AKI Research News

S cientists are making strides in pre-
venting occurrence of acute kidney
injury (AKI) and in evaluating ex-
tensive data on patients who recover from
AKI.
The Department of Veterans Affairs (VA) has
found that it had signed a formal agreement with DeepMind to
gather and analyze data on kidney dis-
case and other conditions. Wired magazine
captured up with the project’s status recently,
and noted that it drew on about 700,000
medical records from veterans. The VA has
been working with DeepMind (owned by
Google’s parent company, Alphabet) to
create software that tries to predict when
patients might develop AKI.
The VA’s director of predictive analyt-
ics, Christopher Nielsen, told Wired that
the project has been “fairly successful in
predicting AKI at an early enough stage to
prevent it.”
The next step may be to use live data from
the VA system to evaluate the accura-
cy of the AKI predictive factors over time,
Wired noted. Then it would be possible to
introduce the system for use in a VA clinic
to see if it helps improve care, a test that is
at least one year away.
Diagnosis and kidney care giant Fresen-
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patient data to learn more about AKI. Of
Fresenius North America outpatient clinics,
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within 90 days of beginning in-center he-
modialysis, according to Fresenius.
Overall, 58% of patients recovered kid-
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Overall, 58% of patients recovered kid-
ney function within 150 days of initiating
outpatient therapy, the company said in a
press release.
The preliminary analysis of the Freseni-
uus data included several clinical measures,
such as type of vascular access used, ultra-
filtration rates, and biochemical measures
during the first 90 days of outpatient di-
lay therapy.
The data also suggested that 20% of
patients who began outpatient in-center
hemodialysis are diagnosed with AKI, and
44% of these patients transition to ESRD
within 150 days of starting outpatient he-
modialysis.
“T his groundbreaking data holds enor-
mous promise for developing further in-
sights into the treatment of acute kidney injury,”
said Frank Maddox, MD, chief medical
officer and executive vice president for
clinical and scientific affairs at Fresenius
Medical Care North America.

Different Fates for two RCC Treatments

One manufacturer has decided not to file
for FDA approval of its renal cell carcino-
ma (RCC) treatment, while another manu-
facturer’s combination of RCC drugs has
won European approval.
Aveo Oncology, based in Cambridge,
MA, decided against filing a new drug
application for tivozanib (brand name
Fortiva) in the United States. The FDA
had informed Aveo that it was unsatisfied
with the drug’s overall survival data, and
that the data failed to improve upon initial
concerns the FDA had when it rejected the
drug in 2013.
In that year, the FDA questioned the
drug’s benefits because data showed that
tivozanib failed to beat the overall survival
rate of Bayer’s drug, Nexavar. FierceBio-
tech reported. An August 2018 analysis of
required data will no longer be Aveo’s final
analysis but rather an interim analysis as
the company continues toward FDA ap-
proval. Fortiva is approved for first-line
therapy of advanced RCC in Europe.
Meanwhile, an RCC treatment that con-
ists of a drug combination was ap-
proved for European patients. Bristol-
Myers Squibb (Princeton, NJ) announced that
the company had approved the combination of its trade-
marked drugs Opdivo (nivolumab) 3 mg/
kg plus Yervoy (ipilimumab) 1 mg/kg
(“low-dose”).
The combination therapy is a first-line
therapy to treat patients with intermedi-
ate- and poor-risk advanced RCC. The
European approval hinged on results from
the CheckMate-214 trial, a phase 3, ran-
donized, open-label study evaluating the
combination of Opdivo plus Yervoy ver-
sus sunitinib in patients with previously
untreated advanced renal cell carcinoma.
The FDA has already approved the com-
bination for certain patients whose cancer
has metastasized.

Industry Spotlight

AKI Research News

VELTASSA® (patiromer) for Oral Suspension

Brief Summary of Prescribing Information. Please see Full Prescribing Information for complete product information.

INDICATION AND USAGE

VELTASSA is indicated for the treatment of hyperkalemia.

Limitation of Use: VELTASSA should not be used as an emergency treatment for life-threatening hyperkalemia because of its delayed onset of action.

CONTRAINDICATIONS

VELTASSA is contraindicated in patients with a history of a hypersensitivity reaction to VELTASSA or any of its components [see Adverse Reactions].

WARNINGS AND PRECAUTIONS

Worsening of Gastrointestinal Motility
Avoid use of VELTASSA in patients with severe constipation, bowel obstruction or impaction, including abdominal post-operative bowel motility disorders, because VELTASSA may be ineffective and may worsen gastrointestinal conditions.

