Continued from page 11

VA Center for Innovation Announces Funding for Innovative Kidney Projects

By Ryan Murray

The Department of Veterans Affairs (VA) Center for Innovation (VACII), the innovation hub within the department, recently released a Broad Agency Announcement (BAA). The announcement seeks to source and fund early stage research, development, prototyping, and piloting of innovative ideas in the kidney space.

VA BAA are competitive procedures in which proposals from outside groups are solicited and contracts are awarded for research and development.

One in 6 veterans have chronic kidney disease and more than 13,000 veterans experience kidney failure each year, according to the VA announcement.

To address the need for innovation in kidney disease prevention, care coordination, and treatment, the BAA announced a competition cycle that seeks applications across the following primary topic areas:

- Kidney Disease Prevention and Treatment
- Data Science Advances to Improve Health Care of People with Kidney Disease
- Rehabilitation of Patients with Kidney Failure
- Education for People with or at Risk for Kidney Disease and/or their Caregivers

The VA is seeking solutions that can be developed, tested, and evaluated within a 12–24 month period that will consist of a Development Phase and a Field Test Phase.

No funding has been reserved for this BAA at this time; however, the VA intends to award multiple contracts and has established the following contract funding limits:

- Development Phase—maximum funding of $250,000
- Field Test/Piloting Phase—maximum funding of $500,000
- Combined Development Phase and Field Test/Piloting Phase—maximum funding of $750,000

Rayaldee Making Inroads in its CKD Niche

One year after US Food and Drug Administration (FDA) approval of Rayaldee (calcitriol), Miami-based OPKO Health, Inc. in June 2017 announced new agreements for the drug with several large Medicare Part D (prescription drug coverage) plan sponsors. The drug helps treat secondary hyperparathyroidism (SHPT) in patients with stages 3–4 chronic kidney disease (CKD) and severe renal 25-hydroxyvitamin D less than 30 ng/mL.

The FDA in 2017 issued a complete response letter, indicating deficiencies at OPKO’s third-party contract manufacturer, which were corrected. No issues were cited about the safety, efficacy, or labeling of Rayaldee.

According to OPKO, “approximately 68% of all insurants have access to Rayaldee. The company notes that it is on track to reach 75% of all insured lives by year end.” The company expects to expand its sales force into certain geographic areas as reimbursement is secured.

Continued on page 19