



GEROPHARM



# INTERNATIONAL RAPIDLY GROWING BIOTECHNOLOGICAL COMPANY WITH ALL INSULIN BLOCKBUSTERS IN PORTFOLIO



- **Over 20 years** on the pharmaceutical market
- **Leader** in the Russian insulin market\*
- Portfolio includes **all the most highly demanded insulins** in the world
- Over 10 years of **successful insulin use**, the trust of doctors and patients
- **Full-cycle technology**: from genetic engineering to a large-scale commercial manufacturing
- **Modern infrastructure**: R&D center and 2 world-class manufacturing sites
- **13 countries of export** and different partnership models



# FROM IDEA TO GLOBAL MARKET

**Petr Rodionov,  
GEROPHARM CEO**

# OVER 20 YEARS OF CREATING A HEALTHY FUTURE

**2001**

Launch of Cortexin® and Retinalamin® original medicinal products

**2006**

Insulin manufacturing process has been developed

**2011**

Opening of its own R&D Center

**2013**

Opening of the Plant in Obolensk, Moscow Region.  
Launch of generics

**2014**

Opening of biotechnological unit in the R&D Center

**2019**

Manufacture of insulin analogues: RinLis®, RinLis® Mix, RinGlar®  
Initial deliveries of insulins to Venezuela and localisation of insulin production in Kazakhstan

**2018**

Launch of the 2<sup>nd</sup> line of the plant in Pushkin to manufacture of insulin substances

**2017**

Launch of the 1<sup>st</sup> line of the plant in Pushkin to manufacture pharmaceutical substances for original medicinal products

**2016**

Taking 1<sup>st</sup> place in the Russian market of human recombinant insulins. Launch of Pineamin®

**2020**

Release of the original medicinal product Evodin®, insulins Rinsulin® Mix 30/70 and RinFast®

**2021**

R&D Center received GLP compliance status, launch of educational project for patients "Academy of Diabetes", release of insulin analogue RinFast® Mix 30

**2022**

First position in the insulin market in Russia\*

**2023**

Registration of GEROPHARM representative office in Venezuela. Localisation of insulin production in Algeria

