Multicenter observational program

TELESPHOR

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DescripTion of the Effectiveness and tolerability of agomeLatine in the trEatment of patientS with dePression occurred after tHe COVID 19 infectiOn in the daily clinical practice in Russia

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Description of the Effectiveness and tolerability of agomelatine in the treatment of patient with depression occurred after COVID-19 infection in daily clinical practice in Russia

A PROSPECTIVE, OBSERVATIONAL (NON-INTERVENTIONAL), MULTI-CENTER STUDY TO DESCRIBE ANTIDEPRESSIVE EFFECTIVENESS OF AGOMELATINE PRIOR COVID-19 PATIENTS WITH DEPRESSIVE EPISODE.

Dear patient,

you are being invited to take part in this observational study because you are suffering from depression. It is important that you have enough time before making a decision to participate in this study to discuss all relevant questions with your physician to be able to understand what a purpose of the program is and what its goals are. Please spare time you need to carefully read information provided here below and in case there are uncertainties that require clarification or if you need more details regarding your participation in the study please do not hesitate to address your questions to the physician responsible for the study.

Please note that this observational study will encompass 20 clinical sites in Russia and about 100 patients will be included for observation.

What is the purpose of this study?

The purpose of this study is to describe the effects of treatment (including a medical treatment) with agomelatine on your depression symptoms and quality of life in real clinical practice.

Do you have to take part?

Your participation in this study is entirely voluntary. It is your choice to take part in this study or not.

If you decide to take part you are still free to withdraw at any time without giving any reason. Your research doctor may ask you the reason for your withdrawal to which you are free to answer or not. Your decision to withdraw will not affect the standard of care you receive and you will continue to receive the same level and quality of medical treatment as before. Any information collected on you up to the point of withdrawal can be used for scientific analysis purpose.

What does this study involve?

During the 8-week observational period, you will continue to be routinely followed-up by your doctor, in accordance with the normal course of your care. Before inclusion in the study you will be administered a medical treatment in accordance to routine clinical practice. Your treatment within this observational study is not reimbursed by the Sponsor. You will be asked to answer to questions to self-describe severity of your disease as well as to complete SF-36 questionnaire to describe changes in your feeling and quality of your life (this usually takes about 20 min). Your participation in this study will not involve any additional clinical examination, tests, or treatments compared to routine care.

At the first visit, your doctor will collect information about you such as your age, sex, your professional status, your disease(s) and the treatments you may have received. Around 2 weeks after the first visit, you will be visiting your doctor who will ask you about your symptoms/ treatment change. A follow-

up visits with your doctor will be proposed to you after about 4 weeks and 8 weeks of the inclusion visit. During the study, on each visit a doctor will ask you to complete two questionnaires.

At each contact with your doctor, he/she will collect information about any potential side-effect from the treatment you may have received.

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

This study involves collection of information about your health status within routine care only. This study is observational in its nature and there is no direct benefit for you in participation in it however, information collected during this study may help improve the current scientific and medical knowledge upon depression and eventually contribute to better depression management approaches in clinical practice in Russia.

Who is sponsoring this study?

The study is being sponsored by a pharmaceutical company called Servier.

DATA PROTECTION

What personal data are we talking about?

Your personal data may be provided directly by yourself to your research doctor and/or may be collected indirectly (via your medical records).

The categories of personal data collected are as follows: identification and demographic data, health data (including medical history, previous treatments...), ethnic origin, etc.

As to identification data, your name and surname will be known only by your research doctor and the staff / authorised persons in charge of controlling the quality of the study. For other people involved in the study (including the sponsor), you will be deidentified by a unique participant number (coded data) without mentioning your name. Your research doctor will securely keep the correspondence table between your name and your participant number (at the research site).

Why do we process your personal data?

Use of your data for the purpose of the study and/or in connection with your disease:

- Your medical records and the data generated during the study will be used for the scientific purpose of the study only. They may be used after the end of the study in connection with your disease.
- The use of your data is mandatory: it is not possible to participate in the study without having your personal data processed.

Use of data for other purposes:

Your coded data may be used after the end of the study to advance science, medicine and public health. In these cases, the data may be shared with private or public third-parties (such as academic, researchers, partners) with appropriate safeguards. In no case neither your name nor any direct identifier will be disclosed. These uses may have to be approved by Ethics Committees and Competent Authorities beforehand.

CONTACTS	
Data Protection Contact *to ask questions and help you exercise your rights*	***Your Research Doctor*** *Include address and phone number*
Data Controller *responsible for the use of your personal data*	Servier JSC -125196, Russia, Moscow, st. Lesnaya 7
Local / National Data Protection Authority *to lodge a complaint regarding the protection of your data*	Federal Service for Supervision of Communications, Information Technology, and Mass Media (Roskomnadzor) 7, bldg 2 Kitaigorodskiy proezd Moscow, 109074 RUSSIA

CONSENT FORM

By signing this consent form, I confirm:

- I have been given a full explanation of the nature, purpose and duration of the study.
- I was able to ask questions regarding all aspects of the study.
- I agree to voluntarily take part in this study.
- I have noted I am free to withdraw from the study at any time if I so desire.
- I have been informed that my personal data will be used for the purpose of the study and/or in connection with my disease and may be used for other purposes as mentioned in the information sheet.

Participant

First name and last name	*Date*	*Signature*

Investigator

First name and last name	*Date*	*Signature*

Witness(es) (if applicable)

First name and last name	*Date*	*Signature*

Give one signed original information and consent form to the participant and keep the other signed original in the study file.