



# GEROPHARM GROUP





# **ABOUT GEROPHARM**



## **PHARMACEUTICAL MANUFACTURING AND DISTRIBUTION**

The Headquarter company:  
business development strategies,  
sales and marketing



## **INNOVATIVE BIOTECHNOLOGY**

GMP compliant manufacturing site

Full cycle production



## **R&D CENTER**

All aspects of drug and  
pharmaceutical development and its  
industrial application

# GEROPHARM IN FIGURES



**3,9 BLN**

rubles revenue in 2016



**35%**

revenue growth to the  
indicator of 2015



**LEADER**

GEROPHARM became the largest  
manufacturer of the human insulin in  
the Russian Federation by the end  
of Q3, 2016 with the share of 23%



**>1,2 MLN**

packs of insulin  
GEROPHARM put on the  
market



**4,7 BLN**

Rubles total investment in  
technological innovations and  
R&D in 2013–2016

# GEROPHARM IN FIGURES



**>10**

drugs in company's portfolio



**>15**

projects in the pipeline



**>650**

highly qualified specialists  
(full-time employees)

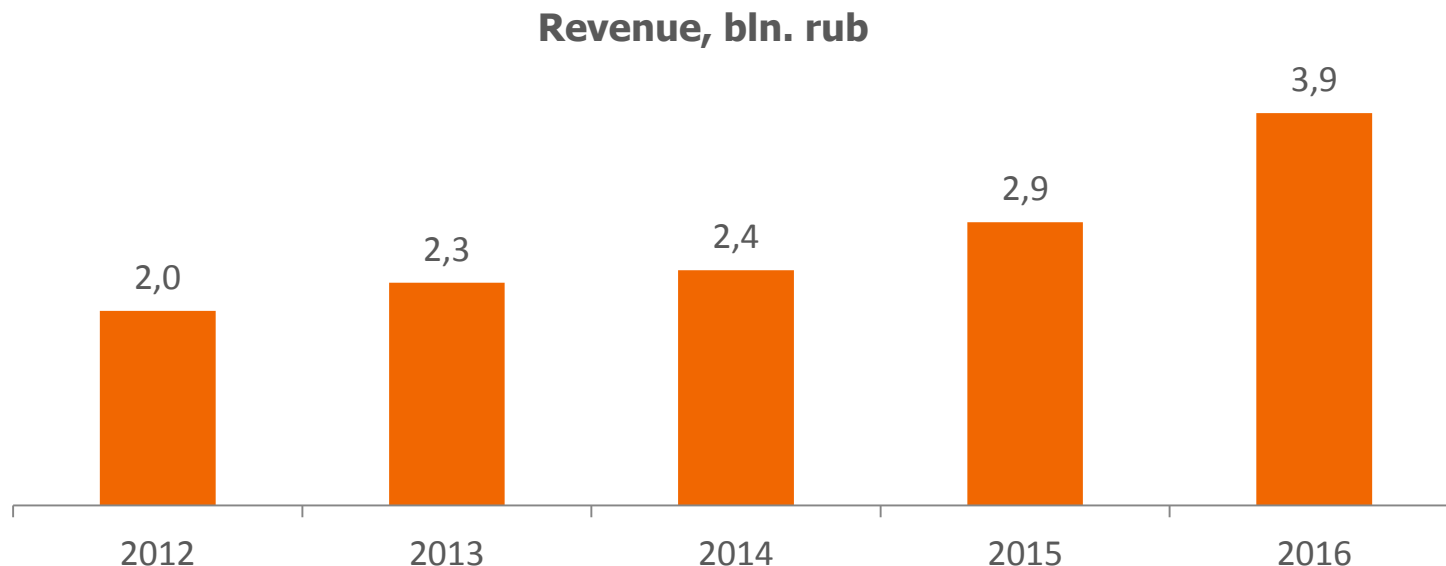


**14**

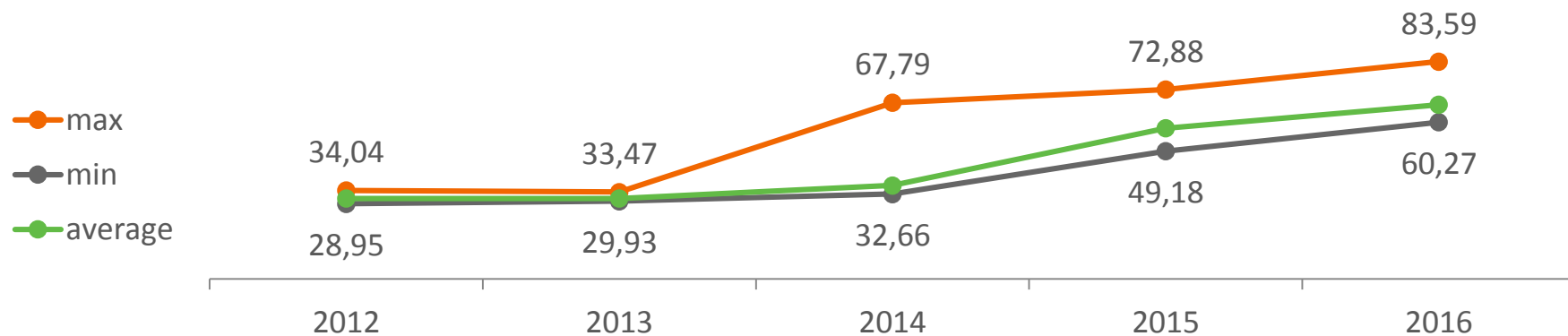
countries and all regions of the  
Russian Federation in which  
company is presented

