Vanessa

17/08/2025 01:01:54

Main Information

Primary registry identifying number
LBCTR2021124932

Protocol number
MO42921

MOH registration number

Study registered at the country of origin
No

Study registered at the country of origin: Specify
Not Applicable

Type of registration
Prospective

Type of registration: Justify
N/A

Date of registration in national regulatory agency

Primary sponsor
F. HOFFMANN-LA ROCHE LTD

Primary sponsor: Country of origin
Switzerland

Date of registration in primary registry
15/04/2024

Date of registration in national regulatory agency

Public title
Vanessa

Acronym
Vanessa

Scientific title
A MULTI-COUNTRY OBSERVATIONAL RETROSPECTIVE STUDY TO EVALUATE THE PREVALENCE OF PD-L1 AND ITS ROLE IN PATIENTS WITH TNBC TREATED WITH SYSTEMIC THERAPY

Acronym
Vanessa

Brief summary of the study: English

This is an observational, multi-country study with secondary data use (NIS SDU); medical/treatment history data will be retrospectively extracted from medical records and archived tissue samples will be analyzed. Approximately 2,700 patients with a new diagnosis of eTNBC or mTNBC between 1st January 2014 and 31st December 2017 will be considered for inclusion in this study. Treatment choice (systemic therapy) has been made at the discretion of the treating physician/multidisciplinary team as per local guidelines and before the patients' enrollment in this non-interventional study. Thus, the treatment choice was independent of participation in this retrospective study.
No study/specific visits are mandated by the study, no additional tests will be performed on patients due to their participation in this study, and no additional tissue samples will be obtained.

Brief summary of the study: Arabic

هذه دراسة رصدية متعددة البلدان باستخدام البيانات الثانوية (NIS SDU)؛ سيتم استخراج بيانات التاريخ الطبي / العلاج بأثر رجعي من مريض جديد بتشخيص2700السجلات الطبية و سيتم تحليل عينات الأنسجة المؤرشفة. ما يقرب من eTNBC أو mTNBC بين1 يناير 2014 و31 ديسمبر 2017 تم النظر في إدراجها في هذه الدراسة .
تم اختيار العلاج (العلاج الجهازي) وفقًا لتقدير الطبيب المعالج / الفريق متعدد التخصصات وفقًا للإرشادات المحلية وقبل تسجيل المرضى في هذه الدراسة غير التدخلية. وبالتالي ، كان اختيار العلاج مستقلاً عن المشاركة في هذه الدراسة بأثر رجعي.
لا تُفرض الدراسة / زيارات محددة من قبل الدراسة ، ولن يتم إجراء اختبارات إضافية على المرضى بسبب مشاركتهم في هذه الدراسة ، ولن يتم الحصول على عينات أنسجة إضافية.

Health conditions/problem studied: Specify

The study population is intended to follow the real-world use of systemic therapy. Eligible patients with either eTNBC or mTNBC will be enrolled consecutively; it is anticipated that sufficient numbers of eTNBC and mTNBC will be achieved with sequential enrollment in as many sites as needed and no stratification will be performed.

Interventions: Specify

Non-interventional study

Key inclusion and exclusion criteria: Inclusion criteria

Patient cases must meet the following criteria for study entry:
1. Signed Informed Consent Form, if and as required, according to local laws and regulations
2. Aged ≥ 18 years at the time of diagnosis
3. Histologically documented TNBC, assessed locally and defined as ER and PR positivity of less than 1% and HER2 IHC0, IHC1+, or IHC2+/ISH-, as determined according to ASCO/CAP guidelines (Allison et al. 2020; Wolff et al. 2018; Wolff et al. 2013)
4- New diagnosis of eTNBC (early or locoregionally advanced TNBC, amenable to treatment with curative intent) or mTNBC (metastatic or locoregionally advanced unresectable TNBC, not amenable to treatment with curative intent) between 1st January 2014 and 31st December 2017
5- Available formalin-fixed paraffin-embedded (FFPE) tumor tissue of good quality based on total and viable tumor content for local and central laboratory PD-L1 testing (see 8.1.1 for detailed requirements)
6- Documentation of tissue source (primary breast cancer, de novo breast cancer, metastatic tumor location), biopsy or resection, tissue size, and tumor content
7- Patients that received any systemic therapy in early-stage disease and/or in metastatic setting

Only patients with documented, locally determined PD-L1 status using Ventana PD-L1 (SP142) assay by trained pathologists, will be eligible for central testing and their data will be included in the study analysis.

