

Investor Call

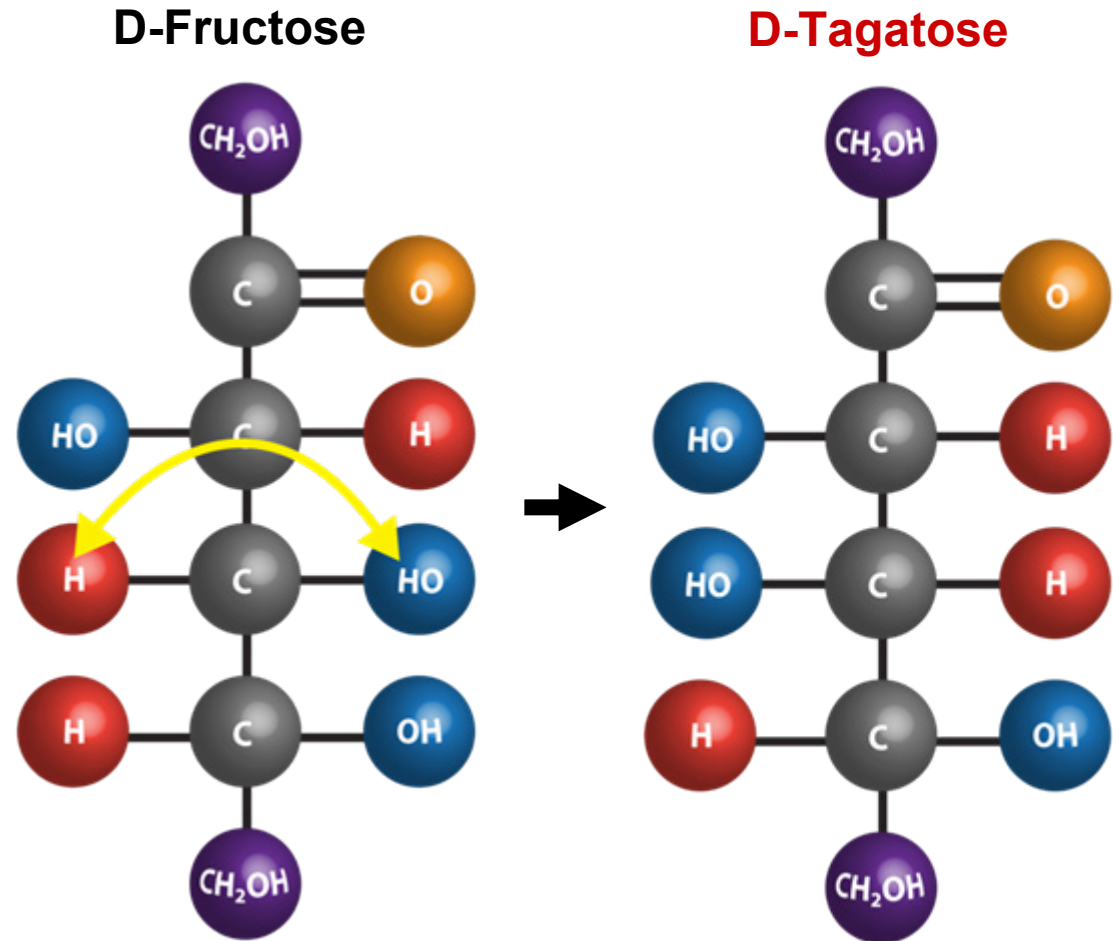
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What is D-tagatose?

- Naturally occurring L-epimer of D-fructose with an inversion at C4
- Spherix used chiral carbohydrate research to create L-sugars that are not metabolized, but retain sweetness
- Does not stimulate insulin production



- **Objective**
 - Evaluate 15 grams of D-tagatose dosed 3-times daily on glycemic control in subjects with Type 2 diabetes not well controlled by diet and exercise
- **Design**
 - Multi-center, double-blind, placebo-controlled study
 - 494 treatment-naïve patients randomized
 - 34 sites in the U.S., 23 sites in India
 - 102 patients enrolled in the U.S., 254 patients enrolled in India; treated for one year
 - Entry HbA1c between 6.6% and 9.0% (avg. 7.5%)
 - $\leq 6\%$ considered normal, $\geq 8\%$ considered high, ADA recommends $\leq 7\%$
- **Clinical Endpoints**
 - Primary: HbA1c (initially powered for reduction of 0.5%)
 - Secondary: glucose, insulin, lipid profiles, body weight