# GEROPHARM REVENUE IN 2010-2016

.....



## OFFICIAL USD/RUB EXCHANGE RATES BY CENTRAL BANK OF RUSSIA



# PRIORITIES OF GEROPHARM

Creation of innovative  
technological platforms



Development of crucial  
technologies



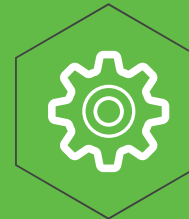
Investment projects in  
regional clusters



Build strong  
collaborations and  
partnerships worldwide



Integrated approach in  
accordance with  
**PHARMA - 2020\***, **BIO - 2020**



*\* State Federal Programs which aim to develop strong local pharmaceutical industry*



# 16 YEARS OF SUCCESSFUL WORK IN THE PHARMACEUTICAL MARKET



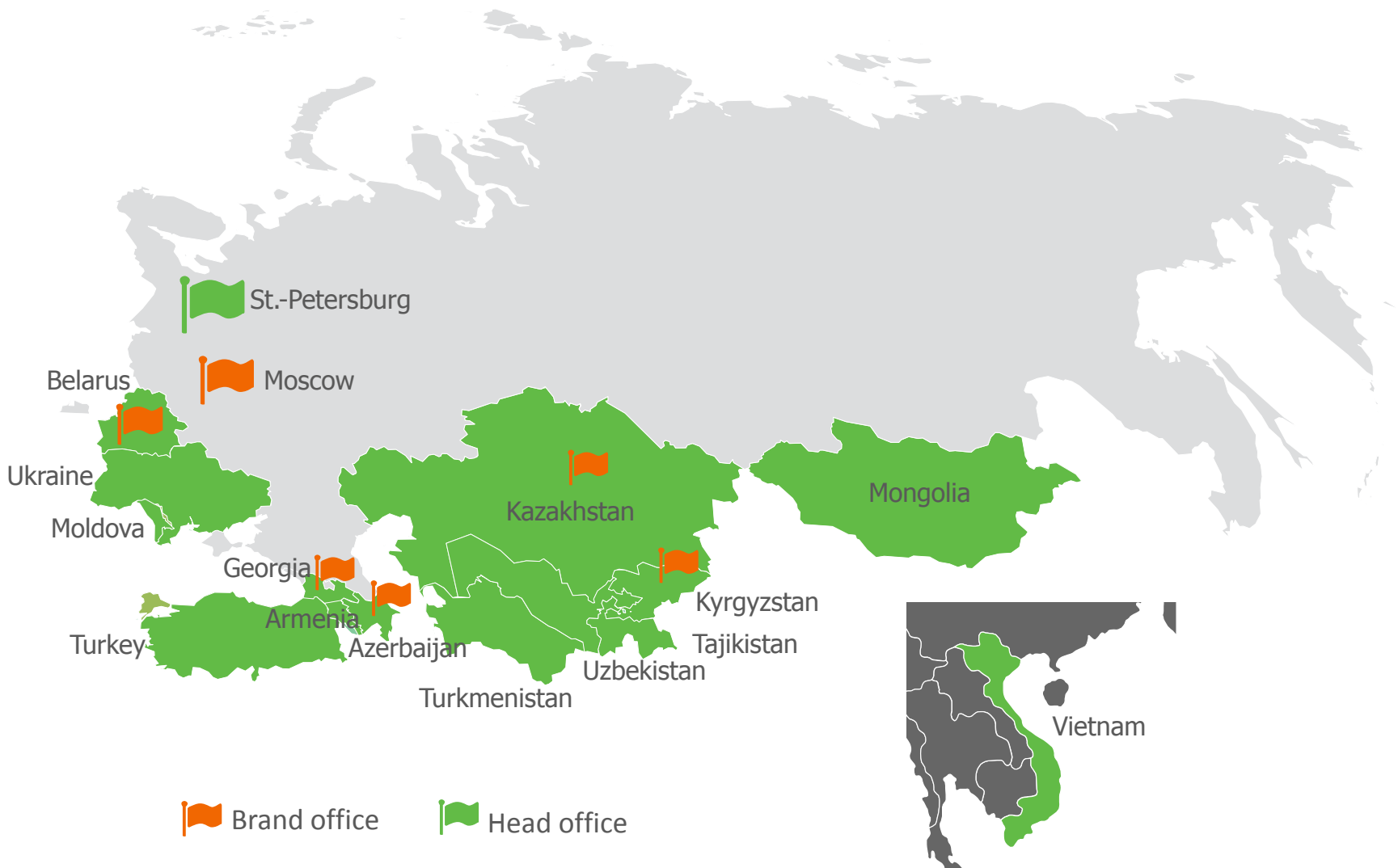


# GEROPHARM DEVELOPS EXPORT



PRODUCTS MARKETED IN  
**14** COUNTRIES

**185** REPRESENTATIVES OF SALES  
FORCE IN RUSSIAN FEDERATION





# ORIGINAL DRUGS. NEUROLOGY



**Cortexin®** , **Cortexin® for children** are used with  
in the comprehensive treatment of:

- » the blood supply to the brain
- » craniocerebral trauma and its consequences
- » different types of encephalopathies
- » cognitive disorders
- » acute and chronic encephalitis and encephalomyelitis
- » epilepsy
- » asthenic conditions (suprasegmental autonomic disorders)
- » reduced learning capacity
- » psychomotor and speech retardation in children
- » different types of cerebral palsy



# ORIGINAL DRUGS. OPHTHALMOLOGY



**Retinalamin®** is used within the comprehensive treatment of:

- » compensated primary open-angle glaucoma
- » diabetic retinopathy
- » post-traumatic and post-inflammatory central retinal dystrophy
- » myopic disease
- » central and peripheral tapetoretinal abiotrophy



# ORIGINAL DRUGS. GYNECOLOGY



Gynecology is a new area of specialization for GEROPHARM. **Pineamin®** is the original drug, produced by technology of peptide extractions from the pineal glands.