Key inclusion and exclusion criteria: Gender

Both

Key inclusion and exclusion criteria: Specify gender

Key inclusion and exclusion criteria: Age minimum

18

Key inclusion and exclusion criteria: Age maximum

100

Key inclusion and exclusion criteria: Exclusion criteria

Patients who meet any of the following criteria will be excluded from study entry:
1- No available archival tumor tissue for PD-L1 testing
2- Tissue samples of poor quality based on total and viable tumor content and/or bad fixation
3- Fine needle aspiration, brushing, cell pellet from pleural effusion, bone metastases, and lavage samples are not acceptable
4- Patients whose tumor tissue is not evaluable for local and central testing

Type of study

Observational

Type of intervention

N/A

Type of intervention: Specify type

N/A

Trial scope

N/A

Trial scope: Specify scope

N/A

Study design: Allocation

N/A

Study design: Masking

N/A

Study design: Control

N/A

Study phase

N/A

Study design: Purpose

N/A

Study design: Specify purpose

N/A

Study design: Assignment

N/A

Study design: Specify assignment

N/A

IMP has market authorization

IMP has market authorization: Specify

Name of IMP

Year of authorization

Month of authorization

Type of IMP

Pharmaceutical class

Therapeutic indication

Therapeutic benefit

Study model

Cohort

Study model: Specify model

N/A

Study model: Explain model

This study will evaluate the prevalence of PD-L1 positivity rates in tumors from patients with TNBC.
The study population will comprise two cohorts:
- Cohort 1 will include patients with eTNBC
- Cohort 2 will include patients with mTNBC

Time perspective

Retrospective

Time perspective: Specify perspective

N/A

Time perspective: Explain time perspective

This is an observational, multi-country study with secondary data use (NIS SDU); medical/treatment history data will be retrospectively extracted from medical records and archived tissue samples will be analyzed. Approximately 2,700 patients with a new diagnosis of eTNBC or mTNBC between 1st January 2014 and 31st December 2017

Target follow-up duration

1

Target follow-up duration: Unit

year

Number of groups/cohorts

2

Biospecimen retention

Samples with DNA**

Biospecimen description

The main study will only use archival tissue (FFPE samples) samples to test the presence of PD-L1. This is an IHC assay and does not involve any genetic testing.

However the Optional Samples for the RBR will be collected from patients who give specific consent to participate in this optional research. RBR samples will be stored, analyzed and used for research purposes, including, but not limited to, research on biomarkers related to cancer treatment or diseases: Additional archival tumor tissue samples (e.g., primary tumor, recurrence, or metastasis) in form of a tissue punch for the generation of a tissue microarray (TMA). & Leftover unstained tissue slides and any derivatives thereof (e.g., DNA, RNA, proteins, peptides). Those samples may be sent to one or more laboratories for analysis of germline or somatic variants via whole genome sequencing (WGS), whole exome sequencing (WES), or other genomic analysis methods.

Target sample size

40

Actual enrollment target size

Date of first enrollment: Type

Date of first enrollment: Date

Anticipated

01/02/2022

Date of study closure: Type

Anticipated

Date of study closure: Date

31/12/2022

Recruitment status

Pending

Recruitment status: Specify

Date of completion

31/12/2022

IPD sharing statement plan

Yes

IPD sharing statement description

During this study, health and personal information about subjects and archived tissue samples will be collected. This below section describes the protection, use, and sharing of information, which consists of the following:
● Information in the medical record, which is held by the study site
● Information that is extracted during this study ("study data"), which is held by the study site, Roche, Roche affiliates, and Roche's representatives (people and companies who work for Roche)
As part of this observational study, the Information will be copied from the medical records and recorded in a way to ensure that the patient Information is kept confidential throughout the observational study and thereafter.