Favorable Tagatose Top-Line Data

Statistically significant reduction of HbA1c in US ITT and PP at all time points

Reduction in HbA1c Over Time

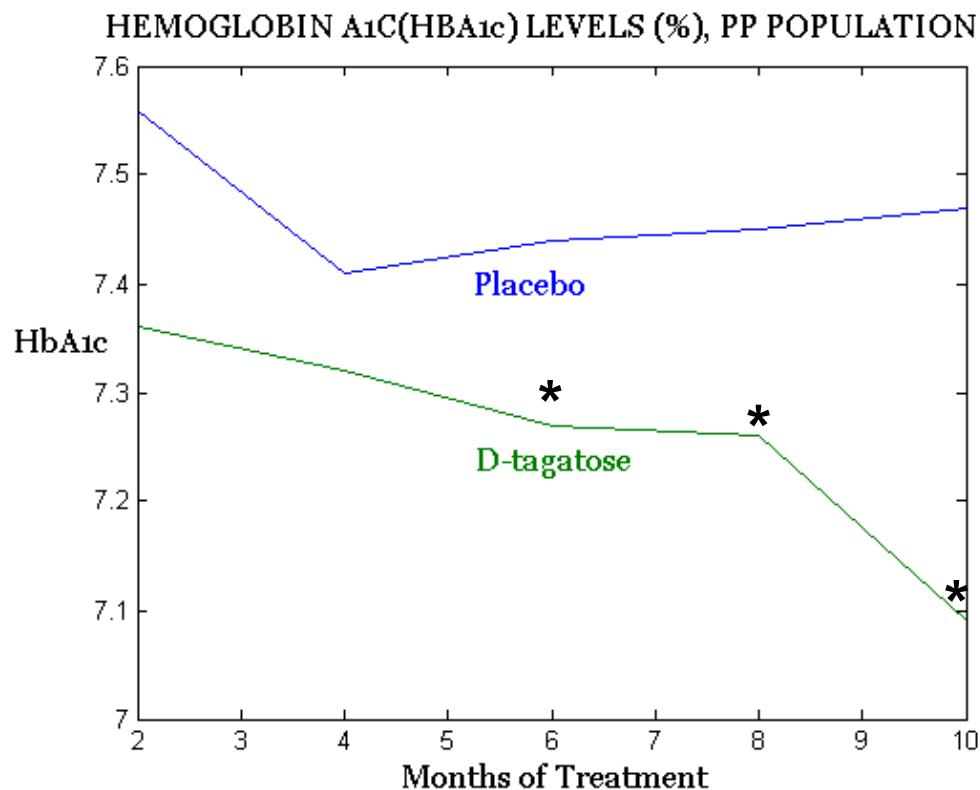
| Patient population | 2 months | 6 months | 10 months |
|----------------------------|---------------|---------------|---------------|
| U.S. PP | -0.4* (n=51) | -0.6* (n=29) | -1.1* (n=20) |
| U.S. ITT LOCF | -0.3* (n=100) | -0.3* (n=101) | -0.4* (n=101) |
| India PP | -0.1 (n=150) | 0.0 (n=117) | -0.2 (n=72) |
| India ITT LOCF | -0.2 (n=253) | -0.1 (n=254) | -0.2* (n=254) |
| Global PP | -0.2 (n=201) | -0.2* (n=146) | -0.4* (n=92) |
| Global ITT LOCF | -0.2* (n=353) | -0.2* (n=355) | -0.2* (n=355) |
| Global ITT (7.5<HbA1c<9.0) | -0.3 (n=175) | 0.1 (n=134) | -0.5* (n=92) |

PP = Per-Protocol; ITT = Intent-to-Treat; LOCF = Last Observation Carried Forward

* p<0.05; all other figures do not have statistical significance

Tagatose Effect on HbA1c: Global Per Protocol vs. Placebo

- **Statistically significant reduction vs. placebo at 6 and 10 months**
 - Diet and exercise may lead to initial drop in the placebo group
- **Decreases in HbA1c in Type 2 diabetics are dependent on baseline HbA1c**
 - Bloomgarden et al., *Diabetes Care*, Vol 29 Number 9 September 2006
- **Patients with HbA1c levels between 8.0 - 9.0% globally showed 0.7% reduction at 10 months of therapy**
 - Per protocol, n=30, p=0.09



