

mAb Summit 2026



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Agenda



1. Why Are We Investing in Monoclonal Antibodies?

Marcelo Hahn – CEO / Founder

2. Technological Challenges in RD&I and National Production of Monoclonal Antibodies

Uilberson Silva – Inventta Director

3. Clinical Biosimilar Development and Concepts in Oncology

Eliana Samano – Medical Director

4. Market Update and Growth Opportunities

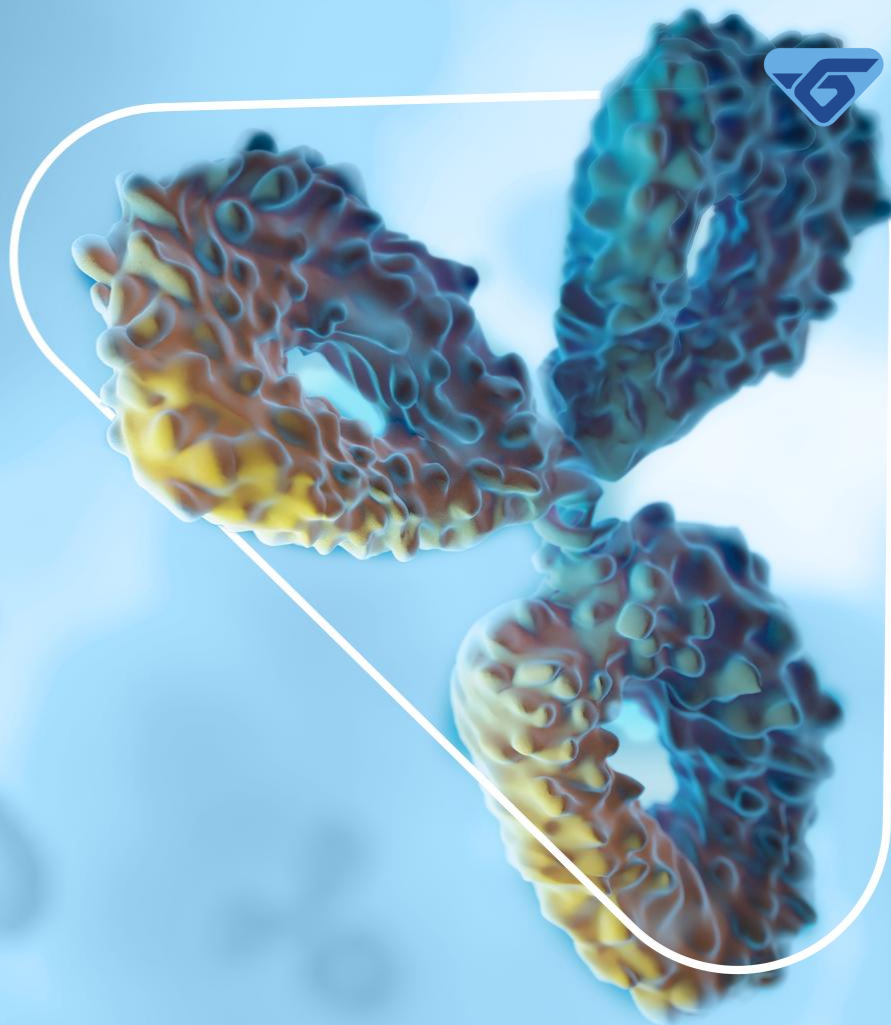
Matheus Fujisawa – IR Manager

5. Q&A

1. Why Are We Investing in Monoclonal Antibodies?



Marcelo Hahn
CEO / Founder



Why Are We Investing in Monoclonal Antibodies?

1

History of investment in biotechnology and biosimilars.

2

Attractive market: mAbs lead the growth of the hospital segment.

3

Local production as a competitive advantage.

4

Very high entry barriers.

5

It is essential to invest in Biotechnology to be relevant in the Hospital Market, it is the technological vanguard of the segment.

History of Investment in Biotechnology and Biosimilars

1987-2000



- **1992:** Importation of highly complex medicines, including biologics and blood products.
- **1999:** 1st registration of Alfaepoetin from Blau, an imported product.
- **Investments in in-house production of medicines, including lines of biological medicines.**

2001-2019



- **2001:** Inauguration of the Headquarters in Cotia/SP, with a focus on injectables.
- **2005:** Anvisa's approval for the production of finished biological medicines in Cotia.
- **2010:** Master working bank of epoetin alfa and filgrastim.
- **More investments in Research, Development & Innovation (RD&I) and verticalization of production.**

2020 onwards



- **2020:** Inauguration of Inventta, a new dedicated RD&I center in Cotia.
- **2021:** Inauguration of the API (active pharmaceutical ingredient) plant in Cotia, with Good Manufacturing Practices (GMP) for epoetin alfa, filgrastim and pegfilgrastim.
- **2025:** Production of the 1st mAb in Cotia, with Anvisa's CBPF.

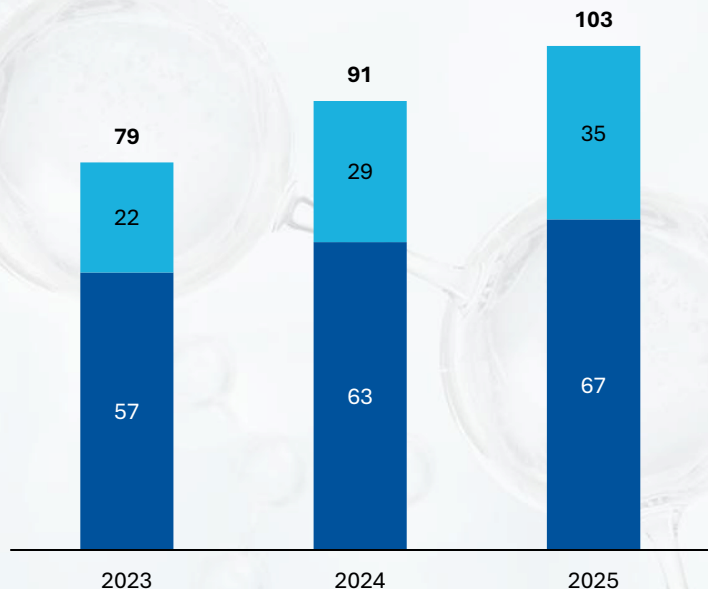
Knowledge Acquired Over Time



Monoclonal Antibodies (mAbs) Grow Above the Market

Hospital Market - Brazil (BRL bi)

CAGR
14%



CAGR
26%

Monoclonal Antibodies

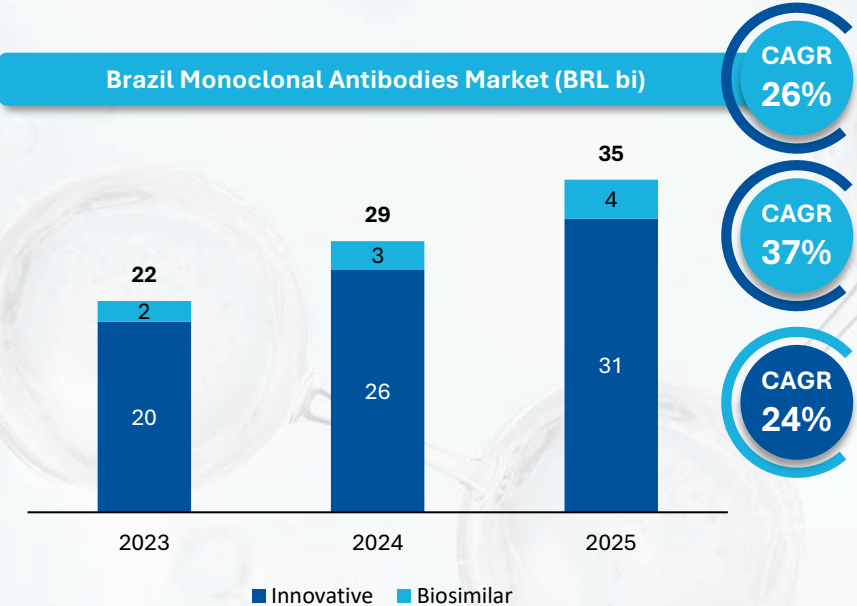
- **88% Innovative**
- High added value
- Increasing number of indications
- Low access

