A New Era for FSGS Treatment

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SPHERIX GLOBAL INSIGHTS

Background:

Focal Segmental Glomerulosclerosis (FSGS) is one of the most prevalent glomerular diseases seen by nephrologists, affecting an estimated ~40,000 people in the United States. There are currently no approved treatments for FSGS, leaving nephrologists with few options to help manage their patient's disease progression.

Methodology:

Data from 102 U.S. nephrologists were collected in August 2024 via an online survey. Additionally, patient records from 518 non-dialysis patients were collected in partnership with 161 U.S. nephrologists via an online, HIPAA-compliant survey in March through April 2025.

Acknowledgements:

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Disclosures:

Ellie McClatchy and Jennifer LaFave are employees of Spherix Global Insights, an independent market intelligence firm and have received no industry funding to conduct and report on this study.

Figure 1

Unmet Needs for New Pharmacologic Treatment Options

Mean rating (Scale: 1-10)

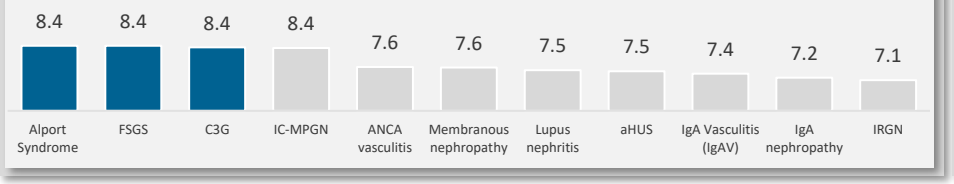


Figure 2

Top 3 Challenges in FSGS Management

% of respondents

Nephrologists consider approximately 57% of their primary FSGS patients to be "**optimally managed**"

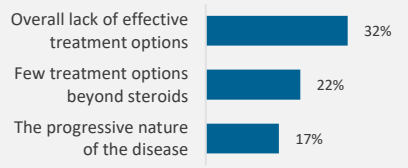


Figure 3

Currently Prescribed SGLT2 Inhibitors

% of patients

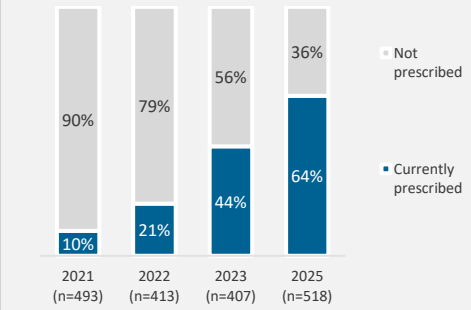


Figure 4

Top Reasons for SGLT2 Inhibitor Use

% of SGLT2i treated patients

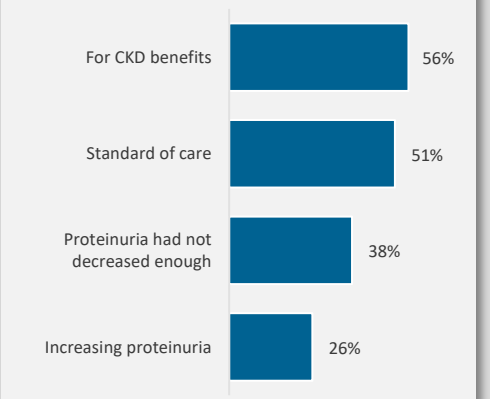
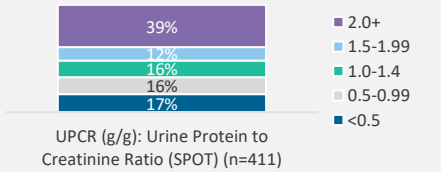


Figure 5

Lab Value Distributions

% of patients



UPCR (g/g): Urine Protein to Creatinine Ratio (SPOT) (n=411)

Figure 6

"Proteinuria is highly correlated with ESRD outcomes in FSGS"

