Generium

Achievements and prospects

Generium is a Russian innovative biotechnology company

that combines a world-class research institute, a clinical trial control center, and high-tech manufacturing

Scientific and production accomplishments of the company have been repeatedly acknowledged and recognized by the foreign and domestic experts, including those from the governmental sector.

Mission

Our ideas and achievements for saving people’s lives and health!

Generium

One of the largest biotech company in Russia and CIS

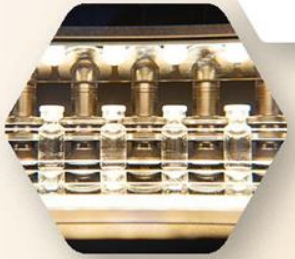
- Hematology
- Orphan diseases
- Neurodegenerative diseases
- Tuberculosis
- Autoimmune diseases
- Cardiovascular disorders

The leader in the Russian orphan biotechnology segment

Clinical trials conducted in accordance with the international standard GCP

A pioneer in the area of biomedical cell products in Russia

Preclinical studies conducted in accordance with the international standard GLP



More than 25 medicinal products in development

Manufacturing in accordance with international standards GMP and GDP

The modern biotechnology park

that brings together world-class scientists

Biotechnology park GENERIUM is located in Volginsky settlement, Vladimir Region, where we have developed the infrastructure for work and life of world-class scientists.

To develop innovative biotechnological products, we have gathered leading experts and brought advanced technologies to Russia.

1 500+

employees

~80 Ha

territory of the biotechnology park

5,000 m^2 +

laboratory facilities

50+

residential buildings

40,000 m^2 +

production facilities

10,000 m^2 +

living space

Research and Development

4500m^2

Lab space

Full cycle

of pre-clinical trials under GLP and GCP standards

30

Projects on different stages of development

~150

Scientists

Manufacturing site

Our manufacturing facilities are equipped with the high-end equipment. We've built the detached full-cycle technological lines that are able to produce any kind of biological pharmaceuticals, from cultivation to finished dosage forms.

21000m^2+

manufacturing space

New manufacturing site

Launched in 2021

20000m^2+

manufacturing space

x3

potential expansion inside the building

Licenses and certificates

License to work with microorganisms

Manufacturing Authorization

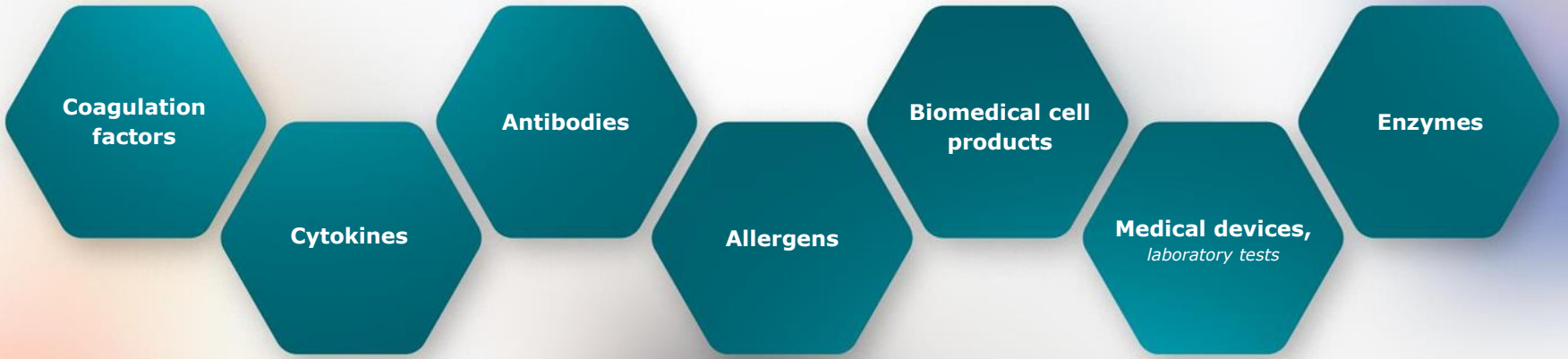
GMP

EDQM PTS

ISO 9001

From molecule design to the finished dosage form

The production facilities of the company are equipped with separate full-cycle production lines, allowing us to offer a wide range of products.



