UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of
The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported)
July 14, 2010

VIVUS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-33389**	**94-3136179**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

1172 CASTRO STREET
MOUNTAIN VIEW, CA 94040
(Address of principal executive offices, including zip code)

(650) 934-5200
(Registrant's telephone number, including area code)

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 7.01. Regulation FD Disclosure

On July 14, 2010, David Allison, M.D., professor and director of the Nutrition Obesity Research Center at the University of Alabama at Birmingham, will present a poster presentation entitled: "Weight Loss at 56 Weeks in Obese Adults with Low-Dose, Controlled-Release Phentermine/Topiramate" beginning at 1:00 p.m. CET at the 11th International Conference on Obesity (ICO) in Stockholm, Sweden. A graphical representation of the poster (including the reproduction of its contents) to be presented by Dr. Allison is attached hereto as Exhibit 99.1.

The information in this Current Report on Form 8-K and the exhibit attached hereto shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference into any of the Registrant's filings under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in any such filing.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits.

Exhibit No.	Description
99.1	Poster dated July 14, 2010, entitled "Weight Loss at 56 Weeks in Obese Adults with Low-Dose, Controlled-Release Phentermine/Topiramate"

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

VIVUS, INC.

By: /s/ Lee B. Perry
Lee B. Perry
Vice President and Chief Accounting Officer

Date: July 14, 2010

EXHIBIT INDEX

Exhibit No.	Description
99.1	Poster dated July 14, 2010, entitled "Weight Loss at 56 Weeks in Obese Adults with Low-Dose, Controlled-Release Phentermine/Topiramate"

Below is a graphical representation of the poster entitled “Weight Loss at 56 Weeks in Obese Adults With Low-Dose, Controlled-Release Phentermine/Topiramate”

Weight Loss at 56 Weeks in Obese Adults With Low-Dose, Controlled-Release Phentermine/Topiramate

Authors: David B. Allison, PhD[a]; George A. Bray, MD[b]; Michael L. Schwiers, MS[c]; Kishore M. Gadde, MD[d]; Wesley W. Day, PhD[e]; Craig A. Peterson, MS[e]

[a]University of Alabama at Birmingham, Alabama, USA; [b]Pennington Biomedical Research Center, Baton Rouge, Louisiana, USA; [c]Medpace, Inc., Cincinnati, Ohio, USA; [d]Duke University Medical Center, Durham, North Carolina, USA; [e]Vivus, Inc., Mountain View, California, USA

Abstract

Introduction

Phentermine/topiramate (PHEN/TPM) is a once-daily, low-dose, controlled-release combination of two agents with demonstrated weight-loss properties. PHEN/TPM reduces food intake and potentially achieves greater improvements in weight and cardiovascular risk reduction than monotherapeutic weight-loss agents.

Methods

This multicenter, randomized, double-blind, placebo-controlled Phase 3 trial randomized 1,267 subjects with BMI ≥35 kg/m² to receive either placebo (n=514), PHEN 3.75 mg/TPM 23 mg (3.75/23 [n=241]), or PHEN 15 mg/TPM 92 mg (15/92 [n=512]) for 56 weeks. Subjects were also instructed to implement diet and lifestyle modifications. Primary efficacy endpoints were percent weight loss (WL) and proportion of subjects with ≥5% WL at Week 56.

Results

In an intent-to-treat (ITT) analysis, defined by the FDA and in the SAP as all randomized subjects with ≥1 treatment and 1 weight measurement post-baseline, WL from baseline was 1.6%, 5.1%, and 10.9% for placebo, 3.75/23, and 15/92, respectively (P<0.0001 vs placebo). The proportion of PHEN/TPM-treated subjects achieving ≥5%, ≥10%, or ≥15% reduction in body weight was significantly greater vs placebo (Table). PHEN/TPM subjects also achieved significant reductions vs placebo in BMI (P<0.0001) and waist circumference (P<0.0005). Most adverse events were mild and occurred more frequently in the PHEN/TPM groups.

Table. Subjects Achieving 5%, 10%, and 15% WL From Baseline

	≥5% WL	≥10% WL	≥15% WL
Placebo	80 (17.5%)	37 (7.4%)	17 (3.4%)
PHEN/TPM 3.75/23	155 (64.9%)*	44 (18.8%)*	17 (7.3%)*
PHEN/TPM 15/92	330 (66.7%)*	235 (47.2%)*	161 (32.3%)*

*P<0.0001; †P<0.0204

Conclusion

PHEN/TPM was generally well tolerated and demonstrated significant WL vs placebo at 1 year.

