MARKET INTELLIGENCE FOR LICENSING & REGISTRATION

Molecule Licensing Intelligence

New Molecular Entities for the Russian Market

FDA · EMA · NMPA & Other Global Regulators (2022–2026)

408	17	35	92%	15
MOLECULES ANALYZED	THERAPEUTIC AREAS	DATA FIELDS PER MOLECULE	RUSSIA EPI COVERAGE	PRIORITY MOLECULES

Oncology 79 · Hem/Onc 55 · Infectious 40 · Endocrinology 37 · Rare Disease 37 · Neurology 28 · Dermatology 25 · Cardiology 22 · +9 more TAs

FULL MOLECULE LANDSCAPE

408 NMEs with 35 data fields each. CSV + Excel for in-house analysis. Russian epidemiology, pricing, competitive landscape.

TA DEEP DIVES

Oncology, Endocrinology, Rare Disease — molecule-by-molecule scoring, market gaps, treatment landscape in Russia.

LICENSING SHORTLIST

Top 15 molecules scored on unmet need, white space, patient population, company readiness, and pricing potential.

HCP PROFILES & PRICING

Key opinion leader maps per molecule. Reference pricing benchmarks with HTA decisions across 7+ markets.

Licensing Priority Shortlist

Molecules scored on 5 dimensions (100 pts max): Unmet Need (30%), White Space (25%), Patient Population (20%), Company Readiness (15%), Pricing Potential (10%). Showing top 3 of 15.

1. Relugolix (Orgovyx) — Oncology — 88 / 100

Myovant Sciences · FDA Approved 2020

Indication	Advanced hormone-sensitive prostate cancer
Russia Population	~52,700 new cases/year (GLOBOCAN 2022). Fastest-growing oncology segment in Russian men. 38.6% present at Stage III-IV.
Why No Competitor	First oral GnRH antagonist — all existing options (leuprolide, goserelin, triptorelin) are injectable. Zero oral alternatives in Russia.
Pricing	US WAC: $33,148/yr · UK NHS: ~$1,333/yr · **Est. Russia: $1,000–2,500/yr**
Key Rationale	Oral formulation eliminates testosterone surge risk. Enormous patient pool. Favorable UK-benchmarked pricing makes Russia reimbursement viable.

2. Zolbetuximab (Vyloy) — Oncology — 85 / 100

Astellas Pharma · FDA Approved 2024

Indication	CLDN18.2-positive gastric / GEJ adenocarcinoma
Russia Population	~38,900 new gastric cases/yr; CLDN18.2+ subgroup: ~14,800–16,700 patients
Why No Competitor	[redacted]
Pricing	[redacted]
Key Rationale	[redacted]

3. [redacted] — Rare Disease — 83 / 100

[redacted]

Indication	[redacted]
Russia Population	[redacted]
Why No Competitor	[redacted]
Pricing	[redacted]
Key Rationale	[redacted]

12 more priority molecules in the full report

Including teprotumumab (TED), vorasidenib (glioma), sugemalimab (NSCLC), fruquintinib (CRC), elacestrant (breast cancer), sebetralstat (HAE), and 6 more — each with full scoring rationale.

SAMPLE PREVIEW — 10 OF 408 MOLECULES SHOWN

Molecule Landscape Database — Oncology Sample

Full database covers 408 molecules across 17 therapeutic areas with 35 data fields each. Showing oncology excerpt.

Molecule	Brand	Company	Regulatory Status	Indication	Russia Pop.	Annual Cost
relugolix	Orgovyx	Myovant Sciences	Approved (2020)	Prostate cancer	~52,700/yr	$33,148
zolbetuximab	Vyloy	Astellas Pharma	Approved (2024)	CLDN18.2+ gastric cancer	~14,800–16,700	$200,000
vorasidenib	[illegible]	[illegible]	Approved (2024)	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	Approved (2023)	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]

Full database: 408 molecules x 35 fields

Includes: molecule name, brand, company, regulatory status (FDA, EMA, NMPA, and others), indication, mechanism of action, Russia registration status,
disease prevalence (global + Russia-specific), annual cost, pricing by market, competitors in Russia, Circle of Kindness status, and more. Delivered as CSV + Excel for in-house filtering and analysis.

Russia Treatment Landscape Gaps (Oncology Sample)

KRAS G12C inhibitors (adagrasib, sotorasib) — not available in Russia. ~5,400 patients/year with no targeted option.

Oral SERDs for breast cancer (elacestrant, imlunestrant) — not available. ~3,600–6,400 ESR1-mutated patients with no oral SERD.

Antibody-drug conjugates — essentially absent from Russian market. Multiple ADCs approved globally.

Next-gen ALK/ROS1 inhibitors — beyond crizotinib, very limited access. ~2,400–4,200 patients.