Pineamin® – the first in class premium injectable drug for alleviating symptoms of menopause. The drug has remarkable rejuvenating effects along with high safety profile and tolerability. It acts centrally through "PPGT class effect" (Polypeptides of Pineal Gland Therapy).



**LAUNCH OF THE DRUG - 2016**

# GENERIC DRUGS. NEUROLOGY



**Levetinol<sup>®</sup>** (INN: levetiracetam)



- » the current standard of remission in epilepsy
- » an optimal option for treatment of most patients with epilepsy
- » high efficacy and tolerability vs other AEDs
- » treatment choice for mono - and combined therapy in focal and generalized epilepsy

Dosage forms: 250 mg, 500 mg, 1000 mg

# GENERIC DRUGS. NEUROLOGY



**Memantinol<sup>®</sup>** (INN: memantine)



- » the current medicine for dementia treatment
- » included in the list of Essential and Vital Medicines, and in the approved standards of Dementia treatment, validated by the Ministry of Health of the Russian Federation
- » various sets pills: №30, №90



# GENERIC DRUGS. NEUROLOGY



**Recognan® (INN: citicoline)** is a neuroprotective agent which has a wide range of therapeutic indications:

- » ischemic stroke (post-stroke rehabilitation)
- » acute and recovery stage of traumatic brain injury
- » cognitive and behavioral impairment associated with neurodegenerative and cerebrovascular diseases
- » mental and cognitive dysfunction



Recognan® is adjusted to human physiology more than any other identified neuroprotective agent. It makes Recognan® the treatment of choice in therapy, prevention and improvement of nervous system functional activity.

# GENERIC DRUGS. NEUROLOGY



Pregabalin is a potent gabapentinoid and structural analogue of the neurotransmitter GABA. It is a ion channel modulator that has rapid analgesic, anticonvulsant and anxiolytic effects.

Pregabalin is used to treat:

- » neuropathic pain
- » epilepsy
- » generalized anxiety disorder
- » fibromyalgia



