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FOR IMMEDIATE RELEASE

Associates of Cape Cod, Inc. (ACC) Achieves Major Regulatory Milestone Advancing Recombinant Endotoxin Testing

East Falmouth, MA — April 20, 2026 — A significant milestone has been achieved in the global adoption of recombinant endotoxin testing methods, as Bayer's Bergkamen site in Germany has secured regulatory approvals for a novel contrast media active pharmaceutical ingredient (API), using both traditional Limulus Amebocyte Lysate (LAL) and PyroSmart NextGen® Recombinant Cascade Reagent (rCR). The API underwent a comprehensive validation process demonstrating equivalency between PyroSmart NextGen® and the compendial LAL method. The technical dossier was submitted to 15 regulatory agencies worldwide of which 7 have accepted to date.

ACC's PyroSmart NextGen® is now officially approved for release testing by several regulatory agencies, including:

- Japan (Pharmaceuticals and Medical Devices Agency)
- United States (U.S. Food and Drug Administration)
- Australia (Therapeutic Goods Administration)
- Canada (Health Canada)
- Singapore (Health Sciences Authority)
- Switzerland (Swissmedic)
- United Kingdom (Medicines and Healthcare products Regulatory Agency)

Notably, approvals in Australia, Canada, Singapore, Switzerland, and the United Kingdom were achieved through the Access Consortium—an international regulatory collaboration established in 2007 to align regulatory requirements and accelerate access to high-quality medicines. This framework enables shared scientific reviews and facilitates near-simultaneous approvals across participating regions.

A Milestone for Innovation and Sustainability
This achievement highlights growing global confidence in recombinant technologies as a reliable and sustainable alternative to traditional animal-derived endotoxin testing methods.

It also underscores the power of collaboration in advancing innovative, science-based solutions.

"This milestone represents a pivotal moment for the industry," said Veronika Wills, Director of Global Technical Services at ACC. "The successful global validation and regulatory acceptance of PyroSmart NextGen® not only demonstrates scientific equivalency to LAL, but also reinforces an industry shift toward using sustainable, future-ready endotoxin testing solutions. We are proud to support Bayer and the broader industry in advancing these innovative approaches."

Learn More
Industry professionals were recently invited to a webinar to learn more about this milestone and its broader implications within the industry. **Watch the webinar here.**

About ACC - A Seikagaku Group Company
Specializing in recombinant and traditional chromogenic and turbidimetric reagent technologies, ACC has been a global leader in endotoxin and (1,3)-β-D-glucan detection products and services for over 50 years. ACC pioneered modern LAL testing methodology and was the first U.S. FDA-licensed company to manufacture LAL reagents; ACC is today recognized as an international leader in endotoxin detection.
Visit www.acciusa.com for more information.

About PyroSmart NextGen® (PSNG)
PyroSmart NextGen® was the first complete recombinant cascade reagent (rCR) on the market and represents the future of sustainable bacterial endotoxin testing (BET). With the recent approval for the addition of Chapter <86> to the U.S. Pharmacopeia National Formulary, this innovative, sustainable, animal-free solution is positioned to become the new industry standard in BET. PSNG utilizes the same methodology, instrumentation, and software as traditional LAL reagents and seamlessly integrates into existing workflows.

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