

IMPLANT FOR DELAYED RELEASE OF THERAPEUTIC BIOLOGICALS

Technology Offer

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Branch

drug formulation, therapy of autoimmunity

Patent Situation

EP patent filed

Offer

license or co-development

Key Words

delayed drug release, autoimmunity, biologicals

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Introduction

Therapeutic biologicals are widely used for the long-term treatment of cancer and autoimmune diseases. Because of their protein nature, they are usually administered parenterally, mainly intravenously (IV) or intramuscularly (IM). On IV administration, the response is rapid, but can be associated with pronounced toxicity and activity tapers off rapidly. A depot effect is achieved on IM administration, but this delayed response is limited, necessitating frequent injections. A delayed release formulation which maintains drug levels constantly over a prolonged period is therapeutically desirable.

Invention

The invention relates to the use of a novel implant formulation, for subcutaneous insertion, which releases the protein drug slowly from the implant, but maintains the stability of the therapeutic protein drug. The implant formulation offers the possibility of regulating the bioavailability of biologicals, thereby reducing their toxicity and obviating the need for frequent injections.

Market Potential

The invention can be applied to the administration of protein drugs for a wide variety of chronic indications, particularly autoimmune disorders.

Development Status

The stability and release properties of the implant formulation have been demonstrated in vitro. The release of formulated drug has also been shown in experimental studies in rodents.



Double-matrix implant carrying model protein conjugated with fluorescent dye and implant syringe.

Reference

S. Beyer, L. Xie, M. Schmidt, N. De Bruin, M. Ashtikar, S. Rüschenbaum, C.M. Lange, V. Vogel, W. Mantele, M. J. Parnham, M.G. Wacker (2016) Optimizing novel implant formulations for the prolonged release of biopharmaceuticals using in vitro and in vivo imaging techniques. *J Controlled Release* 235:352-364.