CAGR
9%

Other Medications

- **60% Patent-free**
- Lower added value
- Recurrent use in hospitals
- High access






Patent Falls Boosts Biossimilares among mAbs



Number of Molecules – Monoclonal Antibodies

	2023	2024	2025
Innovative	68	74	83
Biosimilar	16	18	21

Advantages of Biosimilars:

- 
Patent Expiration
 Several blockbuster biologics will have their patents expire by 2030, including pembrolizumab (Keytruda®).
- 
Biosimilar Journey Reduces Development Risks
 Molecule and dosage are already known, reducing the chances of development failure compared to the innovative.
- 
Increased Access
 Biosimilars can generate savings of 20-30% compared to innovative products, expanding access to treatments.
- 
Market Expansion
 15-20% annual growth in the global biosimilars market, projected to reach USD 85 billion by 2030.
- 
Favorable Regulation
 Regulatory agencies (Anvisa, EMA, FDA) have established clear guidelines for the approval of biosimilars.

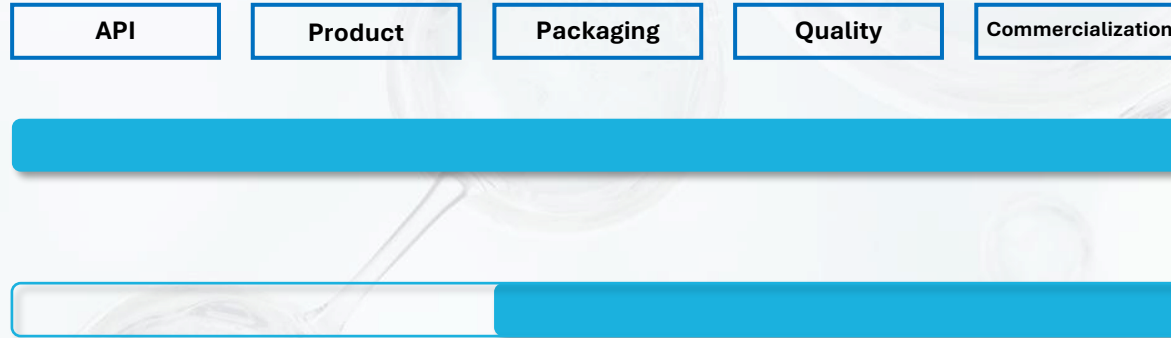


Blau Farmacêutica fully develops in Brazil the Biosimilar of the **Pembrolizumab – Best-selling drug in the world** – in addition to 3 other Monoclonal Antibodies: **National technological sovereignty and reduction of foreign dependence.**

Local Production as a Competitive Advantage vs. Imported



Imported
Product



Competitive Advantages

- **Vertical production captures the entire value of the product chain** (as shown in the chart above).
- **ANVISA's analysis preference** (RDC 1,001, of 11 December 2025).
- **Preference in federal bids** of 5% for national medicine + 10% for national API (CICS/MGI Resolution No. 8, of March 31, 2025).
- **Strategic value:** reduced supplier lock-in.
- **Reduction of exposure** to exchange rate volatility.
- **High cost of nationalization of the imported product**, with significantly more expensive insurance and freight, in addition to import taxes and duties.

Global Market as a Relevant Additional Opportunity

USD
55
Bi

4 Monoclonal
Antibodies
Developed by
Blau



- **Clinical Studies in compliance with EMA, FDA and Anvisa**
- Serving these three agencies, there will be virtually no restrictions on global sales
- License-Out Partnership Opportunities for Overseas Sales

USD
153
Bi

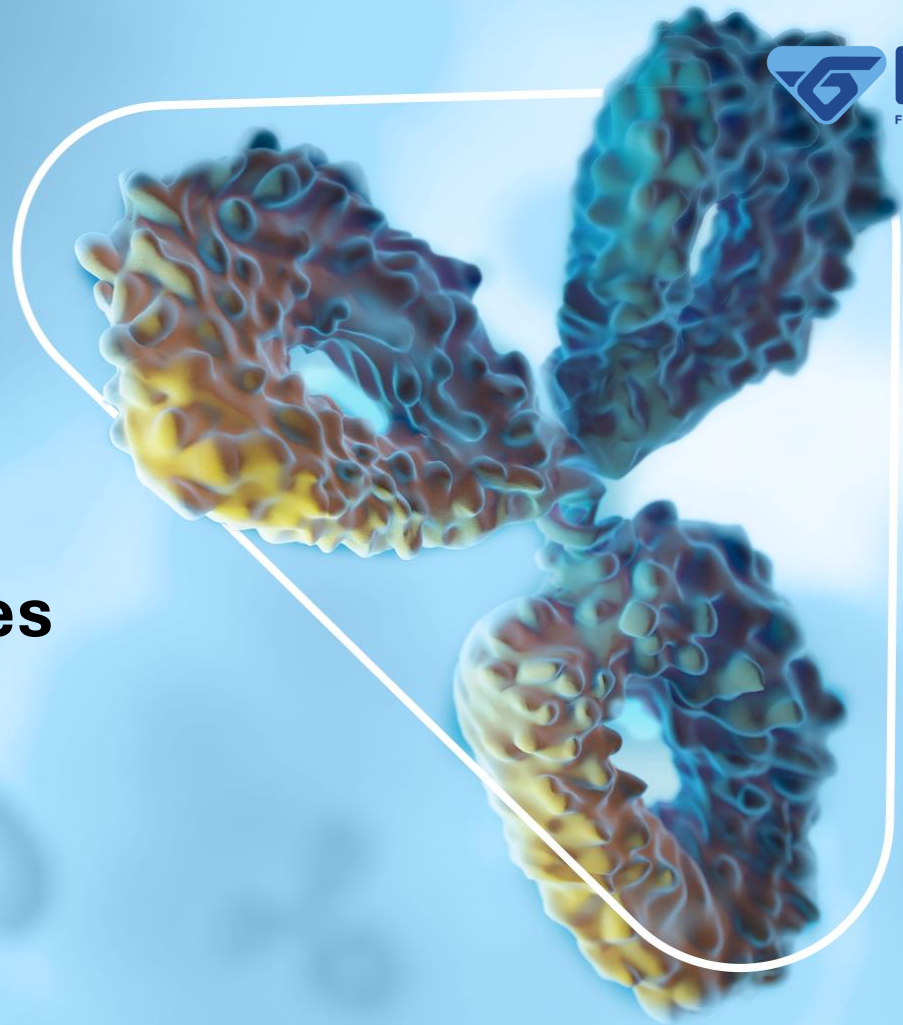
Top 20 – Monoclonal Antibodies in the World

1 KEYTRUDA (pembrolizumab) injection 100mg	2 DUPIXENT (dupilumab) injection	3 Skyrizi risankizumab-rzaa	4 DARZALEX (daratumumab)	5 Stelara (ustekinumab)
6 OPDIVO (nivolumab)	7 HUMIRA adalimumab	8 OCREVUS ocrelizumab	9 Cosentyx secukinumab	10 Entyvio vedolizumab
11 HEMLIBRA emicizumab-kxwh	12 IMFINZI durvalumab	13 prolia tildesinsumab injection	14 VABYSMO faricimab-smba injection 6 mg	15 PERJETA pertuzumab
16 ULTOMIRIS (ravizumab-cwvz) intravenous injection 100 mg/10 mL	17 Tremfya (guselkumab)	18 taltz (ixekizumab)	19 ACTEMRA tocilizumab	20 Xolair omalizumab

2. Technological Challenges in RD&I and National Production of Monoclonal Antibodies



Uilberson Silva
RD&I Director



Why Invest in Research, Development and Pharmaceutical Innovation?



