Pierre Fabre

Privacy Information Notice and Consent to Process Personal Data for Adult

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
Study short title	EBVOLVE
Study protocol	NIS16919
Sponsor	Pierre Fabre Médicament, with registered office at Les Cauquillous, 81 500 LAVAUR, FRANCE
Sponsor's Data Protection Officer (DPO)	dpofr@pierre-fabre.com
Study Centre	[*enter the name of the specific site where the study will be conducted, registered office and contact information*]
Study Centre No.	[*enter the site number*]
Patient No.	[*enter the patient number*]
Study Doctor	[*enter the name of the Study Doctor*]
Study Doctor's Phone number	[*enter the Phone number of the Study Doctor*]
Study Doctor's E-mail	[*enter the E-mail of the Study Doctor*]
Study Centre's Data Protection Officer (DPO)	[*enter the name and address of an individual/office/Site Data Protection Office in charge*].

For sake of clarity, this privacy information notice is intended to clarify the processing of patient's personal data carried out in the context of the Study.

1. Who is the data controller of the processing of your personal data for the Study?

The Study Centre [*enter centre name*] and the Sponsor (both as identified above), which has commissioned the Study described to you, will process your personal data acting as **independent data controllers**. You can contact them at the addresses indicated above.

2. Which personal data are collected to conduct the Study and for which purposes?

"Personal data" means any information relating to an identified or identifiable natural person. An identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.

Only personal data necessary to achieve the objective(s) of the Study are collected and processed, including **information concerning your health status**. Specifically, the Sponsor will process data concerning you such as your age and gender, clinical and medical history, **exclusively in order to implement the Study.**

All information which is collected about you in this study will be held in the strictest confidentiality and will be labelled with a unique code number (ID code). Indeed, the Study Doctor who will take care of you in the Study and will collect the information necessary for the performance of the Study will assign you an ID code. Only the Study Doctor and authorized entities of the Study Centre may link the ID code assigned to you by the Study Doctor at the time of the collection of your data to the information that directly identifies you (such as your name, surname, address, etc.).

The Sponsor will not have access to your identifiable data since data will be received by the Sponsor in a **pseudonymized** format. **Therefore, the Sponsor will never have access to your name and surname and will never be able to link the data processed to you or otherwise identify you as a patient of the Study**. The Sponsor will take measures to protect the confidentiality and security of your coded data and your privacy in accordance with current laws.

The Study Doctor will then forward **safely** your **coded data** to Oracle France SAS, a contract research organization based In France, commissioned by the Sponsor to manage and conduct the study on behalf of the Sponsor. Your coded data will be processed and analysed by Oracle France SAS to answer **the study objectives.**

What is *Pseudonymization*?
According to the European General Data Protection Regulation 679/2016 (GDPR), "**pseudonymisation**" means "*the processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the personal data are not attributed to an identified or identifiable natural person*". **Therefore, pseudonymisation is a privacy technique that removes or replaces information relating to a particular person (such as your name and surname) with an ID randomic code**.

In performing the Study and consequently processing your personal data, the data controllers will not go beyond the respective competences and, in any case, they will comply with the GDPR, the Italian Legislative Decree 196/2003 (Privacy Code), as amended by the Italian Legislative Decree 101/2018, and to the Guidelines for personal data processing in clinical trials on medicinal products (Decision of the Italian Data Protection Authority No. 52 dated July 24, 2008), and the Deontological rules for processing for statistical or scientific research purposes (Decision of the Italian Data Protection Authority dated December 19, 2018), each as subsequently amended and supplemented.

3. Which are the legal bases for the processing of your data?

The collection and processing of your personal data for the purpose of the Study will be performed on the **legal basis** of:

- **Your consent to process** your personal data including health data pursued by the Sponsor in accordance **article 6(1)(a) and article 9(2)a of the GDPR**;
- Data processing is also compatible with a public Interest mission and for the purposes of scientific research described above in accordance **with Article 9(2)(j) of the GDPR**.

In case of **patients who are deceased or lost to follow-up**, the processing of their personal data does not need to rely on their consent. Indeed, the Sponsor makes reasonable efforts to contact the patients with the support of the Study Centre, also verifying their living state. In any case, **the performance of the Study will be disclosed and this privacy information notice will be made available to the deceased patient's or the lost to follow-up patient's next of kin for the entire duration of the Study on the Sponsor's website** (https://clinicaltrials.pierre-fabre.com/) **and, if it possible, on the Study Centre's website. An information note regarding the study will also be available in the waiting room of the Study Centre.**

Processing your personal data, including special categories of personal data (health data), is indispensable to carry out the Study; if you refuse to provide such data, you will not be able to take part in the Study.

In any case, **you may at any time withdraw consent to the processing of your health- related data** that you previously provided and terminate participation in the Study without having to provide any reason.

Any withdrawal will be valid from the date of the withdrawal forward, without affecting the lawfulness of the previous processing based on the consent provided before the withdrawal. No additional information concerning you will be collected, without prejudice to the use of such data as may have already been collected on the basis of your prior consent will be used in order to establish study results without altering them.

4. With which modalities your personal data are processed?

The personal data will be processed both electronically and manually and will only be disseminated in an anonymous format, e.g. via scientific publications, statistics, scientific conferences, etc. A secured, computerized software suitable for the collection of personal data Including health data called "Electronic Data Capture" is used to import Information already collected when you agreed to receive EBVALLO (tabelecleucel) treatment and to collect the additional medical information available in your medical record of your routine visits that will be manually entered by the Study Doctor or assigned hospital staff of the study.