Introduction

- Obesity is a significant health problem in the United States that is associated with comorbidities such as cardiovascular disease and type 2 diabetes mellitus (T2DM) as well as increased mortality.[1-4]
- Modest weight loss of 10% may result in reductions in risks associated with weight-related comorbidities.[5-7]
- Phentermine (PHEN) and topiramate (TPM) are 2 pharmacologic agents with demonstrated weight-loss properties. PHEN is currently approved in the United States as a short-term treatment for weight loss (recommended dose: 37.5 mg/day) as an adjunct to lifestyle modifications while TPM is indicated for treatment of seizures (recommended dose: 400 mg/day) and prevention of migraine headaches (recommended dose: 100 mg/day).[8,9]
- A previous formulation of TPM at doses titrated up to 384 mg/day demonstrated weight loss in clinical trials.[10] Studies have also demonstrated significant improvements in blood pressure and glycemic and lipid parameters.[11-13] Dose-related side effects were significant, and prevented further development of TPM as monotherapy.[10-13]
- An investigational controlled-release (CR) formulation of PHEN/TPM provides a combination therapy, which may potentially achieve greater improvements in weight and cardiometabolic risk reduction, while minimizing adverse events (AEs), than monotherapy with these agents individually.

Objective

- To evaluate weight loss over a 56-week period in obese subjects treated with PHEN/TPM CR.

Methods

- A double-blind, placebo-controlled Phase 3 trial (EQUIP) was conducted in 1267 obese subjects (body mass index [BMI] ≥35 kg/m²), excluding subjects with T2DM. Subjects were randomly assigned to placebo, PHEN 3.75 mg/TPM CR 23 mg (3.75/23), or PHEN 15 mg/TPM CR 92 mg (15/92) for 56 weeks.
- Subjects were instructed to take study drug once daily for 56 weeks. Dosing was initiated with a 4-week titration to randomized dose, which was then administered during the following 52 weeks. Efficacy and safety endpoints were evaluated at baseline, Weeks 2 and 4 of the titration period, and then at 4-week intervals. Subjects were provided counseling on lifestyle changes using the LEARN® Program for Weight Management.[14]

Assessments

- The primary efficacy endpoints were percent change in body weight and percentage of subjects with ≥5% weight loss at Week 56 in the intent-to-treat (ITT) sample with last observation carried forward (LOCF). Additional efficacy endpoints included percentage of patients achieving ≥10% or ≥15% weight loss and changes in systolic blood pressure (SBP), diastolic blood pressure (DBP), waist circumference, and BMI at Week 56. Safety was also assessed at each study visit.
- The ITT sample was defined in the protocol and statistical analyses plan as all randomized subjects with ≥1 dose of treatment and ≥1 weight measurement post-baseline.
- Analysis of covariance (ANCOVA) was used to evaluate changes in weight loss and other outcomes. The ANCOVA model used factors of treatment and gender with baseline weight as a covariate. For each treatment comparison, the difference in least-squares (LS) means, corresponding standard errors, 95% confidence intervals, and *P* values were derived from the ANCOVA model.
- Analysis of percentage of subjects with at least 5%, 10%, or 15% weight loss at Week 56 with LOCF was performed using a logistic regression model with treatment and gender as fixed effects and baseline weight as a covariate. For each treatment comparison of interest, the estimated odds ratio, standard error, 95% Wald confidence interval, and *P* value were derived.

Figure 1. Percent weight loss from baseline to 56 weeks: ITT-LOCF (A) and Study Completers (B).