Dosage forms: 75 mg, 150 mg, 300 mg

# ENDOCRINOLOGY. RINSULIN® R AND RINSULIN® NPH



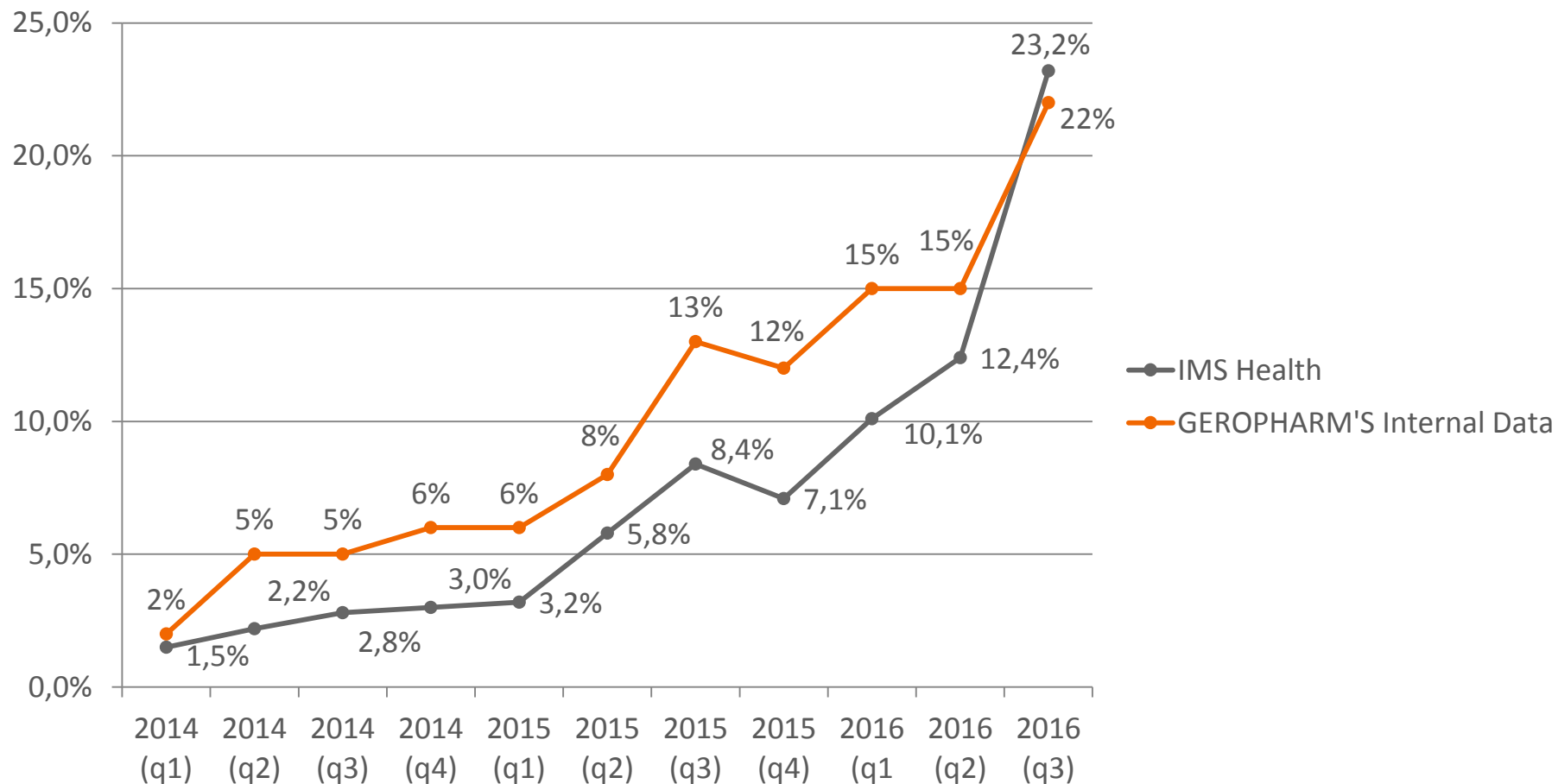
- » Own unique patent protected technology process of the insulin substance synthesis
- » Produced in the various drug forms: vials, cartridges, pre-filled multidose disposable pens
- » Low level of impurities of insulin substance that corresponds to pharmacopeia requirements\*



