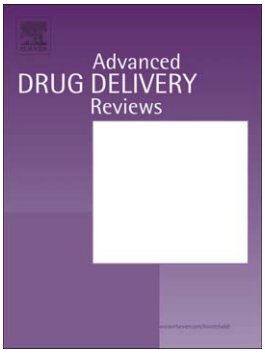

The state-of-play and future of antibody therapeutics

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Title: The state-of-play and future of antibody therapeutics

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Key words: monoclonal antibodies (mAbs), therapeutic antibodies, biologicals, biosimilars, biobetters, antibody engineering, antibody drug conjugates (ADC), bispecific antibodies, manufacture, degradation, stability, formulation

Abstract

It has been over four decades since the development of monoclonal antibodies (mAbs) using a hybridoma cell line was first reported. Since then more than thirty therapeutic antibodies have been marketed, mostly as oncology, autoimmune and inflammatory therapeutics. While antibodies are very efficient, their cost-effectiveness has always been discussed owing to their high costs, accumulating to more than one billion dollars from preclinical development through to market approval. Because of this, therapeutic antibodies are inaccessible to some patients in both developed and developing countries. The growing interest in biosimilar antibodies as affordable versions of therapeutic antibodies may provide alternative treatment options as well potentially decreasing costs. As certain markets begin to capitalize on this opportunity, regulatory authorities continue to refine the requirements for demonstrating quality, efficacy and safety of biosimilar compared to originator products. In addition to biosimilars, innovations in antibody engineering are providing the opportunity to design biobetter antibodies with improved properties to maximize efficacy. Enhancing effector function, antibody drug conjugates (ADC) or targeting multiple disease pathways via multi-specific antibodies are being explored. The manufacturing process of antibodies is also moving forward with advancements relating to host cell production and purification processes. Studies into the physical and chemical degradation pathways of antibodies are contributing to the design of more stable proteins guided by computational tools. Moreover, the delivery and pharmacokinetics of antibody-based therapeutics are improving as optimized formulations are pursued through the implementation of recent innovations in the field.