

Lutroo Imaging Begins Phase 1 Clinical Trial of Radiocaine™, a First-in-Class PET Radiotracer for Pain Imaging

Study marks first-in-human use of Radiocaine™ to image pain-related sodium channels with positron emission tomography (PET)



Lutroo Imaging
Seeing pain for the first time

PALO ALTO, CA, UNITED STATES, July 1, 2025 /EINPresswire.com/ -- [Lutroo Imaging](https://www.lutrooimaging.com),

a clinical-stage molecular imaging company, announced that the first subject has been dosed in a Phase 1 clinical trial of Radiocaine™, the company's investigational PET radiotracer being developed for pain imaging.

Radiocaine™ is the first PET tracer specifically designed to visualize pain-related sodium channels in peripheral nerves, aiming to revolutionize how pain is diagnosed and treated. The first-in-human study is being conducted under an FDA Investigational New Drug application (IND). "Dosing our first human subject is a major step forward," said Dr. P. David Mozley, Chief Medical Officer at Lutroo Imaging. "Radiocaine™ has the potential to transform how we detect and understand pain by allowing clinicians to see what's currently invisible."

Key Study Details:

- First-in-human Phase 1 clinical trial conducted under an IND
- Open-label study assessing safety, biodistribution, and radiation dosimetry
- Radiocaine™ targets voltage-gated sodium channels, which are involved in pain signaling
- Fluorine-18 (18F) labeling enables high-resolution, precision PET imaging

Radiocaine™ is being developed for pain visualization, localization of the pain source, and objective measurement. With more than 50 million U.S. adults living with chronic pain--and no existing technology capable of visualizing pain--Radiocaine™ could potentially fill a critical unmet need in both clinical care and drug development. The ongoing opioid crisis underscores the urgency of developing safer, more targeted approaches to pain management, beginning with the ability to accurately detect and measure pain.

Preclinical data show target selectivity, favorable pharmacokinetics, and strong target-to-background signal.

Radiocaine imaging utilizes PET, a well-established advanced imaging technology broadly available in clinical medicine. By leveraging PET's existing, widespread infrastructure, Radiocaine™ could be well-positioned for rapid clinical adoption and broad accessibility across hospitals, academic centers, and imaging networks.

"There's a critical need to move beyond guesswork in diagnosing pain," said Dr. Braxton Norwood, CEO of Lutroo Imaging. "Radiocaine™ has the potential to not only localize and quantify pain, but also to act as a biomarker in clinical trials, helping us measure whether therapies are working, objectively."

About the Radiocaine™ Phase 1 Clinical Trial

This first-in-human PET imaging study is a single-center, open-label trial enrolling healthy volunteers. The trial's primary goals include safety evaluation, dosimetry profiling, and biodistribution analysis. Findings will inform future trials in pain disorders, such as lower back pain and neuropathic pain.

About Radiocaine™

Radiocaine™ is a Fluorine-18-labeled PET radiotracer designed to bind voltage-gated sodium channels in pain-related peripheral nerves. These channels are upregulated in various painful conditions, including neuropathic, inflammatory, cancer, and post-surgical pain. Radiocaine™ aims to also serve as a quantitative imaging biomarker for both clinical practice and pain research.

Radiocaine™ is an investigational radiopharmaceutical. It is not approved by the U.S. Food and Drug Administration for any use and is currently only available for use in clinical trials.

About Lutroo Imaging

Lutroo Imaging is a clinical-stage, molecular imaging company developing next-generation PET radiotracers for pain and other neurological disorders. The company's mission is to make invisible biological processes visible—redefining how human health conditions are diagnosed, monitored, and treated through precision molecular imaging.

Forward-Looking Statements

This press release contains forward-looking statements regarding the clinical development and potential benefits of Radiocaine™. These statements involve known and unknown risks, including trial outcomes, regulatory timelines, and commercial feasibility. Actual results may differ materially. Lutroo Imaging disclaims any obligation to update forward-looking statements except as required by law.

Tony Babb

Lutroo Imaging

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