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FDA APPROVES SAFETY BIOMARKER PANEL DEVELOPED AND VALIDATED BY PACIFIC BIOMARKERS FOR KIDNEY INJURY

The FDA has approved the Qualification of the Safety Biomarker Panel to aid in the detection of kidney tubular injury.

SEATTLE, WASHINGTON, September 24, 2018 – The U.S. Food and Drug Administration (FDA), announced that the qualification of the Predictive Safety Testing Consortium (PSTC) Safety Biomarker Panel was approved for use in conjunction with standard of care methods to aid in the detection of kidney tubular injury in Phase 1 trials. The panel, developed and validated at Pacific Biomarkers, is comprised of six urinary biomarkers –

Clusterin (CLU), Cystatin-C (CysC), Kidney Injury Molecule-1 (KIM-1), N-acetyl-beta-D-glucosaminidase (NAG), Neutrophil Gelatinase-Associated Lipocalin (NGAL), and Osteopontin (OPN).

The results from each biomarker in the panel can be used to derive a composite measure, which is used to predict the potential severity of kidney tubular injury by the investigated drug. This qualification panel is approved by FDA for testing in first-in-human studies.

”I’m very proud of the overwhelming amount of work that Pacific Biomarkers has dedicated toward the analytical and clinical study data used to support this Qualification. This panel at Pacific Biomarkers is the new Gold Standard toward establishing renal tubular safety of a drug in early development.” – Dr. Candace Adamo

This panel is currently available through Pacific Biomarkers. More information is available at www.pacbio.com

Pacific Biomarkers *is a CAP accredited, CLIA certified biomarker testing services provider, supporting pharmaceutical, biotech and in-vitro diagnostic (IVD) manufacturing companies through preclinical and Phase I-IV studies of drug and IVD development.*

The Predictive Safety Testing Consortium *brings together pharmaceutical companies to share and validate innovative safety testing methods under advisement of the FDA, EMA and PMDA. The mission of the PSTC is to identify new and improved safety testing methods and submit them for formal regulatory qualification by the FDA, EMA and PMDA.*

If you would like more information about this topic, please call Jessette Novero at (415) 385-9499, or email contact@pacbio.com.