The study data will be labeled with a patient identification number (ID) that is unique to the patient and not related to or derived from Information that identifies the patient (such as his/her name, picture, or any other personally identifying information).
Roche, Roche affiliates, and Roche's representatives will only have access to study data labeled with a patient ID number, except as described below. Patient's medical record, which includes personal information that can identify the patient, will not be accessed for the
purposes of this study, except as described below:
To make sure the study is being done properly or to check the quality of the data, the following people and groups of people will be granted direct access to the original medical records (i.e., they may look at and/or copy of the medical and personal information) without violating the confidentiality of patients data:
● Study monitors of Roche and/or IQVIA, a company hired by Roche to perform certain study activities
● The Institutional Review Board or Ethics Committee responsible for protecting the rights and safety of the patients who take part in research studies
● Regulatory authorities (government agencies involved in keeping research safe for people)
Roche, Roche affiliates, and Roche's collaborators and licensees (people and companies who partner with Roche) may use study data labeled with patient ID number. Study data may also be shared with independent researchers or government agencies, but only after personal information that can identify the patients have been
removed. Study data may be combined with other people's data and/or linked to other data extracted from *patient's medical records. Study data may be used to help better understand why people get diseases and how to best prevent, diagnose, and treat diseases, and to develop and provide access to new medicines, medical devices, and healthcare solutions.
If the results from this study are published in a medical journal or presented at a scientific meeting, the patients will not be identified.
Information from this study will be retained by the study site for 5 years after the end of the study or for the length of time required by applicable laws, whichever is longer. In addition, Roche will retain the study data for 25 years after the final study results have been reported or for the length of time required by applicable laws, whichever is longer.

Additional data URL

Admin comments

Trial status

Approved

Secondary Identifying Numbers

No Numbers

Sources of Monetary or Material Support

Name
F. HOFFMANN-LA ROCHE LTD

Secondary Sponsors

No Sponsors

Contact for Public/Scientific Queries

No Contacts

Centers/Hospitals Involved in the Study

Center/Hospital name	Name of principles investigator	Principles investigator speciality	Ethical approval
Hotel Dieu De France	Dr. David Atallah	Professor of Obstetrics and Gynecology Chairman of Department Gynecology and Abnormal Placentation Gynecologic Oncology and Breast Surgery UroGynecology IGCS board member Secretary General of MEMAGO President-elect, Lebanese Society of Obstetrics and Gynecology Editor-In Chief, Lebanese Medical Journal	Approved
American University of Beirut Medical Center	Dr. Nagi El Saghir	Professor and Head of Hematology Oncology Division, Department of Internal Medicine Director, Breast Center of Excellence, Naef K. Basile Cancer Institute (NKBCI)	Approved
Hammoud University Hospital	Dr. Fadi Farhat	Professor of Oncology	Approved

Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
Hotel Dieu de France	26/07/2021	Dr. David Atallah or Dr Nany Al Alam	david.atallah@gmail.com, nancy.alam@usj.edu.lb,	NA
American University of Beirut Medical Center	21/07/2022	Dr Nagi El Saghir or the IRB Office	ns23@aub.edu.lb, irb@aub.edu.lb	NA
Hammoud Hospital University Medical Center	25/05/2023	Dr Fadi Farhat or IRB	drfadi.trials@gmail.com, or info@humc.org.lb	NA

Countries of Recruitment

Name
Chile
Germany
Italy
Kenya
Republic of Korea
Latvia
Algeria
Finland
India
Morocco
Republic of Serbia
Saudi Arabia
South Africa
Tunisia
Viet Nam
United Kingdom
Lithuania
Peru
Turkey

Health Conditions or Problems Studied

Condition	Code	Keyword
EVALUATE THE PREVALENCE OF PD-L1 AND ITS ROLE IN PATIENTS WITH TNBC TREATED WITH SYSTEMIC THERAPY	Neoplasm of uncertain or unknown behaviour of other and unspecified sites (D48)	Triple negative breast cancer - PD-L1

