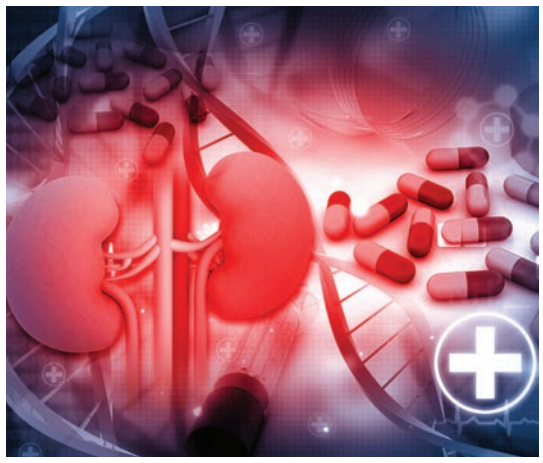
Industry Spotlight



Acute kidney injury news

Two manufacturers reported on recent results in acute kidney injury (AKI) studies.

Biopharmaceutical company AM-Pharma, based in Bunnik, the Netherlands, announced that its phase II STOP-AKI study demonstrated a noteworthy reduction in mortality in a 28-day period. The company is focused on the development of recombinant human alkaline phosphatase (recAP) for the treatment of AKI, ulcerative colitis, and hypophosphatasia. Pfizer acquired a minority interest in AM-Pharma in May 2015 and may acquire the rest of the company through an option.

The 301-patient study compared a treatment group of sepsis patients with AKI with a similar group receiving placebo. Adding recAP to standard of care did not have an effect during week 1 of the study, which was the study's primary endpoint. However, recAP demonstrated a significant and dose-dependent relative reduction in mortality of more than 40% in the treatment group compared with the placebo group. The researchers also reported a significant, progressive, and sustained improvement in renal function over the entire 28-day study period.

Principal investigator Peter Pikkers, chair of experimental intensive care medicine at Radboud University Medical Center, Nijmegen, the Netherlands, presented the data at the International Conference on Advances in Critical Care Nephrology in San Diego in March 2018. He said that the significant improvement demonstrated in survival and kidney function "are very encouraging and strongly support further development of recAP," BioWorld.com reported.

At the same conference, La Jolla Pharmaceutical presented its work, "Outcomes in Patients with Acute Kidney Injury Receiving Angiotensin II for Vasodilatory Shock."

A La Jolla online Power Point presentation refers to Giapreza as a novel vasopressor that is the "first and only synthetic human angiotensin II."

Researchers analyzed the data from 105 AKI patients requiring renal replacement therapy at the initiation of the drug study. Survival through day 28 was 53% for the Giapreza group compared with 30% for the placebo group ($p = 0.012$). By the end of the first week, 38% of patients treated with Giapreza discontinued renal replacement therapy compared with 15% of patients treated with placebo ($p = 0.007$). The study results were published online in *Critical Care Medicine*.

"Acute kidney injury requiring dialysis associated with distributive shock … represents a significant medical risk for patients and a significant financial burden to the healthcare system," said study presenter James Tumlin, MD, professor of medicine at the University of Tennessee at Chattanooga and director of the NephroNet Clinical Trials Consortium. "These analyses of the effect of angiotensin II on AKI patients requiring dialysis in the ATHOS-3 Study demonstrated angiotensin II is a promising therapy to address this unmet need."

DaVita cuts some clinical research jobs

DaVita has cut 38 positions in a clinical research arm of the company based in Minneapolis. The cuts are "part of a company decision to discontinue one of three segments in its clinical research division," a spokesman said in an e-mail to the *Minneapolis Star Tribune*.

The company will be discontinuing its work in "early clinical research" in Minneapolis and also in Denver, according to the *Star Tribune*.

The cuts are a further indication that DaVita will concentrate on its core business, dialysis services. In December 2017, DaVita sold off, for $4.9 billion, its DaVita Medical Group, which joined Optum, part of UnitedHealth Group.

