

ASX Announcement

5 October, 2026
Melbourne, Australia

CSL enters exclusive agreement for rare kidney and liver disease treatment

CSL Limited (ASX:CSL; USOTC:CSLLY) today announces it has entered into an agreement with Alentis Therapeutics to co-develop and co-promote lixudebart, a potential first-in-class treatment for people with rare kidney and liver disease.

Lixudebart is currently being evaluated in an ongoing Phase 2 trial in patients with ANCA-associated vasculitis and rapidly progressive glomerulonephritis (AAV-RPGN), a rare and potentially life-threatening auto-immune disease that can cause irreversible kidney damage and end-stage renal disease. It has a novel mode of action designed to target both inflammation and fibrosis, two key drivers of long-term organ injury.

"We believe lixudebart has the potential to become an important new therapeutic option to help improve kidney function and prevent progression to end-stage kidney disease," said Dr Bill Mezzanotte, Executive Vice President, Head of R&D, CSL. "Our collaboration with Alentis reflects CSL's commitment to building a leading global nephrology franchise, and our strategic intent to create high-value external partnerships."

In addition to AAV-RPGN, CSL and Alentis plan to advance lixudebart as a potential treatment for focal segmental glomerulosclerosis (FSGS), a chronic kidney disease, and primary sclerosing cholangitis (PSC), a chronic liver disease for which there is currently no available therapy.

CSL will make an initial payment to Alentis of US\$355 million, with Alentis eligible to receive up to an additional US\$1.2 billion in commercial milestone payments. In addition to these payments, CSL will fully fund the completion of the ongoing Phase 2 RENAL trial and planned Phase 3 trial in AAV-RPGN, the Phase 2 trials in FSGS and PSC and other supporting development activities. Once commercialised, global profits will be shared 55 per cent to CSL and 45 per cent to Alentis.

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About AAV-RPGN

ANCA (antineutrophil cytoplasmic antibodies) -associated vasculitis with rapidly progressive glomerulonephritis (AAV-RPGN) is a rare, severe and potentially fatal autoimmune disease in which the body's immune system attacks small blood vessels in the kidney. RPGN is characterized by rapid loss of kidney function over a very short period (days to weeks). Despite potent immunosuppressive treatment, most patients develop significant or total loss of kidney function.

About Lixudebart

Lixudebart (formerly known as ALE.F02) is an investigational monoclonal antibody that selectively targets exposed claudin-1, a key driver of inflammatory and fibrotic signalling pathways in numerous fibrotic diseases of the kidney, liver, lung, intestine and other solid organs. In an interim analysis of 26 patients with AAV-RPGN in the ongoing Phase 2 RENAL trial, lixudebart showed promising improvement in kidney function as assessed by eGFR and proteinuria at 24 weeks. In the Phase 1b FEGATO trial in 41 patients with advanced F3/F4 liver fibrosis, lixudebart demonstrated improved liver function at 6 weeks. In both studies lixudebart showed dose-dependent claudin-1 target engagement, along with a favourable safety and tolerability profile. Lixudebart has been granted Orphan Drug designation by the FDA for the treatment of Idiopathic Pulmonary Fibrosis (IPF).
