Latest trial of obesity drug Qnexa may finally lead to FDA approval

By ACSH Staff — April 12, 2011

More than five months after an FDA advisory panel voted to reject Vivus' newly developed weight-loss drug Qnexa — the third weight-loss drug application to be rejected last year — the published results[1] of a Phase III trial may give the drug another shot at FDA approval. Qnexa is a combination of two approved drugs: the appetite suppressant phentermine, and topiramate — which is most commonly used as an anti-seizure drug. Published in The Lancet, the CONQUER trial[2] assessed almost 2,500 patients randomly assigned to receive either a once-daily placebo, low-dose Qnexa or high-dose Qnexa. In addition, all of the participants received information on healthy diet and lifestyle choices. To be eligible for the study, the patients had to have a BMI between 27 and 45 and two or more obesity-related medical conditions, such as high blood pressure or type 2 diabetes. The results indicate that 70 percent of patients in the high-dose group achieved at least 5 percent weight loss, with an average loss of 22 pounds, compared to 18 pounds for patients in the low-dose group. Only 21 percent of patients on placebo reduced their weight by 5 percent or more, with an average loss of three pounds.

Besides weight loss, lead study author Kishore M. Gadde, M.D., researcher and director of the obesity clinical trials program at Duke University, tells WebMD, "This treatment led to significant improvement in excess weight-related diseases such as diabetes and high blood pressure and risk factors such as high cholesterol."

ACSH's Dr. Gilbert Ross hopes that, "When the FDA reconsiders approving this much-needed weight-loss drug, these impressive results, particularly the improved health parameters, will be a point in the drug's favor."

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