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Pulse of the Market Template

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Sent: Thu 12/8/2016 2:09 PM





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## **Competitive News**

#### FDA approves Jardiance to reduce cardiovascular death in adults with type 2 diabetes

- On December 2, the FDA approved a new indication for Jardiance (empagliflozin) to reduce the risk of cardiovascular death in patients with type 2 diabetes and co-existing cardiovascular disease
- Its benefit for cardiovascular risk reduction was demonstrated in the EMPA-REG trial, results of which were reported in 2015. In announcing the approval, the agency said the "availability of anti-diabetes therapies that can help people live longer by reducing the risk of cardiovascular death is an important advance for adults with type 2 diabetes"
- Implication: After an advisory committee delivered a split vote in June, it was unclear whether the FDA would approve the indication or simply include the EMPA-REG trial in the clinical section of the label. The new indication makes Jardiance the first diabetes drug ever with a cardiovascular claim, which could bode well for the SGLT2 inhibitor class

Source: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm531 517.htm

#### Eli Lilly and Boehringer Ingelheim launch new heart health awareness campaign

- Eli Lilly and Boehringer Ingelheim launched a new disease awareness campaign in November partnering with Dr. Travis Stork, who currently co-hosts the TV show "The Doctors" and is a real-life emergency medicine physician. Stork is also known for his appearance as season 8's bachelor on the popular reality show "The Bachelor"
- The campaign, called "For Your Sweet Heart", seeks to empathize with patients, who may struggle to address daily challenges related to diet and exercise in their everyday lives. The website includes a one-minute video featuring Stork talking about the links between heart disease and diabetes and encourages people to take a risk assessment quiz as well as talk to their doctors
- Implication: The campaign takes a similar approach to the HCP campaign, called "That's Life", which is also targeted at health and lifestyle changes. The launch is timed with the new cardiovascular indication for Jardiance

Source: https://www.foryoursweetheart.com

#### FDA approves 2 new GLP-1/insulin fixed-dose combinations

- The FDA has approved 2 new GLP-1/long-acting insulin combination products — Novo Nordisk's Xultophy (insulin degludec and liraglutide) and Sanofi's Soliqua (insulin glargine and lixisenatide) — for the treatment of adults with type 2 diabetes
- Soliqua 100/33 is a combination of insulin glargine (Lantus) and lixisenatide (Lyxumia/Adlyxin), whereas Xultophy is a combination of insulin degludec (Tresiba) and liraglutide (Victoza); both are indicated as a once-daily treatment. Both Soliqua 100/33 and Xultophy will be available in retail pharmacies in the United States in the first half of 2017
- Implication: As an indication of the fierce competition in the marketplace, Sanofi had previously bought a priority review voucher to leapfrog Novo Nordisk to the finish line with its GLP-1 insulin combination. However, with simultaneous clearance, that voucher didn't pay off as planned, and now Sanofi and Novo Nordisk will be engaged in a tough fight for market share

Source: http://www.news.sanofi.us/2016-11-21-Sanofi-Receives-FDA-Approval-of-Soliqua-100-33-for-the-Treatment-of-Adults-with-Type-2-Diabetes; http://press.nov onordisk-us.com/2016-11-21-Novo-Nordisk-Receives-FDA-Approval-for-Xultophy-100-3-6-insulin-degludec-and-liraglutide-injection

### **Publications**

#### Saad M, Mahmoud AN, Elgendy IY, et al. Cardiovascular outcomes with sodium-glucose cotransporter-2 inhibitors in patients with type II diabetes mellitus: A meta-analysis of placebo-controlled randomized trials

- The investigators performed a meta-analysis of 81 randomized, placebo-controlled trials with SGLT2 inhibitors to evaluate the impact on cardiovascular outcomes in patients with type 2 diabetes
- Compared with placebo, SGLT2 inhibitors were associated with a lower risk of all-cause mortality (OR 0.72; P<0.001), cardiovascular mortality (OR 0.67; P=0.001), and heart failure (OR 0.67; P=0.003), but a similar risk of myocardial infarction (OR 0.89; P=0.29) and stroke/transient ischemic attack (OR 1.09; P=0.47). A reduction in all-cause mortality was noted with empagliflozin (OR 0.66; P<0.001), but not with other SGLT2 inhibitors (dapagliflozin OR 1.37 [P=0.35]; canagliflozin OR 0.82 [P=0.59]; luseogliflozin OR 4.6 [P=0.47]; and ipragliflozin OR 4.73 [P=0.46]). Potential harm was observed with dapagliflozin on cardiovascular mortality (OR 2.15; P=0.08)
- Implication: The authors' conclusion that only empagliflozin is associated with cardiovascular benefit is inherently biased given that empagliflozin is the only SGLT2 inhibitor with cardiovascular outcomes data available. While the impact of this publication is expected to be minor, AstraZeneca should consider training sales reps on any objections raised about the "potential harm" of dapagliflozin as implicated in this metaanalysis