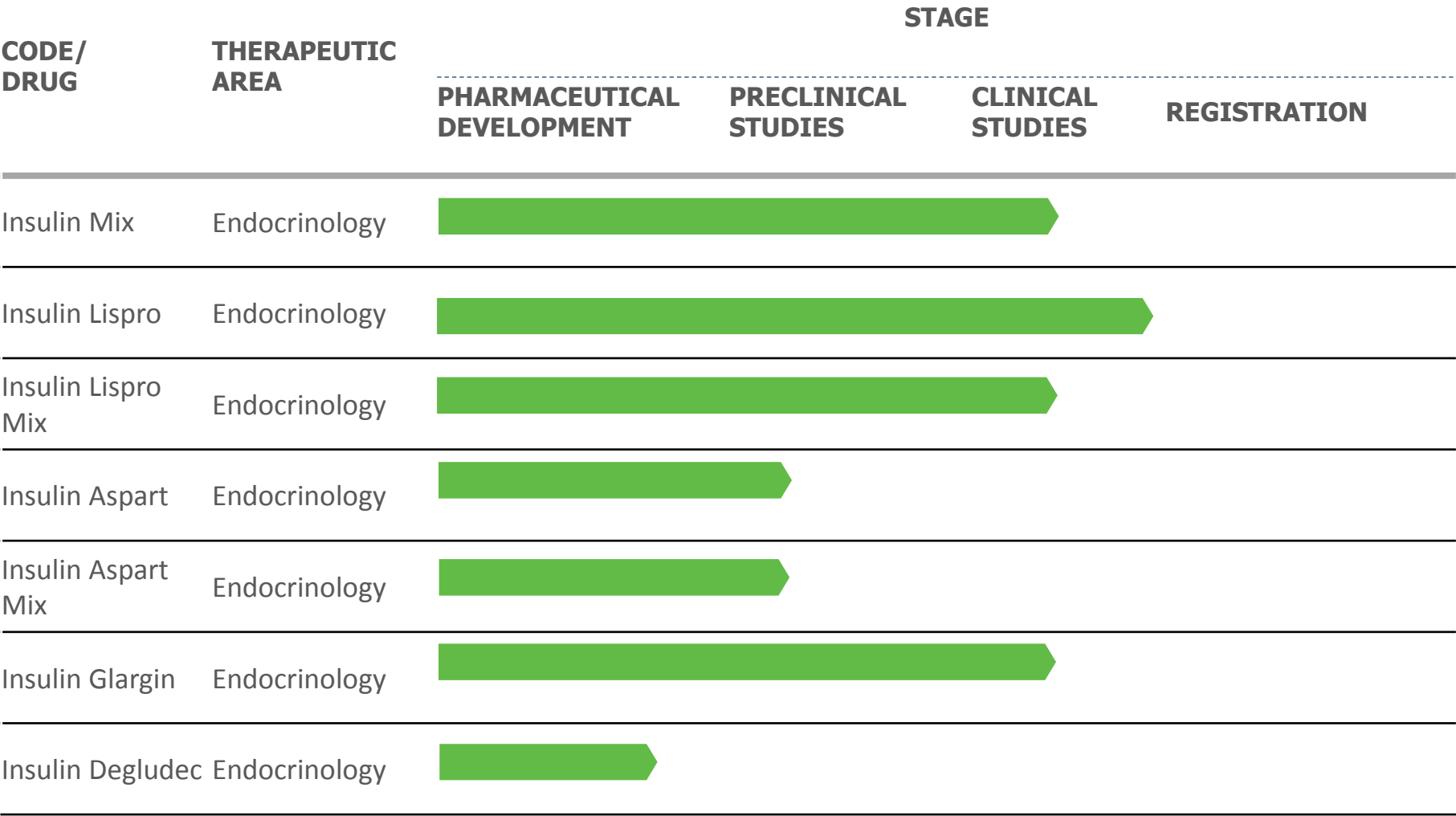
\* USP and Ph.Eur pharmacopoeia reference standard of impurities  
Russian design of packaging is shown. Packaging is adapted to each country's regulatory requirements

# MARKET SHARE INCREASE OF GEROPHARM'S RECOMBINANT HUMAN INSULIN IN 2014-2016

.....



# PRODUCT PIPELINE. INSULIN ANALOGUES





# **RESEARCH AND DEVELOPMENT**

# RESEARCH & DEVELOPMENT



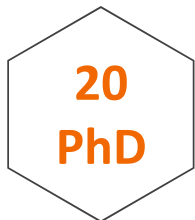
Full cycle of drug development in accordance with ICH, GLP, GCP, GMP standards



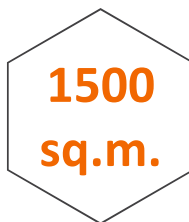
Main R&D areas: neurology, endocrinology, ophthalmology



State-of-the-art technologies: genetic engineering, molecular and cellular biology



Team of more than 20 PhD scientists with extensive hands-on expertise and experience



R&D center covers 1500 sq.m.



