Parexel announces appointments of two FDA luminaries – Lola Fashoyin-Aje, M.D., MPH and Tala Fakhouri, Ph.D., MPH – to its Consulting team, further strengthening regulatory, medical and AI expertise

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DURHAM, N.C., July 01, 2025 (GLOBE NEWSWIRE) -- Parexel, a leading global clinical research organization (CRO) providing insights-driven Clinical and Consulting solutions to the world's life sciences industry, today announced two Food and Drug Administration (FDA) luminaries have joined Parexel's Consulting team – **Lola Fashoyin-Aje, M.D., MPH**, as Senior Vice President, Head of Regulatory Oncology, Cell & Gene, and **Tala Fakhouri, Ph.D., MPH**, as Vice President Consulting, AI & Digital Policy, Real-World Research. These strategic appointments further bolster the company's industry-leading regulatory expertise and add senior leaders to a Consulting team that supported nearly one-third of all sponsor NDA/BLA submissions approved by FDA in 2024.

"We're delighted and honored to welcome Dr. Fashoyin-Aje and Dr. Fakhouri to Parexel during a critical time for our industry and our customers," said Paul Bridges, Ph.D., President, Consulting, Parexel. "As sponsors develop therapies that leverage complex drug modalities and employ innovative technologies, such as AI, they are the early innovators pursuing market approvals in an evolving regulatory landscape. These leadership appointments further demonstrate Parexel's unrivaled regulatory expertise and our ability to help sponsors derisk their portfolios and navigate uncharted global regulatory processes, all while supporting patients in receiving these treatments sooner."

Dr. Fashoyin-Aje is a science-driven, board-certified internist and medical oncologist with a proven track record of accelerating drug approvals and developing and shaping innovative regulatory strategies. During her more than 30-year public health, medical and regulatory career, she has built extensive expertise in clinical development, regulatory policy and evidence standards, and collaboratively engaged stakeholders to drive innovation in drug across varied product classes and diverse therapeutic areas.

Prior to joining Parexel, Dr. Fashoyin-Aje was Director, Office of Clinical Evaluation, Center for Biologics Evaluation and Research (CBER) at FDA. In this role, she provided strategic oversight of clinical development programs evaluating cell, gene, and tissue therapies across all indications. This included providing advice to pharmaceutical and biotech companies developing these products on clinical trial designs for Phase I-IV studies, advising on clinical endpoints, intended use population, dose optimization and the use of medical devices in these programs. She earned a medical degree from the University of Rochester, School of Medicine and Dentistry, a master's in public health from Yale University, and completed both her residency and medical oncology fellowship at Johns Hopkins.

Dr. Fakhouri is a strategic leader with extensive experience in regulatory affairs, AI-driven drug development, real-world data analytics and digital health technology. She has demonstrated success in developing and interpreting complex regulatory landscapes, providing strategic regulatory guidance, and fostering collaborations between regulators, industry and global stakeholders. Dr. Fakhouri has successfully led high-impact teams and managed complex initiatives to optimize regulatory decision-making and de-risk technology use in drug development.

Formerly, Dr. Fakhouri was Associate Director for Data Science and Artificial Intelligence in the Office of Medical Policy, Center for Drug Evaluation and Research (CDER) at FDA. Dr. Fakhouri managed a team tasked with developing, coordinating, and implementing medical policy with a focus on data science and the use of AI in drug development. She also contributed to the development of medical policy related to real-world evidence and the use of digital health technologies for medical product development. She earned a master's in public health from Johns Hopkins University, was a postdoctoral fellow in Molecular and Cellular Biology at Harvard University and received a doctorate in Oncological Sciences from University of Utah.

Dr. Fashoyin-Aje and Dr. Fakhouri join Parexel's distinguished Consulting team, which comprises more than 1,300 regulatory experts, including more than 50 former regulators. This team leverages its extensive experience and deep insights to guide clients through complex global regulations across all stages of drug development – helping to accelerate drug development timelines and optimize paths to market access worldwide.

About Parexel
Parexel is a leading global clinical research organization (CRO) providing insights-driven Clinical and Consulting solutions to the world's life sciences industry. Leveraging deep local knowledge and a global breadth of clinical, regulatory and therapeutic expertise, our 24,000+ professionals worldwide work in partnership with biopharmaceutical leaders, emerging innovators and sites to design and deliver clinical trials with patients in mind — broadening access and making clinical research a care option for anyone, anywhere. Our proven track record spans 40+ years and drives us forward, advancing clinical research in healthcare's most complex areas while harnessing innovation to drive efficiencies across every phase of the clinical development process. Our **insights**-driven approach, proven **delivery** and **trusted** execution are accelerating the delivery of life-changing treatments to patients —*With Heart.*™We continue to earn recognition industrywide, including the 2024 Fierce Biotech CRO Award for "Innovative Approaches to Patient-Centric Research" and the 2024 and 2023 Society for Clinical Research Sites (SCRS) Eagle Award for advancing the clinical research profession through strong site partnerships. For more information, visit parexel.com and follow us on LinkedIn, X, Facebook and Instagram.

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