

November 5, 2025



Processa Pharmaceuticals Announces Poster Presentation of Adaptive Phase 2/3 PCS499 Study in FSGS at ASN Kidney Week 2025

VERO BEACH, Fla., Nov. 05, 2025 (GLOBE NEWSWIRE) -- Processa Pharmaceuticals, Inc. (Nasdaq: PCSA), a clinical-stage biopharmaceutical company developing Next Generation Cancer (NGC) therapies and innovative treatments for rare diseases, today announced that its abstract, "*Adaptive Phase 2/3 Study for PCS499 (499) in Patients with Focal Segmental Glomerulosclerosis (FSGS)*", has been accepted for presentation at the American Society of Nephrology (ASN) Kidney Week 2025, taking place November 5–9, 2025, in Houston, Texas.

The poster will be presented as part of the session "*Glomerular Clinical Trials: From Data to Impact*" on Friday, November 7, 2025, from 10:00 a.m. to 12:00 p.m. Central Time. The poster board number is FR-PO0829.

PCS499 is an analog of a metabolite of pentoxifylline (PTX). PTX has been shown to decrease proteinuria in clinical studies with CKD patients but the dose limiting side effects limits its use. PCS499 has demonstrated a favorable safety profile over PTX allowing for a higher dose and potentially greater therapeutic benefit in rare kidney diseases such as FSGS, a serious condition with limited treatment options. The adaptive Phase 2/3 design that Processa will be discussing with FDA later this year and presenting at ASN aims to optimize dosing and accelerate the path toward regulatory approval.

"We are honored to present our PCS499 program at ASN Kidney Week, the premier forum for advancing kidney disease research and patient care," said David Young, Pharm.D., Ph.D., President of Research and Development at Processa Pharmaceuticals. "This adaptive Phase 2/3 study represents a critical step in addressing the urgent need for safer, more effective therapies for patients with FSGS. We believe PCS499 has the potential to significantly improve patient outcomes in this underserved population."

About FSGS

Focal Segmental Glomerulosclerosis is a rare, progressive kidney disease characterized by scarring in the kidney's filtering units, often leading to end-stage renal disease. There are currently no FDA-approved therapies specifically indicated for FSGS, underscoring the urgent need for new treatment options.

About Processa Pharmaceuticals, Inc.

Processa is a clinical-stage pharmaceutical company focused on developing the Next Generation Cancer (NGC) drugs with improved safety and efficacy. Processa's NGC drugs are modifications of existing FDA-approved oncology therapies resulting in an alteration of

the metabolism and/or distribution of these drugs while maintaining the existing mechanisms of killing the cancer cells. By combining its novel oncology pipeline with proven cancer-killing active molecules and its Regulatory Science Approach, Processa's strategy is to develop more effective therapy options with improved tolerability for cancer patients through an efficient regulatory path. In addition to its core oncology programs, Processa is actively pursuing strategic partnerships for non-oncology assets to unlock additional value

For more information, visit our website at www.processapharma.com.

Forward-Looking Statements

This release contains forward-looking statements. The statements in this press release that are not purely historical are forward-looking statements which involve risks and uncertainties. Actual future performance outcomes and results may differ materially from those expressed in forward-looking statements. Please refer to the documents filed by Processa Pharmaceuticals with the SEC, specifically the most recent reports on Forms 10-K and 10-Q, which identify important risk factors which could cause actual results to differ from those contained in the forward-looking statements.

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