

April 26, 2021

Seikagaku Announces Launch of PyroSmart NextGen™ Recombinant LAL Reagent by Associates of Cape Cod, Inc.

Seikagaku Corporation (Tokyo, Japan; “Seikagaku”) announced today that its overseas subsidiary Associates of Cape Cod, Inc.*1 (Massachusetts, U.S.A.; “ACC”) has decided to launch PyroSmart NextGen™ recombinant LAL reagent in April 2021.

PyroSmart NextGen™ is a new endotoxin-detecting*2 reagent commercialized by ACC that is manufactured using recombinant technology resulting from research and development conducted over many years at Seikagaku.

Applying recombinant technology to produce PyroSmart NextGen™ without using blood harvested from horseshoe crabs, a raw material used in the manufacture of traditional Bacterial Endotoxin Testing (BET) reagents will enable customers to achieve their sustainability goals without a forced change to test methodology or laboratory equipment.

PyroSmart NextGen™ is a next-generation BET reagent designed to deliver highly reliable quantitation of endotoxins. It consists of recombinant proteins of Factor C, Factor B, and a coagulating enzyme precursor, which are components of horseshoe crab blood cells. Since PyroSmart NextGen™ follows the same enzymatic cascade pathway as naturally sourced products and utilizes the same test methods and instrumentation, it is a direct replacement for traditional naturally sourced reagents, ensuring consistency with the endotoxin-detecting reagents used in the manufacture of pharmaceuticals, such as injectable drugs and vaccines, as well as medical devices.

The market introduction of PyroSmart NextGen™ is the successful completion of focused efforts to launch a new class of BET reagent and is the next step in the revenue growth strategy as outlined in Seikagaku’s mid-term management plan. ACC is responsible for development of the Seikagaku Group’s LAL business in markets outside Japan, and will market the product globally. A product launch in Japan is planned for May or later in 2021.

PyroSmart NextGen™ Product Photo



< Reference Information >

*1 Associates of Cape Cod Inc. (ACC)

Associates of Cape Cod Inc. (ACC), a wholly owned subsidiary of Seikagaku, was the first FDA-licensed LAL manufacturer. ACC was established in 1974, became a Seikagaku subsidiary in 1997, and currently plays a central role in the global Bacterial Endotoxin Testing (BET) and clinical glucan detection sectors. ACC's reagent production facility, located at their campus in Falmouth Technology Park in Massachusetts, is vertically integrated with an end-to-end manufacturing operation that extends from harvesting horseshoe crab blood cells, a reagent raw material, to manufacturing, testing, packaging/labeling and distributing endotoxin and glucan in vitro diagnostic agents. From that location, ACC also offers customers in-house contract testing services for BET and clinical glucan product testing.

*2 Endotoxins

Endotoxins are a component of gram-negative bacteria. Since endotoxins exhibit strong pyrogenic activity even in minute amounts and serious side effects can be triggered by endotoxin contamination of pharmaceuticals and other products, they must be rigorously controlled pursuant to regulations in the manufacture of pharmaceutical products and medical devices.

< Cautionary Notes >

This press release contains forward-looking statements regarding future management strategies or performance forecasts. These descriptions are based on judgments derived from information that is currently available to Seikagaku and are subject to risk and uncertainty. Actual results and developments may differ significantly from these descriptions due to various factors. Information about pharmaceutical products or medical devices (including products currently in development) contained in this press release is not intended to constitute an advertisement or medical advice.

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