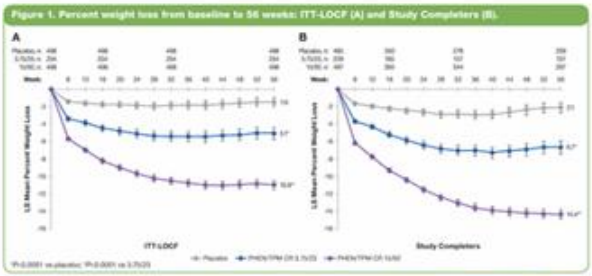
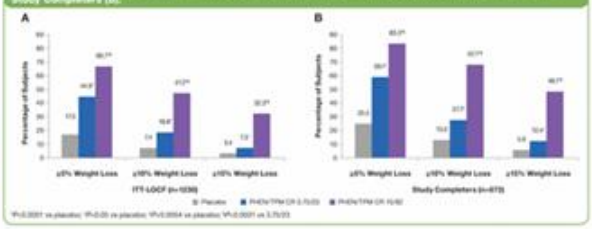


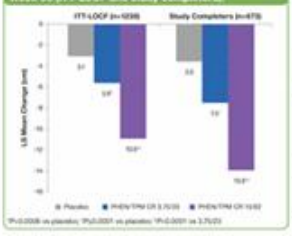
Figure 2. Percentage of subjects achieving ≥5%, ≥10%, and ≥15% weight loss at Week 56: ITT-LOCF (A) and Study Completers (B).



Results

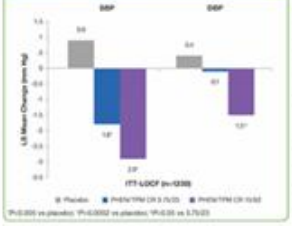
- The majority of the randomized sample (N=1267) was female (83%) and Caucasian (80%) with a mean age of 43 years. At baseline, mean weight was 116.1 kg, mean BMI was 42.1 kg/m², mean waist circumference was 120.5 cm, and mean blood pressure was 122/77 mm Hg.
- LS mean percent weight loss was significantly greater in both PHEN/TPM CR groups vs placebo at Week 56 (P<0.0001 for all comparisons). In the ITT-LOCF sample, LS mean percent weight loss was 1.6%, 5.1%, and 10.9% for placebo, 3.75/23, and 15/92, respectively (Figure 1A). Among subjects completing 56 weeks on study drug (study completers), LS mean percent weight loss was 2.1%, 6.7%, and 14.4% for placebo, 3.75/23, and 15/92, respectively (Figure 1B).
- The percentage of subjects achieving ≥5% weight loss, ≥10% weight loss, and ≥15% weight loss are presented in Figure 2 for both the ITT-LOCF and study completer samples.
- Waist circumference in the ITT-LOCF sample and among study completers was significantly reduced for both doses of PHEN/TPM CR vs placebo (P<0.001) (Figure 3).

Figure 3. Changes in waist circumference (cm) at Week 56 (ITT-LOCF and study completers).



- Both doses of PHEN/TPM CR demonstrated significantly greater reductions in BMI vs placebo (P<0.0001, ITT-LOCF). LS mean changes were -0.6 kg/m², -2.1 kg/m², and -4.6 kg/m² for placebo, 3.75/23, and 15/92, respectively. Treatment with 15/92 resulted in a significantly greater reduction in BMI than treatment with 3.75/23 (P<0.0001).
- After 56 weeks in the ITT-LOCF sample, treatment with both doses of PHEN/TPM CR resulted in significantly reduced SBP compared to placebo (P<0.005). DBP was also significantly reduced for subjects receiving 15/92 when compared to placebo (P<0.0002) (Figure 4).

Figure 4. Changes in SBP and DBP (mm Hg) at Week 56 (ITT-LOCF).



- More patients receiving PHEN/TPM CR completed the study on therapy than those receiving placebo: 46.9%, 57.3%, and 58.8% for placebo, 3.75/23, and 15/92, respectively.
- The most common treatment-emergent AEs (≥5%) are presented in Table 1; most events were mild or moderate in severity, and event rates were generally dose related. Treatment-emergent serious AEs experienced by subjects treated with PHEN/TPM CR were comparable to those receiving placebo (2.3%, 2.5%, and 2.0% in placebo, 3.75/23, and 15/92, respectively), with no individual event occurring in more than one subject treated with PHEN/TPM CR. In total, 12.2% of patients discontinued study medication due to AEs.