Neudorf special economic zone, Saint-Petersburg





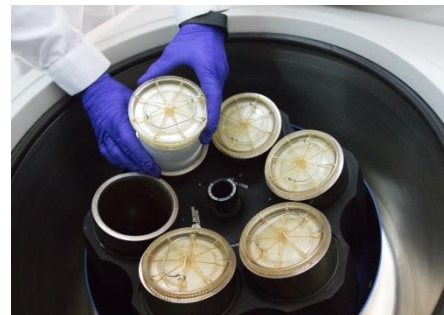
# R&D EXPERTISE AND FOCUS



Synthesis and  
screening of the  
original substances



Full range of pre-  
registration studies



Drug development



Testing and  
implementation of  
new technologies in  
industrial production



## QUALITY BY DESIGN

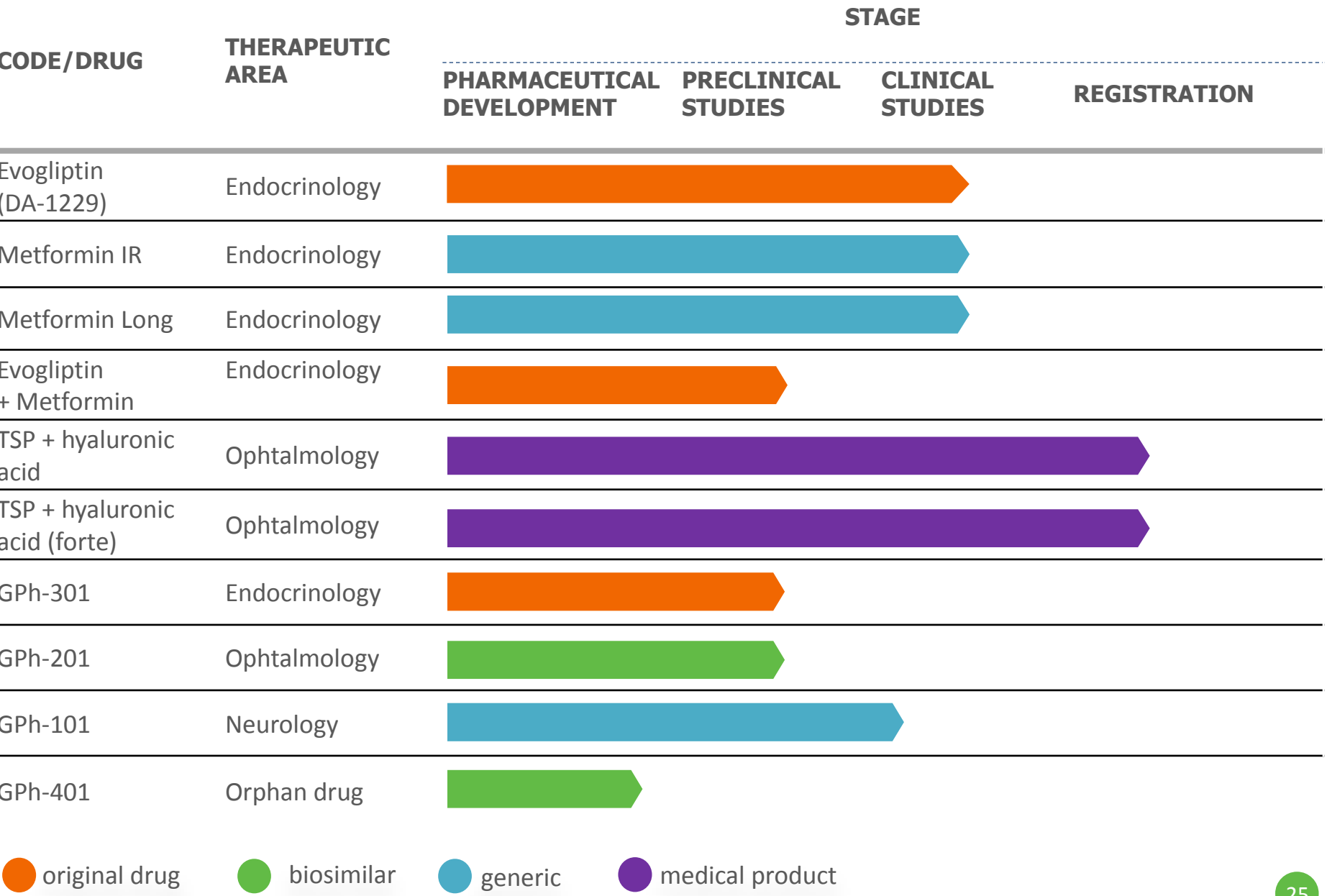
GEROPHARM develops sophisticated technologies in drug development utilizing its expertise and knowledge in the pharmaceutical industry. These endeavours require financial investments as well as time and continued diligence



## LABORATORIES

- ✓ Bioorganic Chemistry
- ✓ Analytical
- ✓ Genetic Engineering
- ✓ Finished Dosage Form
- ✓ Bioprocess Development

# PRODUCT PIPELINE





**PRODUCTION**



# GEROPHARM-BIO PLANT (OBOLENSK, MOSCOW REGION)



**GMP**

A modern GMP manufacturing enterprise



Full cycle basis: from scratch substance to the finished filled drug form



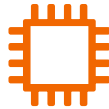
Advanced technologies and the latest methods of control



