Parexel Welcomes Three New Regulatory Experts

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New staff bring significant oncology, immunotherapy and rare disease expertise to Parexel's Regulatory & Access Consulting team of 80+ former regulators to help life sciences companies navigate rapidly changing global regulatory landscape

BOSTON and DURHAM, N.C., July 23, 2020 (GLOBE NEWSWIRE) - Parexel, a leading provider of solutions to accelerate the development and delivery of innovative new therapies to improve world health, from Clinical through Commercialization, today announced the addition of former regulators with significant expertise in oncology, immunotherapy and rare disease to its Regulatory & Access Consulting team, further supporting the advancement of new treatments for patients worldwide.

"The global pandemic has created a highly dynamic regulatory environment as companies adapt quickly to protect patients, preserve supply chains and maintain focus on new emerging therapies," said Paul Bridges, Senior Vice President, Regulatory & Access. "Parexel remains committed now, more than ever, to helping our customers address the rapidly evolving regulatory changes through a strong roster of former regulators and regulatory experts. Our new colleagues bring first-hand experience from their tenure working within global health authorities to help our customers seamlessly navigate the regulatory process and ultimately help deliver new therapies to patients."

The new team members will serve as Technical Vice Presidents and join Parexel's group of more than 1,000 consulting experts whose combined knowledge, skill and experience in quality and compliance expertly guide customers through complex global and in-country regulations. They will provide their perspective on key aspects of the regulatory process, including navigating rapidly evolving landscapes related to regulatory meetings and submissions, compliance and market access. The recent appointments include:

- **Yajie Li, M.D.,** who joins Parexel with more than 16 years of experience in key leadership positions at biopharmaceutical companies as well as hands-on experience as a Senior Clinical Reviewer with the Center for Drug Evaluation (CDE) in Beijing, where she led and managed the clinical evaluation of studies and long-term development plans for chemical and biological products. Most recently, Dr. Li served as the Vice President, Head of Compound Strategy and Pipeline Management Function, at Xuanzhu Pharma, where she advanced the development of new therapies for oncology, infectious disease, metabolic disease and hypertension. Prior to that, she served at Janssen as the Regulatory Affairs Therapeutic Area Director for Infectious Diseases & Vaccines, China Companion Diagnostic Team Leader and the China Compound Team Leader for oncology, where she supported the development of Ibrutinib, Apalutamide, Zytiga and Niraparib in China. Dr. Li began her career as a practicing physician at Beijing Railway Hospital and Peking Union Hospital in Beijing.

- **Jorge Camarero, Ph.D.,** who brings more than a decade of regulatory experience to Parexel, primarily in oncology, having served at the European Medicines Agency (EMA) in The Netherlands as an alternate member of the Committee for Medicinal Products for Human Use (CHMP) and as a member the Oncology Working Party. Prior to his tenure at the EMA, he was Head of the Oncology Area for the Spanish Agency for Medicines and Medical Devices (AEMPS); a Pharmaceutical Inspector for the Spanish Government's Health Department delegation; and a Regulatory Clinical Assessor in Oncology for Spanish Agency for the AEMPS. Among his roles, Dr. Camarero provided critical assessments for advanced therapies. With a doctorate in pharmacology, he has published nearly two dozen scholarly articles in the fields of oncology, pharmacology, neurochemistry and immunotherapeutics.

- **Lucas Kempf, M.D.,** who joins Parexel with significant regulatory and clinical experience acquired over 15 years through multiple positions at the FDA's Center for Drug Evaluation and Research (CDER) and the National Institutes of Health (NIH). As the CDER's Acting Associate Director, Rare Diseases Program, Dr. Kempf supervised a team that supported rare disease drug development across the agency and advised the director on policy issues regarding rare disease drug development programs. At the National Institutes of Mental Health (NIMH), he supported research into experimental therapeutics for rare and major mental illness and translational biomarker development, with a focus on genetics and neuroimaging. He also trained and supervised teams of researchers in clinical care, MRI brain imaging, and genetic analysis and helped design and conduct placebo-controlled, double-blind clinical trials. Prior to his tenure at federal agencies, Dr. Kempf was a practicing clinician at a Veteran's Administration Medical Center and the Medical Director for a clinical practice in Maryland.

About Parexel

Parexel is focused on supporting the development of innovative new therapies to improve patient health. We do this through a suite of services that help life science and biopharmaceutical customers across the globe transform scientific discoveries into new treatments for patients. From clinical trials to regulatory and consulting services to commercial and market access, our therapeutic, technical and functional ability is underpinned by a deep conviction in what we do. For more information, visit our **website** and follow us on **LinkedIn**, **Twitter** and **Instagram**.

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