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| **Une image contenant Police, Graphique, logo, symbole  Description générée automatiquement** | **Pierre Fabre Medicament**  **Les Cauquillous**  **81500 Lavaur-France** |

**Lay Protocol Synopsis**

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| **Lay language title:** | An observationalstudy to describe breast cancer recurrence in patients treated with neratinib |
| **Full study title:** | A Nerlyfe ancillary study to describe recurrence in breast cancer patients treated with neratinib in a real-world setting |
| **Registry number:** | Not applicable |

**What is the reason for the study?**

Cancer is a disease that happens when some of the body's cells start to grow uncontrollably. Breast cancer is one of the most frequently diagnosed cancer. HER2+ breast cancer is a subtype of breast cancer which represents approximately 15% to 25% of breast cancer worldwide.

Nerlynx® is an oral agent containing the active substance neratinib. Nerlynx® has been approved firstly in United States of America in 2017, and in Europe in 2018. Nerlynx is used in people who have early stage breast cancer which:

* Is hormone receptor positive (HR-positive) and human epidermal growth factor receptor 2- positive (HER2) overexpressed/amplified (HER2 positive), and
* Has previously been treated with trastuzumab based therapy that ended less than one year ago.

This ancillary study is attached to the following main study: Nerlyfe which is a post-authorisation safety study (PASS). This means that people participated firstly in the Nerlyfe study during one year, and then could entere in this ancillary study for one additional year. The aim of the main Nerlyfe study was mainly to see how many people had diarrhoea leading to neratinib discontinuation within the first 3 months.

The aim of the ancillary study was to describe cancer recurrence in people with breast cancer treated with neratinib for 2 years.

**What are the objectives of the study?**

The primary objective are to describe the cancer recurrence in people with breast cancer treated by neratinib during 2 years:

* To characterise the tumor (localisation and size of tumor, and the time of onset)
* To describe the incidence by each type of tumor

**How is the study conducted?**

The study was an ancillary study to the Nerlyfe observational, PASS, real-world study. A PASS study is a study that is done after a drug has been authorised. The aim is to obtain further information on the safety of a drug. An observational study looks at how things work in everyday life. Therefore, inclusion and exclusion criteria are less strict compared to clinical interventional trials; as the aim is to reflect the clinical practice of a drug already approved and available in a given indication.

This study was done in people for which the physicians had decided to treat them with neratinib.

The ancillary study total duration was 2 years, including the one year Nerlyfe PASS study.

The main objective of the study was to collect information on the breast cancer recurrence with neratinib treatment during 2 years.

**Who can take part in the study?**

The study took place in Europe. All people who participated in the Nerlyfe PASS study could participate in the ancillary study.

The following people could participate in the study:

* Adult people
* With early stage HER2+ overexpressed/amplified breast cancer
* Who received neratinib as per the Summary of Product Characteristics (SmPC)
* Who received educational material\*
* Who agreed to participate in the study

\* Educational material contained instruction on how to prevent and manage diarrhea if it occurs

**What are the study treatments and how are they administered?**

People received neratinib prescribed by their physician. As per inclusion criteria neratinib should be used as indicated in the Summaries of product characteristics (SmPC). The SmPC is a document approved by the Health authorities. The SmPC is used as basis of information for healthcare professionals on how to use the medicine safely and effectively. The dose received was the one effectively received during the study.

**Ethical considerations**

This study was conducted according to ethical considerations and followed the rules for conducting such study. The study did not start before it was approved. People provided their consent to participate in.

**What are the possible benefits and risks in taking part in the study?**

People were prescribed with neratinib by their physician, according to the usual routine practice. People received information on the study.

There were no risks or discomforts not direct benefit expected due to the participation in this study. However, this study was expected to increase the knowledge of breast cancer and neratinib treatment.