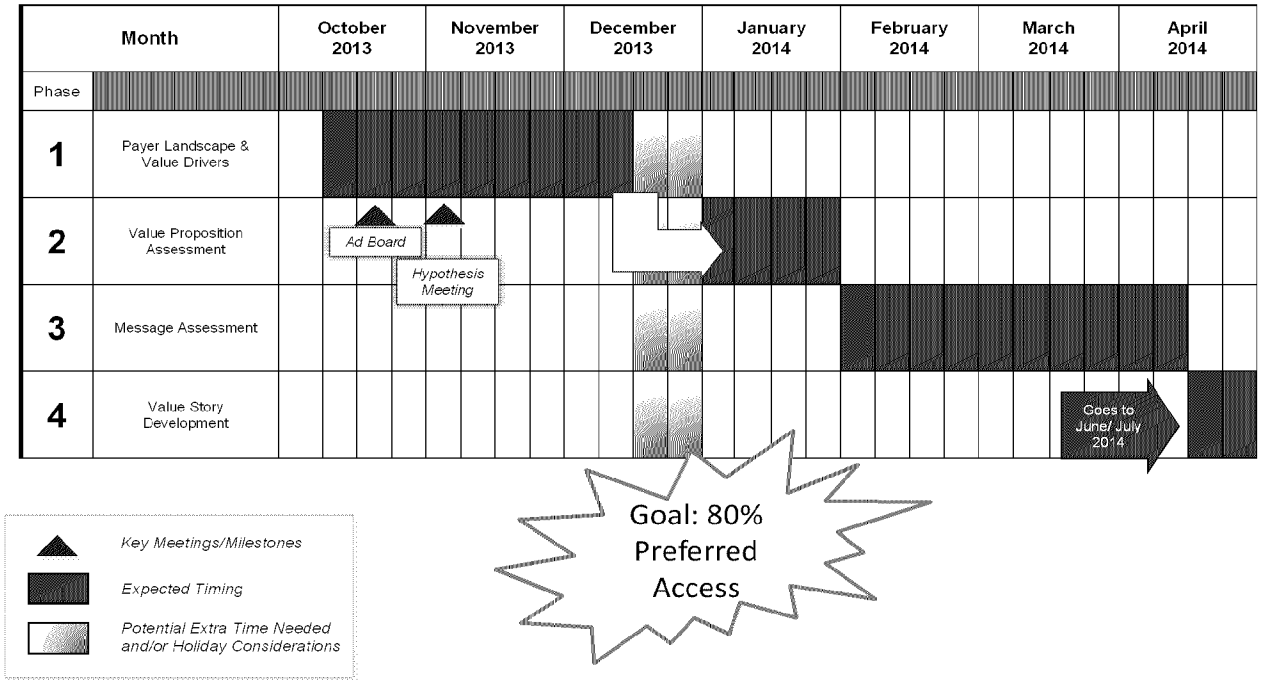
The graphic below highlights some of the key initiatives and milestones planned for 2014. This includes developing and completing:

- Payer landscape assessment
- Value proposition development
- HEOR studies
- Pricing sensitivity analysis
- Contracting and pricing strategies
- Account management team training and educational materials



Value Proposition

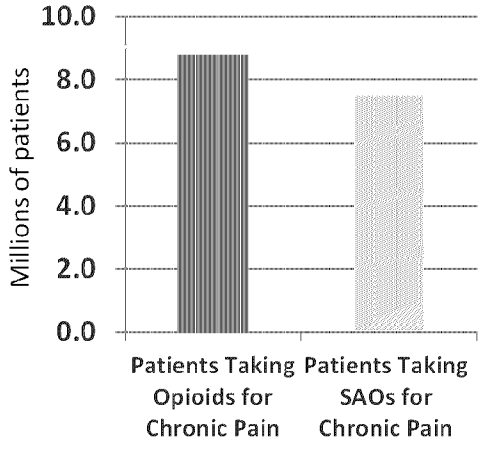
The team is currently developing the value proposition for Vantrela ER which will be the basis for all future payer communications. This was initiated in 2013, beginning with two payer advisory boards followed by payer IDIs. The value proposition will be completed in Q1 2014 and lead to final message development in Q2 2014.



HEOR

Based on the Vantrela ER product profile, the previously discussed insights and strong signals identified from a review of third party source data, the HEOR team is focusing their 2014 plan on the development of 2 studies:

- Determining the Prevalence, Costs and Implications of Using SAOs v. LAOs for Long-term Chronic Pain Treatment. As mentioned in the above insights, payers do not currently manage "chronic pain" like a therapeutic category similar to diabetes, hypertension, cancer, etc. In reviewing data, the team has formulated a hypothesis that chronic pain patients receiving long-term analgesic therapy with only SAOs may be utilizing healthcare system costs at a greater rate than those patients managed with LAOs. This greater utilization would increase managed care organizations' costs at a higher rate than the cost differential between generic SAOs and branded LAOs.