# GEROPHARM AT A GLANCE

176

**million USD\***  
total revenue in 2022

94

**million USD\*\***  
revenue from insulin  
business in 2022

\* endocrinology, neurology, ophthalmology,  
gynecology and urology

\*\* at the rate of 67.6 rub/dollar, data from 07.05.22

**5**  
nosologies\*

**>20**  
products in the  
company's portfolio

**8**  
the most highly  
demanded insulins

**>20**  
projects  
in pipeline

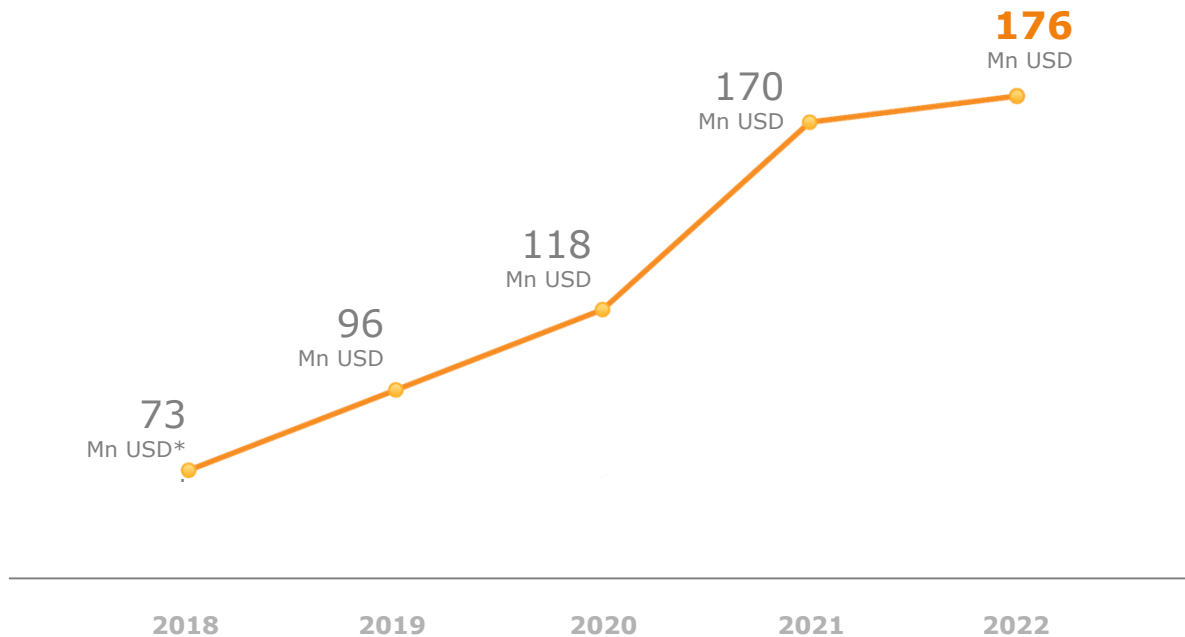
**13**  
countries of export

**>160** **million USD\*\***  
total investment into  
technological innovation  
and R&D in the last 10 years

**>1600**  
highly skilled employees

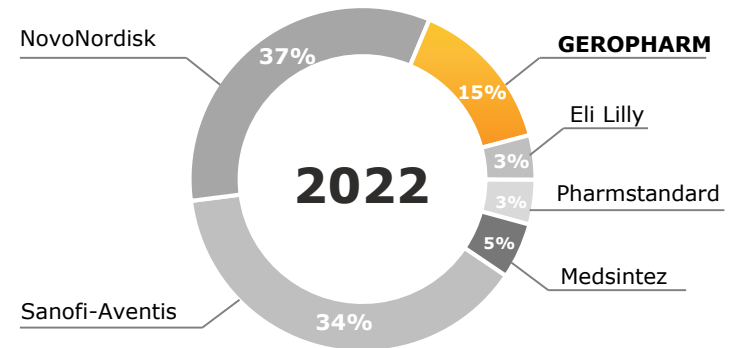
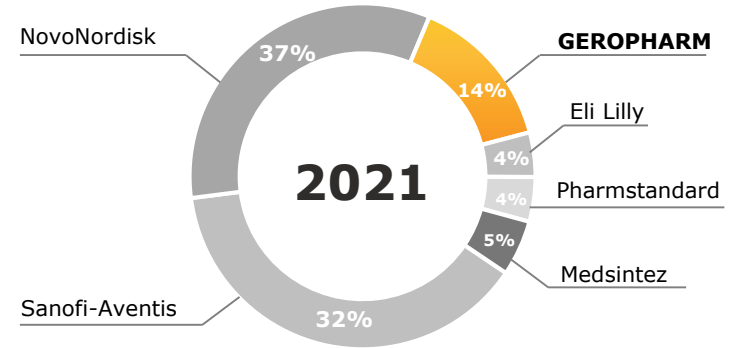
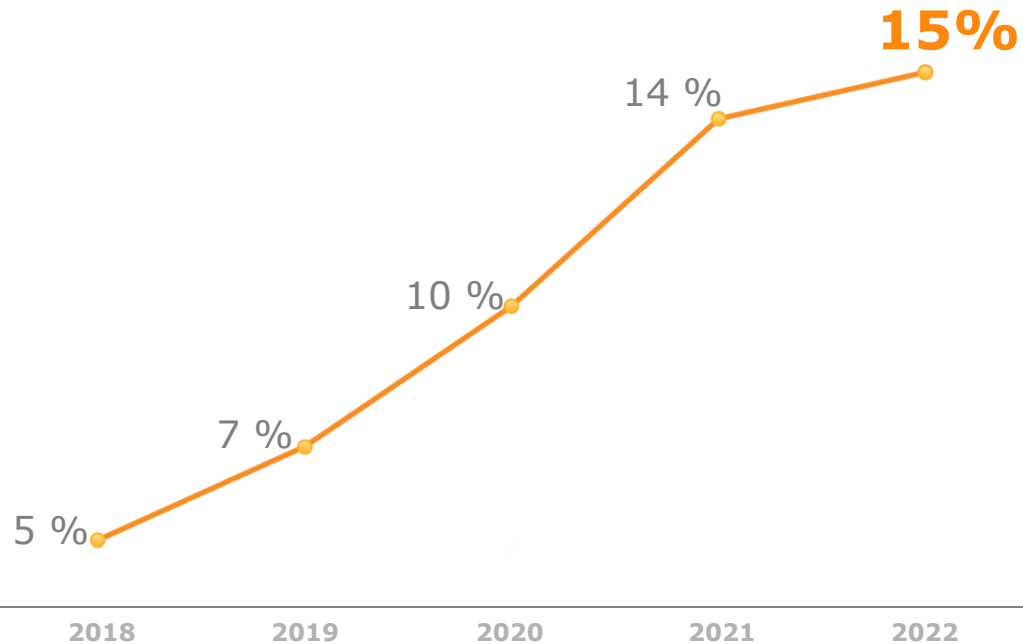
# REVENUE VOLUME

