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**Lay Protocol Synopsis**

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| **Full study title:** | An observational, Post-Authorisation Safety Study (PASS) to describe the safety and effectiveness of tabelecleucel in patients with Epstein-Barr Virus positive (EBV+) Post-Transplant Lymphoproliferative Disease (PTLD) in a real-world setting in Europe: EBVOLVE study |
| **Lay language title:** | An observational study to describe the safety and effectiveness of tabelecleucel in patients with Epstein-Barr Virus positive (EBV+) Post-Transplant Lymphoproliferative Disease |
| **EU PAS Number:** | EUPAS1000000113 |

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

In patients who underwent transplantation, their defenses against infectious diseases can be diminished. When defenses are diminished, Epstein-Barr virus can infect white blood cells. In some very rare cases, it induces an uncontrolled increase in white blood cells named Epstein-Barr virus positive (EBV+) Lymphoproliferative Disease (EBV+ PTLD). EBV+ PTLD is a blood cancer disease that is ultra rare and life-threatening.

Tabelecleucel (Ebvallo®) is a drug that eliminates EBV+ cells. Since 2022, tabelecleucel is indicated in Europe in people aged 2 years and older, for which EBV+ PTLD could not be cured by other treatments.

Information about tabelecleucel has been collected for more than 20 years. European health authorities asked to collect more information, especially in paediatric and elderly people, and also long-term information.

The aim of this observational study is to describe the safety and effectiveness of tabelecleucel for a long-term period.

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

The main objective of the study is to describe the safety of tabelecleucel collected in the everyday life.

The secondary objectives are:

* To describe how well tabelecleucel works
* To learn more about the types of people treated with tabelecleucel
* To gather information on how tabelecleucel is being given.

 **How is the study conducted?**

This is an observational post-authorisation safety study (PASS) conducted in several European countries. A PASS is an observational study looks at how things work in everyday life. This type of study does not have strict conditions to be included like in clinical interventional trials, as the aim is to reflect the real life.

A PASS is a study conducted after a drug has been authorised for use by health authorities. The aim is mainly to obtain further information on the safety of a drug.

The study will be conducted in people for whom the physicians had decided to treat them with tabelecleucel in the real life. All patients will be treated and monitored according to the local clinical practice. No specific visit dates will be required for this study.

The study will include a 3-year follow-up period from the first dose of treatment with tabelecleucel.

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

The study will take place in Europe.

The following people could participate in the study:

* People diagnosed with the disease “EBV+ PTLD” following transplant
* Having prescribed tabelecleucel
* Who will agree to participate in the study and having data collected

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

People will receive tabelecleucel prescribed by their physician. The dose received will be the one according to the usual routine practice.

 **Ethical considerations**

This study will be conducted according to ethical considerations and will follow the rules for conducting such study. The study will not start before it will be approved. People will have to provide their consent to participate.

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

People will be prescribed with tabelecleucel by their physician, according to the usual routine practice.

As this study is purely observational, there is no risk associated with this study, and no direct benefit by taking part in this study. However, results of this study could help the research in the EBV+ Post-Transplant Lymphoproliferative Disease.