GMP

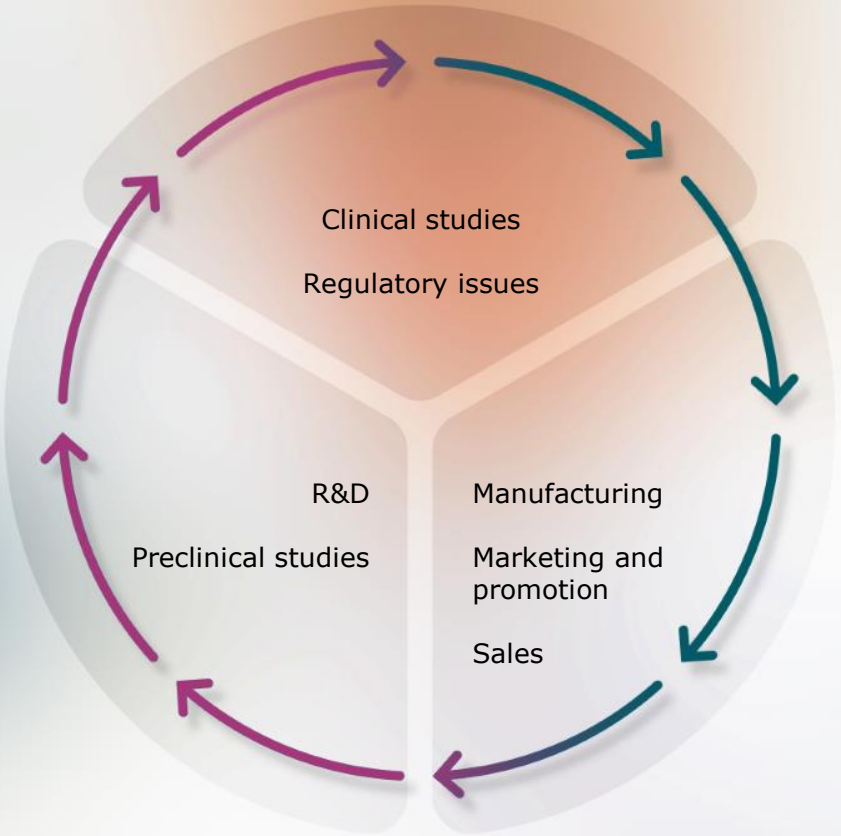
The quality of products is guaranteed by strict adherence to the national and international standards of Good Manufacturing Practice.

The main objective

To provide the healthcare system with modern genetically engineered products, biomedical cell products, and laboratory test systems of domestic production for the diagnosis, prevention and treatment of severe diseases.

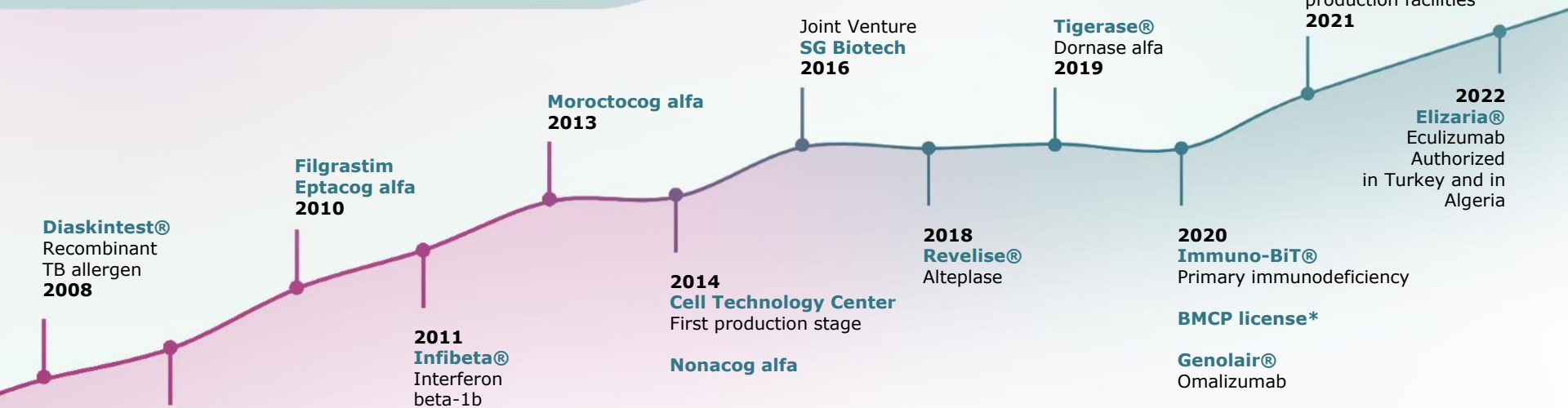
To ensure state budget saving opportunities in pharmaceuticals via cost effective biosimilar products.

