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8226 Regency Drive, Pleasanton, CA 94588, USA

Telephone: +1-925-223-8242 Fax: +1-925-223-8243

E-mail: bpgoffice@wjgnet.com <http://www.wjgnet.com>

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Manuscript Type: Clinical Trials Study

Informed consent statement: All of the subjects gave written informed consent to be included in this study.

Name: Akifumi Kushiyama

Signature: Akifumi Kushiyama **Date:** 6 Mar 2016