Industry Spotlight

Diabetes Drug News

New research shows that an existing type 2 diabetes drug also significantly decreases the risk of other serious conditions. A study published in the *New England Journal of Medicine* demonstrated that the drug canagliflozin, in addition to helping to treat 2 diabetes, also seems to significantly lower the risk of cardiovascular disease (CVD) and kidney disease in patients with diabetes, *Reuters* reported.

Renal-related events specifically were to be measured as part of a post-approval safety exploration of canagliflozin (brand name Invokana and Invokamet, Janssen Pharmaceuticals, a Johnson and Johnson company). The published research combined the new CANVAS-Renal Study, designed to be compared directly with data from the original CANVAS study of 2009 before canagliflozin had achieved FDA approval. The renal outcomes were progression of albuminuria and "the renal composite," a compilation of measures including a 40% reduction in eGFR sustained for at least two consecutive measures, the need for renal replacement therapy (dialysis or transplantation), or death from renal causes.

Progression of albuminuria occurred less frequently among participants assigned to canagliflozin than among those taking placebo (89.4 vs. 128.7 participants with an event per 1000 patient-years). The composite outcome of sustained 40% reduction in eGFR, the need for renal replacement therapy, or death from renal causes occurred less frequently among participants in the canagliflozin group than among those in the placebo group (5.5 vs. 9.0 participants with the outcome per 1000 patient-years).

With regard to the drug's safety, in late May 2017, the FDA issued a Drug Safety Communication about the increased risk of leg and foot amputations with canagliflozin.

A new trial will test a drug candidate in people with type 1 diabetes and diabetic kidney disease (DKD). GKT831 is the lead drug candidate of French biopharmaceutical company Genkyotex. Labiotech.eu noted that an earlier trial of GKT831 for DKD had focused on both the liver and the kidney. The new, dedicated kidney trial will take place in Melbourne, Australia, at the Barker Heart and Diabetes Institute.

Elias Papatheodorou, CEO of Genkyotex, explained to Labiotech that "regarding DKD, we feel that we did not dose long enough. Instead of 12 weeks, we will be treating for 48 weeks. We will also test a higher dose, since we saw a very good safety profile." As part of the study, patients will receive 200 mg of oral GKT831 or placebo twice daily for 48 weeks, the company announced.

Cancer Drug Roundup

Now that positive results from Phase 3 clinical trials have been reported, the European Medicines Agency (EMA) has recommended approval for tivozanib through the EMA's Committee for Medicinal Products for Human Use (CHMP), as treatment for advanced renal cell carcinoma (RCC). The drug, brand named Fotivda (AVEO Pharmaceuticals, Cambridge, MA) could receive a final decision for approval by late August or early September 2017. The US Food and Drug Administration approved the drug in 2013.

EUSA Pharma, a specialty pharmaceutical company based in Hemel Hempstead, UK, that has a distribution network in approximately 40 countries around the world, is poised to distribute tivozanib throughout Europe, South America, and South Africa.

"Tivozanib's unique tolerability profile together with the longest progression-free survival, reported in a Phase 3 first line RCC study, have the potential to fill an unmet patient need for better tolerated treatment in this disease," said Michael Bailey, president and chief executive officer of AVEO. Bailey also noted that the AVEO drug may be on track to become part of a future combination therapy in a Phase 2 trial with Opdivo (nivolumab, Bristol-Myers Squibb, New York, NY).

Bailey said that if the European Commission grants marketing approval for tivozanib, this outcome "would trigger a $4 million research and development reimbursement payment from EUSA (to AVEO)" with possible additional payments of up to 12 million.

The National Health Service in England and Wales has joined Scotland in approving the use of cabozantinib for advanced kidney cancer. The drug, marketed as Cabometyx in the United States, is the second drug for the company Exelixis (South San Francisco, CA).

In late June, researchers reported results of a head-to-head comparison of cabozantinib with everolimus (Afinitor, manufactured by Novartis Pharmaceuticals in East Hanover, NJ). They noted that cabozantinib improved rates of progression-free survival, objective response rate, and overall survival compared with everolimus among patients with advanced renal cell carcinoma regardless of nephrectomy status, according to Phase 3 results of the METEOR trial presented at the American Society of Clinical Oncology Annual Meeting.