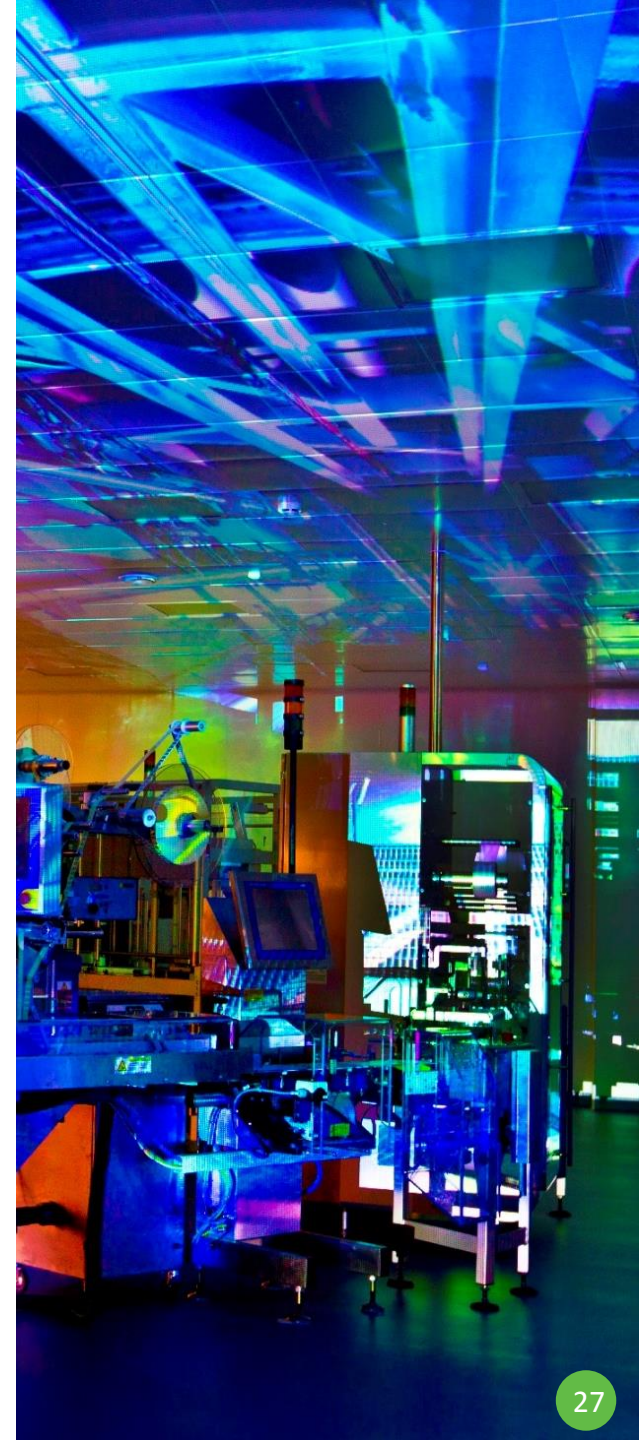
The control service includes a quality control testing laboratory certified by Rosstandart



Proprietary technology



Equipment of the world leading companies -Stilmas, Olsa, Groninger, Seidenader, Bausch+Ströbel, Uhlmann, Pester