Improved **Health**

Scientific Advancement

Development and
Economic Return



World Health
Organization

Urgent and global health challenges

- 1 - Keeping health services clean
- 2- Importance of health in the climate debate
- 3- Care in places of conflict and crisis
- 4- Make health care fairer
- 5- Improve access to medicines
- 6- Fight infectious diseases
- 7- Epidemic preparedness
- 8- Protection of dangerous products
- 9- Invest in health workers
- 10- Keep teens safe
- 11- Gain people's trust
- 12- Use of new technologies
- 13- Drug protection

 **INVENTTA**
Instituto de Ciência, Tecnologia e Inovação

The Solution!



The science of our medicines

We Have Complete Know-how in RD&I




Medicament

Pharmaceutical Product, technically obtained or elaborated, for prophylactic, curative, palliative or diagnostic purposes (Anvisa, 2022)

Complexity involves the origin, production, pharmaceutical technology and the target pathologies

Origin
Biological and/or Biotechnological



Synthetic Origin



Focused in high complexity, intellectual property and fundraising

Drug Development



Reference

Generic and Similar

Development: 2-3 Years



Biological Comparators

Biosimilars

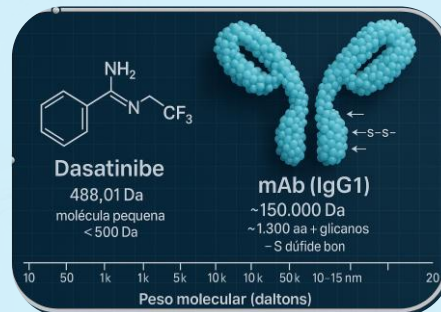
Development: 7-10 Years

Incremental Innovations Opportunities

Incremental Innovations Opportunities

Synthetic Origin

- Produced by chemical synthesis;
- Simple and well-defined molecular structure;
- Less complex manufacturing process;
- Known structural characterization;
- Less Complexity (Market Commons):** ibuprofen, omeprazole and simvastatin;
- Greater Complexity (Blau):** oncological, antibiotic and other molecules.



Biological and/or Biotechnological Origin

- Produced or extracted from biological systems (living organisms, tissues, cells, etc.) derived from human sources.
- Large, complex and heterogeneous molecules;
- Variation-sensitive manufacturing process;
- Extensive biological characterization;
- Greater Complexity (Blau):** recombinant proteins such as monoclonal antibodies, growth hormone, insulin, among others.

Jornada de Desenvolvimento dos mAbs Biossimilares



Drug
Development

Comparability
Studies

Non-
Clinical
Trials

Clinical
Trials

Biosimilar
Register

Physicochemical
and Biological
Characterization

Development
API mAb



KnowHow

Global Development Program



National Production of Biotechnological APIs

Multipurpose Facility

P400 Production –
Anvisa GMP Certification

3 validated processes
& 1 under validation (*)

**New products with
national API**

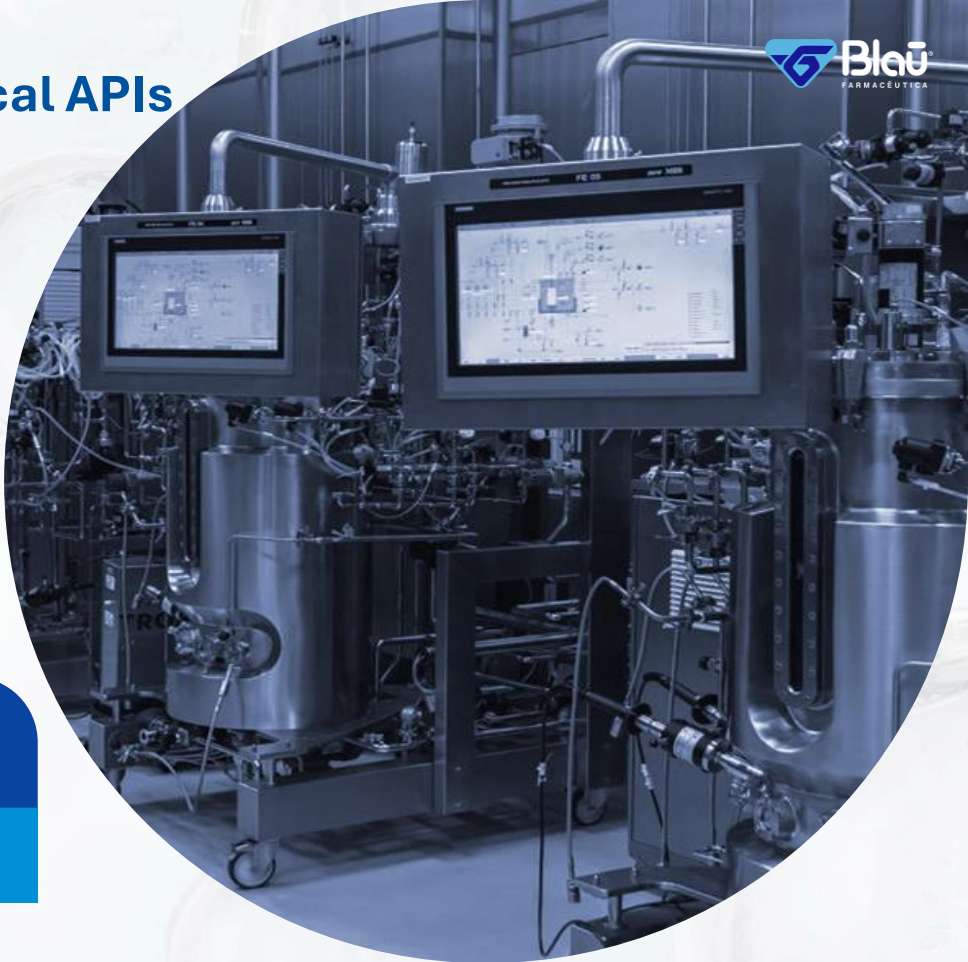


Prokaryotic Plant
(1,377.20 m²)

- Filgrastim
- Pegfilgrastim
- Somatropin (*)

Eukaryotic Plant
(1,442.21 m²)

- Epoetin Alfa
- mAbs



Produção de mAbs Biossimilares

First company in Brazil
with GMP of
Pembrolizumab

P400 Facility –
Anvisa GMP Certification

Monoclonal Antibody
Line



Projects

- ✓ AMDB12
(Pembrolizumab)
- ✓ AMDB13
- ✓ AMDB14
- ✓ AMDB15



Production of Biosimilar mAbs



Pembrolizumab



With 5 production
batches of the API
we serve
100% of the national
market



Brazil Market: Local Production (API and Medicine)

International Market: CMO International (Medicine)

Comparability Studies

Peptide Sequencing

Proven
Mapping!



