An Interview with Kerry Cooper, MD, Vice President, U.S. Medical Affairs, Renal, AstraZeneca

THE “R” FOR RENAL WAS RECENTLY ADDED TO ONE OF ASTRazeneca’s THERAPEUTIC AREAS. WHAT LED TO THIS ADDITION OF “RENAL” TO THE CARDIO PLUS METABOLIC AREA?

As a global organization, we show up as one therapeutic area—cardiovascular, renal, and metabolism or “CVRM.” With our expertise over time in this space, we recognize that science has uncovered commonalities between cardiovascular, renal, and metabolic diseases and their associated complications. Yet in many cases, each condition is managed in isolation.

Our portfolio approach allows us to uncover the interconnectedness of these diseases and additional comorbidities to treat the patient as a whole. We believe that our existing portfolio and scientific approach position us to tackle multiple unmet needs for patients and treat them along the spectrum of their disease overall.

We do recognize that while globally we are positioned the way we know there is a need to prioritize bringing new medicines to patients in the renal space swiftly to address some of the gaps that exist today in parallel with our overall CVRM approach. We are proud to continue to advance science and elevate the discussion around making a meaningful difference to innovate in the renal space. We feel as an organization we have a responsibility to prioritize these efforts to shift the dialogue on the way CKD is treated today and the possibility for greater advancements today and in the future.

TALK ABOUT THE PATIENTS WHO WILL BE THE INTENDED GROUP FOR YOUR RENAL-CARDIO PRODUCTS.

As an organization, we believe in building a portfolio that can make a meaningful difference for all patients living with CKD. With an estimated 30 million Americans affected by this disease, we recognize an obligation to advance science and innovate to help fill substantial gaps in unmet needs that exist today.

This includes looking at the full treatment scope of CKD and its associated complications. It is our perception that these patients need and deserve more to help them navigate the vast complexities that fill their everyday lives. We know that the majority of patients managing their CKD are not managing it alone and that their lives are confounded by multiple comorbidities, such as diabetes and heart disease as well as complications from CKD, including hyperkalemia and anemia, that have a tremendous impact.

As a result, patients lead complex lives filled with making daily tradeoffs for their health, which affects their quality of life and ultimately increases risk for further complications. We must continue to deliver research in new drug therapies that can tackle the significant unmet needs that exist for these patients today. This is truly what drives us in everything we do.

WHAT IS THE HIERARCHY OF IMPORTANCE OF THE ASTRazeneca RENAL PORTFOLIO OF PRODUCTS NOW AND IN THE COMING YEAR?

It is our ambition to deliver across three core areas in renal disease over time. We first aim to address unmet needs that exist today in managing complications that impact CKD patients—in particular, with hyperkalemia and anemia. In parallel, we are investing in research that can intervene earlier and potentially slow progression of the disease—for which there are no treatments today. Ultimately our goal is to work to innovate in CKD and address residual risks and prevent organ damage in CKD while targeting specific patient populations to consider further advancements.

Approved for the treatment of hyperkalemia in adults, LOXELMA is an innovative, highly selective potassium binder with a unique structure that is designed to be highly selective and works in the gastrointestinal tract (GI) tract, resulting in early capture of potassium, providing rapid and sustained results for patients. In the US, only about 10% of patients are treated for their high potassium today, and recognizing the substantial consequences that can be associated with uncontrolled potassium levels, we believe that increased awareness and diagnosis of high potassium, coupled with the availability of LOXELMA, will help to shed light on hyperkalemia as a chronic condition and options to treat it in the long term.

Through a joint partnership with FibroGen Inc., we continue to research and develop roxadustat, a potential first-in-class hypoxia inducible factor prolyl hydroxylase inhibitor (HIF-PHI), which is in phase 3 trials for the treatment of anemia associated with CKD in dialysis-dependent (DD) and non-dialysis-dependent (NDD) patients. In December 2018, FibroGen and AstraZeneca both disclosed positive pipelime efficacy data from several phase 3 trials, and we anticipate further updates from the phase 3 pivotal program for roxadustat upon final review of the totality of evidence in the first half of 2019.

While both of these examples provide details into our portfolio and pipeline today, we have robust plans for continued research in the future so we can continue to innovate in the renal space to identify potential solutions that can change how we understand and treat across the paradigm.

Another example of this is within the sodium glucose co-transporter (SGLT-2) class of medicines that is indicated to treat type 2 diabetes. We recently communicated results from DECLARE-TIMI 58, the largest SGLT-2 inhibitor cardiovascular outcomes trial conducted to date, which showed that FARXIGA (dapagliflozin) significantly reduced the risk of hospitalization for heart failure or cardiovascular death composite vs. placebo by 17%. And, although nominally significant, the renal composite endpoint showed that FARXIGA reduced the rate of new or worsening nephropa- thy by 24% vs. placebo across the broad patient population studied.

To further understand the impact FARXIGA may have on the estimated 200 million people worldwide living with CKD, we look forward to completing the DAPA-CKD Outcomes Trial, a study in CKD patients both with and without diabetes, in 2020.

Looking at the entire pharmaceutical spectrum, is kidney medicine a concern across the board in the Pharma industry?

I believe there is no greater time than now to bring research and medicines to the forefront for kidney disease, and that this is truly an opportunity vs. a concern. We continue to see more and more energy put forth toward navigating this treatment paradigm.

Further, we are pleased to see that this space continues to be recognized by government bodies, in particular with the Advancing American Kidney Health initiative, and additional efforts by the Centers for Medicare & Medicaid Services and the U.S. Department of Health and Human Services, which have specifically called out the need for greater innovations in the advancement of therapy for kidney disease. The agencies have begun to identify opportunities to recognize and reward initiatives that patients have access to them. As an organization committed to this space, it is our belief that we must continue to support and encourage all research that can ultimately make a difference for the millions of patients living with chronic kidney disease.

When you say there has been little innovation in the renal area, are you referencing CKD specifically or renal complications or pathways?

As you are aware, renal disease is a high complexity, specialized area. As a nephrologist, I had the opportunity to practice at a time when we saw some significant advancements in managing complications for chronic kidney disease patients.

However, I also recognize that given the complexity of this space, the investment it takes and at times, much trial and error in research, the progress for which we should be serving such an urgent medical need has lagged in comparison to advancements in other disease areas.

I am more encouraged than I have ever been that now is the time to innovate and raise awareness of how we can tackle CKD as a whole and ultimately work to slow the progression of CKD for patients. We are innovating across many facets of the scope of renal, whether it be tackling complications through approved products and in our late-stage pipeline, continuing life-cycle management for our inline products to understand potential in slowing progression of disease, or as a robust early stage pipeline, which will aim to uncover further research in targeting chronic kidney disease and its associated complications.

Do you think someday—even in the near future—kidneys will be considered as vital as the heart and lungs are today?

As a former practicing nephrologist and with over 20 years in the industry, I certainly hope so. I joined this company because of its belief in emphasizing the criticality of treating the kidney. With the expected advancements and research on the horizon alone from our pipeline, I do believe it will put forth greater awareness for the importance of innovating to advance treatments for kidney disease.

We must continue to hold ourselves accountable to make this a reality and drive positive change in the industry, working with our partners and allies to advocate for the importance of continued science and awareness in renal disease. We are all in to make this ambition a reality. It is our hope that we can rewrite the story behind kidney disease and the way it’s managed today, revolutionize care with significant scientific advancements, and ultimately shift the dialogue to deliver a greater future for those we serve.

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