Source: http://www.internationaljournalofcardiology.com/article/S0167-5273(16)33 658-0/abstract

#### Romera I, Gomis R, Crowe S, et al. Empagliflozin in combination with oral agents in young and overweight/obese Type 2 diabetes mellitus patients: A pooled analysis of three randomized trials

- A pooled analysis of 3 Phase 3 trials with patients <65 years</li> old with BMI 25-35 kg/m2 and AIC ≥8% at baseline was performed. A total of 439 patients were randomized to placebo, empagliflozin 10 mg, or empagliflozin 25 mg once daily (24 weeks) as add-on to metformin, to metformin + sulfonylurea, or to pioglitazone ± metformin
- At Week 24, adjusted mean changes from baseline A1C were -0.19% for placebo vs -1.10% and -1.10% for empagliflozin 10 mg and 25 mg, respectively (both P<0.001). Adjusted mean changes from baseline in weight were -0.33 kg for placebo vs -1.94 kg and -2.14 kg for empagliflozin 10 mg and 25 mg, respectively (both P<0.001)
- Implication: The results of this study do not offer any new or surprising insights, but round out the patient types that can benefit from Jardiance

Source: http://www.jdcjournal.com/article/S1056-8727(16)30295-1/abstract

## **Diabetes News**

## Medicare to roll out diabetes prevention program in 2018

- The US Centers for Medicare and Medicaid Services (CMS) has announced that, as of January 1, 2018, it will be expanding the Diabetes Prevention Program (DPP) out from its current pilot program to provide coverage for all eligible at-risk beneficiaries with prediabetes who are ≥65 years of age. Medicare beneficiaries who have had gestational diabetes and are at high risk for developing type 2 diabetes will also be eligible
- One of the key aspects of this rollout will be that, for the first time, CMS will institute reimbursement for diabetes prevention based on this evidence-based program. A cost analysis of the DPP model test by CMS revealed that the program saved an estimated \$2650 per person over a 15month period, which is more than enough to cover the cost of the program Implication: Many clinicians haven't been performing the
- simple blood test to diagnose prediabetes because of the lack of coverage for care. Having an effective and insured treatment to offer should change this practice

Source: https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2 016-Press-releases-items/2016-11-02.html

#### Asian Americans least likely to get screened for diabetes despite higher risk

- Fewer than half of Asian Americans who should be screened for type 2 diabetes get tested, according to a new survey published in the Journal of General Internal Medicine. Researchers at the University of Chicago found that, even after accounting for education, access to healthcare and other key factors, Asian Americans had 34% lower odds of being screened compared to non-Hispanic whites, even though they have rates of diabetes that are nearly double that of non-Hispanic whites The authors report that it's not that Asian Americans are
- averse to screening in general. Although Asian Americans in the study population had lower numbers of colorectal cancer screenings, compared with other ethnic groups, this was not the case for breast cancer screening, which is much more involved than screening for diabetes. The authors surmise that the American Diabetes Association's changes to its guidelines that recommend screening for Asian Americans with a BMI of ≥23 kg/m2 has not filtered down to physicians or the general population Implication: A diabetes awareness campaign targeted to
- Asian Americans may be very beneficial given the deleterious health effects of delayed diagnosis of diabetes

Source: http://link.springer.com/article/10.1007%2Fs11606-016-3913-x



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Sent: Thursday, December 8, 2016 at 7:08 PM To: Litmus

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# **Competitive News**

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- Its benefit for cardiovascular risk reduction was demonstrated in the EMPA-REG trial, results of which were reported in 2015. In announcing the approval, the agency said the "availability of anti-diabetes therapies that can help people live longer by reducing the risk of cardiovascular death is an important advance for adults with type 2 diabetes"
- Implication: After an advisory committee delivered a split vote in June, it was unclear whether the FDA would approve the indication or simply include the EMPA-REG trial in the clinical section of the label. The new indication makes Jardiance the first diabetes drug ever with a cardiovascular claim, which could bode well for the SGLT2 inhibitor class