Biosimilar

Pembrolizumab Injection Chains B, Light Chain | D10574

	Total	Mass Only	MS/MS Only	Mass and MS/MS				
Overall								
25062481c1								
25062481c2								
25062481c3								
.....1020304050607080	
EIVLTQSPAT	LSLSPGERAT				LIYLASYLE	GVPARFSGSG	SGTDFLTITIS	Overall
EIVLTQSPAT	LSLSPGERAT				LIYLASYLE	GVPARFSGSG	SGTDFLTITIS	25062481c1
EIVLTQSPAT	LSLSPGERAT				LIYLASYLE	GVPARFSGSG	SGTDFLTITIS	25062481c2
EIVLTQSPAT	LSLSPGERAT				LIYLASYLE	GVPARFSGSG	SGTDFLTITIS	25062481c3
.....90100110120130140150160	
SLEPEDFAVY	YQHSRDLP				SGTASVVCLL			Overall
SLEPEDFAVY	YQHSRDLP				SGTASVVCLL			25062481c1
SLEPEDFAVY	YQHSRDLP				SGTASVVCLL			25062481c2
SLEPEDFAVY	YQHSRDLP				SGTASVVCLL			25062481c3
.....170180190200210218			
GNSQESVTEQ	DSKDYSTYLS	STLTLSKADY	EKKHVVYACEV					Overall
GNSQESVTEQ	DSKDYSTYLS	STLTLSKADY	EKKHVVYACEV					25062481c1
GNSQESVTEQ	DSKDYSTYLS	STLTLSKADY	EKKHVVYACEV					25062481c2
GNSQESVTEQ	DSKDYSTYLS	STLTLSKADY	EKKHVVYACEV					25062481c3

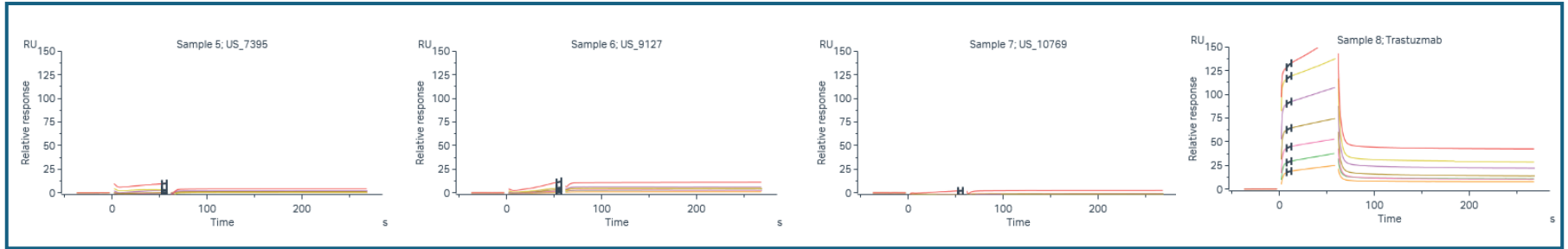
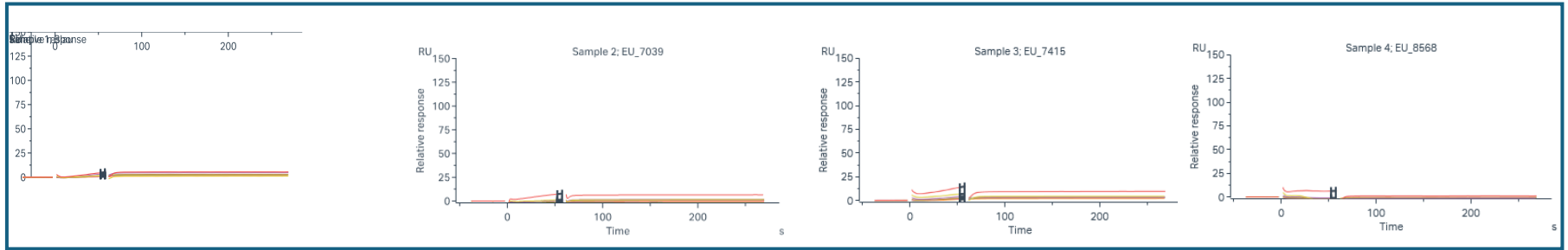
Keytruda

Pembrolizumab Concentrated Solution Chains B, Light Chain | D10574

	Total	Mass Only	MS/MS Only	Mass and MS/MS				
Overall								
Y020844 a								
Y020844 b								
Y020844 c								
.....1020304050607080	
EIVLTQSPAT	LSLSPGERAT				LIYLASYLE	GVPARFSGSG	SGTDFLTITIS	Overall
EIVLTQSPAT	LSLSPGERAT				LIYLASYLE	GVPARFSGSG	SGTDFLTITIS	Y020844 a
EIVLTQSPAT	LSLSPGERAT				LIYLASYLE	GVPARFSGSG	SGTDFLTITIS	Y020844 b
EIVLTQSPAT	LSLSPGERAT				LIYLASYLE	GVPARFSGSG	SGTDFLTITIS	Y020844 c
.....90100110120130140150160	
SLEPEDFAVY	YQHSRDLP				SGTASVVCLL			Overall
SLEPEDFAVY	YQHSRDLP				SGTASVVCLL			Y020844 a
SLEPEDFAVY	YQHSRDLP				SGTASVVCLL			Y020844 b
SLEPEDFAVY	YQHSRDLP				SGTASVVCLL			Y020844 c
.....170180190200210218			
GNSQESVTEQ	DSKDYSTYLS	STLTLSKADY	EKKHVVYACEV					Overall
GNSQESVTEQ	DSKDYSTYLS	STLTLSKADY	EKKHVVYACEV					Y020844 a
GNSQESVTEQ	DSKDYSTYLS	STLTLSKADY	EKKHVVYACEV					Y020844 b
GNSQESVTEQ	DSKDYSTYLS	STLTLSKADY	EKKHVVYACEV					Y020844 c

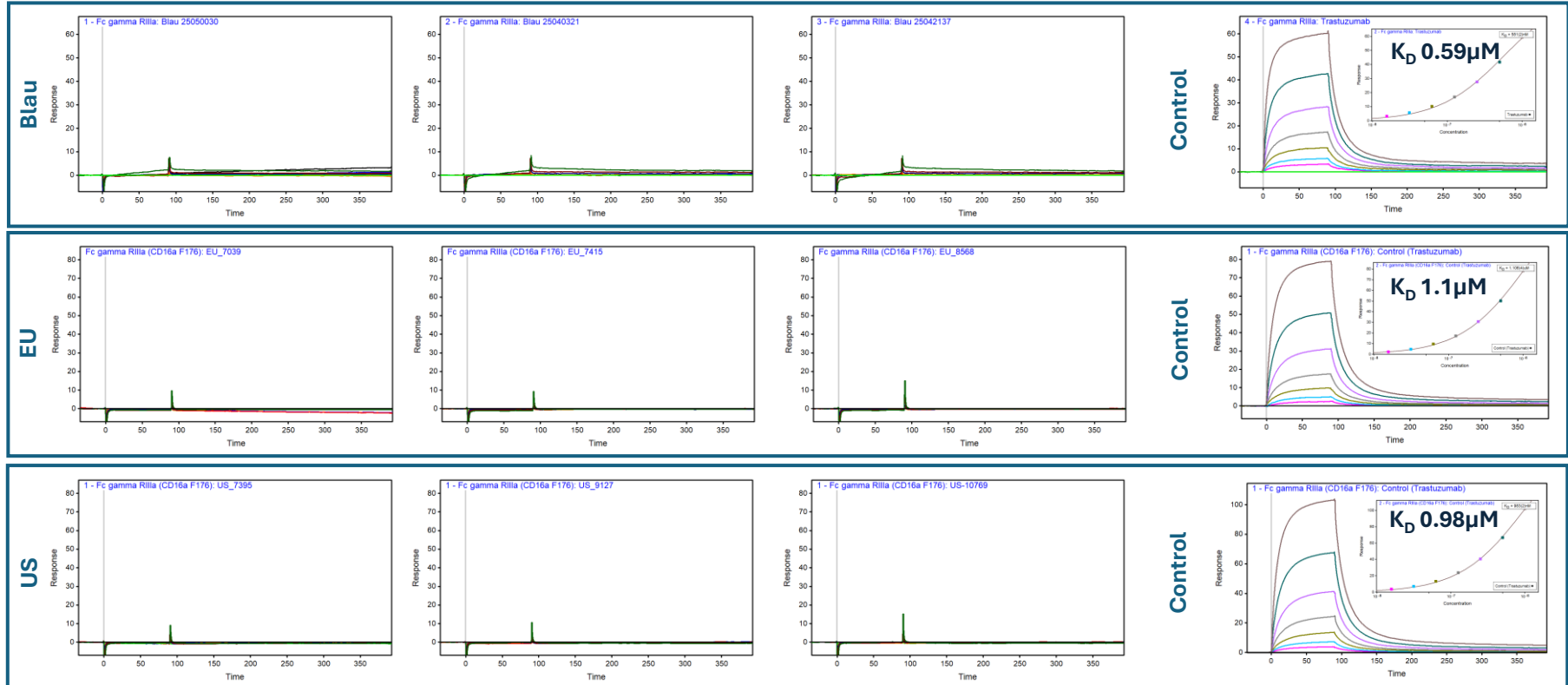
Non-Clinical Trials

Functional Safety - Biomolecular Interaction – SPR (C1q)



