



For Immediate Release
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Sagent Pharmaceuticals Announces FDA Acceptance of Omega Manufacturing Site

TOKYO, Japan and SCHAUMBURG, Ill., September 5, 2019 – Nichi-Iko Pharmaceutical Co., Ltd. (“Nichi-Iko”) and Sagent Pharmaceuticals, Inc., a Nichi-Iko Group Company (“Sagent”), a leader of specialty pharmaceutical products with an emphasis on the injectable market, today announced that their Canadian subsidiary, Omega Laboratories Limited (“Omega”), has been found acceptable for manufacturing FDA-approved products in its initial Establishment Inspection Report issued by the U.S. FDA.

Omega, based in Montreal, Canada, is approved to manufacture small molecule products, and becomes the second FDA-approved facility in the Nichi-Iko Group network. The site provides Sagent with up to 30 million vials of annual internal manufacturing capacity, significantly expanding the Group’s ability to deliver products consistently to patients across the U.S.

“We are excited to announce the successful completion of our Omega expansion project.” said Dr. Peter Kaemmerer, Chief Executive Officer of Sagent. “The acceptance of our facility to manufacture small molecule products for the US market continues the transformation of Sagent that began with the acquisition of the Raleigh manufacturing site earlier this year. The addition of Omega as an FDA-approved site further enhances our developing internal manufacturing capabilities, which will remain a complement to our historic partner-based supply model.”

Yuichi Tamura, President and CEO of Nichi-Iko said, “We welcome the acceptance of Omega’s manufacturing line by the U.S. FDA. Omega’s ability to manufacture products for the U.S. market will help to accelerate the achievement of our mission to deliver a patient-centric experience, providing value-added, high quality generic products.”

About Nichi-Iko Pharmaceutical Co., Ltd.

Headquartered in Tokyo and Toyama Prefecture, Nichi-Iko is one of the largest generic drug manufacturers in Japan by sales. In FY2014, it became the first Japanese generic medicine manufacturer to reach JPY100 billion in annual sales, and consolidated net sales in the fiscal year ended March 31, 2019 reached JPY166.5 billion.

Since its establishment in 1965, Nichi-Iko has earned a reputation for operating at the forefront of quality assurance with premium quality generic pharmaceuticals. Its mission is to provide value-added, high quality generic products which meet the needs of patients and their families, doctors, pharmacists, wholesalers and pharmaceutical companies in the global market as one of the most respected, well established generic companies in the world. In working to fulfil this mission, Nichi-Iko seeks to earn the trust and respect of all stakeholders and to be customers’ first choice.

About Sagent Pharmaceuticals, Inc.

Sagent Pharmaceuticals, Inc., a Nichi-Iko Group Company, is a specialty pharmaceutical company focused on developing, manufacturing, sourcing and marketing pharmaceutical products for the North American market, with a specific emphasis on injectables. Sagent has created a unique global network of resources, comprising rapid development capabilities, sophisticated manufacturing and innovative drug delivery technologies, resulting in an extensive and rapidly expanding pharmaceutical product portfolio that fulfills the evolving needs of patients.