

Biossimilars

Safety, Efficacy and Accessibility

Biosimilars

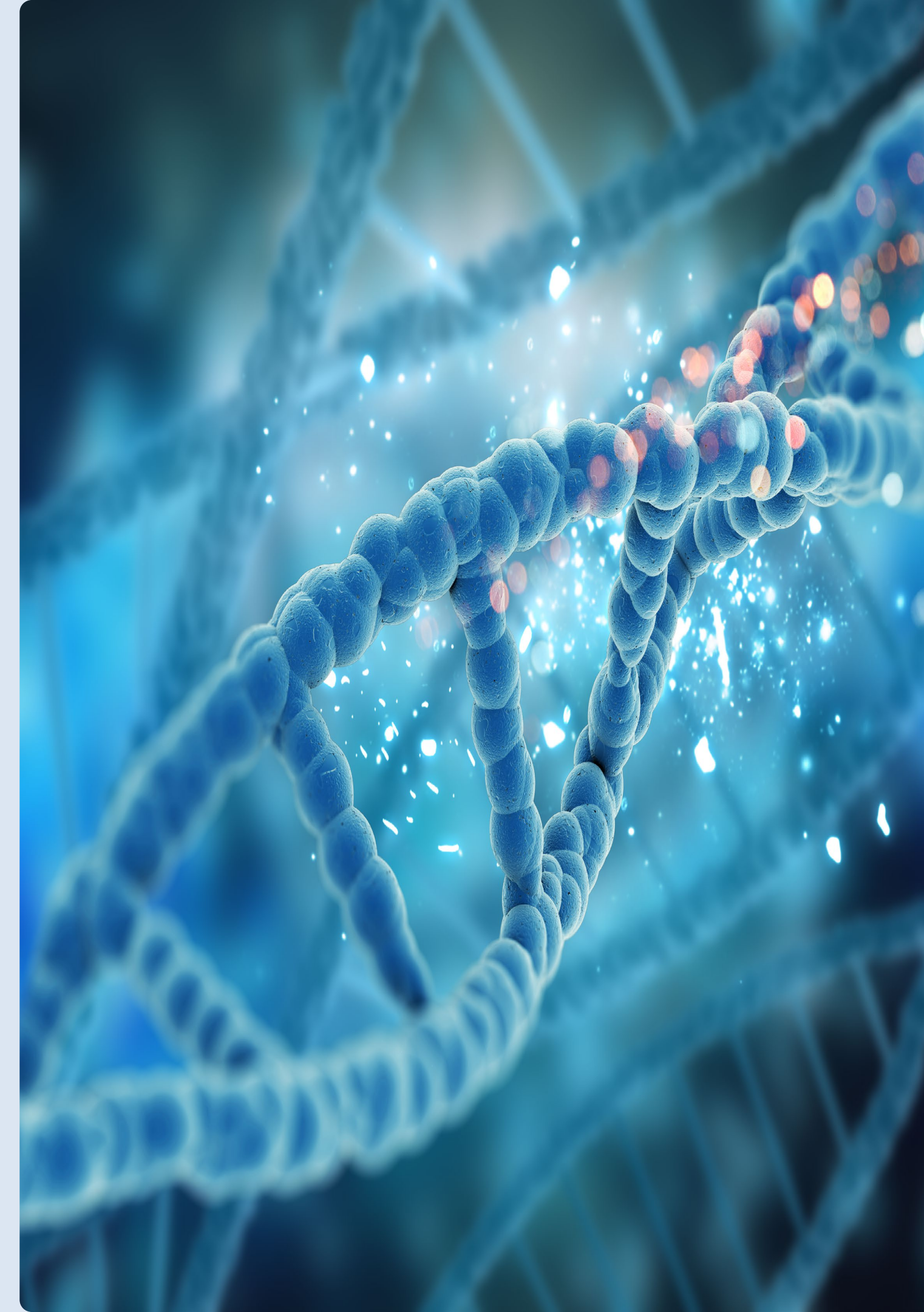
- **High-Quality Alternatives:** Living-organism-derived medicines with the same quality, safety, and efficacy as original biologics
- **Rigorous Approval:** Highly controlled development process, fully approved by Anvisa with no clinically significant differences
- **Regulatory Update:** Technical Note 60/2026 aligns Brazil with WHO guidelines, confirming that switching between biosimilars and reference products has no clinically significant differences
- **Expanded Access:** Reduced costs that deliver effective solutions for chronic, rare, and onco-hematological diseases
- **Health System Support:** Provides patients with more therapeutic options while improving the sustainability of the national health system



PDP'S

Partnerships for Productive Development

- **Core Purpose:** Strategic agreements between public institutions and private companies to ensure modern, affordable treatments through technology transfer
- **Key Benefits:** Reduces import dependency, strengthens the Brazilian pharmaceutical industry, and guarantees the local supply of essential medicines
- **Economic Impact:** Drives economic development, generates skilled jobs, and positions Brazil as a global leader in biopharmaceutical production.
- **How It Works:** At least one public laboratory and one private partner cooperate; advanced or cutting-edge technology is transferred to the public sector for gradual or direct local production.



Portfolio (Originators)



Beta-Interferon (1a)

Indicated for the treatment of multiple sclerosis



Infliximab

Indicated for rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, Crohn's disease, ulcerative colitis, and psoriasis

Portfolio (Originator / Biosimilar)



Golimumab

Indicated for rheumatoid arthritis, ankylosing spondylitis, and psoriatic arthritis



Trastuzumab

Indicated for HER2-positive breast cancer

Portfolio (Biosimilars)



Adalimumab

Indicated for the treatment of rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, among other conditions



Alfataliglicerase

Indicated for the treatment of Gaucher disease

Portfolio (Biosimilars)



Epoetin alfa

Indicated for anemia associated with chronic kidney disease



Etanercept

Indicated for rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, and psoriasis

Portfolio (Biosimilars)



Somatropin 4 IU and 12 IU

Indicated for hypopituitarism and Turner syndrome



Rituximab

Indicated for non-Hodgkin lymphoma, follicular lymphoma, and rheumatoid arthritis

CTIE

Technological Complex in Strategic Inputs

- **Core Focus:** Next-generation biomanufacturing of Active Pharmaceutical Ingredients (APIs)
- **Treatments Provided:** Solutions for Diabetes, Cancer, Chronic and Inflammatory diseases, Turner Syndrome, and Hypopituitarism
- **Infrastructure:** A 225,000 m² land area with 77,000 m² of built area across 24 buildings
- **Impact & Investment:** ~R\$ 1 billion invested, creating around 400 operational jobs





Thank You!

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