

A COMPANY OF NOVEL BIOPHARMACEUTICAL PRACTICES







A portfolio of original products, biosimilar, branded generic drugs and food supplements

**29 years** in the pharmaceutical market

Full-cycle manufacturing in accordance with the **EAEU** and **EU GMP** standards

of drugs per year

One of **the largest exporters** of original medicines and vaccines

**Partnership** with global pharmaceutical companies

Hengrui ISU ABXIS Pfizer Abbott Adimmune

**EU GMP** since 2012

More than 800 employees

R&D center

**The development strategy** focuses on providing patients with in-demand vaccines and biotech drugs for the prevention and treatment of infectious, orphan, and oncological diseases

# **VISION, MISSION, ACHIEVEMENTS**



#### **Vision**

Leading pharmaceutical innovations

#### **Mission**

Expanding access to cutting-edge therapies

#### **Key projects and achievements**

- Development and market launch of original drugs: Polyoxidonium<sup>®</sup>, Longidaza<sup>®</sup>, Grippol vaccines.
- Expansion and provision of the National Vaccination Program with in-demand vaccines against influenza and pneumococcus.
- Prevenar® 13: first localization of a multicomponent foreign vaccine in Russia.
- COVID-19 response: clinical trials of the vaccine Convidecia®, original drugs Polyoxidonium® and Longidaza®
- Fabagal®: first synthesis transfer based on a cell line of an orphan drug in Russia.

#### **DEVELOPMENT HISTORY**

AP Petrovax

- Foundation of Petrovax
- Authorization of original medicinal products: immunomodulator
   Polyoxidonium® and the first adjuvant influenza vaccine Grippol®
- Obtainment of the first patents for molecules and technologies in Russia and abroad



Arkady Nekrasov, founder, Dr. habil. chem., professor, state awardee of the Russian Federation

- Opening of the first manufacturing facility for APIs and FDF
- Market launch of the original enzyme drug Longidaza®
- Partnership with Solvay Pharma (Abbott)



- Opening of the manufacturing complex in the Moscow Region
- Manufacturing of influenza vaccine Grippol® plus in syringes
- Assignment of INN Azoximer bromide for Polyoxidonium® by WHO
- Launch of the line 2 (vials and ampoules)



1996 - 2001

2001 - 2005

2006 - 2010



- A project to localize the manufacturing of the pneumococcal vaccine Prevenar® 13 in cooperation with Pfizer
- Obtainment of the EU GMP certificate, export of Polyoxidonium® to EU
- Market launch of the cosmetic product Imoferaza®
- A new investment strategy as a part of Interros Group



2016 - 2020

- Authorization of the first-ever in Russia tetravalent influenza vaccine Grippol® Quadrivalent
- Manufacturing of thrombolytics Metalyse® and Actilyse® (Boehringer Ingelheim)
- Market launch of Velson®
- A large scale program of clinical trials exploring Polyoxidonium<sup>®</sup> and Longidaza<sup>®</sup> for COVID-19 control
- Launch of the **line 3** (APIs and FDF)

2021 - 2024

- Launch of line 4 for injection dosage forms, beginning of constructing a new biotech complex
- Launch of new products: Uronext<sup>®</sup>, VitaFerr<sup>®</sup>, Gialera<sup>®</sup>, ARTNEO<sup>®</sup>, Demefecil, Omegika<sup>®</sup>, Sandevit<sup>®</sup>, VitaFerr<sup>®</sup> Express, Venarel<sup>®</sup>
- A project to localize the manufacturing of the orphan drug Fabagal® in partnership with ISU ABXIS (South Korea) and the N.F. Gamaleya Center
- A project to launch the oncological drug Areima (camrelizumab) to the Russian market in cooperation with a Chinese partner and the N.F. Gamaleya Center with subsequent localization in Russia

## **PRODUCT PORTFOLIO**















# **BIOTECH: KEY PROJECTS**

# ORPHAN DISEASES Fabagal® (INN: agalsidase beta)

- First technological transfer in Russia, including synthesis based on a cell line of an orphan drug in collaboration with ISU Abxis and N.F. Gamaleya Federal Research Center for Epidemiology and Microbiology.
- Licenses and authorizations in the Russian and EAEU markets were obtained within one year.
- Strategic goal: 100% provision of Russian patients with Fabry disease enzyme replacement therapy using domestically produced drugs.





Licenses in the Russian and EAEU territories with expansion efforts

**2023** The drug autorization in Russia

2024

A full-cycle manufacturing in Russia starting from the substance synthesis

2023 Licenses in the Russian and EAEU territories

**2024** The drug authorization in Russia

A transfer of technology to produce the FDF in Russia followed by the substance synthesis



#### ONCOLOGY Areima® (camrelizumab)

- Launch of an original oncological drug in the Russian market in partnership with a Chinese company and the N.F. Gamaleya Center with subsequent localization in Russia.
- More than 400 studies (including in Russia, Europe, the USA and Korea)
- More than 300,000 treated patients
- Unique indications in treating various cancers, including nasopharyngeal carcinoma, liver, esophageal and lung cancer.

### **R&D CENTER**



Petrovax is the holder of patents for molecules and pharmaceutical manufacturing technologies in Russia and abroad. The company's investment program ensures the financing of advanced R&D projects.

R&D center and vivarium for preclinical studies allow to carry out a full cycle of development and implementation of medicinal products.

- Search for innovative molecules and conducting preclinical studies
- In-depth study of the mechanism of action in terms of the pathogenesis of a corresponding disease
- Proof of the safety and efficacy of drugs in preclinical studies

- Development of quality control methods and manufacturing technologies
- Conducting of preclinical studies in accordance with GCP standards
- Introduction of innovative technologies, development and optimization of manufacturing processes

#### **INTERNATIONAL CLINICAL STUDIES**

2020

International Multicenter Clinical Study of the efficacy and safety of the Convidecia® COVID-19 vaccine in cooperation with CanSino Biologics with participation of 40,000 volunteers 2020

International Multicenter Phase 3 Clinical Study of efficacy and safety of the Polyoxidonium® in Complex Therapy of Patients with COVID-19



## **MANUFACTURING**



High-tech full-cycle manufacturing in accordance with EAEU and EU GMP standards

The manufacturing processes include the synthesis of APIs, the production of sterile and non-sterile medicines, including immunological and biopharmaceutical drugs in various dosage forms.

The pharmaceutical manufacturing and warehouse complex was opened in the Moscow region in 2008.

Manufacturing capacity – 160 mln doses of drugs per year.





Manufacturing medicines in pre-filled syringes

Manufacturing medicines for injection, including lyophilizates

Synthesis of APIs, manufacturing of soft and solid dosage forms Manufacturing of injectable dosage form







# **QUALITY**



The company has implemented and effectively operates a GMP certified pharmaceutical quality system (PQS), confirmed by international partners audits.

Petrovax has been certified EU GMP (Slovakia) since 2012.

The company cooperates only with approved suppliers of raw and other materials.



Quality control of manufactured pharmaceutical products and vaccines is guaranteed at all stages of production, from the sampling of raw materials to the control of finished products.

More than a hundred people work in the quality service.

The pharmacovigilance system functions in accordance with international standards and Russian regulatory requirements to ensure medicine product safety surveillance.





### **GLOBAL PARTNERSHIP**



#### **Collaboration with leading global pharmaceutical companies:**

localization and launch of in-demand vaccines and biotech drugs for the prevention and treatment of infectious, cardiovascular, orphan, and oncological diseases

















## **GEOGRAPHY**



## **Export today**

## Development in non-CIS countries





>2,3 bln rubles in 2024

>10 countries of export



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