KemPharm

Apadaz™ FDA Approval

February 23, 2018

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Apadaz™ Update – Conference Call Participants

- **Travis Mickle, Ph.D.** – President & Chief Executive Officer
- **Rusty Johnson, M.B.A.** – Chief Business Officer
- **Dan Cohen, M.A.L.S.** – EVP, Government & Public Relations

Apadaz™ Approval

✓ **Announced FDA Approval of Apadaz (benzhydrocodone and acetaminophen) for the Short-Term Management of Acute Pain**

- First prodrug of hydrocodone/acetaminophen to be approved by FDA
- Immediate release (IR) combination of KemPharm's prodrug of hydrocodone, benzhydrocodone, and acetaminophen (APAP)
- Completed DEA product scheduling and quota allocation for Apadaz

✓ **Apadaz Approval is Significant Milestone for KemPharm**

- Opportunity to introduce differentiated product for the short-term management of acute pain
- Demonstrates value potential of KemPharm's LAT™ platform and technological approach to drug development
- Validation of KemPharm's business strategy and corporate vision

Apadaz™ Product Overview

- IR opioid fixed-dose combination product comprised of 6.67 mg benzhydrocodone HCl (a prodrug of hydrocodone equivalent to 7.5 mg hydrocodone bitartrate) and 325 mg APAP
- Prodrug consists of hydrocodone plus benzoic acid
- Developed using a 505(b)(2) regulatory pathway
  - Bioequivalent, with no food effect
- Absent of “abuse-deterrent” claims, differentiated properties based on Apadaz development program include:
  - Reduced early systemic hydrocodone exposure and delayed hydrocodone T_{max} for IN Apadaz vs. IN Norco
  - Lowered early Drug Liking for IN Apadaz vs. IN Norco in first 2 hours post dose
  - Conversion (hydrolysis) of benzhydrocodone to hydrocodone in vitro is a difficult process
- Composition-based patent expires in 2031

Apadaz Label – Key Areas of Differentiation

Section 2 (Dosage and Administration)

APADAZ:

- Initiate treatment with APADAZ at 1 to 2 tablets every 4 to 6 hours as needed for pain. Dosage should not exceed 12 tablets in a 24-hour period

Norco:

- The usual adult dosage is 1 tablet every 4 to 6 hours as needed for pain. The total daily dosage should not exceed 6 tablets

Section 12.3 (PK)

Absorption:

- The effect of a high-fat, high-calorie meal on pharmacokinetics is similar between APADAZ and immediate-release tablet of 7.5 mg hydrocodone/325 mg acetaminophen. APADAZ can be administered without regard to food.

Metabolism:

- Benzhydrocodone is a prodrug of hydrocodone and is converted to active hydrocodone by enzymes in the intestinal tract

Apadaz Label – Key Areas of Differentiation

Section 9.2

Intranasal Clinical Abuse Potential

- Over the first 2 hours post-dosing (AUC0-0.5, AUC0-1, and AUC0-2), the cumulative hydrocodone exposure was lower following intranasal APADAZ compared to intranasal hydrocodone/acetaminophen.
- Additional secondary analyses of Drug Liking based on area under the effect curve analyses (AUE) for the first half hour, hour, and 2 hours post-dosing, demonstrated numerically small differences between intranasal APADAZ and intranasal hydrocodone/ acetaminophen.

Human Abuse Liability Trials Results

- The results of the oral and intranasal human abuse potential studies did not support a finding that APADAZ can be expected to deter abuse by the oral or nasal routes of administration.

Section 9.2

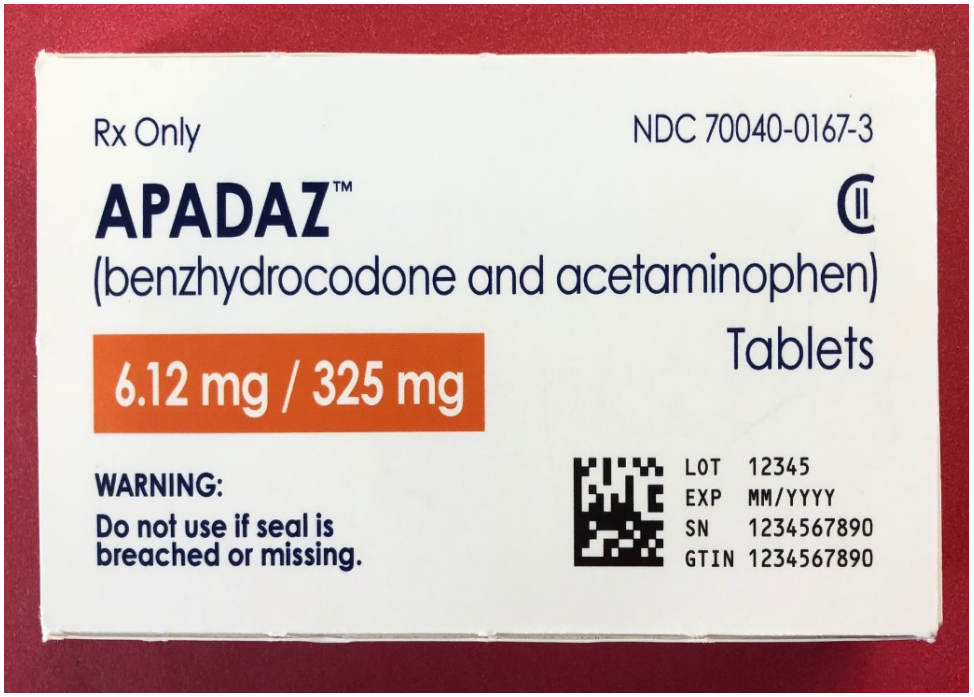
In Vitro Testing

- The efficiency of extracting benzhydrocodone from APADAZ was similar compared to the efficiency of extracting hydrocodone from the non-abuse-deterrent hydrocodone/ acetaminophen control. Further conversion (hydrolysis) of benzhydrocodone to hydrocodone in vitro is a difficult process.

Apadaz Label -- Key Areas of Differentiation

100 Count Bottle

Blister Pac



Apadaz Commercialization Strategy

KemPharm is pursuing two potential strategies for commercializing Apadaz, neither strategy requires KemPharm to establish its own sales force.

Non-traditional PBM Partnerships	Pharma Partnership
• Collaborative partnerships with leading US PBMs who would agree to Tier 1 or equivalent status for Apadaz (including most favorable co-pay) in return for price parity with available generic products	• Partnership with a US-based or global generic pharmaceutical manufacturer and distributor
• PBMs would work to educate prescribers/plan sponsors and actively manage Apadaz prescriptions	• Takes advantage of generic pharma's economies of scale to optimize Apadaz COGS
	• Generic pharma partner may also utilize non-traditional PBM partnership strategy

KemPharm Expected Milestones

Product	Event	Date	
KP484	IND Filing	2017	✓
KP415	Initiate Pivotal Efficacy Study	2017	✓
Apadaz	FDA Approval	02/23/18	✓
KP415 / KP484	IV Human Abuse Liability (HAL) Data	2018	
KP415	Pivotal Efficacy Study Results	2018	
KP484	Initiate Pivotal Efficacy Study	2018	
KP415 / KP484	Oral and IN HAL Data	2018	
KP415	NDA Submission	2019	
KP484	Pivotal Efficacy Study Results	2019	
KP484	NDA Submission	2019	

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