SCIENCE

Binge Eating Targeted as Head Disorder With Shire's Vyvanse

By Meg Tirrell
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Shire Plc (SHP), Ireland's biggest drugmaker, is aiming to introduce a medicine that quells the urge to overeat. Just don't call it a diet drug.

After Alkermes Inc. (ALKS) last week stopped developing a similar medicine, Shire became the top candidate to develop the first approved drug to combat binge-eating disorder. The Dublin-based company says its treatment, Vyvanse, now marketed for hyperactivity, may limit binging by interacting with brain chemicals that affect mood, motivation and inhibition.

In the process, Shire is cutting a new trail through a U.S. regulatory system that has rejected diet products because of their side effects. While drugs made by Vivus Inc., Arena Pharmaceuticals Inc. and Orexigen Therapeutics Inc. have failed to win clearance from the Food and Drug Administration's metabolic drug unit, Shire's effort is being overseen by the agency's psychiatric division, a different approval route that focuses on the drug as treatment for a mental disorder.

"There are a lot of theories about how binge-eating disorder and its related obesity may arise," said James Hudson, a professor of psychiatry at McLean Hospital in Belmont, Massachusetts, and Harvard Medical School. One is that "the brain perceives food more as a drug or substance that's affecting the reward center directly."

Shire rose 22 pence, or 1.1 percent to 2,002 pence in London trading today. The stock has climbed 39 percent in the past 12 months, more than tripling the Bloomberg Europe Pharmaceutical Index.

Patients with the disorder may "have a deficit in their reward pathway such that they will overeat well past when they're not physically hungry," he said.

3% of Americans

About 3 percent of the U.S. population has dealt with binge-eating disorder at some point in their lives, making it the most common eating disorder and more prevalent than anorexia nervosa and bulimia nervosa combined, Hudson said. The condition can lead to obesity, which in turn puts people at risk for diabetes and heart disease.

Shire is pursuing the theory that the condition may be associated with chemicals that affect the ability to control oneself or feel satisfied after food, said Robert Lasser, who heads Shire's research into new uses for Vyvanse. The drug drew $634 million in 2010 revenue, and may gain an extra $750 million a year with an indication for binge-eating disorder, Lasser said.

Brain Rewards

"When you begin to think about food addiction, you automatically turn to a couple of neurochemicals that are important in reward," Lasser said in a telephone interview. "One of those primarily is dopamine, and the other is norepinephrine."

Vyvanse affects both. Shire isn't seeking to apply an indication for binge-eating disorder more broadly to all obese patients, Lasser said. The FDA's psychiatric division focuses on the condition "because it has substantial disability in the realm of psychiatric symptoms," he said.

“Depression, anxiety, reduced quality of life” all are associated with the disorder, Lasser said. That’s “in addition to the more obvious issues related to higher rates of diabetes, hypertension, hypercholesterolemia, GI or heart disease -- all of those are associated with obesity.”

While not all patients with binge-eating disorder are obese, about 25 percent of obese patients who seek treatment are thought to have the condition, said Lasser. Someone with the disorder can consume almost 10,000 calories in a single, hour- long binge, he said.

Macaroni and Cheese

Dick Waller, an 81-year-old Cincinnati musician who has been treated for binge eating for seven years, says the condition is “definitely a disease.”

During a recent family gathering, he ate more macaroni and cheese “than my two grandsons, put together,” Waller said in a telephone interview. He ate stuffed cabbage, salami, cheese, and then, “even though I wasn’t hungry,” went out to eat ice cream with the kids, he said.

“You’re tempted every time you eat,” he said. “Once I take a taste, I feel like I can’t stop.”

Waller isn’t obese. At 5 feet, 5 inches, and about 160 pounds, he has a body mass index of 26.5, on the low end of overweight, according to the U.S. Department of Health and Human Services. About 10 years ago, though, he had reached 190 pounds.

“That’s 30 pounds overweight,” Waller said. “For me, that’s a disaster.”

Treadmill Therapy

Fearful of getting diabetes, which runs in his family, Waller exercises frequently, doing at least 40 minutes of work on a treadmill or with a trainer six days a week, he said. While he’s not enrolled in Shire’s trial, he said he’d seriously consider taking a drug proven to be safe and effective for his condition.

Now, “I’ll go a day where I’ll eat really well, and I’ll think, ‘I’m on my way,” he said. Then, “maybe I’ll go for a day or two and I’ll blow it. The idea of trying a new medication that would help me, I would gladly try that at this point.”

Binge-eating is expected to be formally recognized in the next version of the Diagnostic and Statistical Manual of Mental Disorders, the handbook for U.S. mental-health professionals.

The manual would define the disorder as “recurrent episodes of binge eating,” in which someone eats a much greater amount of food than most people would under similar circumstances, and feels a lack of control over their eating.

Guilt and Depression

To meet the criteria for diagnosis, the episodes, which may also be associated with feelings of embarrassment, guilt and depression, would occur regularly.

The path to approval for a binge-eating disorder drug is already paved with one failure. Alkermes, the Waltham, Massachusetts-based maker of the medicine Vivitrol for alcohol and opioid dependence, announced last week it would stop development of an experimental drug for binge-eating disorder after mid-stage trials didn’t show significant efficacy compared with a placebo. The company is still testing the medicine, ALKS 33, in alcohol dependence, cocaine addiction and treatment- resistant depression.

Shire expects binge-eating data on Vyvanse next year from the second trial phase of three generally required for U.S. marketing approval. The company is also testing the medicine for major depression, schizophrenia and excessive daytime sleepiness.

Attention Deficit

Vyvanse was approved in the U.S. in 2007 to treat attention deficit hyperactivity disorder in children ages 6 to 12, and has since gained approval for use in adolescents and adults.

The medicine is a chemically modified, longer-lasting version of dextroamphetamine. A class of drugs that were used extensively from the 1930s through 1970s, amphetamines fell out of favor in part because they

could be habit-forming and lead to abuse, said Jack Scannell, an analyst with Sanford C. Bernstein in London. For use in ADHD, Shire developed a slow-release amphetamine variant that has reduced the potential for recreational use and is likely safer in the event of overdose, he said.

“It’s been known for years that amphetamine suppresses appetite,” Scannell said in a telephone interview. “Andy Warhol used amphetamine as his favorite weight-loss method.”

Approval isn’t guaranteed, despite the wealth of knowledge about amphetamines and Vyvanse’s use for ADHD, the analyst said.

Regulators may still show concern that there is a potential for abuse, and the drug is tied to side effects, including dry mouth, increased heart rate, trouble sleeping and, in very high doses or overdose, cardiovascular problems, he said.

Heart Risk

Regulators’ concerns about heart risks led La Jolla, California-based Orexigen to shut down U.S. development of its diet pill, Contrave, last month, after the FDA required a large study in that area.

Orexigen and its partner, Osaka, Japan-based Takeda Pharmaceutical Co., had been vying with San Diego-based Arena and Vivus of Mountain View, California, to introduce the first new obesity medicine in the U.S. in more than a decade. Abbott Laboratories pulled its diet pill, Meridia, off U.S. shelves in October after it was tied to heart attacks and strokes. Safety issues also prompted the withdrawal of Wyeth’s fen-phen in 1997.

Vyvanse’s heart risk would only arise at very high, or overdose, levels, Scannell said.

The indications for schizophrenia and depression are likely much bigger opportunities than binge eating, the analyst said.

“Depressed and schizophrenic patients are already seeing their doctors and already getting medication,” said Scannell. “With binge eating, there are two challenges: One is getting the drug approved, and the second is convincing doctors they should prescribe a drug for the condition.”

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