Non-Clinical Trials

Functional Safety - Biomolecular Interaction – SPR (FcR1IIa)



Status of Our Biosimilar mAbs Projects

Patent Expiration Date	AMDB12	AMDB13	AMDB14	AMDB15
	2028 2029 2031	2030	2034	2033
API Development	✓	✓	✓	✓
Physicochemical and biological characterization	✓	✓	✓	✓
Drug Development	✓	⚙️	⚙️	⚙️
Comparability Studies	⚙️	⚙️	🕒	⚙️
Non-clinical Trials	✓	🕒	🕒	🕒
Clinical Trials	🕒	🕒	🕒	🕒

Legend:  Completed  Ongoing  Not started

**Focused
in our
purpose!**

**Develop and deliver
innovative products and
solutions for a healthier and
more sustainable world**

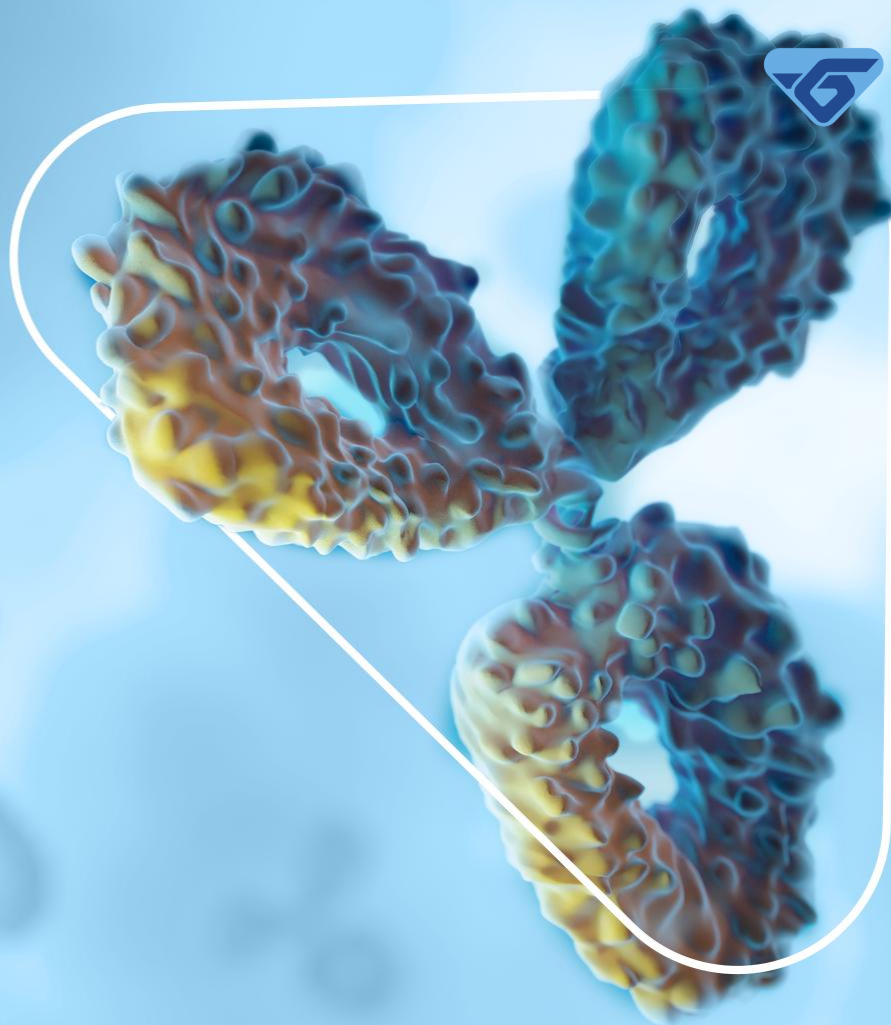


- + Specific and Precise
- + Targeted Action (High Efficacy)
- + Modern Therapies
- + Incremental Innovations
- + Reduction of Side Effects
- + Long-term cost-effectiveness
- + Local Development
- + Economic Progress

3. Clinical Biosimilar Development and Concepts in Oncology

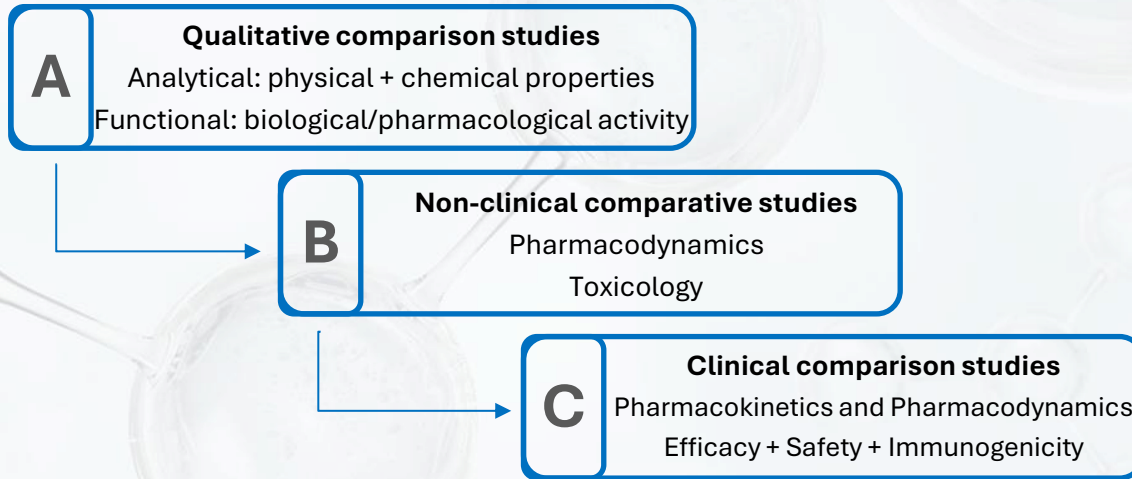


Eliana Samano
Medical Director



Quality analysis, non-clinical and clinical

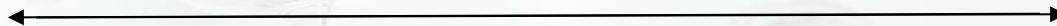
Biosimilar always compared to the reference/innovative product



Innovative Product



Biosimilar Product

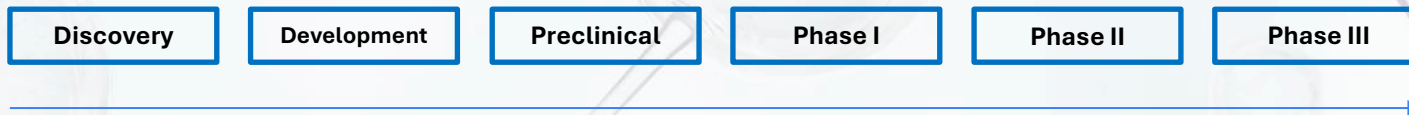


Possibility of Not Conducting a Phase III Clinical Study

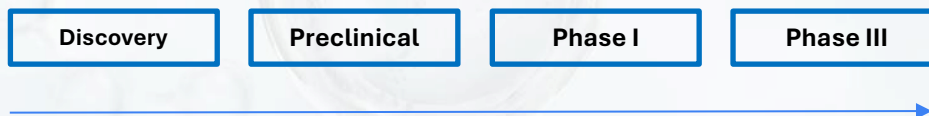
Development of biosimilars is faster than the reference drug



Development of the reference biological product



Biosimilar product development



With robust development data and comparability + Phase I, **there is a possibility of not carrying out Phase III**

Phase III Discontinuation or Reduction Cases

Formycon

At the end of 2024, Formycon submitted a streamlined clinical strategy to the U.S. Food and Drug Administration (FDA) with the intention to demonstrate the therapeutic comparability of FYB206 with the reference drug Keytruda[®] based on comprehensive analytical data and data from the PK study (Dahlia). Following a positive response from the FDA, the company decided in February 2025 to discontinue recruitment for the already-started Phase III trial. This decision accelerates the development of the biosimilar and at the same time significantly reduces the related investments over the coming years. The treatment of patients already enrolled in the Phase III trial has subsequently been continued with the locally available Keytruda[®] outside the trial.

