

April 27, 2018

Patricia Keegan, M.D., Director
Division of Oncology Products 2 (DOP2)
Center for Drug Evaluation and Research
Food and Drug Administration
10001 New Hampshire Avenue
Hillandale Building, 4th Floor
Silver Spring, MD 20993
Tel: 301-796-2320; Fax: 301-796-9849

Re: IND 138435
Request for Written Response, Pre-IND Meeting Background Package

Dear Dr. Keegan,

Beijing Shenogen Pharma Group Ltd. is hereby submitting a pre-IND meeting background package and a Meeting Request to the Food and Drug Administration (FDA). The purpose of this request is to seek the Written Response Only (WRO) feedback to the development program for SNG1153.

Please find following documents enclosed:

Module 1.6.1: Meeting Request

- Pre-IND Meeting Request (Written Response Only) for SNG1153

Module 1.6.2: Meeting Background Materials

- Pre-IND Meeting Background Package for SNG1153

All documents included in this pre-IND are considered proprietary information, and should not be released to any other parties without the expressed written consent of the Sponsor. The legal protection of such confidential material is hereby claimed under applicable provisions of 21 CFR 312.130.

A US Resident Agent has been authorized for the purpose of this pre-IND. The details of the US Resident Agent are below:

Tom Du, M.D., Ph.D.
Chief Consultant
Humphries Pharmaceutical Consulting, LLC
10411 Motor City Drive, Suite 750
Bethesda, MD 20817

All files have been checked and verified to be free of viruses prior to transmission through the FDA Electronic Submissions Gateway using the Windows Defender Security Center (Version created on: 6:15:22 AM: Friday, April 27, 2018; Last update: Friday, April 27, 2018 9:07 AM). The size of this submission is approximately 3.6 MB.

If you have any questions regarding this submission, please contact Dr. Tom Du by phone at 301-637-7737, by facsimile at 240-395-2347, or by email at tom.du@humphriespcc.com.

Sincerely,

Jian Peng
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Jian Peng, Ph.D.
Senior Vice President
Beijing Shenogen Pharma Group Ltd.