GEROPHARM HAS PROVEN ITS BUSINESS SUSTAINABILITY UNDER SANCTIONS



\* at the rate of 67.6 rub/dollar, data from 07.05.22

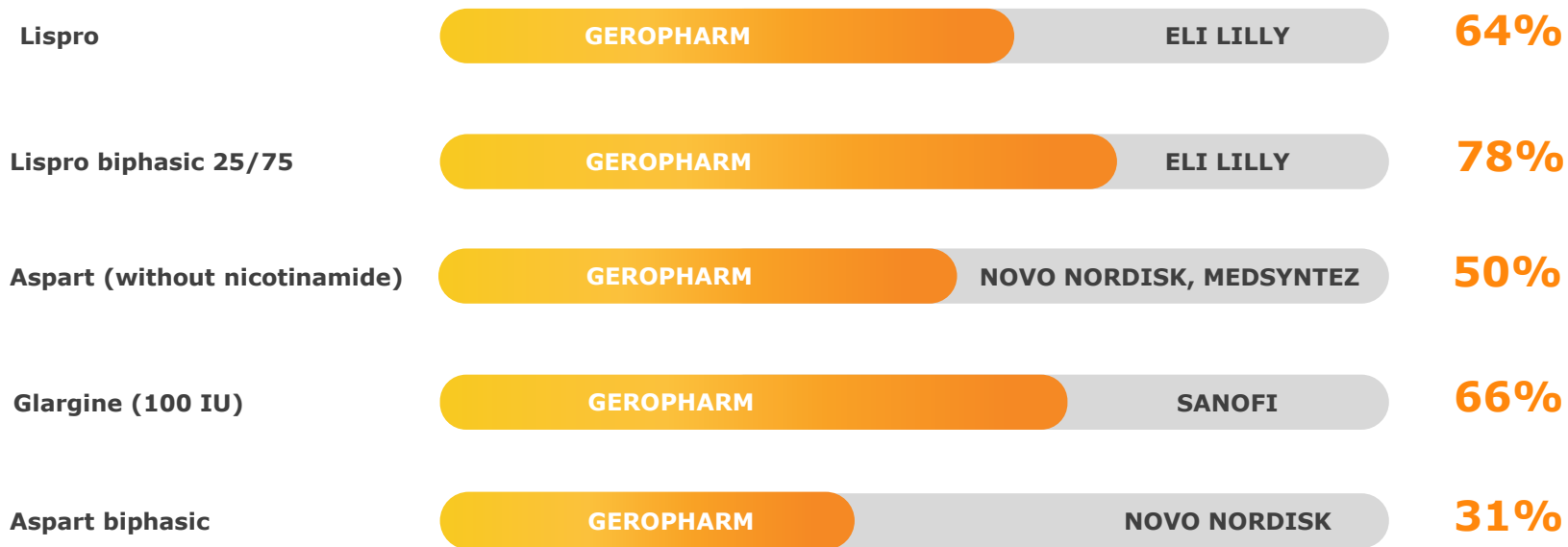
# GEROPHARM IN THE TOP-3 ON THE RUSSIAN INSULIN MARKET



The Russian insulin market in terms of money  
 Source: IQVIA, Budget Market 2022, data from 06/04/23

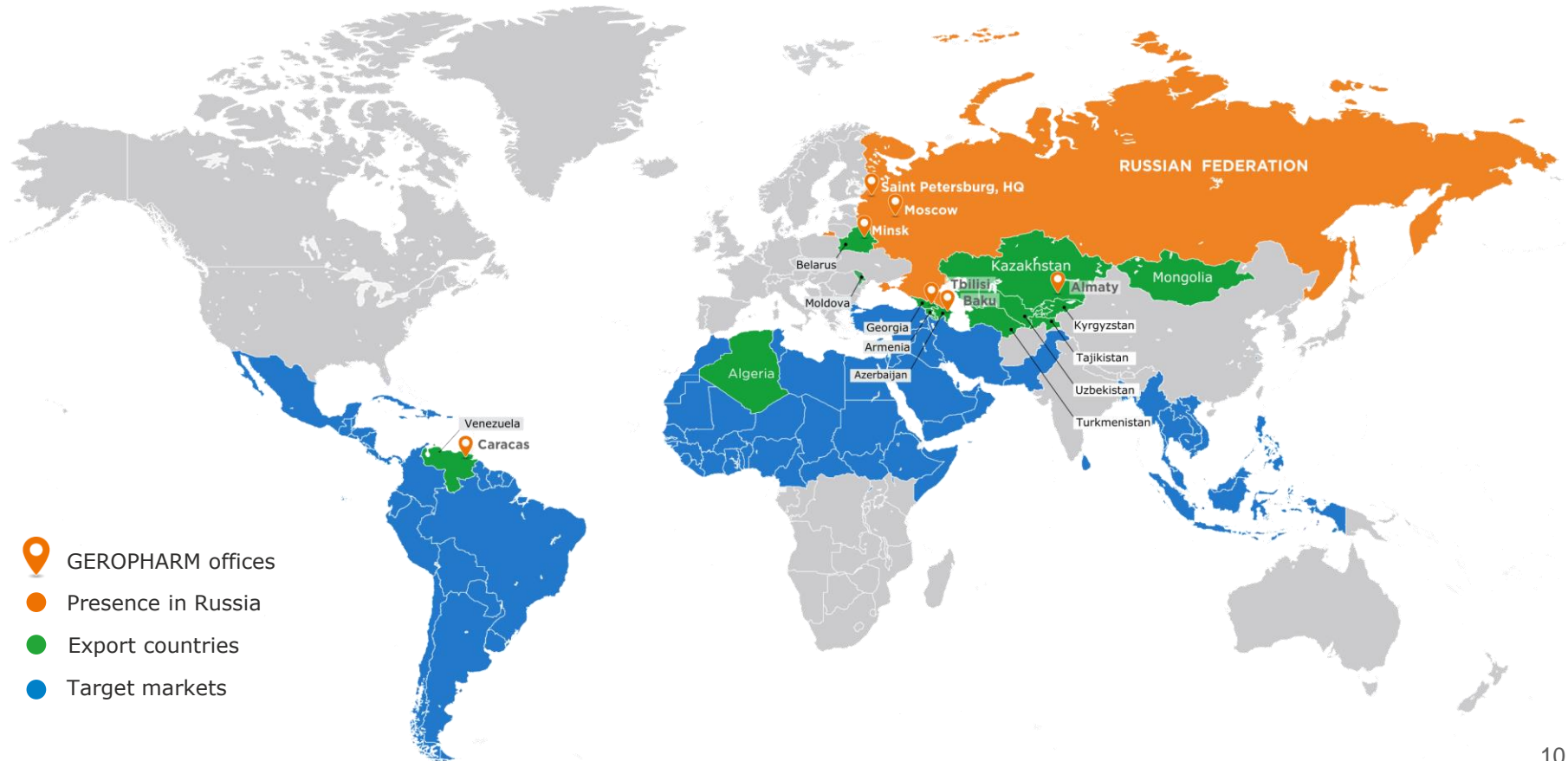
# GEROPHARM ON THE RUSSIAN INSULIN MARKET