Late in 2017, DaVita Chief Executive Officer Kent Thiry said the company would use the $4.9 billion to buy back stock in the next 2 years, to pay down obligations, and to fund general corporate initiatives. Thiry said the company would "pursue other investments in health care services outside of kidney care" in addition to "focusing on U.S. and international kidney care businesses."

Merck and Eisai sign deal for renal cancer drug

Merck & Co., in Kenilworth, NJ, and Tokyo-based Eisai Co. Ltd. signed a collaboration to develop and sell Eisai's renal cancer drug Lenvima (lenvatinib), a tyrosine kinase inhibitor.

The drug is already approved in many countries for advanced renal cancer and for locally recurrent or metastatic differentiated thyroid cancer.

The terms specify that Lenvima will be developed for several types of cancer as a standalone treatment and in combination with Merck's anti–PD-1 immunotherapeutic agent, Keytruda (pembrolizumab).

In January, the U.S. Food and Drug Administration granted a breakthrough therapy designation for the combination of the two drugs. The data showed that Lenvima in combination with Keytruda led to tumor shrinkage in 63% of patients with advanced kidney cancer, Reuters reported.

A phase III study, sponsored by Eisai, currently is investigating separate combinations of Lenvima with Keytruda or Lenvima with everolimus versus chemotherapy alone for the treatment of renal cell carcinoma, Eisai noted.

Merck and Eisai will split the gross profits generated by Lenvima, the companies agreed in an announcement.

Merck will be entitled to half of all global Lenvima sales revenue, even for its thyroid cancer and combination drug uses, Reuters said.

Merck will also make one-time payments totaling 80 billion yen ($756 million) to Eisai along with development milestone payments, according to the Asia.nikkei.com site. The total may reach 611 billion yen (about $5.77 billion). The deal specifies that much of that amount would be paid before the end of 2021, and most would be contingent, depending on eventual sales.

Eisai shares surged 10% when the deal was reported. The deal reflects the structure of another oncology collaboration Merck entered with AstraZeneca in July 2017.

Seeking ASN Co-Chair for Kidney Health Initiative

Since its establishment in September 2012, Prabir Roy-Chaudhury, MD, PhD, FASN, has served as the American Society of Nephrology (ASN) co-chair of the Kidney Health Initiative (KHI). KHI is a public-private partnership among the ASN, FDA, and nephrology community that aims to bring together nephrologists, industry partners, patient advocacy groups, and regulatory agencies to foster development of drugs, devices, and biologics for people with kidney diseases. Dr. Roy-Chaudhury will complete his term at the end of 2018, and ASN is looking for his successor.

The ASN Co-Chair for KHI serves a three-year term, renewable for one additional term, and reports to the ASN Council. Successful candidates should possess a wide knowledge of and experience in nephrology as well as have a broad understanding of issues facing development of therapies for kidney diseases. Additionally, broad knowledge of the kidney community is ideal. Candidates should also possess strong leadership qualities, vision, organizational abilities, and experience relevant to managing a program similar in size and scope to KHI.

In this role, the Co-Chair assists the Kidney Health Initiative by identifying the needs of KHI members, specifically in the broad areas of therapeutic product innovation and patient safety. The Co-Chair provides guidance and direction to KHI staff, project workgroups, and the KHI Board of Directors regarding strategic input to achieve KHI's vision, mission, and goals. KHI relies on the Co-Chair to attend regularly scheduled meetings on a weekly, monthly, and annual basis with various members, including the FDA. The Co-Chair assists with recruiting new members to join KHI through internal and external networks.

KHI
KIDNEY HEALTH INITIATIVE

The three-year term will start on Tuesday, January 1, 2019, and ASN will provide a competitive stipend to cover the estimated percent effort for the position. The ASN Co-Chair for KHI is supported with full time administrative staff as well as support from ASN departments, such as meetings, marketing, finance, and operations.

To read more about the full roles and responsibilities of the KHI Co-Chair, as well as to review the timeline of the application and selection process, please visit the KHI website at http://www.kidneyhealthinitiative.org.

If you have any questions about the position, or about KHI, please contact Anupam Agarwal, ASN Council Liaison to KHI at aagarwal@uabmc.edu or Melissa West, KHI Project Director at mwest@asn-online.org.