* p<0.05

HbA1c and Body Mass Index

| HbA1c | BMI | | TG |
|---|------------|-------|-----------|
| HbA1c | 1 | 0.722 | 0.801 |
| BMI | 0.722 | 1 | 0.718 |
| TG | 0.801 | 0.718 | 1 |
| Values are Pearson product-moment correlation coefficients, $p \leq 0.10$ | | | |

Levels of glycated hemoglobin (HbA1c) are directly correlated to levels of triglycerides (TG) and body mass index (BMI). When one of these measures is elevated, the others are likely to be elevated as well. As a result, hyperphagia could, in effect, lead to “fat cell burn-out”

Diabetes: A Global Health Crisis

- **Diabetes affects >24 million people in the U.S. and ~285 million adults worldwide, and growing significantly^{1,2}**
 - 90-95% of those affected have Type 2 diabetes
- **5th leading cause of death by disease in the U.S.**
- **\$175 billion annually in direct & indirect medical expenses³**
- **Poorly controlled even with aggressive intervention**
 - ~60% of diabetics don't achieve target blood sugar levels with their current treatment⁴
- **Multiple co-morbidities**
 - 85% obesity, cardiovascular problems, renal disease, ophthalmic complications, etc.
- **Up to 57 million Americans have “pre-diabetes”**

¹ International Diabetes Federation Diabetes Atlas. <http://www.diabetesatlas.org/content/some-285-million-people-worldwide-will-live-diabetes-2010>

² Diabetes Statistics. American Diabetes Association. <http://www.diabetes.org/diabetes-basics/diabetes-statistics/>

³ Direct and Indirect Costs of Diabetes in the United States. American Diabetes Association. <http://www.diabetes.org/how-to-help/action/resources/cost-of-diabetes.html>

⁴ Saydah SH, Fradkin J and Cowie CC. Poor control of risk factors for vascular disease among adults with previously diagnosed diabetes. *JAMA*. 2004;291:335-42.

Metabolic syndrome is a combination of medical disorders that increase the risk of developing cardiovascular disease and diabetes. It affects one in five people, and prevalence increases with age.

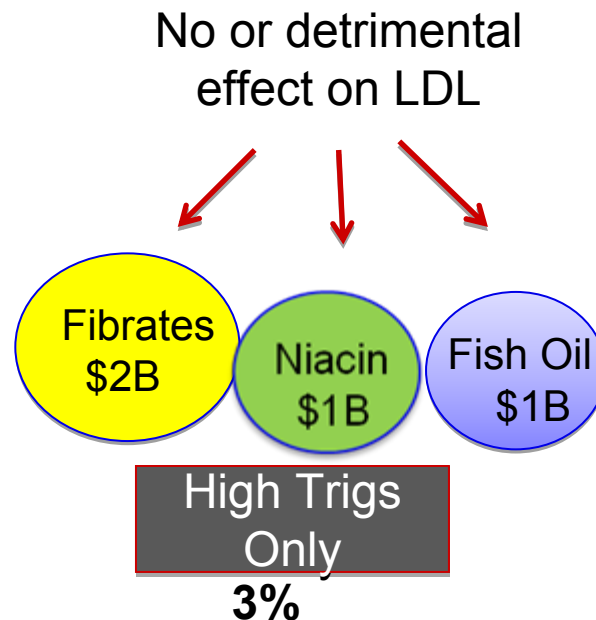
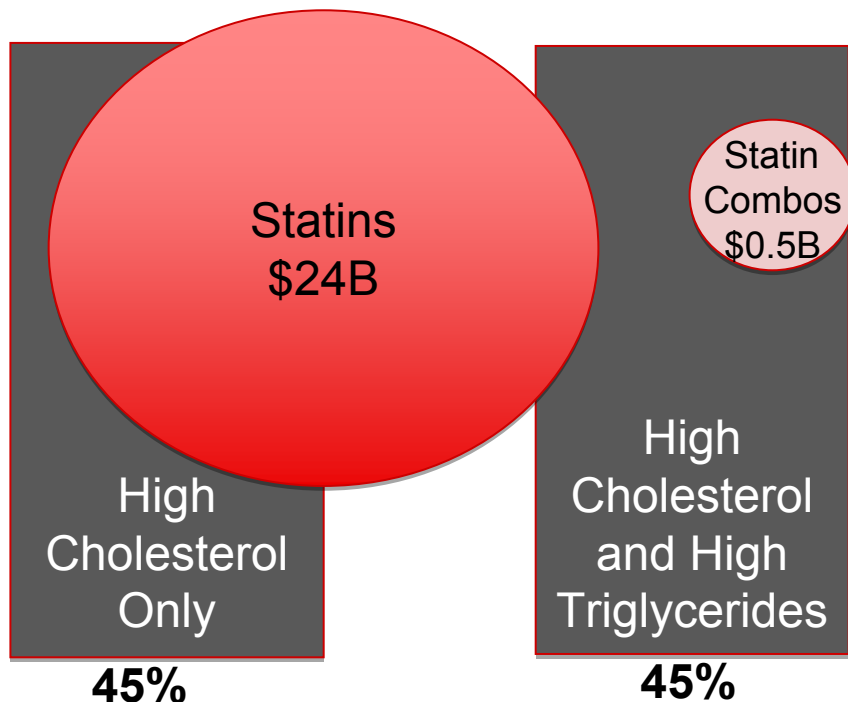
US National Cholesterol Education Program Adult Treatment Panel III (NCEP ATP) (2001) requires at least three of the following:

