

# TrendsRx® Pre-Approval Alert

**lorcaserin (brand name TBD)\***

**Qnexa® (phentermine/topiramate)\***

## Drug Approval

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- Lorcaserin (Arena Pharmaceuticals, Inc) and Qnexa (phentermine/topiramate, VIVUS Inc.) are currently under review and pending approval by the U.S. Food and Drug Administration (FDA) for weight management.
- Phase III trial data for both lorcaserin and Qnexa has demonstrated significant weight loss and improvements in cardiovascular risk factors compared to placebo.

## Mechanism of Action

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- Lorcaserin
  - Serotonin is a neurotransmitter that plays an important role in the central nervous system regulation of many physiological functions, including the control of appetite and metabolism.
  - Studies have shown that stimulation of the serotonin 2C (5-HT<sub>2C</sub>) receptor in the area of the brain involved with appetite has been strongly associated with satiety and decreased food intake.
  - Lorcaserin works by selectively binding to and activating the 5-HT<sub>2C</sub> receptor. This action curbs hunger and reduces food intake, leading to weight loss.
- Qnexa
  - Qnexa is a combination of two FDA-approved drugs, low-dose phentermine and topiramate. Phentermine is currently approved as a short-term adjunct to a weight reduction regimen, and topiramate is indicated for the treatment of epilepsy and prophylaxis of migraines.
  - Evidence suggests that phentermine acts on the appetite center of the brain, thereby reducing hunger and food intake.
  - The exact mechanism by which topiramate induces weight loss is unknown. The drug appears to reduce binge eating by suppressing hunger, enhancing satiety, reducing impulsivity and altering the rewarding properties of food.

## Adverse Effects

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- The most common side effects experienced by patients taking lorcaserin in clinical trials were transient headaches, nausea and dizziness.
- Lorcaserin has little affinity for serotonin 2A and serotonin 2B receptors. This is advantageous, as it reduces the likelihood of adverse psychological effects, cardiac valvulopathy and pulmonary hypertension associated with stimulation of these receptors.
- The most common side effects experienced by patients taking Qnexa in clinical trials were dry mouth, tingling, constipation, altered taste and insomnia.

## Anticipated Dosage Forms and Strengths

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- TBD

## Anticipated Approval Date†

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- Fourth quarter 2010

## Selected Medications Available for Obesity

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- Brands: Meridia® (sibutramine hydrochloride monohydrate, Abbott Laboratories), Xenical® (orlistat, Roche Laboratories Inc.)
- OTC: Alli™ (orlistat, GlaxoSmithKline)

## Background

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- The prevalence of overweight and obesity has notably increased over the past 35 years and poses a major public health challenge in the United States. More than 65% of adult Americans are overweight, and 33% of them are obese.
- Obesity is a complex, chronic condition that significantly increases the risk of developing diabetes, high cholesterol, hypertension, heart disease, joint disease and cancer. Over time, these increased health risks can result in disability, death and high health care costs.
- To achieve and maintain weight loss, the National Institutes of Health recommend a comprehensive intervention of a low-calorie diet, exercise and behavior therapy for six months. If sufficient weight loss is not achieved with this regimen, adding appropriate medications can be considered.
- Weight-loss drugs approved by the FDA may be used for patients with a body mass index (BMI) of  $\geq 30$  kg/m<sup>2</sup> and no associated obesity-related risk factors or diseases and for patients with a BMI of  $\geq 27$  kg/m<sup>2</sup> who have concomitant obesity-related risk factors (e.g., hypertension, high cholesterol, heart disease, diabetes and sleep apnea).
- The recommended goals of treatment include an initial weight loss of 10% of body weight achieved over six months (approximately one to two lbs/week), followed by weight maintenance. If appropriate, further weight loss can be considered after this time.

## CVS Caremark Response

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- CVS Caremark recognizes the unique needs of plan members who partake in weight loss reduction plans.
- CVS Caremark is currently monitoring Qnexa and lorcaserin for potential inclusion in its clinical solutions. More information will be available after FDA approval.
- For more information, call your CVS Caremark account representative.

Please Note: This document provides a brief overview of the subject. This review is provided as a reference only and is based in part on information derived from third parties.

\* This information is current as of June 29, 2010. The information presented is subject to change and is represented to the best of our knowledge at the time of this publication.

† An approval/launch date may not reflect the actual availability of this medication. Due to circumstances beyond the control of CVS Caremark, information related to prospective medication launch dates is subject to change without notice. This information should not be solely relied upon for decision-making purposes. This medication is expected to be available in pharmacies within a few days of launch.

This document contains references to brand-name prescription drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.

## References

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