Sandoz

- Favorable moves towards regulatory streamlining of biosimilar development reflected in decision to minimize pembrolizumab Phase III trial

Blau continues with the same clinical development strategy as other companies



Definition:

Treatment that uses the patient's own immune system to fight diseases, including cancer.



Impacts:

It has revolutionized cancer treatment, providing lasting responses in patients with advanced and metastatic tumors that were previously considered untreatable.



Mechanism of action :

Unlike traditional chemotherapy, which directly attacks cancer cells, **immunotherapy stimulates the body's natural defenses to recognize and attack tumor cells more specifically.**



Main types of immunotherapy:

- Immune checkpoint inhibitors (anti-PD-1, anti-PD-L1, anti-CTLA-4)
- Monoclonal antibodies (mAbs)
- T cell therapy (CAR-T cell)
- Therapeutic vaccines
- Cytokines

Advantages of immunotherapy

- Greater specificity for tumor cells
- Potential for long-lasting responses
- Immune memory against recurrence
- Toxicity profile different from chemotherapy

Immunotherapy: Monoclonal Antibodies (mAbs)



Definition:

Monoclonal antibodies are laboratory-produced proteins that act like natural antibodies in the immune system, designed to bind to specific targets (antigens) on cells.



Mechanism of action:

- Specific binding to target antigens
- Marking cells for destruction by the immune system
- Blocking signals that promote tumor growth



Therapeutic applications:

- Oncology
- Autoimmune diseases
- Inflammatory diseases

Video



NIH NATIONAL CANCER INSTITUTE

How Monoclonal Antibodies Treat Cancer



<https://www.youtube.com/watch?v=dxnjAc-rqz8>

AMDB12 Project: Pembrolizumab

Blau to launch biosimilar version of revolutionary technology in oncology



Pembrolizumab

It is a humanized IgG4 mAb that acts as an inhibitor of the PD-1 (Programmed Death-1) immune checkpoint.

Trade name and manufacturer

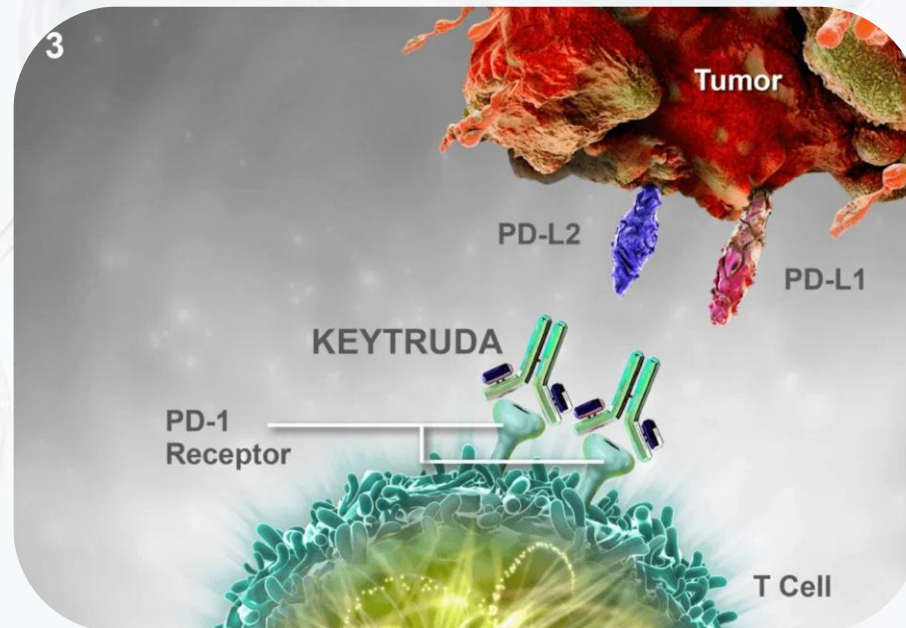
Keytruda® - Merck Sharp & Dohme (MSD)

Characteristics

Administration: Intravenous infusion every 3 or 6 weeks. Standard dosage: 200 mg every 3 weeks or 400 mg every 6 weeks.

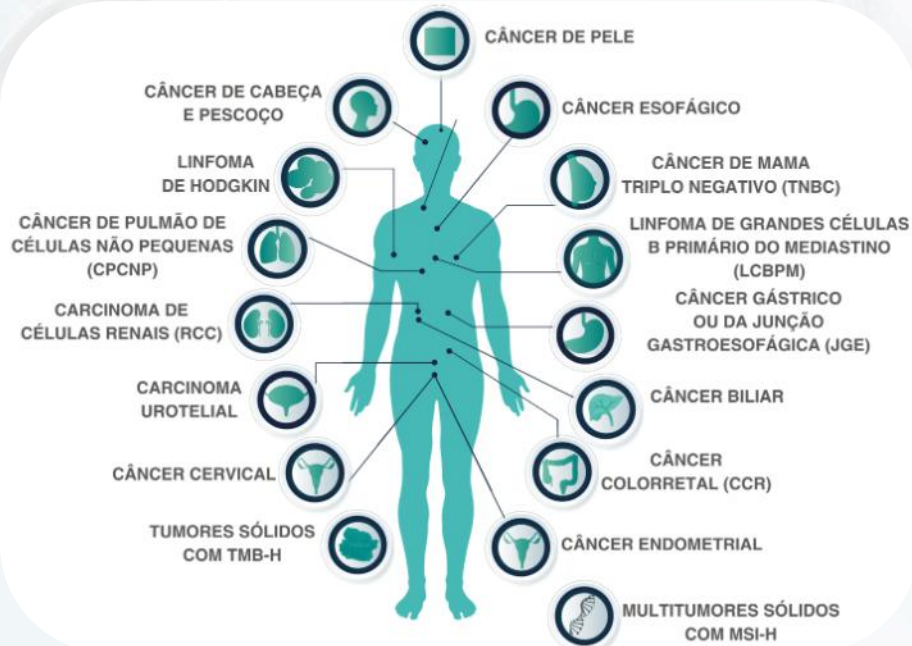
Patent status

Main patent expires in 2028 in Brazil.



Pembrolizumab immunotherapy widely studied worldwide, with more than 1,600 clinical trials registered and more than 30 phase 3 studies (KEYNOTE)

Main approved indications:



Increased number of approved indications

- Initially approved for melanoma in 2014
- First agnostic approval by biomarker (MSI-H/dMMR) in 2017
- More than 30 indications approved globally



Pembrolizumab is present throughout the cancer treatment journey



Neoadjuvant Therapy



Preoperative

Reduce tumor size, facilitate complete resection, and eliminate micrometastases early. Greater chance of complete resection, less invasive surgeries.



Adjuvant Therapy

Postoperative

Eliminate microscopic residual disease and reduce the risk of local/systemic recurrence. Improvement in disease-free survival and overall survival.



Metastatic Therapy

Advanced Disease

Symptom control, prolonged survival, and quality of life in incurable disease. Reduction in pain and symptoms, quality of life.

