Sponsor's Privacy Notice for the US study allo-APZ2-EB-III-01

How is my data processed by the Sponsor and what rights do I have?

Sponsor of the study is RHEACELL GmbH & Co. KG based in the European Union (Germany). The processing of information about you by the Sponsor for the purpose of the study is subject to European Data Protection Laws, in particular the General Data Protection Regulation (GDPR), that ensure the protection of your personal data and your privacy. Personal data is any information that relates, directly or indirectly (e.g. by means of a code or other identifier) to an identified or identifiable individual. This privacy notice tells you how your personal data may be processed by or on behalf of the sponsor in this study and what your rights are in this context.

Identification of Data Controller: During the study, the Sponsor, its authorized representatives, and its agents who perform services on behalf and on the instructions of the Sponsor in conjunction with the study may receive and process your personal data needed for your participation in the study and research purposes. In this respect, the Sponsor is a data controller of your personal data under the European Data Protection Laws. The contact details of the Sponsor are:

RHEACELL GmbH & Co. KG ("Rheacell"), Im Neuenheimer Feld 517, 69120 Heidelberg (Germany), phone: +49 6221 71833-0, email: office@rheacell.com

The contact details of the Sponsor's data protection officer are: datenschutz@rheacell.com

Please note: For any request concerning the processing of your personal data, we strongly advise you to contact only the Investigator or local institution where you are participating in the study ("study center"), as only there your identity is known and an unintentional identification by the sponsor can be avoided. However, you also have the right to contact Rheacell.

Categories of personal data and source of the data: Rheacell, its authorized representatives and agents may collect, store, use and process your personal data relevant for the study, including sensitive personal data (e.g. health data, photographs of the wounds, tissue and blood samples and resulting laboratory and analysis results). Rheacell, its representatives and agents receive this data from the study center (local institutions where you are participating in the study). Rheacell, as a sponsor, receives your data only in a pseudonymised form (i.e. linked to a patient identification number, see for more information under "How and for what purposes your personal data will be processed").

How and for what purposes your personal data will be processed: In principle, your personal data and biological material will only be passed on to Rheacell, its representatives, and agents in pseudonymised (coded) form. This means that they do not receive any information that can directly identify you (e.g. name, contact information, etc.), but only a coded identification number (code). Only the Investigator and authorized staff of the study center will be able to connect this code to your name. They will use a list that will be kept in a secure place to link this code to your name in case of an emergency.

Rheacell, its representatives, and agents will use your (coded) data for the following purposes:

- investigating the safety and efficacy of the study drug and thus for the purpose of medical research,
- conducting a possible approval procedure for obtaining a marketing authorisation for the study drug,

- fulfilling reporting and other legal obligations under applicable law (e.g. in case of adverse events experienced by study participants),
- complying with legal retention periods after the termination of the study,
- payment processing with the study center.

In certain cases, Rheacell's representatives and other individuals and/or companies that act on Rheacell's behalf (such as monitors and auditors) may have direct access to your original medical records (including uncoded personal data) at the study center for monitoring purposes and for the verification of clinical trial procedures and/or data processing, without violating your confidentiality, to the extent permitted by the applicable laws and regulations.

In addition, results of this study may be presented at meetings and/or in scientific publications (e.g. in journals or internet); however, your identity will never be shared in such cases. Your personal data will not be used for any direct marketing purposes.

Legal basis: There are laws about the recording, forwarding, storage, and analysis of your personal data in the study that require your voluntary and explicit consent before you participate in the study. If you have given your consent to participate in the study and the related collection and use of your personal information, the legal basis for data processing is your informed consent pursuant to Art. 6 Para. 1 Letter a and Art. 9 Para. 2 Letter a of the GDPR. You can withdraw your consent at any time. In addition, there are legal provisions that require or allow the collection and processing of personal (health) data in order to ensure the lawful conduct and safety of the study and a high degree of reliability and robustness of the data generated in the study and to pursue legitimate research purposes. In this respect, the legal basis for data processing is Art. 9 Para. 2 Letter i or j of the GDPR (public health interests or scientific research) and Art. 6 Para. 1 Letter c, e or f of the GDPR (legal obligation, public or legitimate interests).

Storage duration: According to legal requirements, your personal data will be stored for whichever time period is longer, as required by applicable laws:

- Data related to the administration of the investigational product will be retained for 30 years
- Other data with shorter retention period will be retained for 25 years
- 2 years after the drug being studied has received its last approval for sale
- 2 years after the drug's development has stopped
- until there are no pending or contemplated marketing applications in an ICH region

The above retention periods may be extended to meet regulatory requirements or based on a legal requirement to which Rheacell as sponsor must comply.

Recipients of your personal data: The recipients who will have access to your data at or through the study center are listed in the informed consent form. Additionally, the following recipients may have access to your data:

- Syneos Health LLC and Syneos Health UK Limited, including their affiliates that perform services in conjunction with the study on Rheacell's behalf;
- Rheacell's representatives and other individuals and/or companies acting as monitors and auditors on Rheacell's behalf;
- Rheacell's contractors (such as PPD Inc, Versiti, Cerba Research, Canfield Scientific)Independent auditors for the purposes of confirming your

participation in the study, monitoring your safety during the study, and monitoring the conduct of the study;
- Regulatory agencies in countries where the study drug may be considered for approval (such as the US FDA, EU EMA);
- Public authorities in response to lawful requests, including those to meet national security or law enforcement requirements.

To keep your identity private, all data sent or provided outside of the study center will show only a coded identification number instead of your name.

A description of this clinical study will be available on http://www.clinicaltrials.gov as required by US law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Your Rights as a Data Participant: You have the **right to withdraw your consent** for the processing of your personal data at any time. However, data collected before you remove your consent are still legally allowed to be used. If you withdraw your consent, you will no longer be able to take part in the study.

If applicable under European data protection law, you may also have the right to request

- access to and correction of your personal data collected about you during the study,
- the deletion of your personal data,
- restriction of or objection to the processing of your personal data, and
- the receipt of your personal data (data portability).

Since the data are used in the context of a clinical study, the rights mentioned above may be restricted. This applies in particular if the application of one of these rights is contrary to statutory obligations or if the implementation of the study would be made impossible or seriously impaired.

You may make these requests by contacting the Investigator or study center, as only there your identity is known and an unintentional identification by the sponsor can be avoided. However, you also have the right to contact Rheacell directly.

You may also have the right to file a complaint regarding the handling of your personal information with a data protection authority. Data protection authority competent for the sponsor is the Baden-Wuerttemberg State Commissioner for Data Protection and Freedom of Information.