Generium
Science



Generium
Pharmaceuticals

Continuous development since 2008



Diaskintest®
Recombinant TB allergen
2008

2009
Somatropin

Filgrastim
Eptacog alfa
2010

2011
Infibeta®
Interferon beta-1b

Moroctocog alfa
2013

2014
Cell Technology Center
First production stage

Nonacog alfa

Joint Venture
SG Biotech
2016

2018
Revelise®
Alteplase

Partnership with **Oxford Immunotec** T-SPOT.TB

Glurazyme®
Imiglucerase

Elizaria®
Eculizumab

Tigerase®
Dornase alfa
2019

2020
Immuno-BiT®
Primary immunodeficiency

BMCP license*

Genolair®
Omalizumab

Launch of **Sputnik V®** production

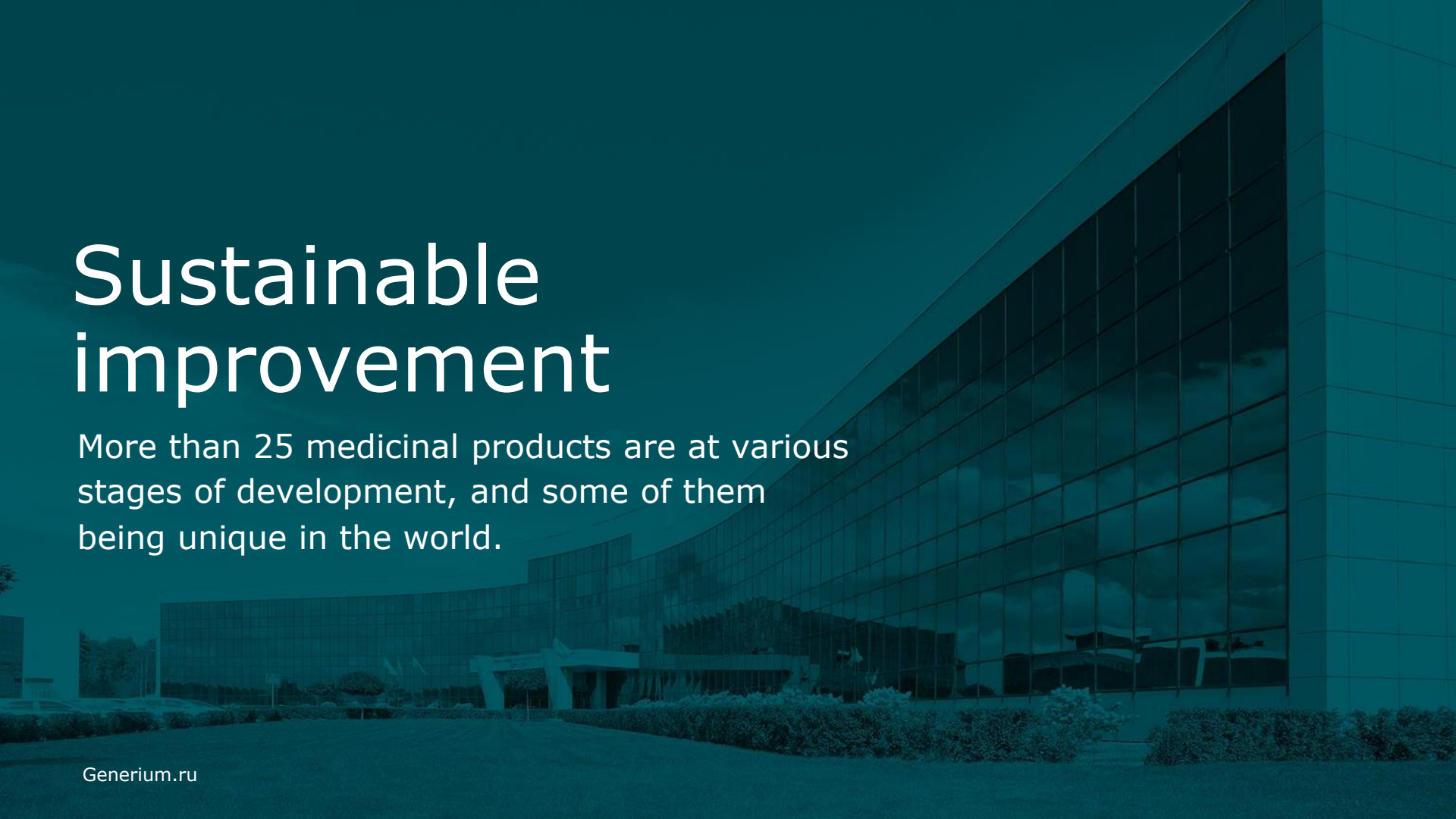
Isotherm SARS-CoV-2 RNA-screen®
COVID-19 detection kit

