DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue Building 51 Silver Spring, MD 20993 301-796-3150 Fax:(301)594-1204	1/12/2026-1/22/2026* FEI NUMBER 3022159116

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Eduardo Patricio Yanez Ruiz, MD, Medical Oncologist

FIRM NAME	STREET ADDRESS
Eduardo Patricio Yanez Ruiz, MD	Hochstetter 298
CITY, STATE, ZIP CODE, COUNTRY Temuco, Region de la Araucania, 4800827 Chile	TYPE ESTABLISHMENT INSPECTED Clinical Investigator

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

An investigation was not conducted in accordance with the signed statement of investigator.

Specifically, in each of two studies, [redacted] (b) (4) and [redacted] (b) (4), subjects were enrolled despite ineligibility due to not meeting all inclusion criteria or by meeting an exclusion criterion. Due to not meeting all of the screening criteria, the following subjects were not eligible to be enrolled in their respective studies as follows:

Study	Subject Number	Screening Criteria #	Screening Criteria	Finding
[redacted] (b) (4)	[redacted] (b) (6)	Exclusion 13	Patients with active Hepatitis B or Hepatitis C	The subject was not tested for Hepatitis C at screening.
		Inclusion 2ai	"***Patients who received taxane, gemcitabine, or platinum agents in the (neo)adjuvant chemotherapy setting can be treated with the same class of chemotherapy	The subject received their last dose of docetaxel on 05/30/2023, and was diagnosed with metastatic triple-

AMENDMENT 2

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	Gavin W Pierce, Investigator	X Gavin W Pierce Investigator Signed By: Gavin W. Pierce -S Date Signed: 01-22-2026 13:06:25	1/22/2026

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			(taxane or gemcitabine/carboplatin if ≥ 12 months have elapsed between the completion of treatment with curative intent (eg, date of primary breast tumor surgery or date of last (neo) adjuvant chemotherapy administration, whichever occurred last) and first documented local or distant disease recurrence."	negative breast cancer on 04/16/2024.
(b) (4)	(b) (6)	nclusion 8	Adequate hepatic function, including serum albumin > 3 g/dL.	The subject's serum albumin at screening was 2.8 g/dL.
		xclusion 9	"Have known active central nervous system (CNS) metastases and/or carcinomatous meningitis. Patients with previously treated brain metastases may participate (with the exception of those treated with	The subject last received radiotherapy for brain lesions on 10/31/2023. The subject was screened on 11/06/2023, prior to a post-treatment MRI of the brain on

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			chemotherapy) provided they have stable CNS disease imaging assessments; one performed during screening) for at least 4 weeks prior to enrollment and all neurologic symptoms have returned to baseline, have no evidence of new or enlarging brain metastases***"	11/07/2023. The subject was then randomized on 11/15/2023.
(b) (4)	(b) (6)	Inclusion 2ai	"***Patients who received taxane, gemcitabine, or platinum agents in the (neo)adjuvant setting can be treated with the same class of chemotherapy (taxane or gemcitabine/carboplatin) if ≥ 12 months have elapsed between the completion of treatment with curative intent (eg, date of primary breast tumor surgery or date of last (neo)adjuvant chemotherapy administration, whichever	The subject last received paclitaxel on 04/04/2023, and disease progression was noted 10/14/2023.

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			occurred last) and first documented local or distant disease recurrence."	
(b) (4)	(b) (6)	Inclusion 2ai	"***Patients who received taxane, gemcitabine, or platinum agents in the (neo)adjuvant setting can be treated with the same class of chemotherapy (taxane or gemcitabine/carboplatin) if ≥ 12 months have elapsed between the completion of treatment with curative intent (eg, date of primary breast tumor surgery or date of last (neo)adjuvant chemotherapy administration, whichever occurred last) and first documented local or distant disease recurrence."	The subject received their last dose of paclitaxel on 12/12/2023, and disease progression was noted on 07/15/2024.
		nclusion 2ai	"***Patients who received taxane, gemcitabine, or platinum agents in the	The subject received their last dose of paclitaxel on

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			(neo)adjuvant setting can be treated with the same class of chemotherapy (taxane or gemcitabine/carboplatin) if ≥ 12 months have elapsed between the completion of treatment with curative intent (eg, date of primary breast tumor surgery or date of last (neo)adjuvant chemotherapy administration, whichever occurred last) and first documented local or distant disease recurrence."	12/01/2023, and disease progression was noted on 06/15/2024.

***DATES OF INSPECTION**

1/12/2026(Mon), 1/13/2026(Tue), 1/14/2026(Wed), 1/15/2026(Thu), 1/16/2026(Fri), 1/19/2026(Mon), 1/20/2026(Tue), 1/21/2026(Wed), 1/22/2026(Thu)

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."