ACCORDING TO INN\*





# GLOBAL BUSINESS



# INTERNATIONAL PROJECTS WITH LOCAL CONTENT

## VENEZUELA

**2022-2024** transfer of recombinant human insulin production technology

## ALGERIA

**2023** transfer of recombinant human insulin production technology in a record two months

## KAZAKHSTAN

**2019-2020** transfer of insulin glargine filling technology in six months

**2023-2024** planned transfer of insulin glargine at a concentration of 300 IU / ml production technology

## BELARUS

**2019-2020** transfer of recombinant human insulin production technology



# EXPERIENCED AND HIGHLY PROFESSIONAL TEAM RESPONSIBLE FOR TECHNOLOGY TRANSFER



**Transfer projects** are a team effort that requires involvement of employees from different subdivisions

- Production
- Analytical Testing Laboratory
- Pharmacology Laboratory
- Quality Department
- Investment Department
- Legal Division
- Purchase Division

**Contractor site audits were organised and successfully completed**

- Espromed Bio (Venezuela, Caracas)
- SAIDAL (Algeria, Constantine)
- KFK (Kazakhstan, Karaganda)

# FULL CYCLE OF INSULIN PRODUCTION

## AND QUALITY CONTROL AT ALL STAGES



1 Molecule synthesis and producer strain production

01 **Pharmaceutical development**

02 **Non-clinical studies**

03 **Clinical studies**

04 **Marketing authorisation**

**GLP**

Good Laboratory Practice

**GCP**

Good Clinical Practice

**GVP**

Good Vigilance Practice



2 Substance production

05 **Manufacturing**

06 **Distribution**

**GMP**

Good Manufacturing Practice

**GDP**

Good Distribution Practice



3 Finished dosage form production



# RESEARCH AND DEVELOPMENT

# OVER 10 YEARS OF INNOVATIONS

## R&D CENTER



Full development cycle in accordance with GLP, GCP, GVP standards



Product development by methods of genetic engineering, molecular and cellular biology



More than 150 highly skilled specialists



Comprehensive approach to clinical trials — in-house expertise



SPECIAL ECONOMIC ZONE "ST. PETERSBURG"  
(NEUDORF MANUFACTURING SITE)



# WORK STREAM

## R&D CENTER



Medicinal products development



Technology validation and implementation in full-scale manufacturing



Full range of pre-approval studies



Pharmacovigilance



Registration activities

# STRUCTURE

## R&D CENTER



### Laboratories

- Drug Development Laboratory
- Bioprocess Development Laboratory
- Genetic Engineering and Fermentation Laboratory
- Analytical Testing Laboratory
- Pre-clinical Pharmacology Laboratory
- Laboratory Support Department

### In-House Specialisation

- Department of Early Drug Development
- Research Department
- Medical Department
- Department of Early Phase Clinical Trials
- Clinical Operations Department
- Data Collection and Processing Department
- Pharmacovigilance
- Project Management Department
- Quality Assurance Department
- Regulatory Department





BIOSIMILARS OF INSULIN  
ANALOGUES HAVE BEEN  
SUCCESSFULLY TESTED IN ALL  
THE NECESSARY CLINICAL TRIALS

**№1**

**GEROPHARM is the first company in the Russian Federation** to conduct clamp studies for the purpose of getting the approval of medicinal products (insulins).



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

**ЭНЦ**  
Эндокринологический  
научный центр



Национальный  
медицинский исследовательский  
центр имени В. А. Алмазова

In accordance with the requirements of Russian laws and regulations and international guidelines of the EMA (European Medicines Agency)

# REGISTRATION ACTIVITIES

## R&D CENTER

- High-quality master file highly available for submission to regulatory authorities in a short time
- All information contained in the master file is obtained independently during the development and production
- All the required documents will be provided to the partner
- Support at all stages of registration
- Strong and experienced team





MANUFACTURING

# MANUFACTURING SITE OBOLENSK

 Serpukhov city district, Obolensk settlement,  
Moscow region

Plant was launched in 2013



**Fill & Finish manufacturing:**  
analogue and human insulins



**Proprietary patented technology**  
of recombinant insulin production



**Advanced technologies**  
and latest control methods, GMP  
Pharmaceutical Quality System

# PRODUCTION SITE PUSHKIN

## Execution deadline:

**2017**

production start-up for the pharmaceutical substances for original medicinal products

**2018**

production start-up for the genetically engineered insulin substances and insulin analogs



**High degree of automation**



**Advanced technologies**

and latest control methods,  
GMP Pharmaceutical Quality System



**Production of active  
pharmaceutical ingredients**



**Saint Petersburg, Pushkin**





PORTFOLIO

# DIABETES MELLITUS - THE EPIDEMIC OF THE XXI CENTURY

> **537 million**

adult patients with diabetes mellitus – 1 in 10

This number is predicted to rise to

**643 million** by 2030

**783 million** by 2045

Diabetes was the direct cause of

**6.7 million** deaths in 2021 –

1 every 5 seconds

**541 million** adults have Impaired Glucose Tolerance (IGT), which places them at high risk of type 2 diabetes



# ENDOCRINOLOGY





# ENDOCRINOLOGY

## INSULIN PORTFOLIO

Human Insulin Soluble

**2011**

Insulin Glargine 100

**2019**

Human Insulin Isophane

**2011**

Human Insulin Biphasic

**2020**

Insulin Lispro

**2019**

Insulin Aspart

**2020**

Insulin Lispro Biphasic

**2019**

Insulin Aspart Biphasic

**2021**

### ALL MODERN DOSAGE FORMS:

vials, cartridges, pre-filled pens (disposable & reusable)



