homa City and Chicago, said in a media release that its Archi
memes dialysis system “aims to reduce healthcare expenditures,
 improve patient health, and make it easier for patients to per-
der dialysis at home.”

The majority of funding for this innovation comes from
the Oklahoma-based company 12E. The funding will support
Simurgent as it continues to design the system, manufacture
the device, and perform regulatory testing needed for FDA ap-
proval.

Website Chicagolimo.com interviewed co-founder and
CEO Steve Lindo and learned that the company will be sell-
ing the product directly to dialysis clinics and providers. In this
way, the cost would “be paid for using Medicare budgets allo-
cated to dialysis providers,” Lindo said. The federal healthcare
program would be able to save money on dialysis by shifting
more patients to the home setting, Lindo noted.

While patients would still interface with the machines at
night through implanted catheters, the device features a way to
prevent peritonitis (inflamed abdominal tissue). The machine
would be quieter compared with current home dialysis ma-
achines, which can disrupt sleep, the company notes.

Simurgent has its eye on foreign sales, too, in countries
such as Mexico, China, and India, that would be attracted to a
lower-cost option. In a 2015 Lancet article, investigators noted
that at least 23 million people may have died prematurely from
kidney failure because they could not access life-saving treat-
ment. Most deaths occurred in China, India, Indonesia,
Pakistan, and Nigeria.

Nephrologists may welcome such a new device, as well as other innovations in dialysis. A recent survey of 202 nephrologists by Spheron Global Insights showed that 41% of nephrologists agreed that “there is less opportunity for innovation in my specialty compared to other specialties.” Overall, 48% of nephrologists re-
should that more innovation exists within the non-di-
alysis setting than in the dialysis setting. Nephrologists’
highest priority was for new agents that could slow the
progression of CKD, the survey found.

Anemia News

Rockwell Medical, Inc. (Wixom, MI) announced that
the United States has approved commercial sales of
Dialysate Triferic.

The company is developing multiple formulations
of Triferic for treating anemia in adult hemodialysis
patients. Dialysate Triferic is the first formulation to be
sold. Rockwell expects to file a New Drug Application
(NDA) with the FDA for its next formulation, I.V. Triferic, within the second quarter of 2019, the
company said in a media release.

Rockwell received a preliminary recommendation from
the Centers for Medicare & Medicaid Services (CMS) on April 26, 2019. Receipt of final approv-
al would result in a unique J-code for the powder
packet formulation of Dialysate Triferic (J-codes are
created and used for non-oraly administered medi-
cations and chemotherapy drugs; the code would be
J1444).

“Dialysate Triferic is an innovative physiological-
cal alternative to existing IV iron formulations,” said
Marcos Rothstein, MD, professor of medicine in the
Division of Nephrology at Washington University
School of Medicine. He said the new product does not
increase iron stores and has no ties to any cases
of anaphylaxis. “Additionally, in patients with reticu-
loendothelial (RE) block, it overcomes functional iron
deficiency,” Rothstein said.

Fibrogen, based in San Francisco, has announced
results from a safety analysis of its Roxadustat Global
Phase 3 program and data reports focused on major
adverse cardiovascular events. The phase 3 trials were
conducted by Fibrogen, as well as partners Astel-
las Pharma (Tokyo) and AstraZeneca (Cambridge,
UK) to learn more about its ability to treat anemia
in CKD patients. Patients who participated fell into
two groups: non-dialysis dependent (NDD), pa-
tients new to dialysis, and dialysis-dependent (DDD)
CKD populations. In dialysis patients, roxadustat
was compared with Epogen (epoetin alfa). For pre-
dialysis patients, the study drug was compared with
a placebo.

The pooled findings from the global trials showed
that roxadustat in some instances did not perform
better than the comparison drug/placebo in the area
of cardiac event data. Only in the “incident dialysis”
(new to dialysis) group was the study drug “superior”
to epoetin alfa in the results for “time to first Major
Adverse Cardiac Events (MACE), plus heart failure
requiring hospitalization and unstable angina requir-
ing hospitalization” (MACE+), according to a media
release.

FierceBiotech noted that “After talking to manage-
ment at FibroGen to unpack a very complex dataset,”
analysts at Jeffries think the readout is far better than
investors feared initially and ultimately a positive for
the biotech company and its partners, AstraZeneca
and Astellas.” Jeffries is an investment banking firm.

The European Medicines Agency (EMA) noted
that the primary safety assessment should be for the
MACE+ category before approval. For a planned
NDA submission to the FDA, one of the key safety
endpoints is MACE. [1]