# RINSULIN PRODUCTION: FROM SUBSTANCE TO THE FINISHED DOSAGE FORM



## SUBSTANCE MANUFACTURING



**1** | Extraction of insoluble protein fraction (inclusion-body preparation)

**2** | Purification of the recombinant proinsulin protein

**3** | Purification of the insulin protein

## PREPARATION OF FINISHED DOSAGE FORM



**4** | Solution preparation

**5** | Aseptic filling

**6** | Inspection

**7** | Packaging and labeling

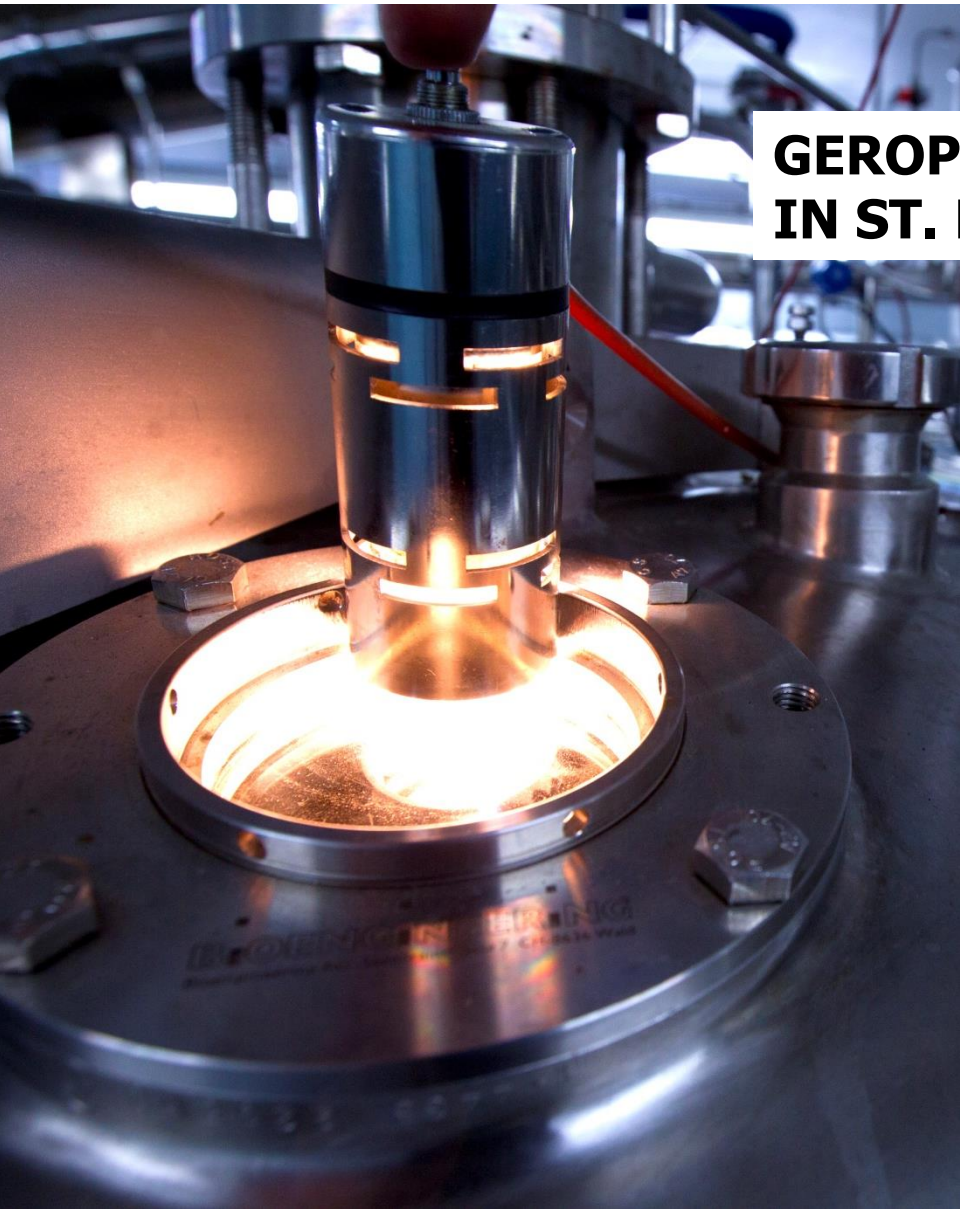




## GEROPHARM INDUSTRIAL PROJECT IN ST. PETERSBURG

- ✓ High industry and social significance recognized at the state level
- ✓ Innovative manufacturing platform for production of biotechnological drugs on a full cycle basis
- ✓ Sophisticated technology: the production of pharmaceutical substances
- ✓ Investment volume: > 2 billion rub.
- 📍 Location: «Pushkinskaya» industrial area, St. Petersburg





## GEROPHARM INDUSTRIAL PROJECT IN ST. PETERSBURG

Launch of production lines:

- ✓ 2017 – pharmaceutical substances for original drugs
- ✓ 2018 - recombinant human insulin and biosimilar insulin analogues

Launch of the new pharmaceutical production will fully meet the needs of the population of Russia in insulin and will allow to export a substance.



## WHY WE ARE THE LEADERS?

GEROPHARM is one of the leaders in the field of biotechnology products – in development and production of recombinant human insulin and insulin analogues in Russia

- ✓ A modern manufacturing site of protein drugs- the first Russian producer of recombinant human insulin which is manufactured on a full cycle basis: from scratch substance to the finished filled form
- ✓ Creation of modern pharmaceutical infrastructure – R&D center and high-tech production in compliance with GMP standards



## WHY WE ARE THE LEADERS?

- ✓ One of the priorities is production of active pharmaceutical substances
- ✓ Production of original drugs by means for treatment of socially significant diseases as well as some generics that have priority in terms of import substitution
- ✓ Aims to operate as a full cycle - defines the business development strategy, engages in drug development, manufacturing, sales and marketing of its drug products



# GEROPHARM CONSIDERS VARIOUS PLATFORMS OF COOPERATION



In-licensing of original drugs and smart generics to Russian and other CIS markets



In-house development and co-development of innovative medicines



Out-licensing of GEROPHARM products



Contract manufacturing and drug development services



# CONTACTS



Business center "Nevskaya Ratusha"  
11B, Degtyarny lane,  
St. Petersburg, 191144, Russian Federation

Tel./fax: +7 (812) 703-79-75  
[inform@geropharm.ru](mailto:inform@geropharm.ru)  
[www.geropharm.com](http://www.geropharm.com)