# ENDOCRINOLOGY

## RECOMBINANT HUMAN INSULINS (RHLS)

**Rinsulin® R**

**Rinsulin® NPH**

**Rinsulin® Mix 30/70**

- Rinsulin substance of is ahead of international standards in terms of the degree of purification from impurities
- Own unique technology
- Independence from foreign suppliers of raw materials



# ENDOCRINOLOGY

## INSULIN ANALOGUES



### RinLis®

INN: insulin lispro

- widely used ultra-rapid-acting prandial human insulin analog
- notable for the reverse sequence of proline and lysine in the amino acid chain of insulin
- rapid absorption from subcutaneous injection sites
- can be used in children and adolescents

**in 15 min**

onset of action  
after SC injection

**30–70 min**

maximum effect

### RinLis® Mix 25

INN: biphasic insulin lispro

- prandial component provides a faster and more predictable onset of action, as well as the rapid elimination specific to the physiological secretion of insulin
- prolonged-action component provides a smooth, peak-free profile of the basal insulin
- can be used from 12 years

**2–5 h**

insulin lispro  
duration of action

**up to 15 h**

biphasic insulin lispro  
duration of action

# ENDOCRINOLOGY

## INSULIN LISPRO TRIALS

### MEDICINAL PRODUCTS

**RinLis®**  
(insulin lispro)

**RinLis® Mix 25**  
(biphasic insulin lispro)

### REFERENCE PRODUCTS

**Humalog®**  
**Humalog® Mix 25**

## 1<sup>ST</sup> STAGE

### CLAMP-BASED STUDIES

 on the basis



28 

subjects  
**RinLis®**

48 

subjects  
**RinLis® Mix 25**

A high level of equivalence was demonstrated between pharmacokinetic and pharmacodynamic profiles of RinLis® / Humalog® and RinLis® Mix 25 / Humalog® Mix 25, confirming the biosimilarity between investigated insulin products and reference products.

## 2<sup>ND</sup> STAGE

### MULTICENTER COMPARATIVE CLINICAL TRIALS OF IMMUNOGENICITY

RinLis® Mix 25/Humalog® Mix 25

18 

clinics

210 

subjects

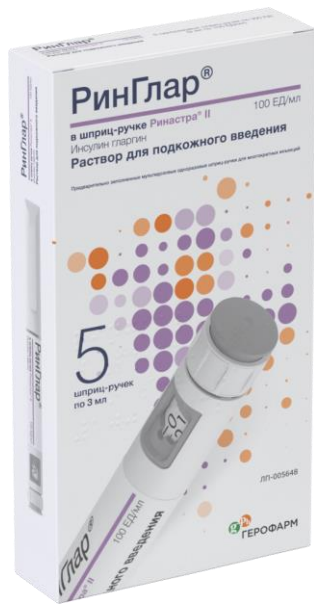
TYPE 2 

diabetes mellitus

The following was proved: safety and immunogenicity characteristics of the biosimilar RinLis® Mix 25 were comparable to those of Humalog® Mix 25.

# ENDOCRINOLOGY

## INSULIN ANALOGUES



### RinGlar®

INN: insulin glargine

- long-acting basal human insulin analog
- the most widely used basal insulin analogue in the world\*
- available in U100 concentration
- can be used in children from 2 years

### in 1 hour

onset of action after  
SC injection

### up to 29 h, average - 24 h

duration of action

\*HUMAN INSULIN DRUGS MARKET - GROWTH, TRENDS, COVID-19 IMPACT, AND FORECASTS (2022 - 2027) <https://www.mordorintelligence.com/industry-reports/insulin-market>

# ENDOCRINOLOGY

## INSULIN GLARGINE TRIALS

MEDICINAL PRODUCT

**RinGlar®**

REFERENCE PRODUCTS

**Lantus® SoloStar®**

### 1<sup>ST</sup> STAGE

**CLAMP-BASED STUDIES**

 on the basis



42   
subjects

TYPE 1   
diabetes mellitus

This study showed high level of equivalence of pharmacokinetics and pharmacodynamics between RinGlar® and Lantus® SoloStar®. Thus, the biosimilarity of these products and the efficacy of the investigational insulin glargine made by GEROPHARM have been confirmed.

### 2<sup>ND</sup> STAGE

**MULTICENTER COMPARATIVE  
CLINICAL TRIALS OF IMMUNOGENICITY**

14   
clinics

180   
subjects

TYPE 1   
diabetes mellitus

As a result, comparable safety and immunogenicity of RinGlar® versus original medicinal product Lantus® SoloStar® have been proven.

# ENDOCRINOLOGY

## INSULIN ANALOGUES



### RinFast®

INN: insulin aspart

- the most common prandial analogue of ultra-rapid-acting insulin in Russia\*
- faster absorption rate compared to regular human insulin
- can be used in children from 1 year

**in 10–20 min**

onset of action after SC injection

**1–3 h**

maximum effect

**3–5 h**

duration of action

\* In kind (IU/pack) according to IQVIA, 2021

# ENDOCRINOLOGY

## INSULIN ASPART TRIALS

MEDICINAL PRODUCT

**RinFast®**

REFERENCE PRODUCTS

**NovoRapid®**

### 1<sup>ST</sup> STAGE

**CLAMP-BASED STUDIES**

 on the basis



26   
subjects

TYPE -   
healthy volunteers

This study demonstrated high level of equivalence of pharmacokinetics and pharmacodynamics between RinFast® and NovoRapid®. Thus, the biosimilarity of these products and the efficacy of the investigational insulin aspart made by GEROPHARM have been confirmed.