Table 1. Most Common Treatment-Emergent AEs

Adverse Event	Placebo (n=513) (%)	3.75/23 (n=240) (%)	15/92 (n=511) (%)
Paraesthesia	1.9	4.2	19.4
Dry mouth	3.7	6.7	17.8
Constipation	5.8	7.9	14.1
Upper respiratory tract infection	10.9	11.8	12.3
Headache	10.1	10.4	11.9
Nasopharyngitis	7.2	12.9	9.0
Dysgeusia	1.0	1.3	8.4
Insomnia	4.9	5.0	7.8
Nausea	4.7	5.8	7.2
Sinusitis	5.5	7.5	7.0
Dizziness	4.1	2.9	6.7
Back pain	5.1	5.4	6.5
Bronchitis	4.9	6.7	5.3
Cough	3.5	3.3	5.1
Influenza	4.7	7.5	5.1
Diarrhea	4.3	5.0	4.7
Fatigue	2.3	5.0	4.5
Vision blurred	3.1	4.2	4.5

Conclusions

- Treatment with PHEN/TPM CR combination therapy resulted in significantly greater weight loss at Week 56 compared to placebo. Significant improvements were also seen in BMI, waist circumference, and blood pressure vs placebo.
- PHEN/TPM CR 15/92 resulted in statistically superior improvements in weight-related efficacy variables and waist circumference when compared to PHEN/TPM CR 3.75/23.
- PHEN/TPM CR was generally well tolerated based on rates of study completion, discontinuation rates, and overall adverse events.
- This randomized, placebo-controlled study suggests that well-tolerated medical treatments for weight loss may lead to dose-related improvements in weight and obesity-related cardiometabolic risk factors.

This trial is registered at ClinicalTrials.gov, number NCT00554216.

References: 1. Rosen OM. Importance of identifying the overweight patient who will benefit the most by losing weight. *Ann Intern Med*. 2003;139:420-423. 2. Flegal KM, Carroll MD, Ogden CL, Johnson CL. Prevalence and trends in obesity among US adults, 1999-2000. *JAMA*. 2002;288:1723-1727. 3. Hossain MM, James WP. Obesity. *Lancet*. 2005;366:1197-1209. 4. Adams KF, Schatzkin A, Harris TB, et al. Overweight, obesity, and mortality in a large prospective cohort of persons 50 to 71 years old. *N Engl J Med*. 2006;355:763-778. 5. American Diabetes Association. Standards of medical care in diabetes—2010. *Diabetes Care*. 2010;33(suppl 1):S11-S61. 6. Pi-Sunyer X. The medical risks of obesity. *Postgrad Med*. 2009;121:21-33. 7. National Heart, Lung, and Blood Institute Obesity Education Initiative. The practical guide to the identification, evaluation, and treatment of overweight and obesity in adults. October 2000. NIH Publication Number 00-4084. 8. Adipex-P [package insert]. Batesville, IN: Teva Pharmaceuticals USA; 2005. 9. Topamax [package insert]. Titusville, NJ: Ortho-McNeil-Janssen Pharmaceuticals, Inc.; 2009. 10. Bray GA, Hollander P, Klein S, et al. A 6-month randomized, placebo-controlled dose, ranging trial of topiramate for weight loss in obesity. *Obes Res*. 2003;11:722-733. 11. Rosenstock J, Hollander P, Gadde KM, Sun K, Strauss R, Leung A, for the OBES-203 Study Group. A randomized, double-blind, placebo-controlled, multicenter study to assess the efficacy and safety of topiramate controlled release in the treatment of obese type 2 diabetic patients. *Diabetes Care*. 2007;30:1480-1486. 12. Bertoli A, Rissone S, Vercruysse F, Kumar A, Fitchet M, Sjostrom L, for the OBEW-003 Study Group. Topiramate in the treatment of obese subjects with drug-naive type 2 diabetes. *Diabetes Obes Metab*. 2007;9:360-368. 13. Wilding J, Van Gaal L, Rissanen A, Vercruysse F, Fitchet M; OBES-002 Study Group. A randomized double-blind placebo-controlled study of the long-term efficacy and safety of topiramate in the treatment of obese subjects. *Int J Obes Relat Metab Disord*. 2004;28:1399-1410. 14. Torstad S, Tykarski A, Weingarten J, et al. Efficacy and safety of topiramate in the treatment of obese subjects with essential hypertension. *Am J Cardiol*. 2005;96:243-251. 15. Tuzcak M, Hamann A, Moore R, et al. Efficacy and safety of topiramate in combination with metformin in the treatment of obese subjects with type 2 diabetes: a randomized, double-blind, placebo-controlled study. *Int J Obes (Lond)*. 2007;31:106-116. 16. Brownell KD. The LEARN Program for Weight Management 10th ed. Dallas, TX: American Health Publishing Company; 2004.

