Office of Orphan Products Development
Food and Drug Administration
WO32- 5295
10903 New Hampshire Avenue
Silver Spring, MD 20993

Innova Therapeutics
10 Tabby Lane
Isle of Palms, South Carolina 29451

Attention: Robert Ryan, PhD
CEO
rryan@innovatherapeutics.com

Re: Designation request # DRU-2020-7726
Dated: 7/21/2020
Received: 7/23/2020

Dear Dr. Ryan:

This letter responds to your request for orphan-drug designation of humanized secreted frizzled-related protein-2 monoclonal antibody for "treatment of osteosarcoma."

Pursuant to section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb), your orphan-drug designation request of humanized secreted frizzled-related protein-2 monoclonal antibody is granted for *treatment of osteosarcoma*. Please be advised that it is the active moiety or principal molecular structural features of the drug[1] and not the formulation of the drug that is designated.

If your drug receives marketing approval for an indication broader than what is designated, it may not be entitled to exclusive marketing rights under section 527 (21 U.S.C. 360cc). Therefore, prior to submission of your marketing application, we request that you compare the drug's orphan designation with the proposed marketing indication and submit additional information to amend the orphan-drug designation if warranted. 21 CFR 316.26.

If the same drug is approved for the same indication before you obtain marketing approval of your drug, you will have to demonstrate that your drug is clinically superior to the already approved same drug in order to obtain orphan-drug exclusivity. Failure to demonstrate clinical superiority over the already approved same drug will result in your drug not receiving orphan-drug exclusivity. 21 CFR 316.34(c).

[1] The term "drug" in this letter includes drug and biological products.

You must submit to the Office of Orphan Products Development a brief progress report of drug development within 14 months after this date and annually thereafter until marketing approval. 21 CFR 316.30.

Please notify this Office within 30 days of submitting a marketing application for the drug's designated use. Once your marketing application is approved, please contact CDR Theodore Garnett at 240-402-0218 or alternatively at 301-796-8660 to assess eligibility for orphan-drug exclusivity.

If you have questions regarding your orphan-drug designation, please feel free to contact Selma Kraft, Health Scientist at 240-402-9700 or alternatively at 301-796-8660. Congratulations on obtaining your orphan-drug designation.

Sincerely,

{See appended electronic signature page}

Janet W. Maynard, M.D., M.H.S.
Director
Office of Orphan Products Development

Henry Startzman

Digitally signed by Henry Startzman
Signed on behalf of Janet Maynard
Date: 10/15/2020 4:22 PM EDT
GUID: 4097