Monotherapy

Combination
+QT or Radio



Head and Neck



Melanoma



Kidney



Lungs



Melanoma



Hodgkin's lymphoma



Endometrial



Breast



Lungs



Breast



Lungs



Head and Neck



Biliary tract



Endometrial

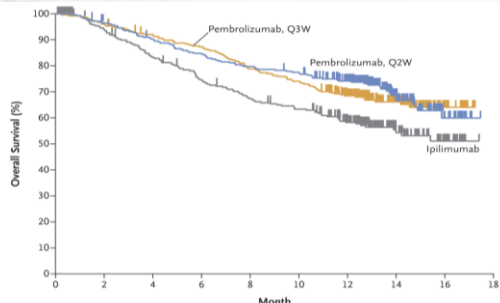
Pembrolizumab: Significant and durable clinical benefit in multiple therapeutic settings



Results in Melanoma

KEYNOTE - 006

Monotherapy for patients with unresectable or metastatic melanoma



No. at Risk	0	2	4	6	8	10	12	14	16	18
Pembrolizumab, Q2W	279	266	248	233	219	212	177	67	19	0
Pembrolizumab, Q3W	277	266	251	238	215	202	158	71	18	0
Ipilimumab	278	242	212	188	169	157	117	51	17	0

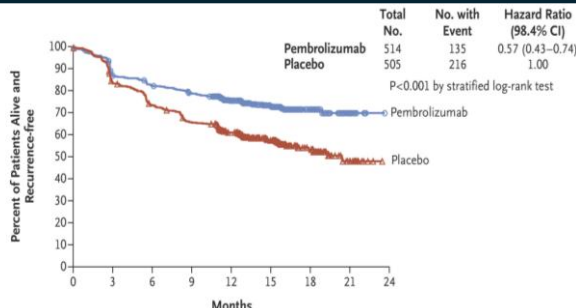
OS 10 years: **34% vs 23.6%**

Median OS: **32.7 vs 15.9m**
HR (IC): 0.71 (0.60-0.85)

MSS 10 years: **45.2% vs 31.3%**

KEYNOTE - 054

Adjuvant monotherapy for patients with completely resected stage melanoma III



No. at Risk	0	3	6	9	12	15	18	21	24
Pembrolizumab	514	438	413	392	313	182	73	15	0
Placebo	505	415	363	323	264	157	60	15	0

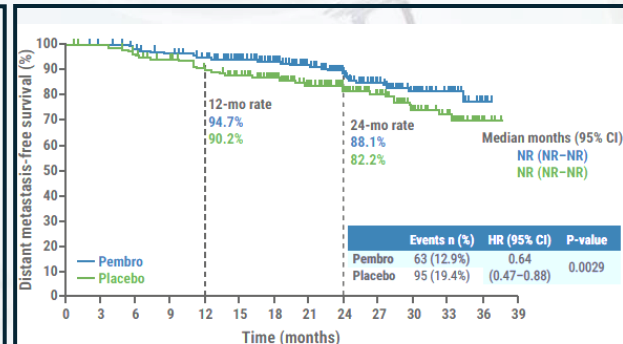
RFS 7 years: **50% vs 36%**
HR (IC): 0.63 (0.53-0.74)

DMFS 7 years: **54% vs 42%**

PRFS2 7 years: **61% vs 53%**

KEYNOTE - 716

Adjuvant monotherapy for patients with completely resected IIB/IIC melanoma



Events n (%)	HR (95% CI)	P-value
Pembro 63 (12.9%)	0.64	0.0029
Placebo 95 (19.4%)	(0.47-0.88)	

RFS 36 months: **76.2% vs 63.4%**
HR (IC): 0.62 (0.49-0.79)

DMFS 36 months: **84.4% vs 74.7%**
HR (IC): 0.59 (0.44-0.79)

OS: overall survival, MSS: melanoma-specific survival, RFS: recurrence-free survival, DMFS: distant metastasis-free survival, PRFS2: progression-free survival 2 HR: Hazard Ratio, CI: confidence interval

Pembrolizumab: Significant and durable clinical benefit in multiple therapeutic settings



Results in Lung Cancer

KEYNOTE - 024

First-line monotherapy for advanced non-squamous and squamous NSCLC

40%

Reduction in risk of death with KEYTRUDA vs. platinum-based chemotherapy
HR=0.60 (95% CI, 0.41–0.89; P=0.005)



KEYNOTE - 189

First-line combination therapy in non-squamous mNSCLC

51%

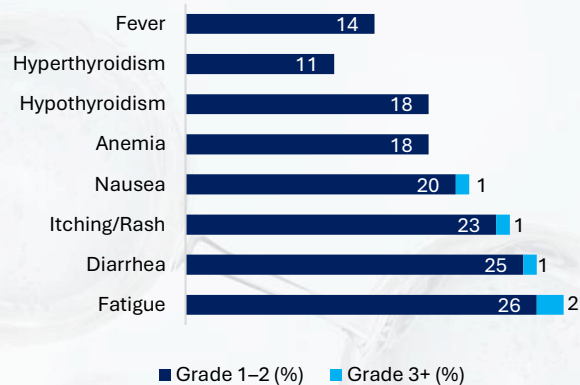
Reduction in risk of death with KEYTRUDA + plat/pem vs. plat/pem alone
HR=0.49 (95% CI, 0.38-0.64; P<0.0001)



Pembrolizumab is a widely studied immunotherapy in the world, with more than 1,600 registered clinical trials and more than 30 phase 3 studies in the KEYNOTE series. Its impact covers several tumors, including lung (NSCLC), melanoma, triple-negative breast, esophagus, gastric, head and neck, endometrium and bladder, consolidating its role as a reference in oncological immunotherapy.

Pembrolizumab has a well-characterized safety profile

Treatment-Related Adverse Events



Adverse events related to treatment occur in 78.6% of patients, most of which are mild to moderate (Grade 1-2).

Immune-mediated adverse events (IMAs)

Grouped incidence: 36.2% (any grade) | 8.6% (Grade 3-5)

imAE Type	Incidence	Grade ≥ 3
Hypothyroidism	18.5%	<1%
Hyperthyroidism	11.0%	<1%
Skin Reactions	10-15%	1.8%
Colitis	5-10%	1.4%
Hepatitis	2-5%	1.4%
Pneumonitis	3-5%	1.2%
Adrenal insuff.	<1%	<1%

Immune-mediated adverse events affect 36.2%, predominantly endocrinopathies (hypothyroidism 18.5%).

Discontinuation due to toxicity occurs in only 8.5%, and directly attributable mortality is rare (0.1%).

