RECORDATI GROUP	**DATA PROTECTION INFORMATION SHEET**

Basel, 15 July 2020

Dear patient,

we wish to inform you that the Study "An open-label, multi-center, roll-over study to assess long term safety in patients with endogenous Cushing's syndrome who have completed a prior Novartis-sponsored osilodrostat (LCI699) study and are judged by the investigator to benefit from continued treatment with osilodrostat" (study n. CLCI699C2X01B), that you joined, previously sponsored by Novartis, has been recently transferred to **Recordati AG**, a company incorporated in Switzerland, with registered office in Lindenstrasse 8, 6340 Baar, Switzerland, which is continuing the study in the capacity as Sponsor, with the same functions and responsibilities.

In its capacity as Sponsor of the Study, Recordati AG also acts as new Data Controller for the processing of personal data you provided in the past. After the transfer of the study by Novartis, in fact, all your personal data previously collected by Novartis have now been transferred to Recordati AG.

This privacy notice is provided to you pursuant to article 14 of the European Regulation No. 679/2016 on the protection of natural persons with regard to the processing of personal data (hereinafter GDPR). Your personal data will be processed in full compliance with the rules and obligations set forth by the GDPR, by the domestic applicable laws and by any additional measure adopted by the competent Authority for the protection of personal data.

Data controller

Following the transfer, the new data controller is **Recordati AG** (hereinafter, Recordati), a company incorporated in Switzerland, with registered office in Lindenstrasse 8, 6340 Baar, Switzerland, which has appointed as its data processing representative in the European Union: **Recordati Rare Diseases Italy s.r.l.** with registered office in Via Matteo Civitali, 1 - 20148 Milano - Italy.

Form the moment of the transfer onwards, Novartis ceases to be the Data Controller and Recordati AG takes over all its rights and obligations.

The Center conducting the study will continue to process your personal data in its capacity as an autonomous Data Controller, and the transfer to Recordati has no consequences whatsoever on this processing, as clarified in the information notice you were previously provided.

Source of the data

The personal data obtained by Recordati after the transfer of the study are provided by Novartis. Novartis has transferred to Recordati all data collected from you in the past, which you specifically consented to be processed.

Purpose of the processing and nature of personal data

Recordati shall process the personal data previously collected and transferred by Novartis for the same purposes that have already been communicated to you by Novartis in its information notice, that is, for research purposes only.

Recordati shall not process your personal data for any additional or different purpose.

Modalities for the processing

Recordati shall process your personal data with the same modalities adopted by Novartis, which have already been communicated to you by Novartis in its information notice.

Recordati shall adopt appropriate technical and organizational measures in order to protect your personal data from loss or accidental, illegal or unauthorized, access, alteration, disclosure or use.
Your personal data will be stored in Medidata's electronic database, located in the United States of America and equipped with an adequate level of data protection.

Data Processors

Recordati may avail itself of external providers for the provision of certain services, which in some circumstances may have to process your personal data. In all these cases, Recordati will ensure (i) to carefully select the service provider, (ii) that the service provider manages the encrypted data in accordance with the instructions provided by Recordati, (iii) that the service provider takes appropriate technical and organizational measures to protect the encrypted data and (iv) that the service provider does not keep the encrypted data upon termination of its services.

Additional details on the service providers and the countries where they are based can be requested to Recordati in writing to its offices.

In particular, and for the purposes of the study, the Data Controller makes use of a Contract Research Organization (CRO), which has been appointed as Data Processor pursuant to article 28 of the GDPR. This company will be responsible for monitoring the study (i.e. checking the quality of the data collected) and for the other formalities required by law for clinical studies. In turn, the Processor may avail itself of the assistance of affiliates or other entities operating in other countries (either within or outside the European Union). For the regulation of data transfer outside the European Union, please see the paragraph below on transfers.

Communication of Data

The following third parties may have access to your personal data for the purposes described above:

- Companies of the Recordati Group;
- Recordati's study/research personnel;
- In case of adverse events, the competent Ethic Committee which approved the study and safeguards your rights;
- Other competent authorities, such as the competent health regulatory authorities.

Transfers of personal data outside the EU

Your personal data may be transferred to subjects based in countries outside the European Union, which may include countries for which no adequacy decision on the level of data protection has been adopted by the European Commission, pursuant to art. 45 GDPR. In those cases, the transfer will take place in the presence of the appropriate safeguards imposed by GDPR on the transfer of data outside the European Union (such as, for example, the adoption of standard contractual clauses, pursuant to articles 46 and following of the GDPR).

Retention of personal data

Recordati will keep your personal data for a period of 25 years from the last follow-up relating to this clinical study. This retention period may be extended if this should prove necessary for Recordati in relation to any dispute, investigation or proceedings or if this should be required by new legislation.

Exercise of rights

You shall always have the right to:

- Request your doctor the access to your personal data;
- If applicable, request the modification, the erasure or the limitation to the processing of collected personal data;
- Request a copy of your data;
- Bring a claim before the Supervisory authority for the protection of personal data.

Contact details of Recordati's Data Protection Officer

If the doctor or research staff were unable to answer any question you may have on the processing of your personal data and your rights, you can contact Recordati by sending an e-mail to the following address: GroupDPO@recordati.com.