YOU ARE INVITED TO PARTICIPATE IN A CLINICAL TRIAL

of PollenVax

If you suffer from mugwort pollen allergy — this notice is for you

ABOUT THE CLINICAL TRIAL

At the Medical Clinic of Medcenter-Rakhat LLP (Almaty) a Phase II clinical trial is currently underway to evaluate the efficacy and safety of PollenVax (subcutaneous emulsion).

Key Study Information:

Study Title	"A Randomized, Double-Blind, Placebo-Controlled Phase II Clinical Trial to Evaluate the Efficacy and Safety of PollenVax in Patients with Allergic Rhinitis Caused by Mugwort Pollen"
Protocol Number	POL-II-2026
Study Phase	Phase II
Investigational Product	PollenVax, subcutaneous emulsion (20 mcg/mL and 40 mcg/mL), manufactured by OtarBioPharm LLP
Study Sponsor	Kazakh National Agrarian Research University (KazNARU), Republic of Kazakhstan
Planned Number of Participants	138 patients
Duration of Participation	Up to 180 days (approximately 6 months)
Compensation	No monetary compensation is provided. Participants will receive complimentary medical examinations and the investigational product at no charge.

WHO CAN PARTICIPATE

Patients meeting the following key criteria are invited to participate:

Key Inclusion Criteria:

- Age 18 to 65 years (inclusive)
- Confirmed diagnosis of Allergic Rhinitis caused by mugwort pollen (Artemisia vulgaris), of moderate or severe degree
- Positive skin prick test result and/or specific IgE to mugwort pollen
- Symptoms of allergic rhinitis documented over at least 2 mugwort pollination seasons

Key Exclusion Criteria (the following individuals are not eligible):

- Prior allergen-specific immunotherapy (ASIT) for mugwort pollen within the last 3 years
- Severe or poorly controlled bronchial asthma
- History of anaphylactic shock or angioedema
- Presence of diseases of the cardiovascular system, liver, or kidneys in the stage of decompensation or exacerbation, as well as autoimmune diseases, which, in the opinion of the investigator, may affect patient safety or the study results
- Pregnancy or lactation (for women), or planned pregnancy during the study period

The final decision on eligibility will be made by the investigator based on the results of the screening visit.

WHAT PARTICIPATION INVOLVES

Upon enrollment, participants are required to:

- **Attend 6 clinic visits** over approximately 6 months in accordance with the approved schedule
- **Receive 4 subcutaneous injections** of the investigational product (or placebo) at weekly intervals, and remain under medical observation for up to 2 hours following each injection
- **Maintain a self-observation diary**: recording allergy symptoms and all medications taken on a daily basis throughout the entire participation period, especially during the mugwort pollination season
- Promptly notify the investigator of any changes in health status and the use of any additional medications
- Use reliable contraception throughout the entire study period and for 90 days after its conclusion (for individuals of reproductive potential)

Treatment Group Assignment: Participants are randomly (randomized) assigned to one of three groups. Neither the participant nor the investigator knows which group the participant has been assigned to (double-blind study).

PARTICIPANT SAFETY

Participant safety is ensured by the following measures:

- The study has been approved by the **Ministry of Health of the Republic of Kazakhstan** and the **Independent Ethics Committee**
- The life and health of each participant are **covered by mandatory insurance** (Nomad Insurance Company)
- Participants' health status is under continuous medical supervision throughout the entire study period
- **Participation is voluntary**.
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CONTACT INFORMATION

For further information or to schedule a screening visit, please contact:

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Contact phone numbers regarding participation in the clinical trial (please write via WhatsApp):

+7 (701) 550-08-99

+7 (706) 500-68-20

IMPORTANT INFORMATION:

This notice does not constitute advertising of a medicinal product. It is intended solely to inform prospective participants about the ongoing clinical trial. The study is conducted in accordance with Order of the Ministry of Health of the Republic of Kazakhstan No. QR DSM-15 dated 04.02.2021, Order No. QR DSM-248/2020 dated 11.12.2020, Decision of the EEC Council No. 79 dated 03.11.2016 "On Approval of the EAEU Good Clinical Practice Rules", and the WMA Declaration of Helsinki. Participation in the clinical trial is voluntary and does not guarantee a therapeutic effect.