
EMPA-REG OUTCOME: What a label update for Jardiance and Synjardy means for patients and physicians - FDA OPH by Helen Gao - June 28, 2016

Executive Highlights

- Our very own Ms. Helen Gao spoke in favor of a cardiovascular mortality benefit indication for Lilly/BI's Jardiance (empagliflozin) and Synjardy (empagliflozin/metformin) at the [June 28, 2016 FDA Endocrinologic and Metabolic Drugs Advisory Committee](#) meeting.

Good afternoon. My name is Helen Gao, and I'm here today representing The diaTribe Foundation, a diabetes patient advocacy nonprofit based out of San Francisco. Donors to the diaTribe Foundation include the Helmsley Charitable Trust and many others including today's sponsor. By way of disclosures, I also work for Close Concerns, a healthcare information company focused on diabetes and obesity. My colleague Emily Regier will review Close Concerns' disclosures later this afternoon.

Today, I'd like to speak about an updated indication reflecting a cardiovascular benefit for Jardiance in high risk patients and what that could mean for patients and physicians.

I was at the presentation of the full results from EMPA-REG OUTCOME at EASD last September and vividly remember the air of excitement and wonder as the risk reduction for each endpoint was revealed to thunderous applause. It was truly a historic moment.

Coming out of the session, I was surprised and disappointed to see that the results weren't front-page news in the mainstream press. I wondered how the average patient or the average primary care physician - who has so many demands beyond diabetes - would learn of these unprecedented results.

An updated indication clearly stating that Jardiance can reduce mortality in high-risk patients through the reduction of cardiovascular death and heart failure would go far in publicizing this historic and clinically meaningful benefit. A 38% relative risk reduction in cardiovascular death is huge, and patients and healthcare professionals need to know about it.

Furthermore, many patients with type 2 diabetes might not even fully understand the link between diabetes and increased cardiovascular risk. If you put clear language about cardiovascular outcomes on the label of a diabetes drug, you increase the chances of a conversation about that risk between doctors and patients.

For the physicians and patients who are already aware of that cardiovascular risk but have not been able to mitigate it as trial after trial showed little impact on cardiovascular outcomes, Jardiance offers a new hope. It could mean a longer, healthier life with less time spent in hospitals.

That's a big win for patients and a big win for the morale of healthcare professionals. For too long, those in the diabetes field have felt, in the words of the musical Hamilton, "outgunned, outmanned, outnumbered, and outplanned." I sincerely hope that the committee will vote today in favor of letting healthcare providers and patients know that they have one more tool in the fight against diabetes. Thank you.

-- by Helen Gao and Kelly Close