Patients with a history of bowel obstruction or major gastrointestinal surgery, severe gastrointestinal disorders, or swallowing disorders were not included in the clinical studies.

Hypomagnesemia
VELTASSA binds to magnesium in the colon, which can lead to hypomagnesemia. In clinical studies, hypomagnesemia was reported as an adverse reaction in 5.3% of patients treated with VELTASSA [see Adverse Reactions]. Monitor serum magnesium.

Consider magnesium supplementation in patients who develop low serum magnesium levels on VELTASSA.

ADVERSE REACTIONS

The following adverse reaction is discussed in greater detail elsewhere in the label:

• Hypomagnesemia [see Warnings and Precautions]

Clinical Trials Experience
Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of VELTASSA cannot be directly compared to rates in the clinical trials of other drugs and may not reflect the rates observed in practice.

In the safety and efficacy clinical trials, 666 adult patients received at least one dose of VELTASSA, including 219 exposed for at least 6 months and 149 exposed for at least one year. Table 1 provides a summary of the most common adverse reactions occurring in ≥2% of patients in patients treated with VELTASSA in these clinical trials. Most adverse reactions were mild to moderate. Constipation generally resolved during the course of treatment.

Table 1: Adverse Reactions Reported in ≥2% of Patients

<table>
<thead>
<tr>
<th>Adverse Reactions</th>
<th>Patients treated with VELTASSA (N=666)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Constipation</td>
<td>7.2%</td>
</tr>
<tr>
<td>Hypomagnesemia</td>
<td>5.3%</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>4.8%</td>
</tr>
<tr>
<td>Nausea</td>
<td>2.3%</td>
</tr>
<tr>
<td>Abdominal discomfort</td>
<td>2.0%</td>
</tr>
<tr>
<td>Flatulence</td>
<td>2.0%</td>
</tr>
</tbody>
</table>

During the clinical studies, the most commonly reported adverse reactions leading to discontinuation of VELTASSA were gastrointestinal adverse reactions (2.7%), including vomiting (0.8%), diarrhea (0.6%), constipation (0.5%) and flatulence (0.5%). Mild to moderate hyperkalemia reactions were reported in 0.3% of patients treated with VELTASSA in clinical trials. Reactions have included edema of the lips.

Laboratory Abnormalities
Approximately 4.7% of patients in clinical trials developed hypokalemia with a serum potassium value < 3.5 mEq/L. Approximately 3% of patients in clinical trials developed hypomagnesemia with a serum magnesium value < 1.4 mg/dL.

DRUG INTERACTIONS

In clinical trials, VELTASSA decreased systemic exposure of some coadministered oral medications. Binding of VELTASSA to other oral medications could cause decreased gastrointestinal absorption and loss of efficacy when taken close to the time VELTASSA is administered. Administer other oral medications at least 3 hours before or 3 hours after VELTASSA.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

VELTASSA is not absorbed systemically following oral administration and maternal use is not expected to result in fetal risk.

Lactation

Risk Summary

VELTASSA is not absorbed systemically by the mother, so breastfeeding is not expected to result in risk to the infant.

Pediatric Use

Safety and efficacy in pediatric patients have not been established.

Geriatric Use

Of the 666 patients treated with VELTASSA in clinical studies, 59.8% were age 65 and over, and 19.8% were age 75 and over. No overall differences in effectiveness were observed between these patients and younger patients. Patients age 65 and older reported more gastrointestinal adverse reactions than younger patients.

Renal Impairment

Of the 666 patients treated with VELTASSA in clinical studies, 93% had chronic kidney disease (CKD). No special dosing adjustments are needed for patients with renal impairment.

OVERDOSAGE

Doses of VELTASSA in excess of 50.4 grams per day have not been tested. Excessive doses of VELTASSA may result in hypokalemia. Restore serum potassium if hypokalemia occurs.

PATIENT COUNSELING INFORMATION

Drug Interactions

Advice patients who are taking other oral medication to separate the dosing of VELTASSA by at least 3 hours (before or after) [see Drug Interactions].

Dosing Recommendations

Inform patients to take VELTASSA as directed with or without food and adhere to their prescribed diets. Inform patients that VELTASSA should not be heated (e.g., microwaved) or added to heated foods or liquids and should not be taken in its dry form.

Manufactured for:
Reylpya, Inc.
Redwood City, CA 94063
Version 05; May 2018

References: