

Kaizen Biosciences Announces Multiple Abstract Acceptances and Presents Pediatric Antibiotic PK Data to ISOM; Targets FDA's New CNPV Pathway Ahead of September NDA Filing

Philadelphia, PA – July 14, 2025 – *Kaizen Biosciences, Co.*, a biopharmaceutical company, today announced the acceptance of its abstract for presentation at **IDWeek 2025**, which serves as a premier forum for infectious disease (ID) professionals to knowledge-sharing around improving patient care and overall public health.

In addition, the company recently presented new pharmacokinetic data at the **International Society of Pharmacometrics (ISoP/ISOM)** a biennially meeting, spotlighting a novel amoxicillin-reduced clavulanate formulation for use in children aged 3-24 months.

The data, presented by **Dr. Carl Peck**, former Director of the FDA Center for Drug Evaluation and Research (CDER), compared the pharmacokinetics of **Augmentin ES-600** with the amoxicillin-reduced clavulanate formulation. The study revealed that Augmentin ES-600 delivered elevated clavulanic acid exposures—exceeding the amount found in adult approved Augmentin formulations, suggesting a need to revisit clavulanate dosing found in the current pediatric approved oral suspension formulations. Dr. Peck further highlighted that the proposed formulation, while containing less clavulanate, still provided the AUC/MIC required for bacterial killing or net bacterial stasis when tested against 5 different *H. influenzae* strains.

Kaizen Biosciences is preparing to submit a New Drug Application (NDA) in September 2025 for its novel amoxicillin-reduced clavulanate formulation. The company is also actively pursuing the FDA's recently announced Commissioner's National Priority Voucher (CNPV) Program, which is designed to accelerate review periods. Kaizen intends to formally request consideration under this pathway, highlighting the public health need for an optimized antibiotic and beta-lactamase inhibitor for children aged 3–24 months, while also supporting increased domestic drug manufacturing—a hallmark of national security.

"We're excited to share this important data with the medical and regulatory communities, and we remain committed to pursuing our company philosophy of 'Change, For the Better,'" said Keith-Harrison Dewedoff, Co-Founder & Executive Chair. "The acceptance of our work at major clinical meetings, along with our anticipated engagement with the FDA's new CNPV program, underscores the significance and urgency of our approach."

About Kaizen Biosciences

Kaizen Biosciences is a clinical-stage biotechnology company focused on serving patients in a variety of therapeutic areas where big, traditional pharmaceutical companies often overlook. The company's lead program is an improved amoxicillin-clavulanate formulation which reduced the unnecessary quantities of clavulanic acid in children aged 3–24 months while remaining efficacious against *S. pneumoniae*, *H. influenzae*, or *M. catarrhalis* pathogens.

For more information, visit: www.kaizenbiosciences.com

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