September 27, 2017

To members of the press:

Company name: Nichi-Iko Pharmaceutical Co., Ltd.
(Security code: 4541 - Tokyo Stock Exchange First Section)
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About Marketing Approval for Infliximab BS for I.V. Infusion 100mg "Nichi-Iko" and the Status of Development in the U.S.A.

We are pleased to announce that today the application for marketing approval for Infliximab BS for I.V. Infusion 100mg "Nichi-Iko" was approved by the Ministry of Labour, Health, and Welfare.

Regarding the overseas development of Infliximab BS for I.V. Infusion 100mg "Nichi-Iko", as of Q4/FY2016 we began Phase III clinical trials in the U.S.A. and are transitioning smoothly towards launch to market.

Based on consultations with the U.S. FDA, Phase III clinical trials in the U.S.A. are being conducted in accordance with protocols that can substantiate interchangeability (able to substitute with a brand name drug based on the judgment of the pharmacist).

In the U.S.A., these trials have been named RADIANCE and represent the first clinical trials that will demonstrate interchangeability. Marketing in the U.S.A. will be conducted by Sagent Pharmaceuticals (Head office: Schaumburg, Illinois), the U.S. subsidiary of Nichi-Iko.

Ongoing forward, Sagent will launch a website for additional information regarding interchangeability and biosimilars at www.SagentBiosimilars.com.

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