*Chronic pain is defined as patients on therapy for >90 days.
Source: Market Sizing Analysis and Treatment Algorithm (IMS October 2011).

- Assessing the Prevalence and Cost of Opioid Misuse with Alcohol – It is well documented that chronic pain patients have higher rates of abusing alcohol than the general population. Taking opioids and consuming alcohol can have serious adverse effects. If the PK profile of the opioid changes, or dose dumps in the presence of alcohol, this can lead to even more detrimental effects. As discussed in the clinical section of this document, we believe the absence of dose dumping in the presence of alcohol is a key feature of the OraGuard™ technology. It is important to note Vantrela ER will more than likely carry a black box warning prohibiting co-administration with alcohol, similar to all LAOs. The lack of dose-dumping may prove beneficial to payers from an overall health economics perspective. Next steps include finalizing the study design and statistical analysis plan followed by Clinical Development Committee approval.

Pricing & Contracting

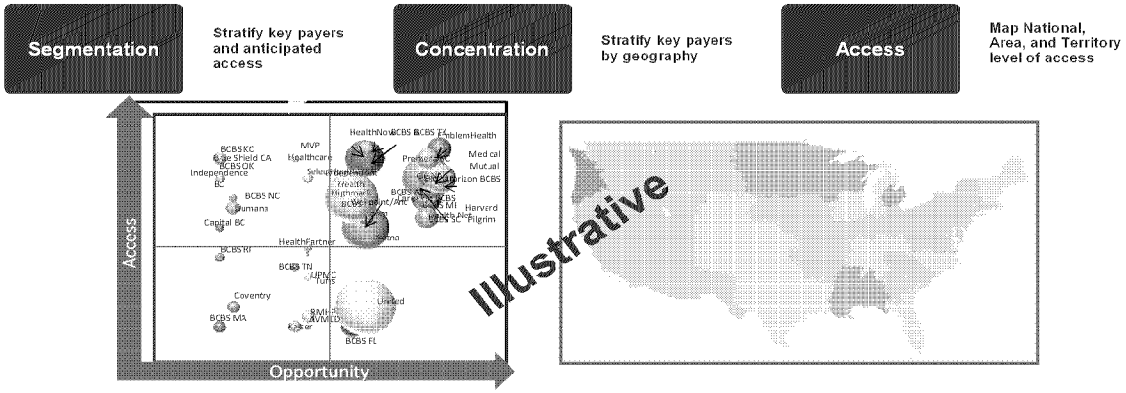
An initial assessment completed in 2012 has provided significant insight into the payer landscape and LAO market. At the time of the assessment, most LAOs were given preferred or unrestricted access in 50% - 80% of all commercial plans. Factors included in this access consisted of volume, pricing and associated rebates. The majority of the time, LAOs were placed in Tier 3 status, with the exception of Oxycontin which was more frequently positioned in Tier 2.

This analysis also provided the rationale for an initial pricing and rebate forecast. It maintained that Vantrela ER would be optimally positioned with payers if the WAC price led to a cost per patient per month within a 10% range of Oxycontin. This pricing, along with a forecasted managed care rebate rate of 20% of net sales should allow for Tier 3 open access in 80% of commercial plans. Since only approved LAOs were included, we will need to monitor the access and pricing for Zohydro ER and Purdue's QD ER hydrocodone. These products may provide additional real world analogs that can also be used to shape the pricing and contracting strategy for Vantrela ER.

g) Sales Force Readiness

The approximately 46,000 LAO prescribers who also prescribe IR hydrocodone will most likely comprise the target list for the pain care sales force. The current pain care sales force of 70 representatives only calls on 11% of these potential targets. In order to properly resource the launch, significant expansion of the sales force will have to occur and be completed by January 2015. This will begin with the hiring of the sales management team and having them on board by early Q4 2014.

Prior to expanding the sales force, the team will be modeling optimal the sales force deployment based on a variety of criteria including physician segmentation (behavioral & attitudinal), physician specialty, physician access, adoption curves, state policies and market access. The diagram below highlights how the impact of market access will be considered, leading to a more effective geographical targeting of the sales force and the ability to apply differential resourcing. This analysis will take be completed by Q2 2014 and utilized for determining specific geographies for the new pain care sales force managers and sales representatives.



IV Financial Forecast

The table below highlights the 3 year top-line revenue forecast for Vantrela ER along with the competitive assumptions. Vantrela ER is forecasted to be the 4th ER hydrocodone product to market, launching in Q2 2015. In lieu of this timing, the product still provides significant financial opportunity for the company as well as sets the stage for other pain care NTEs in development.