5. To whom your personal data may be communicated?

Your participation in the Study entails that – in line with the legislation on clinical studies – the **staff** of the Sponsor and/or the **external companies** that perform study monitoring activities on the Sponsor's behalf as its **data processors**, the **Ethics Committee**, and Italian and foreign **health care authorities** may become apprised with the data relating to you – including those contained in your original medical records – in such a manner as to ensure that **your identity is kept confidential**.

In particular, **the Study Centre will collect your personal data Including health data and forward it under coded format to the Sponsor** and, within the limits necessary for the performance of the Study, to **its affiliates**, **research partners**, **designees** and **representatives** acting as the Sponsor's data processors, assisting with the Study research.

In any case, personal data will be communicated only to authorized third parties and within the limits necessary for the performance of the Study and when required by applicable laws, including the **contract research organization Oracle France SAS**, and **study monitors** which may also be established in non-European Union (EU) countries, including the United States of America. Any transfer of personal outside the EU will be carried out in compliance with Articles 45 and 46 of the GDPR, as well as taking into account any other measures required by the applicable data protection laws, including the stipulation of the Standard Contractual Clauses, unless an adequacy decision for the transfer of data to such non-EU country has been issued by the European Commission.

Please note that these individuals and organizations are all obliged to maintain **confidentiality** by the nature of their work, or are bound by confidentiality agreements, and in certain cases may act on behalf of the Sponsor according to Article 28 of the GDPR. A complete list of them is available upon request by emailing the Sponsor's Data Protection Officer at dpofr@pierre-fabre.com.

6. Further use of your coded data for medical research

With this informed consent, you may also help the Sponsor to conduct **further medical research** beyond this study. This means that Pierre Fabre will also analyse your coded data to learn more about Epstein Barr Virus Positive (EBV+) Post-Transplant Lymphoproliferative Disease (PTLD), why individuals respond to treatments differently and new treatment options. This will increase the understanding of EBV+PTLD and similar diseases and support the development of drugs or other therapeutic and/or diagnostic products.

The results of these further analyses will never contain direct personal data about you. They will only show the combined statistical results considered anonymous data. These statistics will never be linked with your data and will not be used for any decisions regarding any individual patients.

You are free to consent to those further research on your study data and you can withdraw your consent for future research at any time without any effects for your current participation of this study and on your medical care. Please contact your study doctor.

7. How long will be data relating to the Study retained?

Given the relevance of your personal information for the performance of the Study and the consequential need to access such data for a long period of time to verify information useful to the research purposes underlying the Study, the Sponsor will retain your personal data, in a **pseudonymized** format and without being able to link that data to you, **for at least 15 years after the end of this Study**.

In any case, at the end of the retention period above, your personal data **will be erased** or **irreversibly anonymized** or **aggregated**.

8. Which are you rights and how to exercise them?

In accordance with the provisions of the GDPR, you may exercise the following rights at any time:

Access (Art. 15 GDPR)
you are entitled to request access to your personal data also in the form of a free copy.

Correction (Art. 16 GDPR)
you are entitled to request that any incomplete or inaccurate personal data which is hold about you is corrected.

Restriction (Art. 18 GDPR)
you are entitled to ask us to suspend the processing of certain of your personal data, for example if you want us to establish their accuracy .

Portability (Art. 20 GDPR)
you are entitled to obtain and receive in structured, commonly used and machine-readable form the personal data previously provided to use such information for your own purposes.

Erasure (Art. 17 GDPR, also known as "Right to be forgotten")

you are entitled to request the erasure of the data collected by the Sponsor. However, it will not be possible to erase all the collected data if this deletion is likely to make impossible or seriously jeopardize the achievement of the research objectives. Furthermore, once the link between your data and your identity has been deleted, meaning that the data has become anonymous, destruction is no longer possible.

You can also request a copy of the mechanism adopted and measures implemented to lawfully transfer your personal information outside the EU.

If you want to exercise the above mentioned rights, or if you have any questions about your personal data protection rights as a participant in this Study, or a complaint about the use of your personal information you can contact the Sponsor's Data Protection Officer (DPO): dpofr@pierre-fabre.com.

You can also contact the Study Centre Data Protection Officer (DPO): [*enter the name and address of an individual/office/Site Data Protection Office in charge*].

You may also exercise the right to make a complaint to the Garante per la Protezione dei Dati Personali using the below contact details as indicated on the website https://www.garanteprivacy.it:

Piazza Venezia n. 11 - 00187 Rome
Telephone number: (+39) 06.696771
Fax: (+39) 06.69677.3785
Email address: protocollo@gpdp.it

In the event of the patient's decease, the aforementioned rights may be exercised by individuals with an own interest, or acting in their capacity as the patient's representative, or for family reasons worthy of protection. Prior to his/her death, the patient may expressly prohibit the exercise of some of the rights listed above by his/her assignees by sending a written declaration to the Sponsor or the Study Centre in the manner indicated above. This declaration may be revoked or modified later in the same manner.

Consent

By undersigning this form, **I consent to the processing of personal data related to my health for the performance of the Study**. Such data processing will entail the transfer of such data to the offices of Pierre Fabre Médicament, and to the third-party recipients of the data (such as the Contract Research Organization Oracle France SAS), including outside the EU for the purposes of the study, in accordance with the terms and mechanisms specified in the privacy information notice provided herewith.

By ticking the relevant "Yes/ No" boxes below, I give or not my consent to the additional statements:

I agree for the reuse of my data in future research as explained in this Patient Information Letter above.	□ Yes □ No

Signature

Patient's full printed name: _____

Patient's signature: _____

Date

_____