Acknowledgements: We would like to acknowledge and thank the EQUIP investigators and study coordinators, the Medpace team (study CRO), The Lockwood Group (for poster development assistance), and VIVUS internal contributors.

Disclosure: Dr. Allison has received grants, honoraria, donations, and consulting fees from numerous food, beverage, and pharmaceutical companies, as well as other commercial and nonprofit entities with interests in obesity. These companies include but are not limited to: Vivus, Inc., Merck, Pfizer, Eli Lilly and Co., Abbott Laboratories, Glen Kaul Foods, and Arena Pharmaceuticals.

Below is a reproduction of the contents of the poster entitled “Weight Loss at 56 Weeks in Obese Adults With Low-Dose, Controlled-Release Phentermine/Topiramate”

Authors: David B. Allison, PhD(a); George A. Bray, MD(b); Michael L. Schwiers, MS(c); Kishore M. Gadde, MD(d); Wesley W. Day, PhD(e); Craig A. Peterson, MS(e)

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· Abstract

Introduction

Phentermine/topiramate (PHEN/TPM) is a once-daily, low-dose, controlled-release combination of two agents with demonstrated weight-loss properties. PHEN/TPM reduces food intake and potentially achieves greater improvements in weight and cardiovascular risk reduction than monotherapeutic weight-loss agents.

Methods

This multicenter, randomized, double-blind, placebo-controlled Phase 3 trial randomized 1,267 subjects with BMI ≥35 kg/m^2 to receive either placebo (n=514), PHEN 3.75 mg/TPM 23 mg (3.75/23 [n=241]), or PHEN 15 mg/TPM 92 mg (15/92 [n=512]) for 56 weeks. Subjects were also instructed to implement diet and lifestyle modifications. Primary efficacy endpoints were percent weight loss (WL) and proportion of subjects with ≥5% WL at Week 56.

Results

In an intent-to-treat (ITT) analysis, defined by the FDA and in the SAP as all randomized subjects with ≥1 treatment and 1 weight measurement post-baseline, WL from baseline was 1.6%, 5.1%, and 10.9% for placebo, 3.75/23, and 15/92, respectively (P<0.0001 vs placebo). The proportion of PHEN/TPM-treated subjects achieving ≥5%, ≥10%, or ≥15% reduction in body weight was significantly greater vs placebo (Table). PHEN/TPM subjects also achieved significant reductions vs placebo in BMI (P<0.0001) and waist circumference (P<0.0005). Most adverse events were mild and occurred more frequently in the PHEN/TPM groups.

Table. Subjects Achieving 5%, 10%, and 15% WL From Baseline

	≥5% WL	≥10% WL	≥15% WL
Placebo	86 (17.3%)	37 (7.4%)	17 (3.4%)
PHEN/TPM 3.75/23	105 (44.9%)*	44 (18.8%)*	17 (7.3%)†
PHEN/TPM 15/92	332 (66.7%)*	235 (47.2%)*	161 (32.3%)*

*P<0.0001; †P=0.0234

Conclusion

PHEN/TPM was generally well tolerated and demonstrated significant WL vs placebo at 1 year.

· Introduction

- Obesity is a significant health problem in the United States that is associated with comorbidities such as cardiovascular disease and type 2 diabetes mellitus (T2DM) as well as increased mortality.(1)-(4)
- Modest weight loss of 10% may result in reductions in risks associated with weight-related comorbidities.(5)-(7)
- Phentermine (PHEN) and topiramate (TPM) are 2 pharmacologic agents with demonstrated weight-loss properties. PHEN is currently approved in the United States as a short-term treatment for weight loss (recommended dose: 37.5 mg/day) as an adjunct to lifestyle modifications while TPM is indicated for treatment of seizures (recommended dose: 400 mg/day) and prevention of migraine headaches (recommended dose: 100 mg/day).(8),(9)
- A previous formulation of TPM at doses titrated up to 384 mg/day demonstrated weight loss in clinical trials.(10) Studies have also demonstrated significant improvements in blood pressure and glycemic and lipid parameters.(10)-(15) Dose-related side effects were significant, and prevented further development of TPM as monotherapy.(10)-(15)
- An investigational controlled-release (CR) formulation of PHEN/TPM provides a combination therapy, which may potentially achieve greater improvements in weight and cardiometabolic risk reduction, while minimizing adverse events (AEs), than monotherapy with these agents individually.