Interventions

No Interventions

Primary Outcomes

Name	Time Points	Measure
This study will evaluate the prevalence of PD-L1 positivity rates in tumors from patients with TNBC.	End of the sudy	To evaluate the prevalence of PD-L1 positivity on primary or metastatic tissue (defined by expression on tumor- infiltrating immune cells covering ≥ 1% of tumor area by IHC using the Ventana PD-L1 [SP142] assay, as determined in the local laboratory) among early TNBC (eTNBC) and metastatic TNBC (mTNBC) patients treated with systemic therapy

Key Secondary Outcomes

Name	Time Points	Measure
To evaluate the inter-observer concordance on PD-L1 positivity using the Ventana PD-L1 (SP142) assay between local and central laboratories.	End of study	To evaluate the inter-observer concordance on PD-L1 positivity using the Ventana PD-L1 (SP142) assay between local and central laboratories.
Patient demographic and clinicopathologic characteristics as available and described at the time of diagnosis, by PD- L1 status (positive/negative)	End of study	Patient demographic and clinicopathologic characteristics as available and described at the time of diagnosis, by PD- L1 status (positive/negative)
Treatment choices in the neoadjuvant, adjuvant and metastatic setting	End of study	Treatment choices in the neoadjuvant, adjuvant and metastatic setting
PD-L1 positivity rates in core biopsy and surgical samples in patients treated with or without neoadjuvant chemotherapy (paired samples where available)	End of study	PD-L1 positivity rates in core biopsy and surgical samples in patients treated with or without neoadjuvant chemotherapy (paired samples where available)
PD-L1 positivity rates among metastatic sites and primary tumor (paired samples where available)	End of study	PD-L1 positivity rates among metastatic sites and primary tumor (paired samples where available)
tpCR in eTNBC patients after neoadjuvant chemotherapy, by PD-L1 status (positive/negative). The tpCR is defined as the eradication of invasive disease in the breast and lymph nodes irrespective of ductal carcinoma in situ	End of study	tpCR in eTNBC patients after neoadjuvant chemotherapy, by PD-L1 status (positive/negative). The tpCR is defined as the eradication of invasive disease in the breast and lymph nodes irrespective of ductal carcinoma in situ
iDFS in eTNBC patients by PD-L1 status (positive/negative). iDFS is defined as the time from last surgery with curative intent prior to start of adjuvant chemotherapy to the local or regional invasive recurrence; contralateral breast cancer recurrence; metastatic recurrence, breast, and non-breast second cancers and death from any cause, whichever occurs earlier, as determined by the treating physician and/or the multidisciplinary team, based on clinical, radiological and/or other criteria	End of study	iDFS in eTNBC patients by PD-L1 status (positive/negative). iDFS is defined as the time from last surgery with curative intent prior to start of adjuvant chemotherapy to the local or regional invasive recurrence; contralateral breast cancer recurrence; metastatic recurrence, breast, and non-breast second cancers and death from any cause, whichever occurs earlier, as determined by the treating physician and/or the multidisciplinary team, based on clinical, radiological and/or other criteria
PFS in mTNBC patients by PD-L1 status (positive/negative). PFS is defined as the time from initiation of treatment with first line chemotherapy to first documented disease progression, as determined by the treating physician and/or the multidisciplinary team, based on clinical, radiological and/or other criteria, or death from any cause, whichever occurs earlier	End of study	PFS in mTNBC patients by PD-L1 status (positive/negative). PFS is defined as the time from initiation of treatment with first line chemotherapy to first documented disease progression, as determined by the treating physician and/or the multidisciplinary team, based on clinical, radiological and/or other criteria, or death from any cause, whichever occurs earlier
OS in eTNBC and mTNBC patients by PD-L1 status (positive/negative). OS is defined as the time from confirmed histopathological diagnosis to death from any cause	End of study	OS in eTNBC and mTNBC patients by PD-L1 status (positive/negative). OS is defined as the time from confirmed histopathological diagnosis to death from any cause

Trial Results

Summary results

Study results globally

Date of posting of results summaries

Date of first journal publication of results

Results URL link

Baseline characteristics

Participant flow

Adverse events

Outcome measures

URL to protocol files