### 2<sup>ND</sup> STAGE

**MULTICENTER COMPARATIVE  
CLINICAL TRIALS OF IMMUNOGENICITY**

19   
clinics

264   
patients

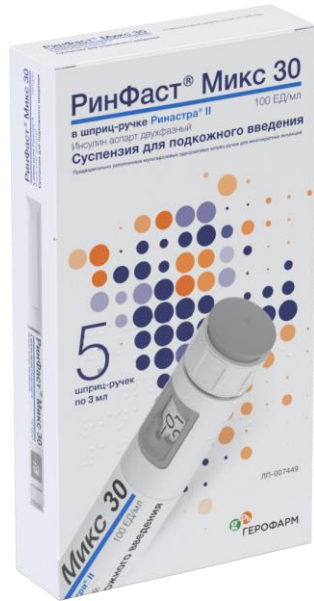
TYPE 1   
diabetes mellitus

As a result, the comparable safety and immunogenicity of RinFast® versus original medicinal product NovoRapid® have been proven.



# ENDOCRINOLOGY

## INSULIN ANALOGUES



### RinFast® Mix 30

INN: biphasic insulin aspart

- contains 30% ultra-rapid-acting soluble insulin aspart and 70% protamine-crystallized insulin aspart with medium-term hypoglycemic effect
- the first component acts mainly in the postprandial period, the second component controls the basal level of glycemia
- can be used in children from 6 year

**in 10–20 min**

onset of action after  
SC injection

**1–4 h**

maximum effect

**up to 24 h**

duration of action

# ENDOCRINOLOGY

## BIPHASIC INSULIN ASPART TRIALS

MEDICINAL PRODUCT

**RinFast® Mix 30**

REFERENCE PRODUCTS

**NovoMix® 30**

### 1<sup>ST</sup> STAGE

**CLAMP-BASED STUDIES**

 on the basis



**34**   
subjects

**TYPE 1**   
healthy volunteers

### 2<sup>ND</sup> STAGE

**MULTICENTER COMPARATIVE  
CLINICAL TRIALS OF IMMUNOGENICITY**

**17**   
clinics

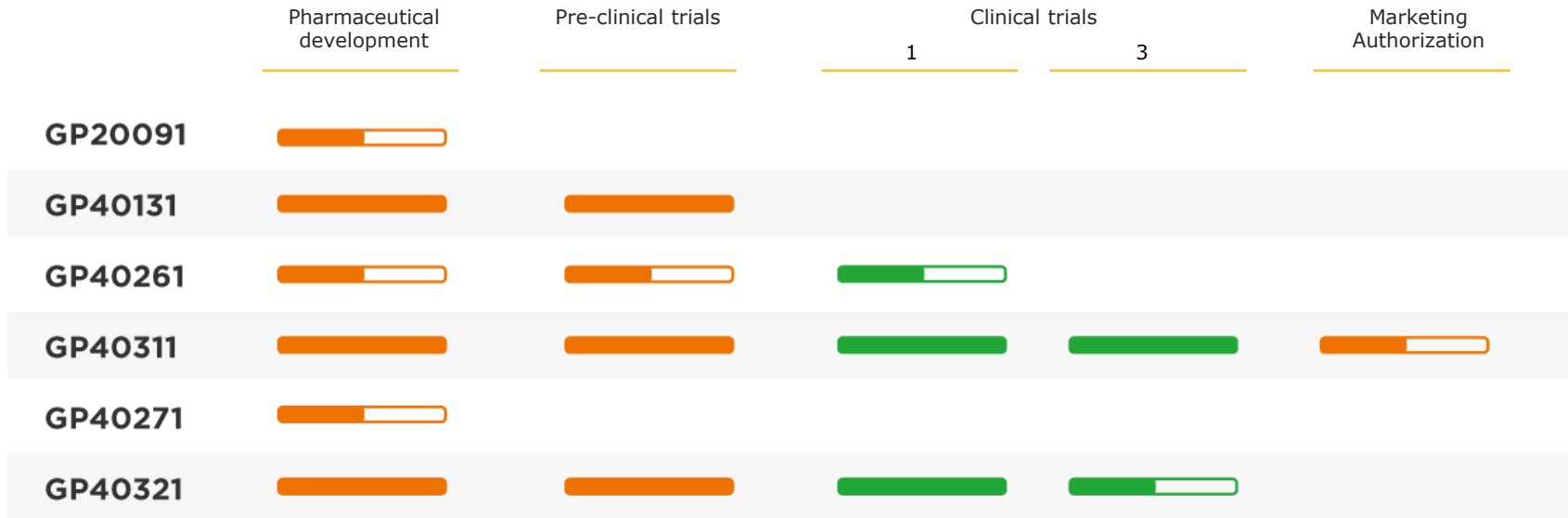
**264**   
subjects

**TYPE 2**   
diabetes mellitus

This study demonstrated high level of equivalence of pharmacokinetics and pharmacodynamics between RinFast® Mix 30 and NovoMix® 30. Thus, the biosimilarity of these products and the efficacy of the investigational insulin aspart made by GEROPHARM have been confirmed.

As a result, the comparable safety and immunogenicity of RinFast® Mix 30 versus original medicinal product NovoMix® 30 have been proven.

# INSULIN PIPELINE



# ENDOCRINOLOGY

## EVODIN®



### INN: evogliptin

evogliptin is a hypoglycemic medicinal product of dipeptidyl peptidase-4 inhibitors (iDPP-4) class, which is prescribed to patients with type 2 diabetes mellitus.