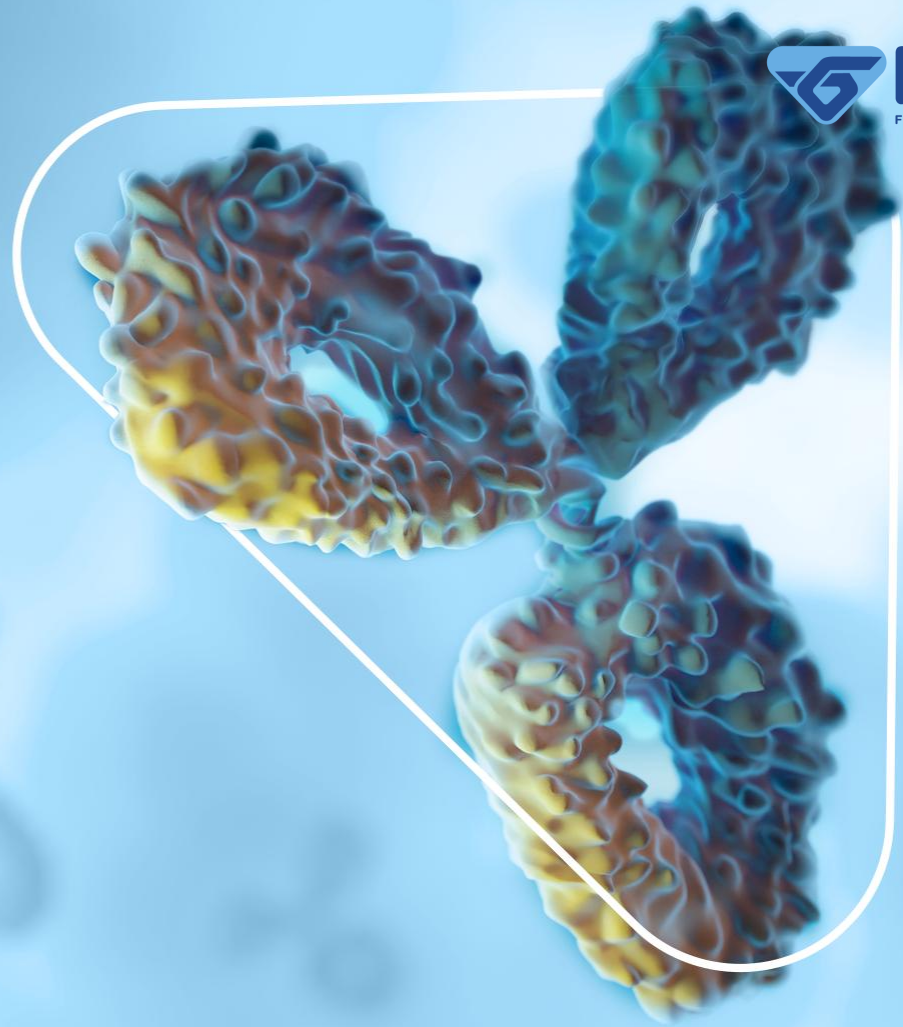
**We take care of
people's health
through modern
treatments**



4. Market Update and Growth Opportunities



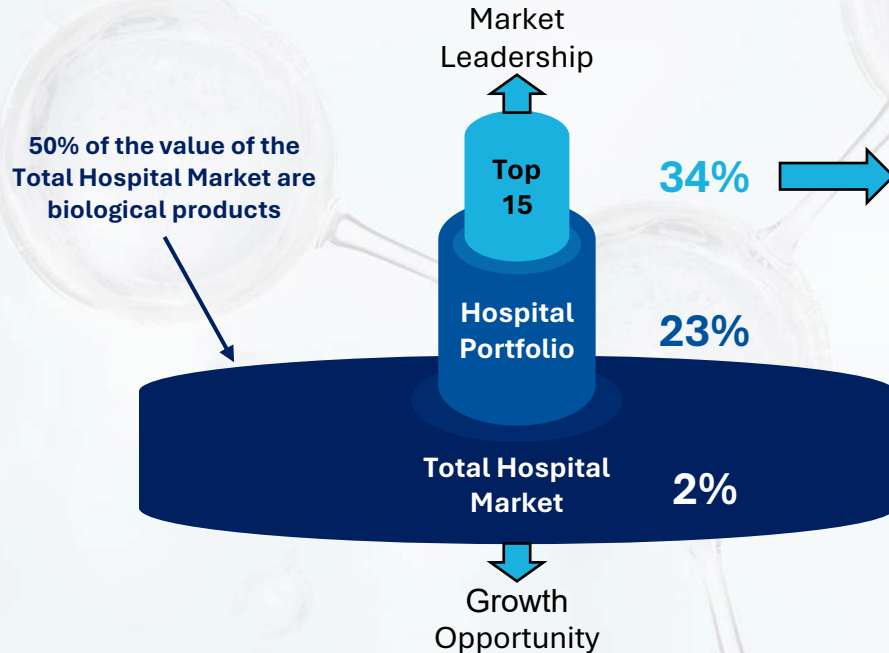
Matheus Fujisawa
IR Manager



Blau Combines Leadership in the Hospital Market Portfolio with Transformational Growth Opportunity



Market Share Blau – Hospital¹



Competitive advantages:

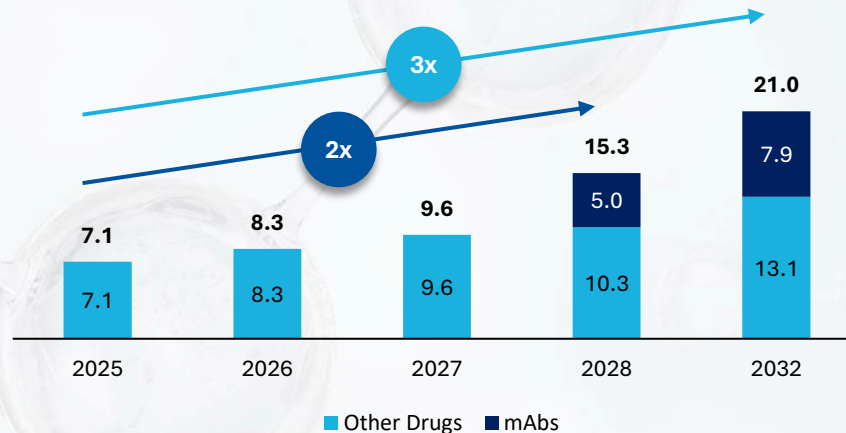
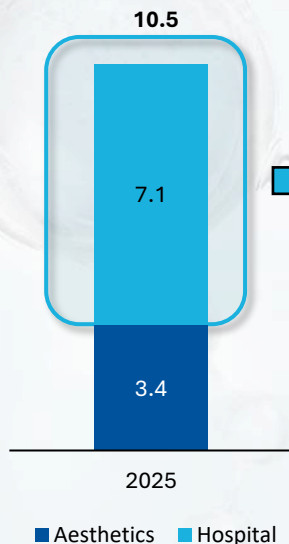
- High-scale, low-cost local production for the vast majority of the Top 15
- High capillarity: over 9,500 institutions served in Brazil alone
- Complete range of products for hospitals: biological and synthetic

Despite its leadership in the current portfolio, Blau has room for growth:

Blau's TAM³ covers only 7% of the hospital segment.

TAM¹ has the potential to double by 2028 and triple by 2032

Total Addressable Market (BRL bi)²



- Transformational opportunity with mAbs.
- Other drugs include those already submitted to Anvisa by 2027 and BRL 700 million per year from 2028 to 2032.
- Only includes Brazil, export opportunity.

Sensitivity Analysis Shows Transformational Potential

mAbs Potential Net Revenue – BRL bi

Considering Blau's Total Addressable Market (TAM) of BRL 7.9 billion for mAbs in Brazil

	20%	25%	30%	35%	40%	Market Share
80%	1.3	1.6	1.9	2.2	2.5	
75%	1.2	1.5	1.8	2.1	2.4	
70%	1.1	1.4	1.7	1.9	2.2	
65%	1.0	1.3	1.5	1.8	2.0	
60%	0.9	1.2	1.4	1.7	1.9	

Conversion of TAM to Net Revenue

Consolidated Gross Margin Potential

Considering a gross margin of 42% on the remainder of the portfolio

	20%	25%	30%	35%	40%	Participation of mAbs in Net Revenue
70%	46%	48%	49%	51%	52%	
65%	45%	46%	48%	49%	50%	
60%	44%	45%	46%	47%	48%	
55%	43%	44%	45%	45%	46%	
50%	42%	43%	43%	44%	44%	

Gross Margin mAbs

Recapping the Key Messages



Blau has the technology, ownership, infrastructure, team and investment capacity necessary for the complete production of mAbs.



The mAbs lead the growth of the Hospital Segment, and the trend should continue due to clinical results and the growing number of indications.



In the mAb market, biosimilar drugs are growing more, driven by patent expirations and increased access.



Among the 4 mAbs projects presented, Blau is the only company to produce them entirely in Brazil, which provides competitive advantages.



Blau is the leader in the main molecules in its portfolio, and mAbs have great potential to be relevant for the Company.

THANK YOU!



5. Q&A