- ✓ central obesity: waist circumference ≥ 102 cm or 40 inches (male), ≥ 88 cm or 36 inches (female)
- ✓ **dyslipidemia: TG ≥ 1.7 mmol/L (150 mg/dl)**
- ✓ dyslipidemia: HDL-C < 40 mg/dL (male), < 50 mg/dL (female)
- ✓ blood pressure $\geq 130/85$ mmHg
- ✓ fasting plasma glucose ≥ 6.1 mmol/L (110 mg/dl)

1. In the U.S. alone, more than 100 million people have elevated triglycerides, defined as more than 150 mg/dl.
2. Approximately 10 million are poorly served by current drug regimens
3. The U.S. market for triglyceride-lowering drugs is in excess of \$4 billion
4. The path to commercialization is shorter than for an oral antidiabetic drug

Large and Growing Triglyceride Market Opportunity

- A growing epidemic of metabolic syndrome and dyslipidemia supports blockbuster products in an area with limited competition
- Unmet needs still exist due to: adverse events with niacin, lack of robust cardiovascular benefit with fibrates, and unwanted lipid effects of raising the bad LDL cholesterol (fish oils) or decreasing the good HDL cholesterol (fibrates).
- Need new safe agents for use in patients with both high cholesterol and high triglycerides.



- Single-blind study designed to establish the minimum dose capable of causing a beneficial effect, three different doses of D-tagatose
 - Administered to patients orally with meals TID.
 - 2.5, 5.0, and 7.5 g doses. The comparator was the 2.5 g dose. The study was designed with a minimum of 34 patients in each of the three groups for a total of 102 evaluable patients.
 - The primary endpoint for the study was reduction in HbA1c after six months of treatment.

By the end of the six-month trial, the 7.5 g dose reduced serum triglycerides vs. the 2.5 g dose by **-42 mg/dl** from a mean of **180 mg/dl** in the Evaluable Efficacy (EE) population (-23%).

The reduction in serum triglycerides became statistically significant in the Intent-To-Treat (ITT) population at three months of treatment (-31 mg/dl, $p=0.03$) and the reduction essentially held steady at the six-month end-of-study visit (-29 mg/dl).

Unlike other drugs, D-tagatose lowered triglycerides without elevating LDL.

D-tagatose in the 7.5 g dose reduced LDL vs. the 2.5 g dose by -11 mg/dl by the third month of treatment

The reduction essentially held steady at the six-month end-of-study visit (-10 mg/dl). HDL was unchanged, increasing only between 0.3 and 1.4 mg/dl over the entire course of the study vs. comparator.

Analysis of patient subgroups in the U.S. and India with elevated body mass and/or HbA1c is in progress.