

FDA backs drug that treats diabetes via the brain

May 6 2009, By LAURAN NEERGAARD , AP Medical Writer

(AP) -- People with Type 2 diabetes may soon get a very different treatment approach: A drug that helps control blood sugar via the brain - an idea sparked, surprisingly, by the metabolism of migrating birds.

The Food and [Drug](#) Administration approved Cycloset, maker VeroScience Inc. announced Wednesday. It's a new version of an old drug called bromocriptine, used in higher doses to treat Parkinson's disease and a few other conditions. But unlike its older parent, Cycloset is formulated to require a low, quick-acting dose taken just in the morning - no other time of day.

That timing provides a bump of activity in a brain chemical that seems to reset a body clock that in turn helps control metabolism in [Type 2 diabetes](#), said VeroScience's Anthony Cincotta, who led the drug's development.

Company studies suggest that one morning dose helped lower the usual post-meal [blood sugar](#) rise at breakfast, lunch and dinner. Over six months, 35 percent of Cycloset users reached recommended average blood sugar levels, compared with 10 percent of diabetics given a dummy drug, Cincotta said.

Cycloset is the first drug to win FDA approval under new guidelines that require better evidence that diabetes treatments are heart-safe. Diabetics are at increased risk of heart disease. In a yearlong safety study involving 3,000 diabetics, those given Cycloset had 42 percent fewer heart attacks

and other cardiovascular complications than those given a dummy drug.

Where do the birds come in? Years ago, Louisiana State University researchers were studying how migrating birds arrived at their destinations without being emaciated. They develop seasonal insulin resistance, the very condition that in people leads to Type 2 diabetes.

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The researchers discovered a [biological clock](#) - in the brain's hypothalamus - that controlled when the metabolism change kicked in for the birds, and also in hibernating mammals. Different concentrations of certain brain chemicals, including dopamine, at different times of day dictated whether the bird metabolized like a fall bird or a summer bird, said Cincotta.

People don't have those seasonal variations but the theory is the dopamine plays a role anyway in sensitivity to insulin, although Cycloset apparently did not affect weight.

Bromocriptine mimics dopamine: "We're regulating the regulator," Cincotta said.

Side effects include nausea and dizziness, sometimes because of blood pressure dips upon standing. Nursing women shouldn't use it. Bromocriptine inhibits lactation, and although no link is proven, there have been reports of strokes in postpartum women using higher doses. The FDA said it also should be used cautiously with people taking blood pressuring-lowering medication.

It's uncertain how soon sales can begin, or the drug's cost: VeroScience, of Tiverton, R.I., is in negotiations with larger drug companies to find a

distributor.

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