



December 4, 2019

Sami Abunadi, President and CEO
BTS Research
9990 Mesa Rim Road, Suite 100
San Diego, California 92121

Dear Mr. Abunadi:

This letter describes the results of a Food and Drug Administration (FDA) inspection that concluded on June 21, 2019. An FDA investigator met with you and your staff to review the conduct of the following non-clinical studies:

- Protocol [REDACTED], entitled, "A 2-Week Toxicity Study of [REDACTED] by Slow Bolus Intravenous Administration in Sprague Dawley Rats Followed by a 4-Week Recovery"; and
- Protocol [REDACTED], entitled, "A GLP-Compliant Repeat Oral Dose (26-Week) Study Followed by a 4-Week Recovery of [REDACTED] in Beagle Dogs."

These studies were performed under the Good Laboratory Practice for Nonclinical Studies regulations [Title 21, Code of Federal Regulations, Part 58]. The FDA conducted this inspection under the Bioresearch Monitoring Program that includes inspections designed to review the conduct of research involving investigational products.

At the conclusion of the inspection, a Form FDA 483, Inspectional Observations, was issued and discussed with you and your staff. We reviewed the Establishment Inspection Report, the Form FDA 483, and your responses to the Form FDA 483, dated July 1, 2019, September 9, 2019, and November 13, 2019. We also received your letter dated October 2, 2019, informing FDA of your firm's new mailing address.

The corrective actions that you described in your letter appear adequate. Your corrective action plans and compliance with federal regulations may be assessed and verified during a future FDA inspection.

We do not request a response to this letter. If you have any questions about this letter or any aspects of non-clinical laboratory studies, you may contact:

Haecin Chun
Division of Inspection and Surveillance
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research
10903 New Hampshire Avenue, Building 71, Room 5124
Silver Spring, MD 20993-0002
Telephone: [REDACTED]

Sincerely,

**Carrie M.
Mampilly -S**

Digitally signed by Carrie M. Mampilly -S
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Carrie M. Mampilly
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