



Vanessa

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## 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**

15/09/2022

**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**

سيتم استخراج بيانات التاريخ الطبي / العلاج بأثر رجعي من (NIS SDU) هذه دراسة رصدية متعددة البلدان باستخدام البيانات الثانوية يناير 2017 بين mTNBC أو eTNBC مريض جديد بتشخيص 2700 السجلات الطبية و سيتم تحليل عينات الأنسجة المؤرشفة. ما يقرب من 2700 مريض جديد بتشخيص eTNBC أو mTNBC بين 1st January 2014 and 31st December 2017 will be considered for inclusion in this study. يتم النظر في إدراجها في هذه الدراسة 2017 ديسمبر 31 و 2014 تم اختيار العلاج (العلاج الجهازية) وفقاً لتقدير الطبيب المعالج / الفريق متعدد التخصصات وفقاً للإرشادات المحلية وقيل 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  $\geq$  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		
<b>Study model</b> Cohort	<b>Study model: Explain model</b> This study will evaluate the prevalence of PD-L1 positivity rates in tumors from patients with TNBC. The study population will comprise two cohorts: <input type="checkbox"/> Cohort 1 will include patients with eTNBC <input type="checkbox"/> Cohort 2 will include patients with mTNBC	
<b>Study model: Specify model</b> N/A		
<b>Time perspective</b> Retrospective	<b>Time perspective: Explain time perspective</b> 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	
<b>Time perspective: Specify perspective</b> N/A		
<b>Target follow-up duration</b> 1	<b>Target follow-up duration: Unit</b> year	
<b>Number of groups/cohorts</b> 2		
<b>Biospecimen retention</b> Samples with DNA**	<b>Biospecimen description</b> 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.	
<b>Target sample size</b> 40	<b>Actual enrollment target size</b>	
<b>Date of first enrollment: Type</b>	<b>Date of first enrollment: Date</b>	



Anticipated

01/02/2022

**Date of study closure: Type**

**Date of study closure: Date**

Anticipated

31/12/2022

**Recruitment status**

**Recruitment status: Specify**

Pending

**Date of completion**

31/12/2022

**IPD sharing statement plan**

**IPD sharing statement description**

Yes



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

Full name of issuing authority	Secondary identifying number
NA	NA

## Sources of Monetary or Material Support

Name
F. HOFFMANN-LA ROCHE LTD

## Secondary Sponsors

Name
NA

## Contact for Public/Scientific Queries

Contact type	Contact full name	Address	Country	Telephone	Email	Affiliation
Public	David Attalah	Hotel-Dieu De France, Achrafieh, Beirut Lebanon BP : 166830	Lebanon	961160400 0	david.attalah@g mail.com	Hotel-Dieu De France
Scientific	David Attalah	Hotel-Dieu De France, Achrafieh, Beirut Lebanon BP : 166830	Lebanon	961160400 0	david.attalah@g mail.com	Hotel-Dieu De France

## Centers/Hospitals Involved in the Study

Center/Hospital name	Name of principles investigator	Principles investigator speciality	Ethical approval
Hotel-Dieu De France	David Attalah	Gynecologist	Approved

## Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
Hotel Dieu de France	26/07/2021	Prof. Sami Richa	cue@usj.edu.lb	+961-1 - 421 229



## Countries of Recruitment

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

## Health Conditions or Problems Studied

Condition	Code	Keyword
Patients with eTNBC and Patients with mTNBC	Breast (D48.6)	Breast Cancer



## Interventions

Intervention	Description	Keyword
Non-interventional study	NA	NA

## Primary Outcomes

Name	Time Points	Measure
To evaluate the prevalence of PD-L1 positivity in primary or metastatic tissue among eTNBC and mTNBC patients treated with systemic therapy.	Analyzing the archived Tissues	defined by expression on tumor-infiltrating immune cells covering $\geq 1\%$ of tumor area by IHC using the Ventana PD-L1 [SP142] assay, as determined in the local laboratory

## Key Secondary Outcomes

Name	Time Points	Measure
Secondary Objective: To evaluate the inter-observer concordance on PD-L1 positivity	Using Archived Tissues	using the Ventana PD-L1 (SP142) assay between local and central laboratories.





## 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**