News Release

Chugai Files New Drug Application in Japan for Sparsentan for the Treatment of IgA Nephropathy

TOKYO, June 19, 2026 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced today that it filed a regulatory application with the Ministry of Health, Labour and Welfare for sparsentan for the treatment of patients with IgA nephropathy.

“In IgA nephropathy, a designated intractable disease, there are patients in whom proteinuria is not adequately controlled with existing treatments, and long-term decline in kidney function has remained an unmet challenge. Sparsentan has a novel mechanism of action that inhibits both the endothelin receptor and angiotensin II receptor, and has demonstrated a significant reduction in proteinuria in clinical studies, with results suggesting a potential benefit in preserving kidney function. Together with the convenience of once-daily dosing, we aim to support long-term disease management for patients and contribute to establishing a treatment foundation for IgA nephropathy,” said Dr. Osamu Okuda, President and CEO of Chugai.

This application is based on the results from the global Phase III study (the PROTECT study) conducted outside of Japan and Japanese Phase III study (the RE-021-001 study), both conducted in patients with IgA nephropathy with persistent presence of proteinuria.

In the global Phase III study (PROTECT study), sparsentan demonstrated a statistically significant improvement in the primary endpoint—the percent change from baseline in urine protein/creatinine ratio (UPCR) at Week 36—compared with the active control irbesartan (-49.8% vs -15.1%, $p<0.0001$). In addition, results of the key secondary endpoint, the total slope of estimated glomerular filtration rate (eGFR) over time, suggested a potential long-term benefit in preserving kidney function. Sparsentan was generally well tolerated, and its safety profile was consistent with data from previous clinical studies. In the sparsentan group, treatment-emergent adverse events observed during the double-blind period included hypotension, hyperkalemia, dizziness, and peripheral edema.

In the Japanese Phase III study (the RE-021-001 study), the primary endpoint—the percent change from baseline in urine protein/creatinine ratio (UPCR) at Week 36—achieved -58.5% reduction, consistent with the findings from the global Phase III study (the PROTECT study), demonstrating efficacy in Japanese patients. The safety profile was consistent with previously known findings, and no new safety signals specific to Japanese patients were identified.

[Reference]
Notice Concerning Making Renalys Pharma, Inc. a Wholly-Owned Subsidiary (News release issued on Oct 24, 2025)

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About global Phase III study (the PROTECT study)
The PROTECT study is an international, multicenter, double-blind, active-controlled trial conducted by Travere Therapeutics outside Japan, in patients with IgA nephropathy who have persistent overt proteinuria despite treatment with angiotensin-converting enzyme (ACE) inhibitors or angiotensin II receptor blockers (ARBs). The primary endpoint was the percent change from baseline in urine protein/creatinine ratio (UPCR) at Week 36. Key secondary endpoints included the slope of eGFR from Week 6 to Week 110 and from Day 1 to Week 110.

About Japanese Phase III study (the RE-021-001 study)
The RE-021-001 study is a multicenter, open-label, single-arm Phase III clinical trial conducted in Japan to evaluate the efficacy and safety of sparsentan in Japanese patients with IgA nephropathy. A total of 35 patients were enrolled in the study. The primary endpoint was the percent change from baseline in the urine protein/creatinine ratio (UPCR) at Week 36. Secondary endpoints included the change in eGFR at two years and safety assessments.

About sparsentan
Sparsentan is an oral, small molecule that inhibits both endothelin receptor type A (ETAR) and angiotensin II type 1 receptor (AT1R) in a single molecule. By simultaneously inhibiting the endothelin pathway in addition to the renin–angiotensin (RA) system, Sparsentan has been shown to provide a more potent reduction in proteinuria, while maintaining once-daily dosing similar to conventional RA system inhibitors.

Sparsentan was granted full approval as FILSPARI for the treatment of IgA nephropathy in the United States in September 2024 and standard marketing authorization in Europe in April 2025, based on efficacy and safety data from the global Phase III study (the PROTECT study) in adults with IgA nephropathy conducted in 18 countries, including South Korea and Taiwan. In addition, in April 2026, FILSPARI was approved in the United States to reduce proteinuria in adult and pediatric patients 8 years and older with focal segmental glomerulosclerosis (FSGS) without nephrotic syndrome. FSGS is a rare kidney disease also characterized by elevated proteinuria.

About IgA Nephropathy
IgA nephropathy (designated intractable disease No. 66) is a type of chronic glomerulonephritis characterized by the persistent presence of hematuria and proteinuria, caused by the deposition of abnormal immunoglobulin A (glycosylation-aberrant IgA) in the glomeruli of the kidneys[1]. Disease progression can lead to a decline in kidney function, and kidney transplantation or dialysis may become necessary when end-

stage renal disease occurs[2]. In Japan, the number of patients is estimated to be approximately 33,000[3], and it is known that nearly 40% of patients progress to end-stage renal disease within 20 years of diagnosis[4]. Existing treatments, such as renin–angiotensin (RA) system inhibitors or corticosteroids, may not sufficiently prevent disease progression in some patients, highlighting the need for new treatment options with greater efficacy.

Sources

1. Japan Intractable Diseases Information Center. IgA nephropathy (designated intractable disease 66) [Internet; cited June 2026]. Partially modified from: https://www.nanbyou.or.jp/ (in Japanese only)
2. Evidence-based Clinical Practice Guidelines for IgA Nephropathy 2020 Available from: https://jsn.or.jp/academicinfo/report/evidence_IgA_guideline2020.pdf [Intern et; cited June 2026]. (in Japanese only)
3. Japan Intractable Diseases Information Center. IgA nephropathy (designated intractable disease 66) [Internet; cited June 2026]. Partially modified from: https://www.nanbyou.or.jp/ (in Japanese only)
4. Evidence-based Clinical Practice Guidelines for IgA Nephropathy 2020 Available from: https://jsn.or.jp/academicinfo/report/evidence_IgA_guideline2020.pdf [Intern et; cited June 2026]. (in Japanese only)

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