Antigma® tests
Test systems for COVID-19 antibody detection

MagniTest®
Reagent kit for detection of SARS-CoV-2 RNA by the loop-mediated isothermal amplification

Launch of new production facilities
2021

2022
Elizaria®
Eculizumab
Authorized in Turkey and in Algeria



Sustainable improvement

More than 25 medicinal products are at various stages of development, and some of them being unique in the world.

17 medicinal products and diagnostic tools

have been authorized over 14 years

We work in the following disease areas:

- **Orphan diseases**
- **Infectious diseases**
- **Traumatology and orthopedics**
- **Neurodegenerative diseases**
- **Autoimmune diseases**
- **Cardiovascular diseases**
- **Ophthalmology**
- **Hematology**
- **Phthisiology**
- **Pulmonology**
- **Oncology**

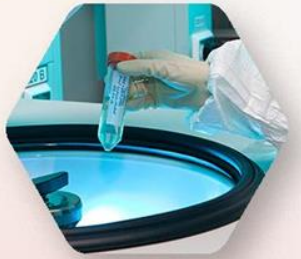
GENERIUM has at its disposal the first BMCP manufacturing site licensed in Russia, which is also one of the largest in Europe*

* As of 01.01.2022

Medicinal products

Biomedical cell products

Diagnostic systems



Vaccines

Medicinal products

Elizaria®

INN: Eculizumab

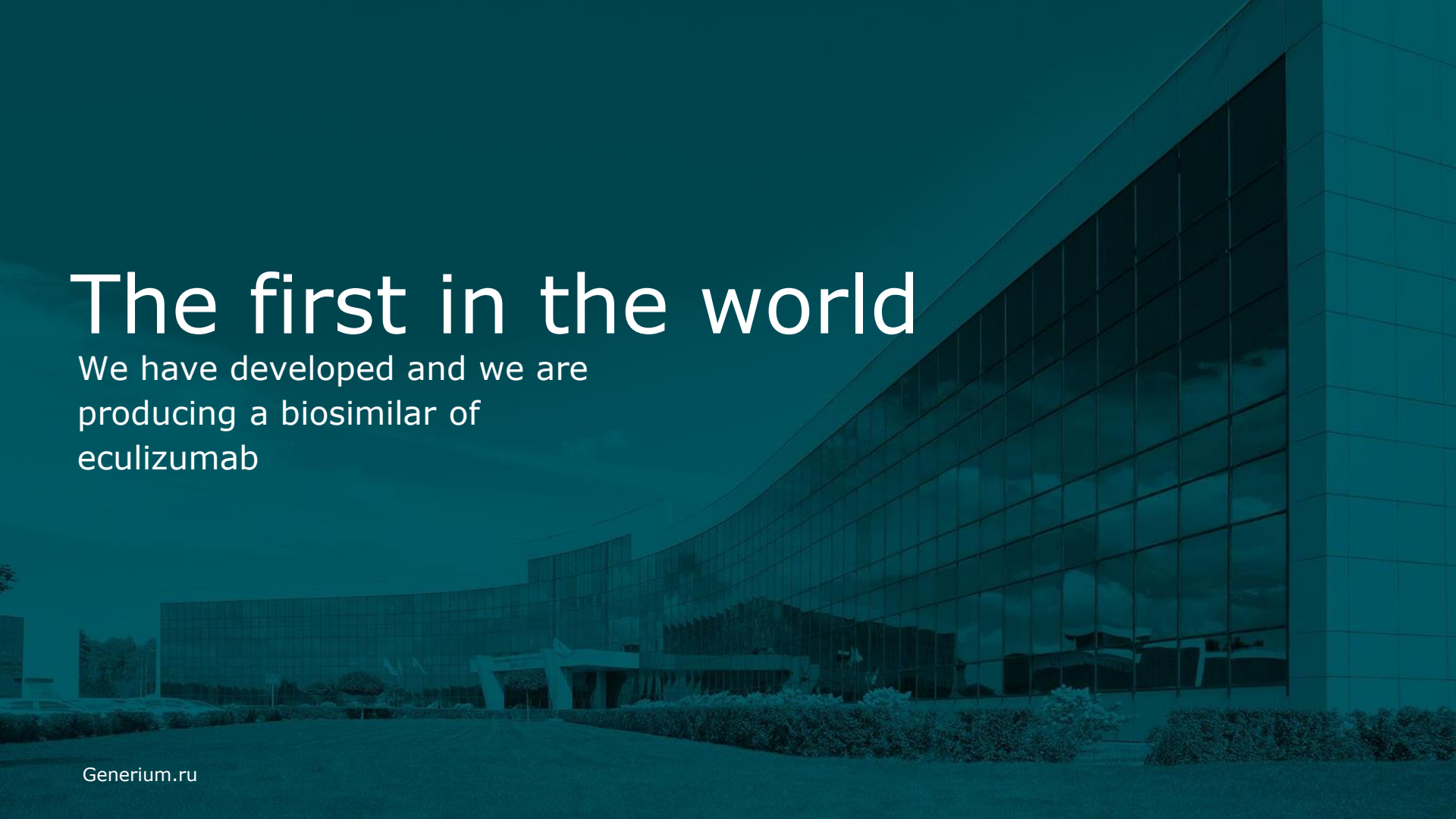
Development stage: Commercialized
Dossier status and format: CTD
Available Studies (Pharmaceutical Equivalence, Bioequivalence, Clinical Trials): all studies are available
Countries where product has Marketing Authorization: Russian Federation, Republic of Belarus, Kazakhstan, Turkey, Algeria, Columbia
Countries where product is commercialized: Russian Federation, Belarus, Algeria, Oman
GMP: Russian Federation, Columbia, Turkey, Brazil (expired in 2022)

