

Changing the game in type 2 diabetes treatment: Some drugs not only lower blood glucose but reduce risk of major cardiovascular events.

Boulder, Colorado, December 6, 2017 -- Blomquist & Associates report the high-level results of a comparison study evaluating the cardiovascular benefits of next-generation diabetes drugs for the treatment of Type 2 diabetes (T2DM).

There is growing awareness of the link between diabetes and cardiovascular disease ([Rydén et al., 2013](#)). For some time, it has been known that cardiovascular disease is the leading cause of death for people with T2DM. More than 70% of people with T2DM die of cardiovascular causes ([Laakso 2008](#)).

Since December 2008, the US Food and Drug Administration (FDA) has required randomized clinical trials assessing cardiovascular safety for all new type 2 diabetes drugs entering the US market (See [FDA Guidance for Industry. Diabetes Mellitus – Evaluating Cardiovascular Risk in New Antidiabetic Therapies to Treat Type 2 Diabetes](#)).

Some of the next-generation diabetes drugs for the treatment of T2DM have demonstrated both cardiovascular safety and a cardiovascular benefit (reduction of risk for a cardiovascular event, such as death, heart attack or stroke). The following table shows a high-level view of the cardiovascular (CV) benefit offered by the next-generation drugs.

Table of Next-generation T2DM Drugs and Cardiovascular Benefit

Drug	Class	CV Safety Trial	CV Death Prevention	Heart Attack Prevention	Stroke Prevention
Victoza (liraglutide)	GLP-1	LEADER	+	+	+
Ozempic (semaglutide)	GLP-1	SUSTAIN-6		+	
Invokana (canagliflozin)	SGLT-2	CANVAS	+	+	+
Jardiance (empagliflozin)	SGLT-2	EMPA-REG Outcome	+	+/-	-
Bydureon (exenatide ER)	GLP-1	EXSCEL	-	-	-
Adlyxin / Lyxumia (lixisenatide)	GLP-1	ELIXA	-	-	-
Trulicity (dulaglutide)	GLP-1	REWIND	<i>Results not yet posted</i>		

Although all the drugs (with results) demonstrated CV safety, not all demonstrated a CV benefit (e.g. reduction in risk of death). Some drugs in the GLP-1 class (Bydureon and Adlyxin/Lyxumia) showed no CV benefit, while others (Victoza and Ozempic) demonstrated a significant CV benefit.

Thus far, Jardiance and Victoza have received FDA label extensions on [2016-12-5](#) and [2017-8-25](#), respectively, including an indication for CV benefit.

Diabetes drugs that prove they can not only lower blood sugar, but ward off CV problems may be a game changer in the sizeable, \$35B market for diabetes therapies. This provides a new angle for differentiation of the diabetes agents, and may drive a major shift away from those agents without a demonstrated CV benefit. This view is reflected in a recent “Viewpoint” column by Dr. James Flory published in [JAMA Internal Medicine](#). Dr. Flory questions “Will cardiovascular outcomes data on newer diabetes drugs bury the older agents?”

The [FDA approval](#) of Ozempic, Novo Nordisk’s once weekly GLP-1 diabetes drug, may spell big trouble for Trulicity. In the SUSTAIN-7 head-to-head trial, Ozempic [demonstrated](#) superior reductions in blood sugar and double the weight loss compared to Trulicity.

For questions about Blomquist & Associates’ evaluation of the CV benefit of next-generation diabetes agents, or to discuss specific projects, contact Bob Blomquist at +1.303.786.8310 or bob@blomquist-associates.com.