

# NATIVA GROUP Inspired by Innovation and Technology





#### INNOVATION & TECHNOLOGY IS OUR PASSION

Nativa is a leading group of pharmaceutical companies in Russia. It develops and produces world-class complex medicines essential for human health. Nativa is focusing on oncology, pulmonology, and multiple sclerosis.

## Unique product portfolio and pipeline:

a broad **Cancer** drugs portfolio

sustained-release **peptides** (Russia's widest range) and products with high barrier to entry (glatiramer acetate, LAI octreotide, LAI triptorelin, LAI goserelin)

full-cycle development of **biopharmaceuticals** (both APIs and finished dosage forms) based on recombinant proteins, including chemically modified products

a complete **pulmonary** medications portfolio, including all kinds of inhaler devices

Headquartered in Moscow, Nativa owns state-of-the-art research, production and quality control facilities in the Moscow Region. R&D activities performed at the same site according to international good practices and ensures that Nativa is on point of modern technologies and formulations.

Nativa's main goal is to constantly strive for excellence and never stop innovating for the well-being of its customers.

## Nativa group in brief:

\$167 mln	annual turnover in 2016	
<b>3.7</b> mln	production units in 2016	
800+	employees incl. 80+ specialists with Ph.D. and D.Sci degrees	
<b>2,200</b> sq.m.	of own production and R&D areas and 2 CMOs hosted by the largest Russian manufacturer Pharmstandard	

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1996	Pulmomed LLC was founded to develop pulmonary medications
1997	Top Russian scientists teamed up to develop peptide synthesis and produce medicines
2001	Pharmapark LLC was founded to develop and commercialize recombinant biopharmaceuticals and finished medicinal products
2008	Launch of <b>BUDESONIDE</b> – the only budesonide preparation in the world in the form of solution for inhalation
2009	F-Sintez LLC was established to develop LAI and cancer drugs
2010	Nativa LLC was founded to create and sell pulmonary medicines
2012	Launch of Russia's 1st IMATINIB generic*
2013	Launch of IPRATROPIUM BROMIDE+FENOTEROL – the 1st local generic*
2014	Ingal LLC was incorporated to develop and produce original medical devices for inhalation and hyaluronic acid injections  Nativa acquired Pulmomed product portfolio
2015	Launch of Russia's 1st BORTEZOMIB generic and 1st Unit Dose Dry Powder Inhaler SALMETEROL + FLUTICASONE*
2016	Nativa started marketing <b>GLATIRAMER ACETATE</b> , <b>TRIPTORELIN LONG</b> and <b>TIOTROPIUM BROMIDE</b> – the 1 <sup>st</sup> generic versions in Russia* <b>Nativa</b> acquired <b>F-Sintez</b> product portfolio <b>Oncon LLC</b> was founded to develop and commercialize cancer bioproducts
2017	Marketing authorization of <b>SUNITINIB</b> , <b>DASATINIB</b> , <b>NILOTINIB</b> , <b>SORAFENIB</b> – the <b>1</b> <sup>st</sup> generics in Russia
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\*State Register of Medicines

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### **EXPANDING PIPELINE AND PRODUCT PORTFOLIO**

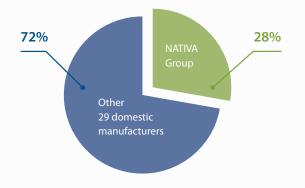
**50+** patents granted or pending

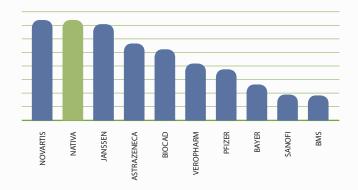
**40+** products in portfolio

**30+** products in pipeline

The 1<sup>st</sup> domestic company on the Russian pharmaceutical reimbursement market, 2016\*

The 2<sup>nd</sup> largest company in the oncology segment (excluding biosimilars) in Russia, 2016\*





#### **TECHNOLOGY LEADER**

Sophisticated generics and biosimilars

Large-scale peptide synthesis and purification (buserelin, goserelin, octreotide, desmopressin, glatiramer acetate)

Multi-step sophisticated synthesis of complex small organic molecules (bortezomib, kinase inhibitors, etc.)