- Evogliptin is the newest original molecule of the iDPP-4 group
- tasks of combining all clinically significant positive characteristics for this group acted as prerequisites for the development of evogliptin, resulting in reduction of the daily dose to 5 mg once a day while maintaining therapeutic effects
- product is associated with a lower risk of hypoglycemia compared to the oral hypoglycemic medicinal products of other groups
- product has no effect on body weight

# ENDOCRINOLOGY

## RINFORMIN® LONG



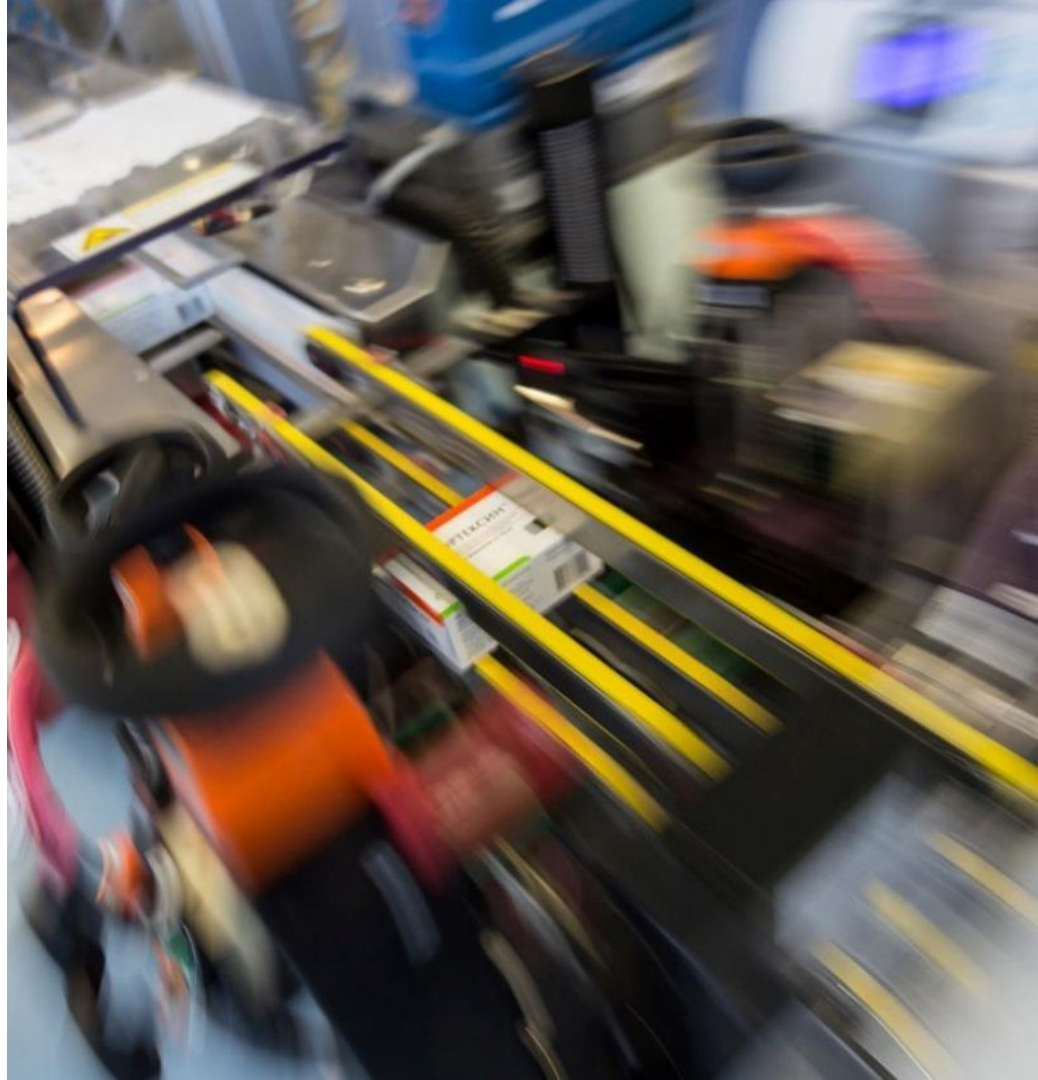
### INN: metformin

Priority starting line product for type 2 diabetes mellitus

### Clinical benefits:

- low risk of hypoglycemia
- no effect on body weight
- lipid profile improvement
- reduced risk of myocardial infarction in patients with type 2 diabetes mellitus and obesity
- reduced risk of type 2 diabetes mellitus in impaired glucose tolerance (IGT)

# ORIGINAL MEDICINAL PRODUCTS



# NEUROLOGY

## CORTEXIN®

### **Cortexin®, 10 mg** **Cortexin®, 5 mg (for children)**

neuropeptide, which provides protection and restoration of nervous tissue in various nervous system diseases.

### **The product is used as part of combined therapy for:**

- epilepsy
- asthenic conditions (suprasegmental autonomic disorders)
- decreased learning ability
- delays in psychomotor and speech development in children
- various forms of cerebral palsy
- traumatic brain injury and its consequences
- encephalopathies of various origins
- cognitive impairments
- acute and chronic encephalitis and encephalomyelitis
- traumatic brain injury and its consequences



The information is intended for healthcare professionals and pharmaceutical specialists

# GYNECOLOGY

## PINEAMIN®

the **1<sup>st</sup> exclusive injectable medicinal product with an innovative PPG** (Polypeptides of Pineal Gland) class effect and anti-age effect for the treatment of the menopausal syndrome.

