

Experimental diet pill shows promise, little risk

July 14 2010, By MIKE STOBBE , AP Medical Writer

(AP) -- An experimental diet pill helped about half the people who tried it lose some weight and keep it off a year later, without the heart problems that some earlier drugs caused, a study found.

Arena Pharmaceuticals' lorcaserin is one of three drugs that are boosting hope for a new generation of more effective weight-loss medicines. One gets a [Food and Drug Administration](#) review on Thursday and the others, later this year.

In the study, lorcaserin (lore-KASS-ah-rin) caused more people to lose at least 5 percent of their [body weight](#) over one year, more than twice the rate achieved by those on dummy pills.

Most people don't stick to diets. And diet pills have had bad side effects or can't be taken long-term. A low point came in 1997 when the popular "fen-phen" was pulled from the market after it was tied to heart valve problems.

But now comes lorcaserin, a round blue tablet that would be the first truly novel weight-loss pill in a dozen years if it wins approval. The drug targets the same appetite pathway fen-phen did but in a more selective, and perhaps safer, manner.

Results of a large company-funded study of it are in Thursday's [New England Journal of Medicine](#).

The study involved more than 3,100 obese or overweight people given either the drug or dummy pills.

After a year, nearly 48 percent of the lorcaserin group had lost at least 5 percent of their body weight - about 13 pounds on average. Just 20 percent of the placebo group lost that much weight.

Only about half of those in the study stuck with it a year. That's not unusual; diet studies typically have lots of dropouts. But more of the people on lorcaserin stayed in than those on placebo, suggesting that side effects were not a problem.

A second phase of the study began after one year with the original participants who remained. Those on dummy pills kept taking them, while the people on lorcaserin were assigned either to keep getting it or to switch to dummy pills. Neither they nor their doctors knew which treatment they were receiving.

Of those in the lorcaserin group who had lost at least 5 percent of their body weight in the first year of the study, about 68 percent who kept taking the drug kept the weight off, versus 50 percent of those switched to dummy pills.

Except for headaches and dizziness, side effects were essentially no worse with the drug than placebo. There was no higher rate of heart valve problems - a key concern. However, larger studies are needed to conclusively rule out this risk.

Unlike some other obesity drugs, lorcaserin did not raise heart rates or blood pressure. In fact, cholesterol levels and other risk factors for heart disease improved in those on the drug.

"It looks very safe at this point," said study leader, Dr. Steven Smith of

the Sanford-Burnham Medical Research Institute in Orlando.

Some experts described the drug's effectiveness as moderately good, and its safety as apparently very good. The findings are probably sufficient to meet FDA benchmarks and win approval, they predicted.

Current diet pills include the appetite suppressant phentermine; sibutramine, an appetite suppressant sold as Meridia; and orlistat, a drug that blocks fat absorption and is sold as the prescription drug Xenical or the over-the-counter Alli.

They are all problematic. Phentermine has been linked to heart palpitations and higher blood pressure. Sibutramine has been tied to heart risks and has been removed from the market in Europe; the FDA will review its risks and benefits later this year. And orlistat can cause stomach pains, gas, and bowel leakage.

San Diego-based Arena hasn't put a price on lorcaserin. But it could be especially useful for obese patients with [heart problems](#).

"There's a whole group of individuals we cannot use these current medications on," said Dr. Robert Kushner, a weight-loss expert at Chicago's Northwestern University who advises a company that makes another experimental diet drug.

The two other drugs before the FDA are combinations of medicines already on the market.

Vivus Inc.'s Qnexa is up for review Thursday. It combines phentermine and topiramate, a drug used for migraines and epilepsy that has raised safety concerns. Topiramate carries warnings about possible suicidal tendencies.

Contrave, made by Orexigen Therapeutics Inc., combines bupropion and naltrexone. The first is used to help people quit smoking and deal with depression. The second is used to decrease cravings for alcohol and illegal drugs.

More information: New England Journal: <http://nejm.org>

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