Marketing Approval for Infliximab Biosimilar 100mg "Nichi-Iko" in Japan

Sagent Pharmaceuticals Announces U.S. Infliximab Phase III Study Underway

SCHAUMBURG, ILLINOIS, UNITED STATES, September 28, 2017 /EINPresswire.com/ -- Sagent Pharmaceuticals, Inc., a wholly-owned subsidiary of Nichi-Iko Pharmaceuticals Co. Ltd., is pleased to announce that Nichi-Iko's application for marketing approval of their infliximab biosimilar for intravenous (I.V.) infusion 100mg "Nichi-Iko" was approved by the Ministry of Labour, Health, and Welfare in Japan earlier today.

Nichi-Iko initiated the overseas development of their infliximab candidate with a phase III clinical trial in the U.S. Based on consultations with the U.S. Food and Drug Administration (FDA), the phase III RADIANCE (NCT02990806) study is underway to demonstrate that infliximab is interchangeable with US-Licensed Remicade®1 (infliximab) in patients with rheumatoid arthritis not adequately responding to methotrexate.2

RADIANCE represents the first clinical trial that will demonstrate interchangeability in the U.S. for an infliximab candidate. Interchangeable biosimilars are defined by the FDA as products that are expected to produce the same clinical result as an FDA-approved reference product in any patient.3 A product that is awarded the interchangeability designation by the FDA may be exchanged for the reference product without the intervention of the prescribing health care provider, subject to individual state law.

Marketing and distribution of infliximab in the U.S. would be conducted by Sagent Pharmaceuticals. Going forward, Sagent will launch a website for additional information regarding interchangeability and biosimilars at www.SagentBiosimilars.com.

1. Remicade® is a registered trademark of Janssen Biotech
2. ClinicalTrials.gov. 'A Phase 3 Study of NI-071 in Patients With Rheumatoid Arthritis (RADIANCE)'. [Online] Available at: https://clinicaltrials.gov/ct2/show/NCT02990806?term=ni-071&rank=2 [Accessed: September 2017].
3. U.S. Food & Drug Administration. 'Information for Healthcare Professionals (Biosimilars)'. [Online] Available at:

https://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/therapeuticbiologicapplications/biosimilars/ucm241719.htm [Accessed: September 2017]

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, with a specific emphasis on injectables. For more information, visit www.SagentPharma.com

About Nichi-Iko Pharmaceutical Co.

Nichi-Iko Pharmaceutical Co., Ltd is a leading generic pharmaceutical company in Japan, engaging in the manufacture, distribution, export, import and sale of generic drugs and other medical products. Nichi-Iko was founded in 1965 and is headquartered in Toyama, Japan. For more information, visit www.nichiiko.co.jp/english

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