- high therapeutic activity
- high level of safety and tolerability
- long-term effect
- short injection courses





# OPHTHALMOLOGY

## RETINALAMIN®

a medicinal product that stimulates retinal regeneration

### The product is used as part of combined therapy for:

- compensated primary open-angle glaucoma
- diabetic retinopathy
- inflammatory or traumatic central retinal degeneration
- central retinal degeneration
- myopia (as part of comprehensive treatment)
- central and peripheral tapetoretinal degeneration
- rhegmatogenous and traumatic retinal detachment (post-operative rehabilitation period, as part of comprehensive treatment)



ALL  
INSULIN  
BLOCKBUSTERS  
IN  
PORTFOLIO

WE CREATE A HEALTHY FUTURE  
YEARS ON THE MARKET

- AMONG TOP-3 INSULIN MANUFACTURERS IN RUSSIA
- ACCORONA VACCINE ORIGINAL MANUFACTURER

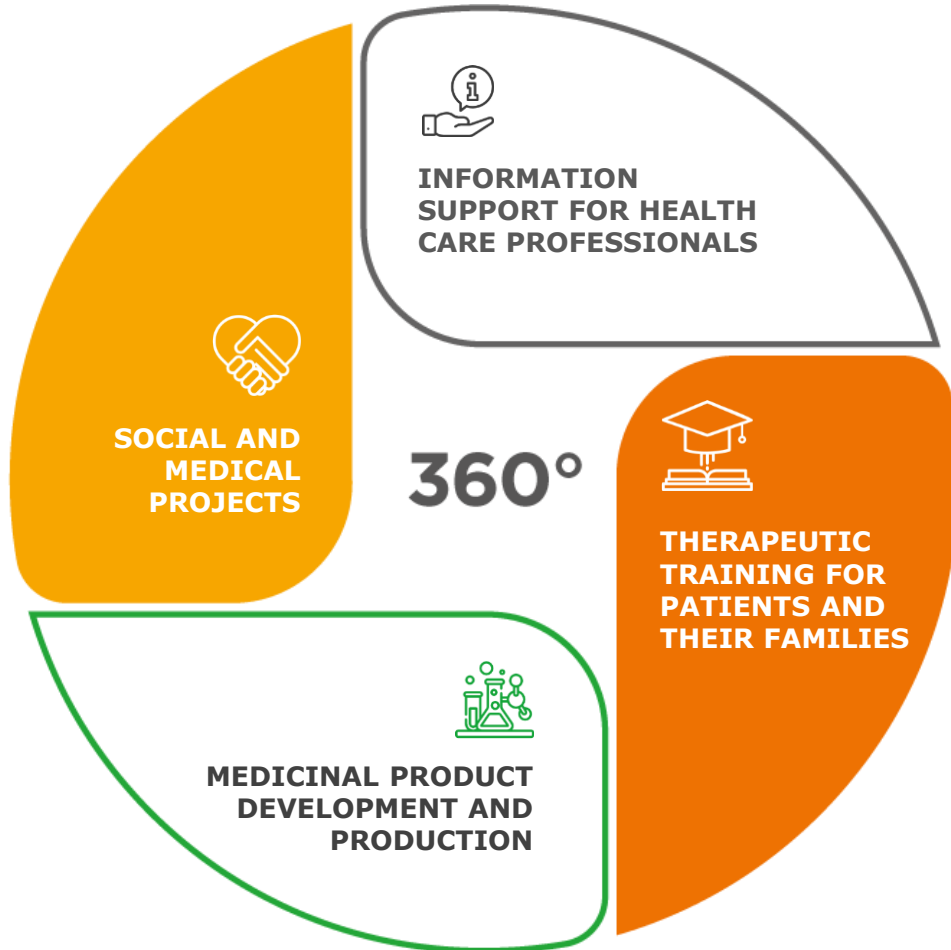


GEROPHARM

RAPIDLY GROWING BIOTECHNOLOGICAL COMPANY. COMPREHENSIVE SOLUTIONS IN DIABETES TREATMENT.

ENDOCRINOLOGY  
NEUROLOGY  
PSYCHIATRY  
OPHTHALMOLOGY  
GYNECOLOGY

INTEGRATED APPROACH  
TO SALES & MARKETING



## **GEROPHARM is committed to the patient-oriented approach**

It is applied to the production of safe and high-quality medicinal products, but not only

For years, the Company has been consistently engaged in efforts for improving the prevention, diagnosis, and treatment of various diseases

# STRONG EXPERTISE IN WORKING WITH THE MEDICAL COMMUNITY

**The main objective** is to build awareness about biosimilars and form a stable loyalty among health care professionals



Working with leading national and regional KOLs



Active participation in conferences, forums, advanced training programmes for doctors and other scientific and educational healthcare events



Conducting post-marketing observational studies



Doctor of the Future: GEROPHARM Digital Academy for medical practitioners



Publications in the professional media



# SOCIAL PROJECTS



**Diabetes in Persons** is a social project on diabetes for physicians and patients. It helps create a strong community whose objective is to improve the disease prevention, diagnosing, and treatment

- Extracurricular activities for children
- Information about the disease and living with it
- Support programmes for children in difficult straits
- Studies of social and medical issues in the life of patients and their families
- Information campaigns to raise awareness of the disease
- Events for children



**We use the social franchise format to share our best practices**



# GEROPHARM

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