bluepharma 25 years

Passion for Science.
Committed to Life.

ANTIBODY-DRUG-CONJUGATES (ADCS)

Biological Precision Meets Cytotoxic Potency

Continuing its strategic expansion across Advanced Modalities - including peptides and RNA-based therapies - Bluepharma is strengthening its positioning in one of the fastest-growing areas of modern oncology: Antibody-Drug Conjugates (ADCs).

ADCs represent a highly innovative therapeutic class that combines the precision of monoclonal antibodies with the cytotoxic potency of highly active drugs (HPAPIs). This targeted conjugation enables selective delivery of the therapeutic payload directly to tumours cells, maximizing clinical efficacy while significantly reducing systemic toxicity.

A Sophisticated Three-Component Architecture

Structurally, ADCs are composed of three key elements:

- A monoclonal antibody that selectively recognizes an antigen expressed on the surface of target cells;
- A chemical linker, engineered to ensure stability in circulation and controlled intracellular release;
- A highly potent cytotoxic drug (payload) responsible for the therapeutic effect.

This sophisticated design transforms extremely potent molecules — which would be too toxic for conventional systemic administration — into safe and highly effective targeted therapies directed exclusively at diseased tissue.

Expanding Clinical Impact in Oncology

ADCs have demonstrated particularly meaningful clinical outcomes across multiple cancer types, including breast, lung, haematological, and gastrointestinal tumours.

Their rapid growth is driven by the ability to address unmet medical needs and by the modular flexibility of combining different antibodies, linkers, and payloads to generate next-generation therapies with enhanced efficacy.

The continued expansion of clinical pipelines and regulatory approvals confirms ADCs as one of the most dynamic segments in oncology therapeutics.

Technological and Industrial Complexity

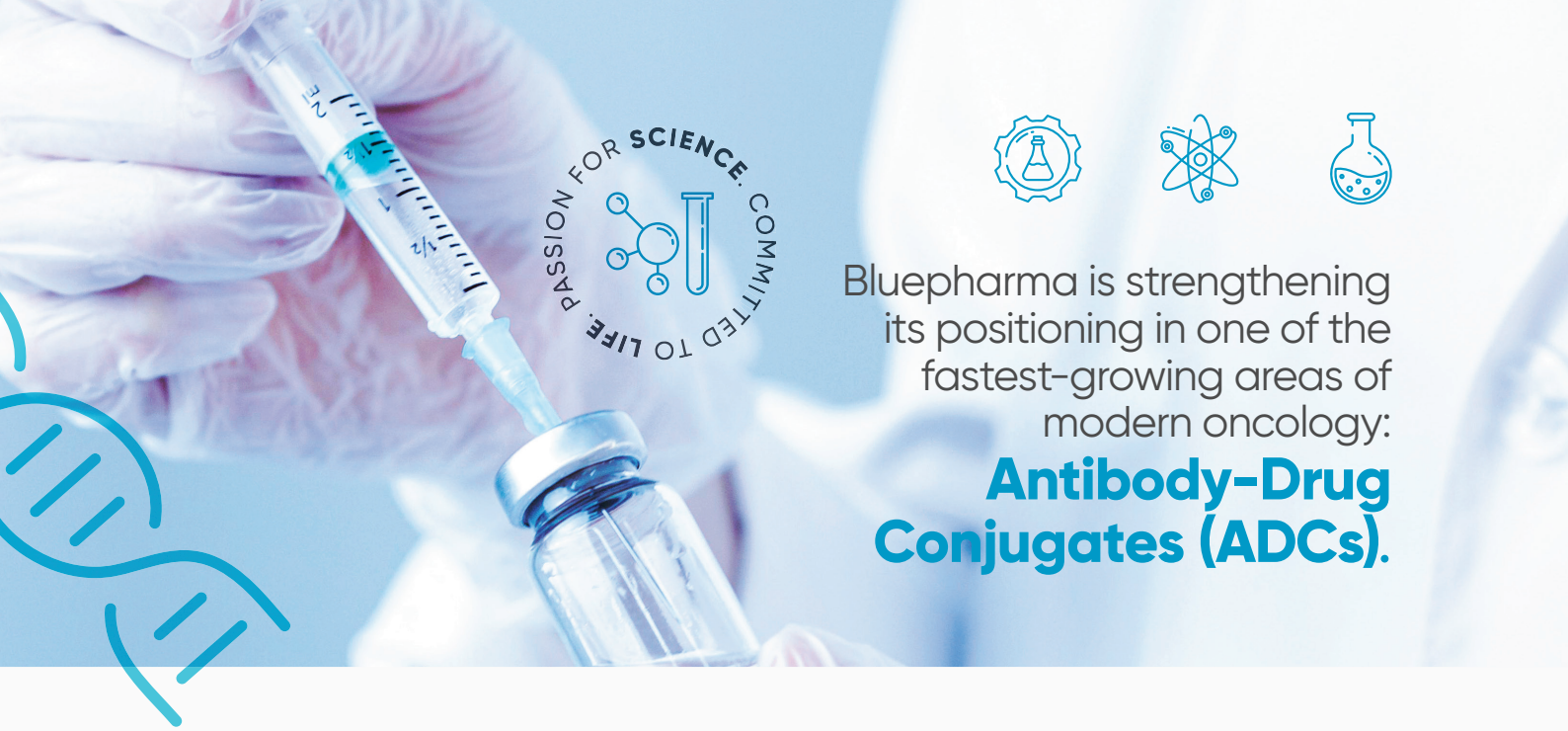
From both a scientific and manufacturing perspective, ADCs represent one of the most demanding areas of modern biopharmaceutical development. Their successful development requires integrated expertise in:

