SynCrest Launches CRDMO Service for Peptide-based Therapeutics

- Integrated support across the drug development value chain with continuous flow synthesis -

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Fujisawa, Japan – SynCrest Inc., a peptide and nucleotide CRDMO (Contract Research, Development and Manufacturing Organization) joint venture between Otsuka Chemical Co., Ltd. and Yokogawa Electric Corporation[*1], announces its services are now available for pharmaceutical companies and research institutions in Japan, Europe, North America, and South America. Using its advanced continuous flow synthesis with in-line measurement[*2], the company can produce active pharmaceutical ingredients (APIs), intermediates, and raw materials while addressing the specific challenges at each stage of the drug development value chain.

SynCrest delivers a one-stop service for peptide-based therapeutics, from library synthesis and process development for drug discovery through to manufacturing of experimental medicine for clinical studies, support for new product releases, and on-demand commercial manufacturing. In particular, with the recent diversification of needs related to peptide-based therapeutics, demand is increasing for special amidites, which are nucleic acids that have been modified into a non-natural form, and peptides containing non-natural amino acids, and so the company has been developing technology to meet these latest demands in drug discovery research. Regarding nucleic acids, SynCrest has been able to lower costs and dramatically improve purity of the amidites that comprise the raw material. With respect to peptide synthesis, the company has developed a new manufacturing method for special amino acids that enables the delivery of more than 100 types of non-natural amino acids with high quality and short lead time. SynCrest is also actively engaged in research on fluorine-related compounds and is able to introduce fluorine in peptide and nucleotide compounds.

SynCrest has developed an industry-leading continuous flow synthesis method with in-line measurement that enables non-destructive, high-precision measurements in real time. This technology connects reaction, separation, concentration, and crystallization phases into a continuous flow and integrates in-line monitoring, allowing unique responses to issues and needs related to quality, delivery, and cost in the value chain. From special raw materials to intermediates and middle molecular APIs, the company can provide rapid, highly efficient, and high-quality manufacturing to accelerate a wide range of exploratory and drug discovery research.

Manufacturing of the APIs, intermediates and raw materials is carried out at SynCrest's Naruto Plant in Tokushima, Japan. This is the first multi-purpose, multi-product plant in the country to utilize the continuous flow synthesis method while being GMP[*3]-compliant for highly potent substances (OEB Category 4[*4]). It also has a non-GMP area, enabling a diverse and flexible production system and

environment.

SynCrest's President and Representative Director, Pengyu Xu, stated, "We are very pleased that we have reached this milestone of officially starting sales operations. With flow synthesis technology, sensing technology, and an advanced management system as our three key pillars, we will address the quality, delivery, and cost challenges that exist in the development and manufacturing of peptide and nucleotide therapeutics, and aim to become a flagship CRDMO in this field by delivering exceptional value for our customers throughout the entire process, from basic research through to commercial production."

SynCrest is attending at TIDES USA, the industry's largest event for oligo and peptide therapeutics (May 8-10, San Diego).

*1 Otsuka Chemical and Yokogawa Electric to Launch SynCrest Inc., a Joint Venture Targeting the CRDMO Business for Middle-molecular Drugs

*2 A flow synthesis method that enables process continuity by using in-line measurement to rigorously control multiple processes in production, from reaction to purification/extraction.

*3 Standards for manufacturing and quality control for the production of safe and effective pharmaceuticals and foods. Each country has its own rules and guidelines.

*4 Operational Exposure Band. This is the permissible exposure amount control category for active pharmaceutical ingredients.

About SynCrest

SynCrest helps researchers and producers of middle-molecular drugs be more productive by providing integrated services ranging from basic drug research through to process development and commercial manufacturing. We respond to challenges and needs related to quality, delivery, and cost in the manufacturing value chain for middle-molecular drugs and other pharmaceutical compounds by providing the desired quantity of products at the right time and with optimal quality.
For more information, visit http://syncrest.com/en/