Pharmacodynamic action

- **Inhibits the activity of the human terminal complement complex**
- **Restores the regulation of complement activity in the blood and prevents intravascular hemolysis in PNH patients**
- **Prevents excessive activity of the terminal complex in patients with aHUS**
- **Eculizumab therapy substantially reduces risks of aggravations, decreases hospital stay cases and corticosteroids use within patients with neuromyelitis optica**

Application

- **Paroxysmal nocturnal hemoglobinuria**
- **Atypical hemolytic uremic syndrome (aHUS)**
- **refractory generalized myasthenia gravis (GMG)**
- **recurrent neuromyelitis optica spectrum disorders (NMOSD)**

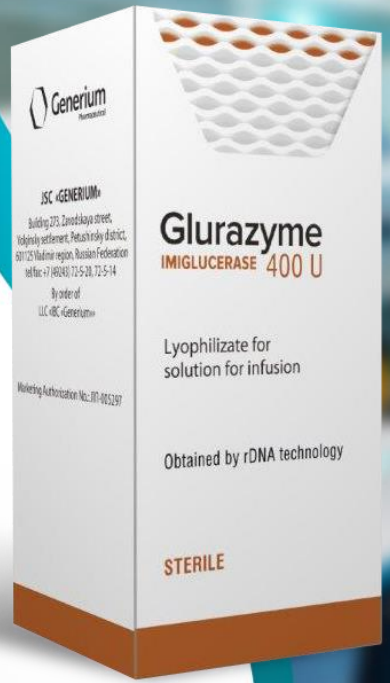

The first in the world
We have developed and we are producing a biosimilar of eculizumab
Generium.ru

Medicinal products

Glurazyme®

INN: Imiglucerase

Development stage: Commercialized
Dossier status and format: CTD
Available Studies (Pharmaceutical Equivalence, Bioequivalence, Clinical Trials): all studies are available
Countries where product has Marketing Authorization: Russian Federation, Republic of Belarus
Countries where product is commercialized: Russian Federation, Republic of Belarus
GMP (Country of origin/Brazil): Russian Federation, Turkey



Pharmacodynamic action

- **Leads to a decrease in the size of the spleen and liver**
- **Improves or normalizes blood platelet counts and bone mineral density**
- **Reduces bone marrow infiltration**
- **Relieves or weakens bone pain and bone crises**

Application

Gaucher disease

Indicated for adult and pediatric patients: as long-term enzyme- replacement therapy in patients with a confirmed diagnosis of non-neuronopathic (Type 1) or chronic neuronopathic (Type 3) Gaucher disease, who exhibit clinically significant manifestations of the disease, including one or more of the following symptoms: anemia, thrombocytopenia, bone diseases, hematomegaly, or splenomegaly.

