DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

February 10, 2022

Peter R. Mathers, Counsel to Taiho Oncology Inc.
Kleinfeld Kaplan Becker
1850 M Street N.W., Suite 800
Washington, DC 20036

Sent via email to: sjensen@kkblaw.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting that FDA take the following two actions described below:

1) Refuse to approve any abbreviated new drug application for generic trifluridine and tipiracil tablets that relies on Lonsurf as the reference listed drug ("RLD") that does not include in the proposed labeling those portions of the Lonsurf label describing pharmacokinetics in and dosage reduction instructions for patients with severe renal impairment, and other information from Taiho's dedicated renal impairment study; and
2) Require applicants seeking approval to market generic trifluridine and tipiracil tablets that rely on Lonsurf as the reference listed drug ("RLD") to submit a patent certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii) to United States Patent No. 10,456,399.

This petition was received by this office on 02/10/2022 and it was assigned docket number FDA-2022-P-0155. Please refer to this docket number in future correspondence on this subject with the Agency.

Also, note that the acceptance of the petition for filing is a procedural matter and in no way reflects the agency's decision on the substantive merits of the petition.

Sincerely,

Dynna Gorham-bigby -S

Digitally signed by Dynna Gorham-bigby -S
Date: 2022.02.10 14:21:04 -05'00'

Dynna Bigby
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)