

# Hydrogel capsule, Gelesis100, reduces weight in overweight and obese subjects

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A new "smart pill" called Gelesis100 safely leads to greater weight loss in overweight and obese individuals compared with those who receive an active comparator/placebo capsule, while all subjects have similar diet and exercise instructions, an international multicenter study finds. The three-month results of the First Loss Of Weight (FLOW) study were presented Sunday June 22, 2014 at the joint meeting of the International Society of Endocrinology and the Endocrine Society: ICE/ENDO 2014 in Chicago.

Gelesis100 (formerly Attiva) is an orally administered capsulated device designed to cause weight loss by inducing satiety and reducing caloric intake, according to its manufacturer, Boston-headquartered Gelesis, which funded the FLOW study. In 128 nondiabetic [subjects](#), weight loss was most pronounced in those who had impaired levels of fasting blood glucose (sugar), also known as prediabetes, said Hassan Heshmati, MD, chief medical officer for Gelesis and a study co-investigator.

"Given the excellent safety profile observed in the FLOW study, Gelesis100 has the potential to fulfill the unmet need for a safe and effective weight loss agent. This is particularly impactful for individuals with mildly elevated [blood sugar](#) (prediabetic subjects), for whom weight loss is particularly important because they are at increased risk for diabetes," Heshmati said.

This proof-of-concept study tested two doses of Gelesis100, a superabsorbent hydrogel, when taken twice a day with water before a

meal. Forty-three subjects were randomly assigned to receive 2.25 grams (g) of Gelesis100 before lunch and dinner, another 42 subjects received 3.75 g of Gelesis100 and a third group of 43 subjects received a placebo capsule containing cellulose, a fiber which is used as a bulking agent. All subjects were instructed to eat 600 fewer calories a day. Neither the subjects nor the investigators knew which treatment they received during the 12 weeks of the study.

Among 125 subjects who weighed in at the start of the study and at least once after treatment, the average reductions in body weight by group at the end of treatment were as follows: 6.1 percent for 2.25 g of Gelesis100, 4.5 percent for 3.75 g of Gelesis100 and 4.1 percent for placebo. For subjects receiving the 2.25-g dose of Gelesis100, those with initial high fasting blood sugar (greater than the median level of 93 milligrams per deciliter, or mg/dL) had greater weight loss than did the others, losing 8.2 percent of their body weight on average, Heshmati reported.

The greatest weight loss reportedly occurred in prediabetic subjects whose starting fasting blood sugar level was 100 to 125.9 mg/dL. They lost an average of 10.9 percent of their [body weight](#).

Heshmati said he thinks the higher dose of Gelesis100 resulted in less [weight loss](#) because of lower tolerability leading to lower compliance with the study requirements. The most common side effects reported were bloating, flatulence, abdominal pain and diarrhea, which he said occurred less often with the smaller dose and were tolerable at that dose. No apparent serious problems occurred in either Gelesis100 group.

Gelesis100 capsules contain thousands of tiny hydrogel particles that expand in the stomach and mix with digested foods, said Gelesis' founder and chief executive officer, Yishai Zohar. He said this increases the volume and elasticity of the stomach and small intestine contents,

inducing satiety and reducing [caloric intake](#). The particles are composed of two components which are used as food ingredients, but when cross-linked together form a unique structure that increases in volume.

Gelesis100 does not create one big mass, rather thousands of small individual gel beads which have exactly the same elasticity (rigidity) as digested foods, but without any calories.

The first in a new class of weight management and obesity therapies, Gelesis100 will be regulated as a medical device if approved by the Food and Drug Administration, Zohar said.

Provided by The Endocrine Society

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