Diet drugs face tough test before FDA

September 17 2010, By Bruce Japsen

There has never been a magic prescription to help millions of obese Americans lose weight. Whether one is any closer to reality is now under scrutiny.

A Food and Drug Administration advisory panel will decide Wednesday whether the diet drug Meridia will remain on the market amid calls that it be removed. And on Thursday, another drug, known as lorcaserin, is up before an advisory committee where its developer will face questions from panelists and a possible recommendation for agency approval.

With estimates by the U.S. Centers for Disease Control and Prevention that two in three Americans are overweight and one in three are obese, the drug market is hungry for an effective diet pill.

But the idea has proved difficult to pull off.

There has not been a prescription pill for weight loss approved in more than a decade, since 1999 when Xenical, which works by blocking the absorption of fat, was approved. And though the FDA gave a version of Xenical known as Alli the go-ahead to be sold over the counter, its gastrointestinal side effects such as diarrhea have kept many consumers from taking it for long periods, doctors say.

Neither Xenical nor Meridia has been a big seller, and Meridia sales have deteriorated amid criticism of its heart risks. Meridia's maker, Abbott Laboratories, says it no longer promotes the drug in the U.S., where its sales are projected this year to be $30 million.

"Those of us who are in this business are pretty concerned as well as frustrated that there are not more treatments," said Dr. Robert Kushner, medical director of the Northwestern University Comprehensive Center on Obesity.

"Americans are spending millions, if not billions of dollars, on supplements and other products that have no benefit, so clearly there is a need for prescription drugs," he said. "Diet and exercise are not effective for everyone who is overweight."

Prescription diet pills have had trouble winning respect with consumers and doctors because of safety issues and side effects. In particular, the diet drug combination known as fen-phen was a disaster for the drug industry when it was linked to heart valve damage and subsequently yanked from pharmacy shelves in 1997.

Meridia has been attacked by doctors and consumer groups based on studies that show increased risks of heart attacks and strokes.

In part because of issues with past treatments, drug developers in recent years turned to combinations of drugs already on the market, thinking years of safety and efficacy data on low-dosage versions would help win approval. But that strategy did not work for Vivus Inc., which in July had its anti-obesity drug Qnexa rejected by an FDA advisory panel by a 10-6 vote in part due to heart-attack risks.

Following the panel's decision on Qnexa, Biotech Stock Research, a research firm that follows drug development, Tweeted that it believes "no drug will ever be proven to be as safe as exercise in the minds of reviewers."

Analysts see a huge category if an effective diet drug is ever approved, especially since the obese tend to already have chronic conditions such

as diabetes, high cholesterol and hypertension -- conditions that generate some of the biggest categories of drug sales in the U.S.

Cholesterol drugs, for example, are the second most lucrative sales category, tallying $14.3 billion in revenue last year, according to market research for IMS Health. Antipsychotics were the top-selling class, with $14.6 billion in 2009 U.S. sales, IMS said.

Lorcaserin has not shown the similar heart-attack risks as Qnexa or Meridia so some analysts believe peak sales could one day surpass $500 million annually. It works similarly to how fen-phen worked, stimulating a receptor in the brain to help block signals linked to appetite so the person taking the drug eats less.

San Diego-based Arena Pharmaceuticals Inc. and studies have shown lorcaserin is more selective in the receptors it targets than the fen-phen combination, so its side effect profile is better, data seems to indicate.

But an FDA staff report issued Tuesday on lorcaserin in preparation for Thursday's panel said the drug satisfied the agency's "categorical efficacy criterion" only "by a slim margin" and raised safety issues such as memory problems and a link to heart-valve damage.

Wall Street frowned on that news as shares of Arena lost about 40 percent of their value Tuesday.

Studies show patients who took lorcaserin lost just 3 percent more of their body weight compared to those on placebos.

Even percentages of weight loss in the single digits will be helpful for some, given the obesity epidemic, some physicians say.

"If prescribed wisely by physicians knowledgeable about obesity, there

are going to be groups of individuals -- large groups -- that will benefit," Kushner said.