Source: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm5315 17.htm

### Eli Lilly and Boehringer Ingelheim launch new heart health awareness campaign

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- The campaign, called "For Your Sweet Heart", seeks to empathize with patients, who may struggle to address daily challenges related to diet and exercise in their everyday lives. The website includes a one-minute video featuring Stork talking about the links between heart disease and diabetes and encourages people to take a risk assessment quiz as well as talk to their doctors
- Implication: The campaign takes a similar approach to the HCP campaign, called "That's Life", which is also targeted at health and lifestyle changes. The launch is timed with the new cardiovascular indication for Jardiance

Source: https://www.foryoursweetheart.com

### FDA approves 2 new GLP-1/insulin fixed-dose combinations

- The FDA has approved 2 new GLP-1/long-acting insulin combination products - Novo Nordisk's Xultophy (insulin degludec and liraglutide) and Sanofi's Soliqua (insulin glargine and lixisenatide) — for the treatment of adults with type 2 diabetes
- Soliqua 100/33 is a combination of insulin glargine (Lantus) and lixisenatide (Lyxumia/Adlyxin), whereas Xultophy is a combination of insulin degludec (Tresiba) and liraglutide (Victoza); both are indicated as a once-daily treatment. Both Soliqua 100/33 and Xultophy will be available in retail pharmacies in the United States in the first half of 2017
- Implication: As an indication of the fierce competition in the marketplace, Sanofi had previously bought a priority review voucher to leapfrog Novo Nordisk to the finish line with its GLP-1 insulin combination. However, with simultaneous clearance, that voucher didn't pay off as planned, and now Sanofi and Novo Nordisk will be engaged in a tough fight for market share

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## **Publications**

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- The investigators performed a meta-analysis of 81 randomized, placebo-controlled trials with SGLT2 inhibitors to evaluate the impact on cardiovascular outcomes in patients with type 2 diabetes
- Compared with placebo, SGLT2 inhibitors were associated with a lower risk of all-cause mortality (OR 0.72; P<0.001), cardiovascular mortality (OR 0.67; P=0.001), and heart failure (OR 0.67; P=0.003), but a similar risk of myocardial infarction (OR 0.89; P=0.29) and stroke/transient ischemic attack (OR 1.09; P=0.47). A reduction in all-cause mortality was noted with empagliflozin (OR 0.66; P<0.001), but not with other SGLT2 inhibitors (dapagliflozin OR 1.37 [P=0.35]; canagliflozin OR 0.82 [P=0.59]; luseogliflozin OR 4.6 [P=0.47]; and ipragliflozin OR 4.73 [P=0.46]). Potential harm was observed with dapagliflozin on cardiovascular mortality (OR 2.15; P=0.08)
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### Romera I, Gomis R, Crowe S, et al. Empagliflozin in combination with oral agents in young and overweight/obese Type 2 diabetes mellitus patients: A pooled analysis of three randomized trials

- A pooled analysis of 3 Phase 3 trials with patients <65 years</li> old with BMI 25-35 kg/m2 and AIC ≥8% at baseline was performed. A total of 439 patients were randomized to placebo, empagliflozin 10 mg, or empagliflozin 25 mg once daily (24 weeks) as add-on to metformin, to metformin + sulfonylurea, or to pioglitazone ± metformin
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# **Diabetes News**

### Medicare to roll out diabetes prevention program in 2018 The US Centers for Medicare and Medicaid Services (CMS)

- has announced that, as of January 1, 2018, it will be expanding the Diabetes Prevention Program (DPP) out from its current pilot program to provide coverage for all eligible at-risk beneficiaries with prediabetes who are ≥65 years of age. Medicare beneficiaries who have had gestational diabetes and are at high risk for developing type 2 diabetes will also be eligible One of the key aspects of this rollout will be that, for the first
- time, CMS will institute reimbursement for diabetes prevention based on this evidence-based program. A cost analysis of the DPP model test by CMS revealed that the program saved an estimated \$2650 per person over a 15month period, which is more than enough to cover the cost of the program Implication: Many clinicians haven't been performing the
- simple blood test to diagnose prediabetes because of the lack of coverage for care. Having an effective and insured treatment to offer should change this practice Source: https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/201

6-Press-releases-items/2016-11-02.html Asian Americans least likely to get screened for diabetes

#### despite higher risk Fewer than half of Asian Americans who should be screened for type 2 diabetes get tested, according to a new survey

- published in the Journal of General Internal Medicine. Researchers at the University of Chicago found that, even after accounting for education, access to healthcare and other key factors, Asian Americans had 34% lower odds of being screened compared to non-Hispanic whites, even though they have rates of diabetes that are nearly double that of non-Hispanic whites The authors report that it's not that Asian Americans are
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health effects of delayed diagnosis of diabetes

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# Competitive News

awareness campaign

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### **Publications**

market share

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658-0/abstract

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