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# Oncology Diseases

# INN Bevacizumab

Type of product: Biosimilar
International trade name: **Avegra®, Bevalast®, Bonmab®**

## Description/Summary

Recombinant humanized monoclonal antibody that blocks angiogenesis by inhibiting vascular endothelial growth factor (VEGF) and causes reduction of microvascular growth in tumor and inhibition of metastatic disease progression.

## Indications

- Metastatic colorectal cancer
- Local recurrent or advanced breast cancer
- Inoperable or advanced non-squamous NSCLC
- Advanced and/or metastatic renal cell cancer
- Glioblastoma (grade IV glioma)
- Epithelial ovarian, fallopian tube and primary peritoneal cancer
- Persistent, recurrent or metastatic cervical carcinoma

## Therapeutic class (ATC code)

VEGF/VEGFR Inhibitors (L01FG)

## Presentation

Concentrate for solution for infusion in vials

- 25 mg/ml, 4 ml (100 mg)
- 16 ml (400 mg)

## Route of administration

Intravenous Infusion

## Marketing Authorizations

- Russian Federation (2015)
- 30+ countries

## Packs sold

4,3 M+ packs*


April 2025

* 25.11.2015 – 25.02.2025

# INN Rituximab

Type of product: Biosimilar
International trade name: **Acellbia®, Biorimab®, Rituxell®**

## Description/Summary

Chimeric monoclonal antibody which specifically binds to the transmembrane antigen CD20.

## Indications

- Non-Hodgkin’s lymphoma
- Chronic lymphocytic leukemia
- Rheumatoid arthritis
- Granulomatosis with polyangiitis (GPA) and microscopic polyangiitis (MPA)
- Moderate to severe Pemphigus Vulgaris (PV)

## Therapeutic class (ATC code)

CD20 Inhibitors (L01FA)

## Presentation

Concentrate for solution for infusion in vials

- 100mg #2
- 500mg #1

## Route of administration

Intravenous Infusion

## Marketing Authorizations

- Russian Federation (2014)
- 30+ countries

## Packs sold

1,2 M+ packs*


April 2025

* 17.11.2024

# INN Trastuzumab

Type of product: Biosimilar
International trade name: **Herticad®, Tuzdant®, Trasticad®**

## Description/Summary
Recombinant humanized IgG1 monoclonal antibody against the human epidermal growth factor receptor 2 (HER2) that has been shown to inhibit the proliferation of HER2 overexpressing cancer cells.

## Indications
- HER+ Breast cancer
- Gastric cancer

## Therapeutic class (ATC code)
HER2 Inhibitors (L01FD)

## Presentation
Lyophilized powder for concentrate for solution for infusion in vials

- 150mg #1
- 440mg #2

## Route of administration
Intravenous Infusion

## Marketing Authorizations
- Russian Federation (2015)
- 25+ countries

## Packs sold
2,1 M+ packs*




*31.12.2015 – 24.09.2024

# INN Pembrolizumab

Type of product: Biosimilar
International trade name: N/A

## Description/Summary

Humanized monoclonal antibody that selectively binds to the PD-1 receptor and blocks its interaction with its ligands PD-L1 and PD-L2.

## Indications

- Melanoma
- NSCLC (squamous and non-squamous)
- Head & Neck (HNSCC)
- Classical Hodgkin Lymphoma (cHL)
- Primary Mediastinal Large B-Cell Lymphoma (PMBCL)
- Urothelial carcinoma (UC)
- MSI-H cancers (CRC, non-CRC)
- Gastric Cancer
- Renal Cell carcinoma (RCC)
- Esophageal cancer
- Hepatocellular Carcinoma (HCC)
- Merkel Cell Carcinoma (MCC)
- Colorectal cancer (CRC)
- Cervical cancer
- Endometrial carcinoma (EC)
- Triple Negative Breast Cancer (TNBC)
- Cutaneous squamous cell carcinoma
- Tumor Mutational Burden-High (TMB-H) Cancer

## Therapeutic class (ATC code)

PD-1/PDL-1 Inhibitors (L01FF)

## Composition

Concentrate for solution for infusion
25 mg/ml, 4 ml (100 mg) in vial

## Route of administration

Intravenous infusion

## Marketing Authorizations

- Russian Federation (2022)
- Belarus
- Kazakhstan
- Algeria
- Syria (submitted)

**Pharmacovigilance data** on the use of over 26 million mg (11,000+ patients), revealed no unexpected safety concerns or efficacy issues.

## Packs sold

346,000+ packs*


* 15.02.2025

# INN Prolgolimab

Type of product: Original
International trade name: **Centema®, Hirteco®**

## Description/Summary

A fully human monoclonal antibody that
has specific affinity for the PD-1 receptor.
It is the first immune checkpoint inhibitor developed in Eastern Europe.

## Indications

- Unresectable or metastatic melanoma
- NSCLC
- Cervical cancer (2025*)

## Therapeutic class (ATC code)

PD-1/PDL-1 Inhibitors (L01FF)

## Presentation

Concentrate for solution for infusion
20 mg/ml, 5 ml (100 mg) in vial

## Route of administration

Intravenous infusion

## Marketing Authorizations

- Russian Federation (2020)
- Belarus
- Kazakhstan

## Packs sold

48 000+ packs*


* 15.10.2024

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# Autoimmune Diseases

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# Rheumatology

# INN Netakimab

Type of product: Original
International trade name: **Aleira®, Efleira®**

## Description/Summary

Humanized monoclonal IgG1 antibody that binds to the protein interleukin (IL)-17A
and IL-17F and inhibits IL-17A in therapeutic concentrations.