Portfolio
Marketed Priority Products

Product	Indication	Status
Elizaria®* INN: eculizumab	• Paroxysmal nocturnal hemoglobinuria Atypical hemolytic uremic syndrome (aHUS) • Myasthenia gravis • Neuromyelitis optica	The first in the world biosimilar of Soliris® (Alexion). Already, being supplied in CIS countries, Oman, and Asian region by NPP.
Glurazyme®* INN: imiglucerase	Gaucher disease	The first in Russia biosimilar of Cerezyme® (Genzyme)
Diaskintest®* INN: Recombinant TB allergen	Innovative intradermal diagnostic test for detection of tuberculosis	Registered in Russia and EAEU In 2022 was included in WHO guidelines for diagnosis of the tuberculosis infection
Genolair® INN: omalizumab	• Bronchial asthma • Chronic idiopathic urticaria	The first in the world biosimilar of Xolair® (Novartis)
Revelise® INN: alteplase, tPA	• Acute myocardial infarction • Ischemic stroke • Massive pulmonary embolism (PE)	The first in the world biosimilar of Actilyse® (Boehringer Ingelheim)
Tigerase® INN: dornase alfa	Cystic fibrosis	The first in the world biosimilar of Pulmozyme® (Genentech)

*** High-potential products**

Portfolio
Marketed Products

Product	Indication	Status
Coagil-VII® INN: Eptacog alfa [activated]	Inhibitor Hemophilia	Registered in Russia and EAEU
Octofactor® INN: Moroctocog alfa	Hemophilia A	Registered in Russia and EAEU
Innonafactor® INN: Nonacog alfa	Hemophilia B	Registered in Russia and EAEU
Infibeta® INN: Interferon beta-1b	Multiple sclerosis	Registered in Russia and EAEU
Rastan® INN: somatropin	Growth hormone deficiency	Registered in Russia and EAEU
Neipomax® INN: filgrastim	Neutropenia in Oncology patients, Transplantation patients, HIV-patients	Registered in Russia and EAEU

Product pipeline clinical development

Orphan diseases

ID	INN	Type	Therapy area	Status
GNR-069	**Romiplostim**	**biosimilar**	**Idiopathic thrombocytopenic purpura**	**Phase 3**
GNR-071	**Galsulfase**	**biosimilar**	**Maroto-Lami syndrome, MPS**	**Phase 3**
GNR-068	Ustekinumab	biosimilar	Plaque psoriasis	Phase 3
GNR-060	Tenecteplase	biosimilar	Myocardial infarction	Phase 3
GNR-067	Ranibizumab	biosimilar	Macular degeneration	Phase 3
GNR-087	Tocilizumab	biosimilar	Rheumatoid arthritis	Phase 3
GNR-055	**HIR-FAB-IDS**	**original**	**Mucopolysaccharidosis, type II**	**Phase 1/2**
GNR-062	**Agalsidase beta**	**biosimilar**	**Fabry Disease, MPS**	**Phase 1**
GNR-084	Anti CD3xCD19	original	Acute lymphoblastic leukemia	Phase 1
GNR-086	Canakinumab	biosimilar	Systemic juvenile idiopathic arthritis	Phase 3
GNR-093	Natalizumab	biosimilar	Remitting multiple sclerosis	Phase 1

International co-operation

Research activities on individual projects are carried out in cooperation with leading biotech companies and research organizations from around the world.

Export activities

Regular supplies to all regions of Russia and the CIS countries. Deliveries to non-CIS countries.

Marketing authorization of medicinal products in Latin America, the Middle East, and North Africa.

Contact information

General issues:generium@generium.ru
M&A and licensing: bd@generium.ru
Press: pr@generium.ru
Website: generium.ru

Headquarters

10 Testovskaya street,
Entrance 2, Moscow, 123112
+7 (495) 988-47-94

R&D Park

14 Vladimirskaya street, Volginsky settlement,
Petushinsky district, Vladimir region, 601125
+7 (49243) 7-31-04

Manufacturing

Building 273, Zavodskaya street, Volginsky settlement,
Petushinsky district, Vladimir region, 601125
+7 (4922) 37-93-17