Innovations
UNIVERSITY OF COLORADO
ANSCHUTZ MEDICAL CAMPUS

Non-Invasive Detection of Tissue Inflammation Using Molecular Imaging

Category
Clinical Diagnostic - mAb

Problem
Accurate detection of kidney inflammation requires an invasive biopsy procedure

Technology Overview
Noninvasive probe to detect C3d and C4d by positron emission tomography to detect kidney inflammation

IP Status
- Issued Patent, Available for Licensing

Value Proposition
- Diagnostic precision by reporting inflammation in both kidneys
- Minimally-invasive, reducing risks of complications
- Less expensive than biopsy and hospital admission
- Can be applicable for other organs and diseases

Market Attractions
- Estimated cost of dose at $4,500 would generate nearly $113M annually
- ~25,000 biopsies/year but frequency could be increased from 10-20 yrs to as little as 6 mo with this less invasive method

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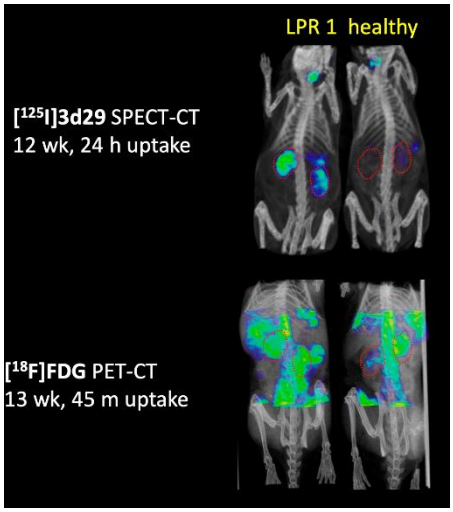
Problem:

Systemic lupus erythematosus (SLE) is an autoimmune disease which can affect different organs throughout the body and is battled by nearly 4 million Americans in the United States. Up to 50% of patients with SLE develop renal abnormalities during the disease's progression. Lupus nephritis, the presence of which is associated with poorer clinical outcomes, requires a kidney biopsy for accurate diagnosis. Renal function must be consistently monitored for tailoring the aggressiveness of immunosuppressant treatment. Not only are biopsies invasive and carry their own complications, but the procedure requires patients to stay in the hospital overnight, increasing costs. Additionally, other methods and biomarkers for monitoring SLE are not accurate enough to guide treatment. Therefore, there is an unmet clinical need for a method of serially monitoring lupus nephritis, as well as other autoimmune diseases.

Solution:

A team at the University of Colorado, led by Drs. Joshua Thurman and Michael Holers, has developed a molecular imaging method to noninvasively detect inflammation in kidneys and other organs. The technology centers around a positron emission tomography (PET) probe which detects complement C3d, a marker that is typically quantified during biopsies. The lead compound is a monoclonal antibody which does not bind intact C3 in plasma, but does bind the C3d activation fragment in human tissue deposits. The radiolabeled mAb can be detected by PET and distinguish kidneys with lupus-like disease from healthy controls. Our researchers believe this will be a more accurate, less invasive and more cost-effective diagnostic procedure than the current standard of care.



Proof-of-concept single photon emission computed tomography (SPECT)/computed tomography (CT) imaging experiments in which 125I-labeled 3d8b was used to detect C3d deposits in 12- week- old MRL/lpr mice (a model of lupus nephritis) and age-matched healthy controls. These results demonstrate that radiolabeled 3d8b can be used to detect C3d deposits in this murine model of lupus. FDG PET-CT, another method to detect altered metabolism associated with inflammation, revealed non-specific signals in multiple sites outside of the kidney.

Key References and Intellectual Property

- US 9,259,488 B2 - "Anti-C3d Antibody Conjugates and Methods of Detecting Complement Activation" issued February 16th, 2016
- Thurman et al. JCI 2013 *123*, 2218-2230.