# Parexel Introduces Expert Series – New Medicines, Novel Insights

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**New evidence-based reports offer timely analysis and actionable guidance to drug developers bringing critical new therapies to market**

DURHAM, N.C., Feb. 28, 2023 (GLOBE NEWSWIRE) -- Parexel, one of the world's largest clinical research organizations (CROs) providing the full range of Phase I to IV clinical development services, today announced the launch of a new expert series, *New Medicines, Novel Insights.* The series will feature fresh insights from the company's global, cross-functional experts analyzing trends impacting drug development and offering evidence-based guidance to the biopharmaceutical industry. The inaugural report —*Advancing Rare Disease Drug Development* — explores the unique regulatory, scientific and market access challenges surrounding rare disease drug development and shares best practices to address them.

"Cutting-edge medicines are becoming more personalized and precise across the therapeutic landscape, while the process to develop those therapies is reaching new heights of complexity," said Amy McKee, MD, Chief Medical Officer and Head of Oncology Center of Excellence. "Parexel's *New Medicines, Novel Insights* research series offers expert-led guidance to deliver on the promise of patient-focused drug development and bring impactful treatments to patients more rapidly."

Key takeaways from *New Medicines, Novel Insights: Advancing Rare Disease Drug Development* include strategies for:

- **Keeping the promise of patient focus:** Parexel leaders explain why understanding rare diseases from the perspective of patients and their caregivers and choosing patient-relevant endpoints are central to fulfilling the promise of patient-led drug development.
- **Navigating regulatory pathways:** Parexel regulatory luminaries — including former regulators from FDA, EMA and other major regulatory bodies — share insights on misconceptions about orphan drug designations, approaches to accelerate FDA Breakthrough Therapy designation, common pitfalls to authorization, and ways to meet patients' needs earlier.
- **Designing adaptive trials**: Parexel's scientific experts offer guidance on how to select optimal endpoints for rare diseases, how to successfully deploy complex innovative designs (CID) for rare disease trials, and how to collaborate with patient advocacy groups to design patient-focused trials.
- **Clearing the way for patient access**: Parexel's market access experts share effective strategies for navigating reimbursement in the US and EU by understanding how payers and health technology assessment (HTA) agencies evaluate value.

"Patients are the customers in healthcare, yet the industry lags far behind other sectors in focusing product development on the people it is intended to serve," Rachel Smith, Executive Director, Rare Disease Center of Excellence. "The *Advancing Rare Disease Drug Development* report enables the biopharmaceutical industry to address challenges associated with drug development while maintaining a sharp and consistent focus on the needs of rare disease patients."

Parexel's *New Medicines, Novel Insights* series will serve as a trusted industry resource for predictive insight and actionable recommendations to make clinical development faster, more efficient and patient friendly. To view the full *New Medicines, Novel Insights: Advancing Rare Disease Drug Development* report and subscribe to receive future reports, please visit the interactive experience.

**About Parexel**
Parexel is among the world's largest clinical research organizations (CROs), providing the full range of Phase I to IV clinical development services to help life-saving treatments reach patients faster. Leveraging the breadth of our clinical, regulatory and therapeutic expertise, our team of more than 21,000 global professionals works in partnership with biopharmaceutical leaders, emerging innovators and sites to design and deliver clinical trials with patients in mind, increasing access and participation to make clinical research a care option for anyone, anywhere. Our depth of industry knowledge and strong track record gained over the past 40 years is moving the industry forward and advancing clinical research in healthcare's most complex areas, while our innovation ecosystem offers the best solutions to make every phase of the clinical trial process more efficient. With the people, insight and focus on operational excellence, we work With Heart™ every day to treat patients with dignity and continuously learn from their experiences, so every trial makes a difference. For more information, visit parexel.com and follow us on LinkedIn, Twitter, Facebook and Instagram.

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