## Indications

- Moderate to severe plaque psoriasis
- Psoriatic arthritis
- Ankylosing spondylitis

## Therapeutic class (ATC code)

Interleukin inhibitors (L04AC)

## Presentation

Solution for subcutaneous injection
60 mg/ml, 1 ml #2

## Route of administration

Subcutaneous injections

## Marketing Authorizations

- Russian Federation (2019)
- Belarus
- Kazakhstan
- Uzbekistan

## Packs sold

360 000+ packs*


April 2025

* 01.12.2024

# INN Adalimumab

Type of product: Biosimilar
International trade name: **Dalibra®**

## Description/Summary

Fully human recombinant monoclonal antibody that works by inactivating tumor necrosis factor-alpha (TNFα).

## Indications

- Rheumatoid arthritis
- Ankylosing spondylitis
- Axial spondyloarthritis
- Psoriatic arthritis
- Plaque psoriasis
- Hidradenitis suppurativa
- Juvenile Idiopathic Arthritis
- Enthesitis-related arthritis
- Crohn’s disease
- Ulcerative colitis
- Uveitis
- Behcet’s disease

## Therapeutic class (ATC code)

Tumor necrosis factor alpha (TNF-α) inhibitors (L04AB)

## Presentation

Solution for subcutaneous injection 40mg/0,8ml #2

## Route of administration

Subcutaneous injections

## Marketing Authorizations

- Russian Federation (2019)
- Belarus
- Kazakhstan
- Algeria
- Syria
- Uganda

## Packs sold

189 000+ packs *


April 2025

* 02.01.2025

# INN Infliximab

Type of product: Biosimilar
International trade name: **Liarta®**

## Description/Summary
Chimeric monoclonal antibody consisting of a murine anti-TNF Fab fragment fused to the Fc portion of human IgG1

## Indications
- Rheumatoid arthritis
- Ankylosing spondylitis
- Crohn’s disease
- Ulcerative colitis
- Psoriasis
- Psoriatic arthritis

## Therapeutic class (ATC code)
Tumor necrosis factor alpha (TNF-α) inhibitors (L04AB)

## Presentation
Lyophilizate for concentrate for solution for infusion 100mg

## Route of administration
Intravenous infusion

## Marketing Authorizations
- Russian Federation (2018)
- Belarus
- Kazakhstan
- Algeria
- Syria

## Packs sold
283 000+ packs*


April 2024

*01.12.2024

# INN Darbepoetin Alfa

Type of product: Biosimilar
International trade name: N/A

## Description/Summary

A novel erythropoeisis stimulating protein with longer half-life, increased biologic activity and decreased receptor affinity comparing with recombinant human erythropoietin.

## Indications

- Symptomatic anemia in adults and children with chronic renal failure
- Anemia caused by chemotherapy in patients with cancer

## Therapeutic class (ATC code)

Other antianemic preparations (B03XA)

## Presentation

Solution for infusion

- 10 mcg
- 15 mcg
- 20 mcg
- 30 mcg
- 50 mcg
- 60 mcg
- 80 mcg
- 100 mcg
- 150 mcg
- 300 mcg

## Route of administration

Intravenous, subcutaneous Infusion

## Marketing Authorizations

Russian Federation (2019)
Algeria
Cambodia

## Packs sold

122 000+ packs*


April 2025

* 150 mcg pack equivalent, 01.08.2024

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# Orphan Diseases

# INN Eculizumab

Type of product: Biosimilar
International trade name: **Acveris®**

## Description/Summary

A humanized monoclonal antibody that works by selectively inhibiting activation of specific proteins in the complement system (C5a and C5b), which play a role in the pathophysiology of multiple rare diseases

## Indications

- Paroxysmal nocturnal hemoglobinuria
- Atypical hemolytic uremic syndrome
- Generalized myasthenia gravis
- Neuromyelitis optica spectrum disorder

## Therapeutic class (ATC code)

Selective immunosuppressants (L04AA)

## Presentation

Concentrate for solution for infusion 10 mg/ml, 30 ml (300mg)

## Route of administration

Intravenous infusion

## Marketing Authorizations

Russian Federation (2021)
Algeria

# Key points of SMA

**Spinal muscular atrophy** is a **rare genetic neuromuscular disorder** that results in the loss of motor neurons and causes progressive muscle wasting (atrophy) and weakness.

## Diagnosis & Classification

- It is usually diagnosed in infancy or early childhood and if left untreated it is the most common genetic cause of infant death.
- SMA is caused by low levels of the survival motor neuron protein (SMN) due to inactivating mutations in the encoding gene SMN1
- A second duplicated gene, SMN2 («SMA back-up gene»), produces very little but sufficient functional protein for survival, but at a significantly lower quantity compared to the SMN1 gene.

| Type | Age of onset | Expectancy of life | SMN2 copy N |
|---|---|---|---|
| 1 | <6 months | <2 years | 2 |
| 2 | 6-18 months | 10-40 years | 3 |
| 3 | >18 months | Adult | 3-4 |
| 4 | >5 years | Adult | >4 |

## Therapeutic strategies

- SMN-enhancing treatments target the SMN2 gene, causing it to make more useable SMN protein (SMN2 antisense oligonucleotide (ASO) or small molecule (SMN2) splicing modifiers)
- Other SMN-enhancing approaches work to replace the function of the mutated SMN1 gene (gene therapy)
- Thanks to newborn screening, spinal muscular atrophy (SMA) can be detected and treated early enough to change the natural course of the disease.


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