· Objective

- To evaluate weight loss over a 56-week period in obese subjects treated with PHEN/TPM CR.

· Methods

- A double-blind, placebo-controlled Phase 3 trial (EQUIP) was conducted in 1267 obese subjects (body mass index [BMI] ≥35 kg/m^2), excluding subjects with T2DM. Subjects were randomly assigned to placebo, PHEN 3.75 mg/TPM CR 23 mg (3.75/23), or PHEN 15 mg/TPM CR 92 mg (15/92) for 56 weeks.
- Subjects were instructed to take study drug once daily for 56 weeks. Dosing was initiated with a 4-week titration to randomized dose, which was then administered during the following 52 weeks. Efficacy and safety endpoints were evaluated at baseline, Weeks 2 and 4 of the titration period, and then at 4-week intervals. Subjects were provided counseling on lifestyle changes using the LEARN® Program for Weight Management.(16)

· Assessments

- The primary efficacy endpoints were percent change in body weight and percentage of subjects with ≥5% weight loss at Week 56 in the intent-to-treat (ITT) sample with last observation carried forward (LOCF). Additional efficacy endpoints included percentage of patients achieving ≥10% or ≥15% weight loss and changes in systolic blood pressure (SBP), diastolic blood pressure (DBP), waist circumference, and BMI at Week 56. Safety was also assessed at each study visit.

- The ITT sample was defined in the protocol and statistical analysis plan as all randomized subjects with ≥1 dose of treatment and ≥1 weight measurement post-baseline.

- Analysis of covariance (ANCOVA) was used to evaluate changes in weight loss and other outcomes. The ANCOVA model used factors of treatment and gender with baseline weight as a covariate. For each treatment comparison, the difference in least-squares (LS) means, corresponding standard errors, 95% confidence intervals, and *P* values were derived from the ANCOVA model.

- Analysis of percentage of subjects with at least 5%, 10%, or 15% weight loss at Week 56 with LOCF was performed using a logistic regression model with treatment and gender as fixed effects and baseline weight as a covariate. For each treatment comparison of interest, the estimated odds ratio, standard error, 95% Wald confidence interval, and *P* value were derived.

Figure 1. Percent weight loss from baseline to 56 weeks: ITT-LOCF (A) and Study Completers (B).