Production areas for eukaryotic upstream and downstream processing and prokaryotic upstream and downstream processing

Own production site and 2 CMOs hosted by the largest Russian manufacturer granted a EU GMP certificate

## **CANCER DRUGS**

#### **SOLID TUMOR TREATMENT**

- **Pemetrexed**
- Temozolomide
- **Ibrutinib**
- **Erlotinib**
- Lapatinib
- Pazopanib
- Gefitinib
- Sorafenib

#### **BLOOD CANCER TREATMENT**

- Fludarabine
- Lenalidomide
- Bortezomib with a market share of 58% (Russia) in 2016\*
- Imatinib with a market share of 63% (Russia) in 2016\*
- **Nilotinib**
- Sunitinib
- Dasatinib

#### **BONE METASTASES**

Zoledronic acid

## **BIOPRODUCTS**

One of the few companies in Russia that possess the know-how and experience of complete biotechnological drug development and full-cycle commercial production

#### **MARKETED**

- Filgrastim
- Epoetin beta
- Interferon alpha-2b
- Pegylated interferon alpha-2b

#### **PRECLINICAL**

- Trastuzumab
- Bevacizumab
- **Eculizumab**
- Adalimumab
  - Interferon beta-1a

**PHASE I** 

#### **PHASE III**

- Darbepoetin alfa
- Infliximab





# Nativa heads the Russian pharmaceutical market of LAI PEPTIDES with a share of 44%\*

#### **GOSERELIN LONG**

The 1st fully automated extrusion and assembly line in the world

#### TRIPTORELIN LONG

Nativa launched the world's 1<sup>st</sup> triptorelin generic for one-month administration

#### **OCTREOTIDE LONG**

### **BUSERELIN LONG**

# Nativa is the only **GLATIRAMER ACETATE** supplier to 12,000 Russian patients under the terms of contract with the Russian Ministry of Health

#### **GLATIRAMER ACETATE**

Nativa is the 1<sup>st</sup> company that launched a glatiramer acetate generic on the Russian market with a share of 95 % in 2017\*

# Nativa invested in high-tech production of HYALURONIC ACID (HA)

#### REPART, REPART LONG

Highly purified HA solutions for intraarticular injections for pain relief and improving movement in OA patients

#### REPART° FILLERS

HA injectable facial fillers for reducing or eliminating wrinkles, raising scar depressions, enhancing lips and replacing soft-tissue volume loss

# The 2<sup>nd</sup> biggest company in the ANTI-ASTHMA AND COPD segment (reimbursement channel) of the Russian pharmaceutical market with the share of 29%\*

#### **INHALATION SOLUTION**

Budesonide
Salbutamol
Ipratropium bromide
Fenoterol
Ipratropium bromide + fenoterol

#### **METERED DOSE INHALERS (MDI)**

Beclometasone Fenoterol Ipratropium bromide Ipratropium bromide + fenoterol Salmeterol + fluticasone

#### **UNIT DOSE DRY POWDER INHALERS (DPI)**

Budesonide + formoterol Salmeterol + fluticasone Tiotropium bromide Formoterol

# ORIGINAL "ONE-CLICK" MULTIDOSE DRY POWDER INHALERS (DPI)

Budesonide + formoterol Salmeterol + fluticasone

# MULTIDOSE NEBULIZER ORIGINAL PORTABLE HANDHELD

A portable nebulizer for tiotropium bromide and other pulmonological medicines is currently under development





## **WE OFFER:**

A wide range of products for distribution

Technology transfer of advanced processes and know-how

A joint venture for developing innovation platforms

**B**usiness alliances for acquiring new technological competencies

Out-licensing for emerging markets

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