% of respondents

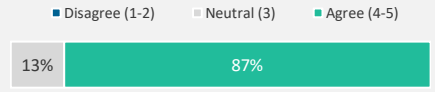


Figure 7

Progression to Dialysis

% of patients

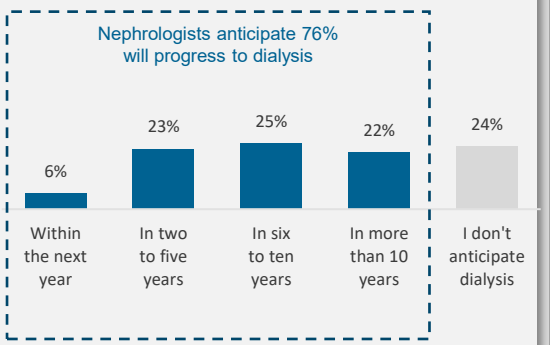


Figure 8

Most Desired Attributes in a New FSGS Treatment

% of respondents

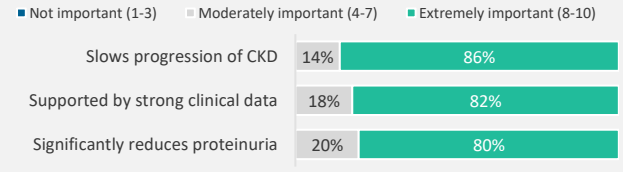


Figure 9

"If a pipeline product is being developed for multiple glomerular diseases, clinical trial data from other indications would likely impact my future use of a drug if it is approved for FSGS and vice versa"

% of respondents

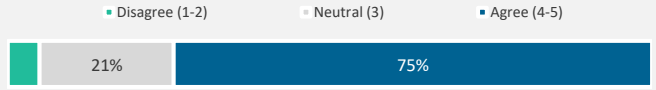
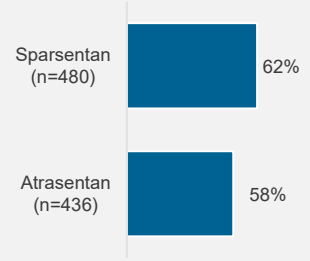


Figure 10

Patient Candidacy for Pipeline FSGS Products

% of patients; rating high (4-5) on patient candidacy



Results:

Nephrologists rank FSGS among the top three rare kidney diseases with sizable unmet therapeutic needs. They report just 57% of their non-dialysis FSGS patients are "optimally managed" and consider the lack of effective treatment options (32%), few treatment options beyond steroids (22%), and the progressive nature of the disease (17%) to be their greatest challenges (Fig. 1-2).

In the absence of any approved therapies, nephrologists have increased their use of SGLT2 inhibitors (64% of patients are now on SGLT2is vs. 10% in 2021). SGLT2is are being used for their CKD benefits (56%), as standard care (51%), and to reduce proteinuria (38%) (Fig. 3-4). However, patients continue to present with elevated UPCR levels (67% >1.0g/g), which is perceived to be highly correlated with ESRD outcomes in FSGS patients (87% agreement) and 76% are expected to progress to dialysis within 10 years (Fig.5-7).

Physicians are eager to prescribe new targeted FSGS pipeline agents upon their approval. When deciding to use a new therapy, physicians prioritize strong clinical data supporting reduction of proteinuria and improving eGFR slope. Most nephrologists (75%) agree that when pipeline products are in development for multiple glomerular diseases, clinical trial data from other indications will impact its future use pending FSGS approval – presenting an advantage for sparsentan and atrasentan which are already approved for IgAN (Fig. 8-10). Participating nephrologists currently estimate 60% of their FSGS patients will be candidates for sparsentan and 58% for atrasentan, if/when they are approved and available.

Conclusion:

Nephrologists are eager to begin using new FSGS treatment options and will look to clinical trial data (for FSGS and other glomerular diseases if available) that prove efficacy in reducing proteinuria and slowing eGFR decline.

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