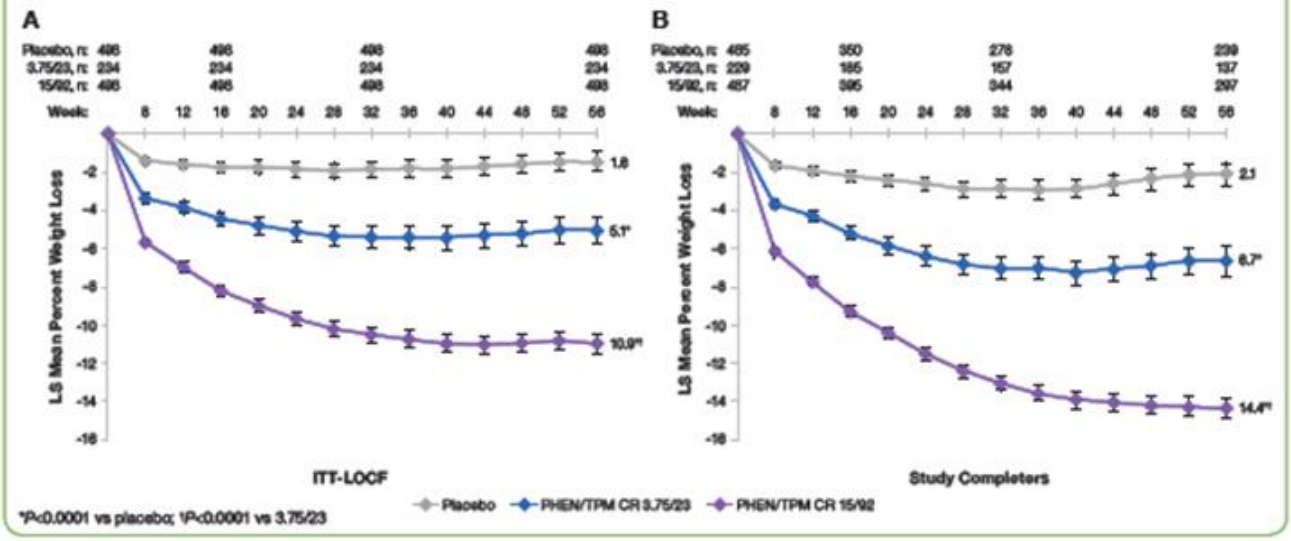
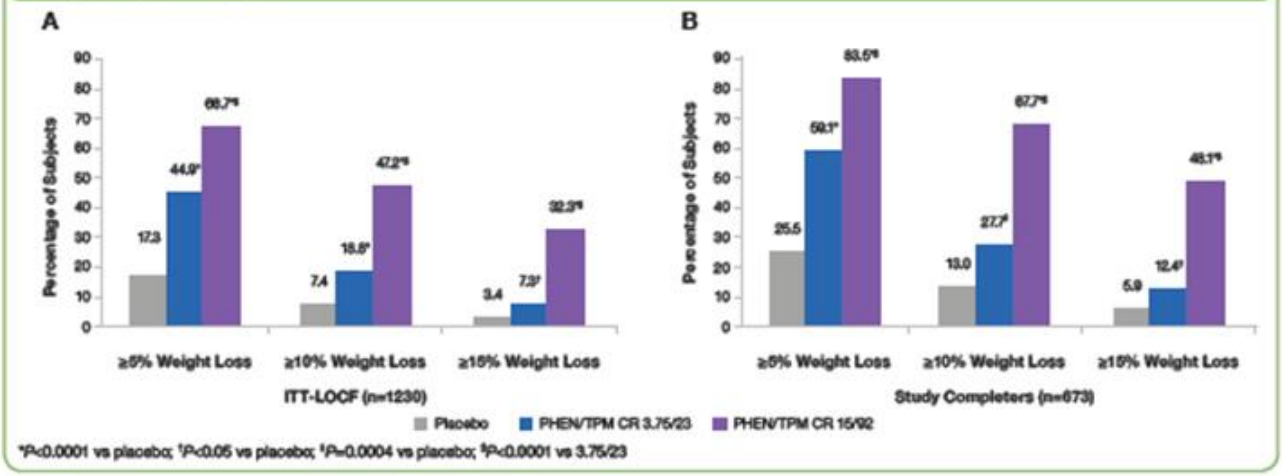


Figure 2. Percentage of subjects achieving ≥5%, ≥10%, and ≥15% weight loss at Week 56: ITT-LOCF (A) and Study Completers (B).



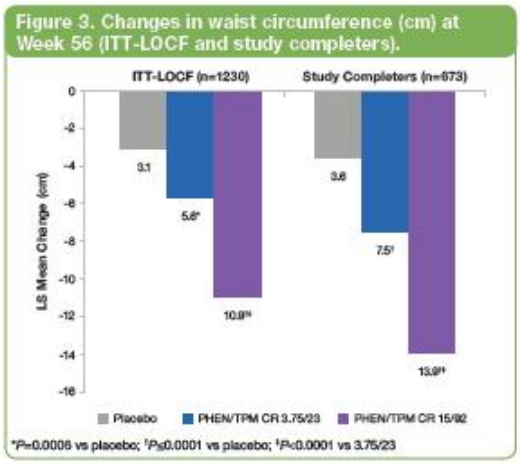
· Results

- The majority of the randomized sample (N=1267) was female (83%) and Caucasian (80%) with a mean age of 43 years. At baseline, mean weight was 116.1 kg, mean BMI was 42.1 kg/m^2, mean waist circumference was 120.5 cm, and mean blood pressure was 122/77 mm Hg.

- LS mean percent weight loss was significantly greater in both PHEN/TPM CR groups vs placebo at Week 56 (*P*<0.0001 for all comparisons). In the ITT-LOCF sample, LS mean percent weight loss was 1.6%, 5.1%, and 10.9% for placebo, 3.75/23, and 15/92, respectively (Figure 1A). Among subjects completing 56 weeks on study drug (study completers), LS mean percent weight loss was 2.1%, 6.7%, and 14.4% for placebo, 3.75/23, and 15/92, respectively (Figure 1B).