- Monoclonal antibody production and characterization;
- High-precision conjugation chemistry;
- Safe handling of highly potent molecules (HPAPIs) in high-containment environments;
- Sterile formulation and fill & finish of complex injectable medicines.

Strict control of the Drug-to-Antibody Ratio (DAR), linker stability, and final product homogeneity is essential to ensure safety, efficacy, and regulatory compliance.

These technical requirements make ADC development particularly challenging — but also highly differentiating for organizations with integrated scientific expertise and advanced GMP manufacturing capabilities.

To support these highly demanding modalities, Bluepharma is expanding its industrial capabilities with a new state-of-the-art sterile manufacturing facility designed for complex injectable medicines and high-potency compounds.



Bluepharma is strengthening its positioning in one of the fastest-growing areas of modern oncology:

Antibody-Drug Conjugates (ADCs).

Strategic Market Positioning

ADCs are positioned among the highest-value segments of the pharmaceutical market, supported by a strong and rapidly expanding clinical pipeline.

Their technical complexity creates significant barriers to entry, favouring partners equipped with specialized GMP infrastructure, expertise in potent compounds, and experience in complex injectable manufacturing.

Beyond their direct clinical impact, ADCs also enable portfolio extension and incremental innovation strategies. Existing antibodies can be repurposed with optimized linkers or novel payloads, accelerating the development of differentiated therapies while mitigating technological risk.

Integrated Capabilities for Sterile Manufacturing

By expanding capabilities across peptides, RNA-based therapies, and Antibody-Drug Conjugates, Bluepharma continues to strengthen its role as a strategic partner in Advanced Therapeutic Modalities.

To support this vision, Bluepharma recently expanded its industrial infrastructure with a new state-of-the-art sterile manufacturing unit dedicated to complex injectable medicines. Designed to meet the highest regulatory standards, including the revised EU GMP Annex 1, the facility enables the production of complex sterile products across multiple development stages — from pilot and clinical batches to small-scale commercial manufacturing.

This new unit will play a key role in supporting the manufacturing of next-generation medicines requiring advanced sterile processing and high-containment capabilities.

Together, these capabilities position Bluepharma as a trusted partner for the development, scale-up, and GMP manufacturing of advanced therapeutic modalities — including ADCs.

Through the integration of precision biology, formulation science, high-containment manufacturing, and complex sterile injectable expertise, Bluepharma contributes to the development and industrialization of the next generation of targeted therapies.

Integrated Capabilities for Sterile Manufacturing

By expanding capabilities across peptides, RNA-based therapies, and Antibody-Drug Conjugates, Bluepharma continues to strengthen its role as a strategic partner in Advanced Therapeutic Modalities.

To support this vision, Bluepharma recently expanded its industrial infrastructure with a new state-of-the-art sterile manufacturing unit dedicated to complex injectable medicines. Designed to meet the highest regulatory standards, including the revised EU GMP Annex 1, the facility enables the production of complex sterile products across multiple development stages — from pilot and clinical batches to small-scale commercial manufacturing.

This new unit will play a key role in supporting the manufacturing of next-generation medicines requiring advanced sterile processing and high-containment capabilities.

Together, these capabilities position Bluepharma as a trusted partner for the development, scale-up, and GMP manufacturing of advanced therapeutic modalities — including ADCs.

Through the integration of precision biology, formulation science, high-containment manufacturing, and complex sterile injectable expertise, Bluepharma contributes to the development and industrialization of the next generation of targeted therapies.

Bluepharma

Precision. Innovation. Value.

With this strategic focus on Advanced Therapeutic Modalities, Bluepharma is positioning itself as a technology-driven partner in the development and manufacturing of high-complexity peptide therapeutics, combining scientific innovation, industrial excellence, and a forward-looking market vision.

bluepharma 25 years

S. Martinho do Bispo, 3045-016 Coimbra, Portugal · (+351) 239 800 300 · **business@bluepharmagroup.com**

www.bluepharmagroup.com

PRR Plano de Recuperação e Resiliência · REPÚBLICA PORTUGUESA · Financiado pela União Europeia NextGenerationEU