Evaluate Vantage

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Trulicity needs to pull it out of the bag with heart benefit claim

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As Bernstein analysts put it, Rybelsus getting a cardiovascular risk-reduction claim on its label so soon was always a long shot. The FDA yesterday confirmed that it wanted results from Novo Nordisk's long-term outcome study, Soul, before this accolade can be bestowed on the oral GLP-1 agonist. The agency did, however, allow data from Pioneer 6 on Rybelsus's label; this shorter trial only showed non-inferiority to placebo, with a 21% reduction in Mace failing to hit statistical significance for superiority. Still, the new data should give Rybelsus a boost in the meantime – 21% is impressive compared with other outcome studies in this field. Meanwhile, once-weekly Ozempic – both agents contain the same active ingredient – got its risk-reduction claim thanks to the Sustain 6 result. Trulicity is up next, and Lilly could win an important differentiation if the FDA allows a risk-reduction claim in all type 2 diabetes patients, regardless of prior cardiovascular disease. Rewind was unique in that it recruited subjects without existing heart problems, though the results were far from clear-cut. If the decision goes Lilly's way the company would be handed an advantage when it comes to payer negotiations, a crucial factor in this highly competitive space.

Major type 2 diabetes drugs and the cardiovascular claims

					Sales ($bn)	
Product	**Mechanism**	**Company**	**CV risk reduction claim?**	**Result and study**	**2020e**	**2024e**
Trulicity	Once-weekly GLP-1 agonist	Lilly	Decision due in H1'20	12% reduction in Mace in Rewind	4,797	6,634
Ozempic	Once-weekly GLP-1 agonist	Novo Nordisk	Yes, FDA approved Jan 2020	26% reduction in Mace in Sustain 6	2,819	6,178
Jardiance	SGLT2 inhibitor	Boehringer Ingelheim/Lilly	Yes, FDA approved late 2016	14% reduction in Mace in Empa-Reg	2,498	3,849
Rybelsus	Oral, once-daily GLP-1 agonist	Novo Nordisk	Label describes non-inferiority to placebo	21% risk reduction in Pioneer 6; data from Soul outcome study due 2024.	377	3,305
Farxiga	SGLT2 inhibitor	Astrazeneca	Claim for reduction of risk of hospitalisation for heart failure (hHF)	13% reduction in hHF in Declare-TIMI58	1,913	2,979
Victoza	Once-daily GLP-1 agonist	Novo Nordisk	Yes, FDA approved 2017	13% reduction in Mace in Leader	2,947	1,129
Invokana	SGLT2 inhibitor	Johnson & Johnson	Yes, on label since 2018	14% reduction in Mace in Canvas	668	588
Steglatro	SGLT2 inhibitor	Merck & Co	No	Vertis study should report later this year.	229	520

Source: EvaluatePharma, clinicaltrials.gov