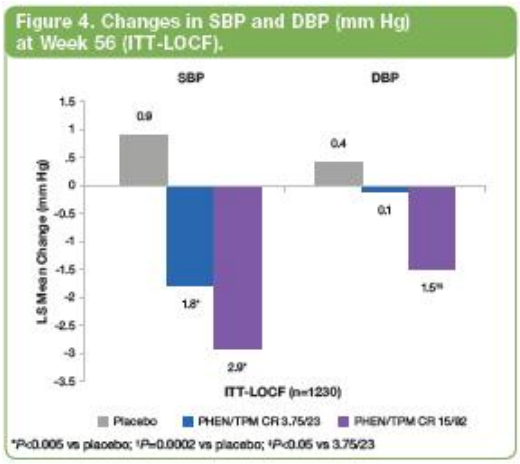
- The percentage of subjects achieving ≥5% weight loss, ≥10% weight loss, and ≥15% weight loss are presented in Figure 2 for both the ITT-LOCF and study completer samples.

- Waist circumference in the ITT-LOCF sample and among study completers was significantly reduced for both doses of PHEN/TPM CR vs placebo (*P*<0.001) (Figure 3).



· Both doses of PHEN/TPM CR demonstrated significantly greater reductions in BMI vs placebo (P<0.0001; ITT-LOCF): LS mean changes were -0.6 kg/m^2, -2.1 kg/m^2, and -4.6 kg/m^2 for placebo, 3.75/23, and 15/92, respectively. Treatment with 15/92 resulted in a significantly greater reduction in BMI than treatment with 3.75/23 (P<0.0001).

· After 56 weeks in the ITT-LOCF sample, treatment with both doses of PHEN/TPM CR resulted in significantly reduced SBP compared to placebo (P<0.005). DBP was also significantly reduced for subjects receiving 15/92 when compared to placebo (P=0.0002) (Figure 4).



· More patients receiving PHEN/TPM CR completed the study on therapy than those receiving placebo: 46.9%, 57.3%, and 58.8% for placebo, 3.75/23, and 15/92, respectively.

· The most common treatment-emergent AEs (≥5%) are presented in Table 1; most events were mild or moderate in severity, and event rates were generally dose related. Treatment-emergent serious AEs experienced by subjects treated with PHEN/TPM CR were comparable to those receiving placebo (2.3%, 2.5%, and 2.0% in placebo, 3.75/23, and 15/92, respectively), with no individual event occurring in more than one subject treated with PHEN/TPM CR. In total, 12.2% of patients discontinued study medication due to AEs.

Table 1. Most Common Treatment-Emergent AEs

Adverse Event	Placebo (n=513) (%)	3.75/23 (n=240) (%)	15/92 (n=511) (%)
Paraesthesia	1.9	4.2	18.8
Dry mouth	3.7	6.7	17.0
Constipation	6.8	7.9	14.1
Upper respiratory tract infection	10.9	15.8	12.3
Headache	10.1	10.4	11.9
Nasopharyngitis	7.2	12.5	9.0
Dysgeusia	1.0	1.3	8.4
Insomnia	4.9	5.0	7.8
Nausea	4.7	5.8	7.2
Sinusitis	5.5	7.5	7.2
Dizziness	4.1	2.9	5.7
Back pain	5.1	5.4	5.5
Bronchitis	4.3	6.7	5.5
Cough	3.5	3.3	5.1
Influenza	4.7	7.5	5.1
Diarrhea	4.5	5.0	4.7
Fatigue	3.3	5.0	4.5
Vision blurred	3.1	6.3	4.5

· Conclusions

· Treatment with PHEN/TPM CR combination therapy resulted in significantly greater weight loss at Week 56 compared to placebo. Significant improvements were also seen in BMI, waist circumference, and blood pressure vs placebo.

- PHEN/TPM CR 15/92 resulted in statistically superior improvements in weight-related efficacy variables and waist circumference when compared to PHEN/TPM CR 3.75/23.

- PHEN/TPM CR was generally well tolerated based on rates of study completion, discontinuation rates, and overall adverse events.

- This randomized, placebo-controlled study suggests that well-tolerated medical treatments for weight loss may lead to dose-related improvements in weight and obesity-related cardiometabolic risk factors.

This trial is registered at ClinicalTrials.gov, number NCT00554216.

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