Full report covers treatment gaps across all 17 therapeutic areas — not just oncology.

Pricing Benchmark Analysis (Sample)

Reference pricing across 7+ markets for each priority molecule. Russia uses ERP with a 12-country reference basket.

Market	Relugolix (prostate)	[redacted]	[redacted]
US (WAC)	$33,148/yr	[redacted]	[redacted]
UK (NHS)	~$1,333/yr (NICE recommended)	[redacted]	[redacted]
EU/Germany	Est. $2,000–4,000	[redacted]	[redacted]
Japan	Approved (different indication)	[redacted]	[redacted]
Est. Russia	**$1,000–2,500/yr**	[redacted]	[redacted]

Full report includes pricing benchmarks for all 15 priority molecules with HTA decision analysis.

Patient Population Deep-Dive (Sample)

Detailed TAM/SAM analysis for each priority molecule with Russia-specific epidemiology data.

Relugolix — Prostate Cancer in Russia

Incidence (2023)	~58,000 new cases (Russia's fastest-growing cancer in men)
Stage III-IV at diagnosis	38.6% — significantly worse than US (~21%)
TAM	~23,000–25,000 patients/year (ADT-eligible)
SAM	~8,000–12,000 patients/year (adjusted for access)
Regional variation	Highest: Siberian FD (43.1/100k) · Lowest: North Caucasus (21.1/100k)

[redacted]

Incidence	[redacted]
Biomarker prevalence	[redacted]
TAM	[redacted]
SAM	[redacted]

Full report includes deep-dive population analysis for 5 priority molecules with regional breakdowns.

HCP Landscape Profiles (Sample)

Key Opinion Leader mapping per molecule. Institution affiliations, guideline authorship, clinical trial participation.

Relugolix — Prostate Cancer HCP Map

33 HCPs profiled · 7 Tier 1 · 15 Tier 2 · 11 Tier 3

39% verified emails

HCP Name	Institution	City	Role / Influence	Tier
[redacted]	[redacted]	Moscow	[redacted]	T1
[redacted]	[redacted]	[redacted]	[redacted]	T1
[redacted]	[redacted]	[redacted]	[redacted]	T1
[redacted]	[redacted]	[redacted]	[redacted]	T1

... 29 more HCPs in full relugolix profile · 5 more molecules have dedicated HCP maps ...

WHAT YOU RECEIVE

Complete Deliverable Package

Deliverable	Contents	Format
Molecule Landscape	408 NMEs, 35 fields each — indication, global regulatory status (FDA, EMA, NMPA, and others), Russia epidemiology, pricing, competitive landscape, Circle of Kindness matching	CSV + Excel + Full Report (PDF)
TA Deep Dives	Oncology (79 mol.), Endocrinology (37 mol.), Rare Disease (37 mol.) — molecule-by-molecule scoring, market gaps, treatment landscape	PDF (3 reports)
Licensing Shortlist	Top 15 molecules scored on 5 dimensions (100 pts). Detailed profiles with competitive analysis and licensing strategy	PDF
Pricing Benchmarks	Reference pricing across US, UK, EU, Japan, Turkey, Brazil. HTA decisions. Estimated Russian pricing	PDF
Patient Populations	TAM/SAM analysis for top 5 molecules. Russia-specific epi, regional distribution, diagnosis gaps	PDF
HCP Profiles	Key opinion leader maps for 6 priority molecules. Institution mapping, guideline authorship, verified contacts	PDF + CSV

Research Methodology

Regulatory Data
FDA, EMA, NMPA, PMDA, and other national agency approvals. GRLS (Russian State Registry), ESKLP drug catalog

Clinical Sources
MinZdrav clinical guidelines, RUSSCO recommendations, ClinicalTrials.gov Russian sites

Epidemiology
GLOBOCAN 2022, Russian cancer registry (ZIS-2023), subtype-specific prevalence corrections

Pricing / HTA
NICE, CADTH, AMNOG, PMDA decisions. ERP benchmarking. Russia ЖНВЛП feasibility analysis

Competitive Landscape
GRLS registry status, biosimilar pipeline, compulsory licensing tracker, Circle of Kindness cross-reference

HCP Mapping
Guideline authorship, RUSSCO/ROOU society membership, clinical trial investigator databases, eLibrary.ru

Request the Full Report

408 molecules · 17 therapeutic areas · 15 priority licensing candidates

Pricing benchmarks · Patient population analysis · HCP profiles

All data delivered as interactive Excel/CSV for your team's analysis

Contact us to discuss your needs

This is a preview document. Data is based on FDA, EMA, NMPA, and other regulatory databases, GLOBOCAN 2022, Russian regulatory registries, clinical guidelines, and publicly available sources. Methodology adapts to any target regulatory authority. Full provenance trail included with deliverable. March 2026.