ASN LEADING THE FIGHT AGAINST KIDNEY DISEASE

1510 H Street NW • Suite 800 • Washington, DC 20005
p 202.640.4660 • f 202.637.9793 • www.asn-online.org

Press Release

EMBARGOED FOR RELEASE until July 19, 2018 – 5:00 PM (ET)

Contacts: **Tracy Hampton • (312) 339-9067 • thampton@nasw.org**
Christine Feheley • (202) 640-4638 • cfeheley@asn-online.org

STUDY REVEALS LONG-TERM EFFECTIVENESS OF THERAPY FOR COMMON CAUSE OF KIDNEY FAILURE

Highlights

- Among individuals with autosomal dominant polycystic kidney disease, those who were treated with tolvaptan for up to 11 years had a slower rate of kidney function decline compared with historical controls.
- Annualized kidney function decline rates of tolvaptan-treated patients did not change during follow-up.

Washington, DC (July 19, 2018) — New research provides support for the long-term efficacy of a drug used to treat in patients with autosomal dominant polycystic kidney disease (ADPKD), a common cause of kidney failure. The findings appear in an upcoming issue of the *Clinical Journal of the American Society of Nephrology* (CJASN).

The hormone vasopressin promotes the progression of ADPKD, the fourth leading cause of end stage kidney disease. In the three-year TEMPO 3:4 and in the one-year REPRISE phase 3 clinical trials, tolvaptan (a vasopressin receptor antagonist) slowed the decline of kidney function in patients with ADPKD at early and later stages of chronic kidney disease, respectively. The results suggest that tolvaptan might delay the need for dialysis or kidney transplantation, provided that its effect on kidney function decline is sustained and cumulative over time, beyond the relatively short duration of TEMPO 3:4 and REPRISE. Because all patients participating in these clinical trials were given the opportunity of continuing tolvaptan in an open-label extension study, investigators have now gathered information on the long-term efficacy of tolvaptan.

A team led by Vicente Torres, MD, PhD (Mayo Clinic) retrospectively analyzed information on 97 ADPKD patients treated with tolvaptan for up to 11 years at the Mayo Clinic. Kidney function was measured as estimated glomerular filtration rate (eGFR).

The investigators found that patients treated with tolvaptan had lower eGFR slopes compared with controls (-1.97 vs -3.50 ml/min per 1.73 m^2 per year) and a lower risk of a 33% reduction in eGFR from baseline. Also, the annualized eGFR slopes of patients treated with tolvaptan did not change with the duration of follow-up. The team also compared the eGFR values observed at the last follow-up in the tolvaptan treated patients to the anticipated last follow-up eGFR values, estimated using a previously

validated predictive equation. Differences between observed and predicted eGFRs at last follow-up increased with duration of treatment, suggesting that the beneficial effect of tolvaptan on the eGFR accumulates over time.

“The results of the study suggest that the effect of tolvaptan on eGFR in patients with ADPKD is sustained, cumulative, and consistent with potentially delaying the need of kidney replacement,” said Dr. Torres.

Study co-authors include Marie Edwards; Fouad Chebib, MD; Maria Irazabal, MD; Troy Ofstie, RN, CCRP; Lisa Bungum, CCRP; Andrew Metzger; Sarah Senum; Marie Hogan, MD, PhD; Ziad El-Zoghby, MD; Timothy Kline, PhD; Peter Harris, PhD; and Frank Czerwiec, MD, PhD.

Disclosures: Dr. Torres is a member of the steering committees for the TEMPO and REPRISE clinical trials, has received research support from Otsuka Pharmaceutical, and is a consultant for Vertex, Sanofi-Genzyme, and Palladio. Dr. Czerwiec is an employee of Otsuka Pharmaceuticals. The authors reported no other financial disclosures.

The article, entitled “Long-Term Administration of Tolvaptan in Autosomal Dominant Polycystic Kidney Disease,” will appear online at http://cjasn.asnjournals.org/ on July 19, 2018, doi: 10.2215/CJN.01520218.

# # #

Tweet: Study suggests long-term effectiveness of therapy for common cause of kidney failure.

Facebook: New research provides support for the long-term efficacy of a drug used to treat in patients with autosomal dominant polycystic kidney disease, a common cause of kidney failure. The findings appear in the *Clinical Journal of the American Society of Nephrology*.

Media:
Jessie Fenske fenske.jessica@mayo.edu and
Joe Dangor (Dangor.Yusuf@mayo.edu)