An *Investor's Business Daily* profile on Exelixis noted the company was confirming the effectiveness of its breakout compound for treating kidney cancer, posting first-time operating profit, and retiring the majority of its debt.

In late June, AstraZeneca and Hutchison China MediTech announced they had initiated a global late-stage clinical trial of the experimental drug savolitinib in a relatively rare type of kidney cancer. The Phase 3 study will test savolitinib in c-MET-driven papillary renal cell carcinoma.

AstraZeneca will pay China MediTech (Shanghai) $5 million, *Reuters* reported.

FDA nixes Pfizer's Epogen biosimilar and requests a fix

For the second time in 2017, Pfizer has received a disappointing letter about its progress toward FDA approval for a biosimilar product similar to the drug Epogen. The root of the problem lies with manufacturing facilities that may produce the biosimilar, not with the safety or biosimilarity to Epogen, Pfizer notes.

In February 2017 Pfizer received a letter from the FDA that warned about particulate matter (cardboard) in some batches of other drugs manufactured in its facility in McPherson, KS, in 2016. The company responded by taking steps to address the concerns.

On May 25, Pfizer received good news: the FDA Oncologic Drugs Advisory Committee (ODAC) voted to recommend the company's proposed biosimilar for approval. "The ODAC's recommendation was based, in part, on the FDA's briefing materials, which concluded that proposed biosimilar epoetin alfa is highly similar to its reference product, Epogen and Procrit (epoetin alfa), and supports a demonstration that there are no clinically meaningful differences in terms of the safety, purity and potency of the product," Pfizer said.

Regarding the reference product for the biosimilar, a generic form is not yet available. Epoetin is manufactured and marketed by Amgen as band name Epogen. Johnson & Johnson subsidiary Janssen Biotech sells the same drug under the name Procrit, per a product license agreement.

Pfizer announced in late June, however, that it had received an FDA Complete Response Letter (CRL) about the company's Biologics License Application (BLA) for its proposed epoetin alfa biosimilar. This CRL relates to matters noted in the FDA's original warning letter issued in February, following a routine agency inspection of Pfizer.

"The issues noted in the Warning Letter do not relate specifically to the manufacture of epoetin alfa," Pfizer wrote in its announcement about the CRL. "This facility was listed as the potential manufacturing site in the BLA (Biologics Licensee Application) for the proposed epoetin alfa biosimilar."

Fierce Biopharma reported that "the agency couldn't approve the biosimilar because the potential manufacturing site in the BLA for the biosimilar was "the same Hospira unit plant which was responsible for an FDA rejection of Glatopa, the highly anticipated long-lasting generic version of Teva's Copaxone."

Cricket Health and American Kidney Fund to Deliver Education, Support

A new program sponsored by a company that develops technology-based solutions for chronic kidney disease (CKD) will give 100 patients access to new formats for care and education.

Cricket Health, based in San Francisco, along with support from the American Kidney Fund, says it will enroll patients through mid-August into the pilot program. The patients and those close to them can connect with multichannel educational content, virtual healthcare opportunities, and an online community of peers. The partners have designed the program so that CKD patients may better understand their treatment options and plan ahead to ensure an orderly transition to advanced care, for those who progress to end-stage renal disease.

"The lack of timely and comprehensive CKD education represents an enormous missed opportunity to increase rates of home dialysis therapies and kidney transplantation among eligible patients," said Vince Kim, co-founder of Cricket Health. "We are excited to work with a leading advocate like the American Kidney Fund to enhance the quality of life for these patients and demonstrate a better way to provide patients the tools and resources necessary to make enduring decisions about the care and management of their disease."

Cricket Health intends to roll the program out to more patients in the future, based on results of this pilot program, the company announced. The program, called Health Options Patient Education (HOPE), lets patients share information with their caregivers, families, and friends. Multi-channel content—such as video, chat, and written information—accounts for differing styles of learning.

Cricket Health states its goal is to reduce the clinical, psychosocial and economic burdens associated with chronic kidney disease. Cricket Health was co-founded in 2015 by CEO Arvind Rajan, a former senior executive at LinkedIn, and Kim, a former general partner at Aberdare Ventures, a healthcare technology venture capital firm.