24 July 2019

Dear Sir or Madam,

We would like to inform you that UZ Leuven, under the oversight of Prof. Dr. Séverine Vermeire, is collaborating with Takeda Development Center Americas, Inc. (Takeda) in the study titled "Evaluation of the Exposure-Response Relationship of Vedolizumab in Inflammatory Bowel Disease: A Pooled Multi-Center Observational Cohort Analysis of Real World Clinical and Modeled Pharmacological Data" (ERELATE).

ERELATE is a retrospective, noninterventional study in which Takeda, the sponsor will collect and analyze patient health records from patients with a known diagnosis of Crohn's disease (CD) or ulcerative colitis (UC) and who received treatment with vedolizumab (Entyvio®). It is our intention to include your medical information in this study.

> ***The purpose of this study is to better understand how the drug works over time in treating patients with your condition. This study is retrospective, meaning that the study will include only information that has been already collected in the past and stored in your medical record; no additional treatments or visits are necessary. Your data will help us understand the relationship between the dose of Entyvio®, and its impact on your medical condition.***

We would like to provide you with the following information about how your personal data will be processed in the context of the ERELATE study. This information is required by the new European General Data Protection Regulation (GDPR) that has been in effect since 25 May 2018.

The sponsor will be analyzing information from your health records including:

- Age
- Gender
- Information about your disease (CD or UC)
- Information related to your treatment with Vedolizumab

We would like to draw your attention to the fact that aside from regular personal data, such as information about your age and your gender, "special categories" of personal data will be collected. Examples of these include:

- your state of health and medical condition, including your medical history;
- your treatments and your response to treatments;
- the results of biological sample analysis;
- the results of the review of your medical imaging material, e.g. scans, X-rays

Protecting the privacy of patients is an important obligation of sponsors who conduct clinical studies. In the context of this study, the data will be transferred in an encoded manner. The data is linked to your personal health information with code numbers, without your name and address, so that you cannot easily be identified from it. The code numbers will be kept secure by the study doctor at UZ Leuven.

Based on the GDPR, we are also obliged to inform you who is responsible within the study in which you are participating for the processing (management, storage, use, etc.) of your data. As sponsor of the study, Takeda Development Center Americas, Inc. and its affiliate, Takeda Development Centre Europe Ltd., are joint data controllers of your personal information that is being processed in the context of the study. This means that they determine the reason and manner of the processing in the study. However, the participating hospitals remains the controller of your medical record.

We are obliged to inform you about the legal grounds for admission based on which we process your information. The processing of your information is necessary for scientific research purposes as well as to meet the legitimate interests of the sponsor.

Coded information collected for the study may be used by sponsor and other companies and organisations for the following purposes:

- to conduct the research and use the results of the study as described in this letter; and
- for scientific meetings, presentations and/or publications about the study

Furthermore, we would like to reiterate that your personal data, among other things, could be reviewed by the following people:

- study monitors and auditors, possibly employed by the sponsor, its authorized representatives, who will check whether the study is being conducted correctly and whether the information collected about you is accurate;
- the ethics committee that approved this study and ensures that your rights and well-being are guaranteed;
- national and international competent governmental authorities that are involved in keeping the study safe for participants;

It is therefore important to stress that some of these receivers of your information could be located in countries that do not have the same standards of legal data protection as the EU. However, sponsor will do everything possible to keep your coded information confidential. With respect to transfers to its affiliates and business partners located outside of the EU, sponsor has put in place appropriate contractual provisions (e.g. so called “Standard Data Protection Clauses”), or is otherwise satisfied that there are measures in place to achieve the level of protection of coded personal information equivalent to that under European law. In any case, all parties involved in the study are obliged to respect the confidentiality of your personal data.

The parties that may receive the coded data include the following:

- The sponsor and other companies and people acting for or with the sponsor, including the sponsor's business and licensing partners
- Regulatory agencies and other health authorities
- Institutional review boards and ethics committees

The coded information collected during this study may also be added to research databases and used in the future by the sponsor and other companies and people working for or with the sponsor to:

- develop a better understanding of the safety and effectiveness of the sponsor's drugs;
- study other therapies for patients;
- develop a better understanding of diseases included in the study; and
- improve the efficiency, design and methods of future studies.

The Ethics Committee Research UZ / KU Leuven was informed and approved this Study. Your information collected as part of this study will be stored for 5 years following completion of the study, or otherwise in accordance with any retention period required by hospital and/or local law/regulations, whichever is longer. We will start collecting and transferring medical information for the ERELATE study immediately.

Subject to the need for us to manage your information in specific ways in order for the research to be reliable and accurate, you can:

- Request additional information about the processing of your data.
- Request access to your data that is being stored, as long as this does not hinder the scientific integrity of the study. Indeed, to guarantee the scientific integrity of the study, it is possible that you will not have access to certain data before the end of the study.
- Request corrections if the data are incorrect or incomplete. During the assessment of this request, you have the right, in certain circumstances, to restrict your data processing.
- Request to erase your data or have your data erased insofar that this does not render the achievement and validity of the scientific research purposes impossible or it does not seriously hinder them or insofar the data are not part of your medical record.

If you have any questions about how we use your personal information after reading this letter or at any other point in time, or if you prefer that your data not be included in this study, please contact the study staff:
+32 16 34 42 18 – severine.vermeire@uzleuven.be
+32 16 34 16 01 – vera.ballet@uzleuven.be

The data protection officer of the sponsor and the hospital are also at your disposal. The contact information is as follows:

The sponsor's Data Protection Officer's (DPO) contact details:
Mailing Address: Takeda Pharmaceuticals International AG, Attn: Data Protection Officer, Legal Department, Thurgauerstrasse 130, CH-8152 Glattpark-Opfikon (Zuerich), Switzerland.
Email Address: dataprivacy@takeda.com

The Hospital's Data Protection Officer's (DPO) contact details:
Mailing Address:

DPO - UZ Leuven
Herestraat 49
3000 Leuven

Email Address: gdpr.research@uzleuven.be

However, in order to guarantee the protection of your identity regarding the sponsor, the data protection officer of the hospital will act as intermediary and will contact the sponsor's data protection officer in the case of questions.

Finally, you also have the right to file a complaint about how your information is being processed, to the Belgian authority that is responsible for enforcing the data protection law:

Data Protection Authority (DPA)
Drukpersstraat 35
1000 Brussels
Tel. +32 2 274 48 00
email: contact@apd-gba.be
Website: www.gegevensbeschermingsautoriteit.be