Biological Autoimmune Therapeutics

Drugs, Devices, Packaging, Therapeutics & Forecasts

Report Brochure

Greystone Research Associates

Greystone Research Associates is pleased to announce the publication of a new market assessment. **Biological Autoimmune Therapeutics: Drugs, Devices, Packaging, Therapeutics, Strategies and Forecasts** is a comprehensive evaluation and analysis of the technology, products and participants providing the driving force behind this evolving segment of the healthcare sector. The study is designed to provide drug company decision makers, drug delivery developers, device designers, healthcare marketers, and supply chain participants with a detailed understanding of the economics, technologies, disease segments, and commercial opportunities for biological drugs for treating autoimmune conditions. Provider organization business managers, healthcare administrators and investors will also benefit from this study.

Meaningful Therapeutic Outcomes and User-Friendly Presentations

The administration of therapeutic immune modulators is becoming an increasingly important healthcare treatment option for a growing number of diseases and indications having broad implications for patient health and well-being. But to fully exploit the value of this class of therapeutics in both human and commercial terms, developers must successfully navigate the inherent limitations of drug storage and administration, moving away from infusion and toward injection as a route of administration. Antibody drug products indicated for chronic conditions such as autoimmunity are often re-formulated, re-packaged and re-labeled into injectable form and re-introduced two to three years post-market launch to address the growing economic pressure and patient desire to avoid the need for out-patient infusion in favor of self-injection. This report describes key factors in the trend toward user acceptance and designed-in usability. The influence of biosimilars on as-supplied packaging strategies is yet to be determined, but the need for product differentiation in an increasingly crowded market segment will make product packaging a key competitive factor.

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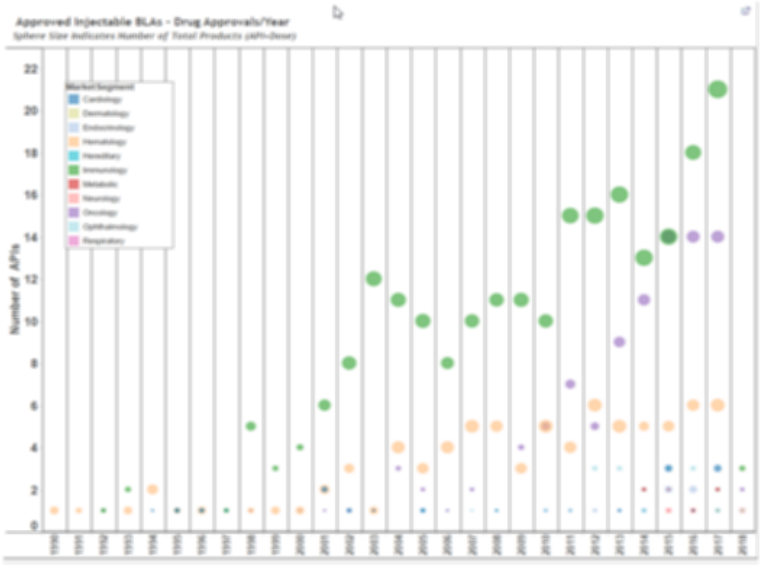
Market Dynamics

……..Companies competing in the autoimmune therapeutics sector must deal with all of the development issues present in biologicals/ recombinant protein development, including protein purity, scale-up requirements, yield, practical manufacturability and overall cost. Other product development decision points revolve around optimization of expression systems (choice of vector, choice of cell line and clonal selection), optimization of cell culture conditions, and purification steps.



A longer life span is expected to translate to a growing number of patients diagnosed with chronic conditions. To counteract the financial and medical infrastructure implications of this trend, pressure from the public sector and managed care organizations will place a premium on therapeutic self-administration, an expectation that is creating an increased interest in routes of administration that are patient-friendly and cost-effective. Pharma company decision makers have come to the realization that for many products, success no longer only depends on the medication itself but also on achieving a consumer-compatible form of packaging and application……..

Product Design & Patient Enablement Factors

The advent of the Internet has ushered in the age of the Informed Patient. Patients now routinely arrive for medical appointment with some basic knowledge of the issues the seek to understand. They are increasingly engaging caregivers, asking questions and probing for knowledge. This has led to a concept called Shared Decision Making (SDM). Shared Decision Making is most effective when patient feel empowered by their ability to discuss health issues and medical history freely with their provider. The use of decision aids, like the one shown below, are increasing as caregivers continue to find an approach and method that meet the goals of SDM while coinciding with their learned and developed views of the clinician-patient relationship.

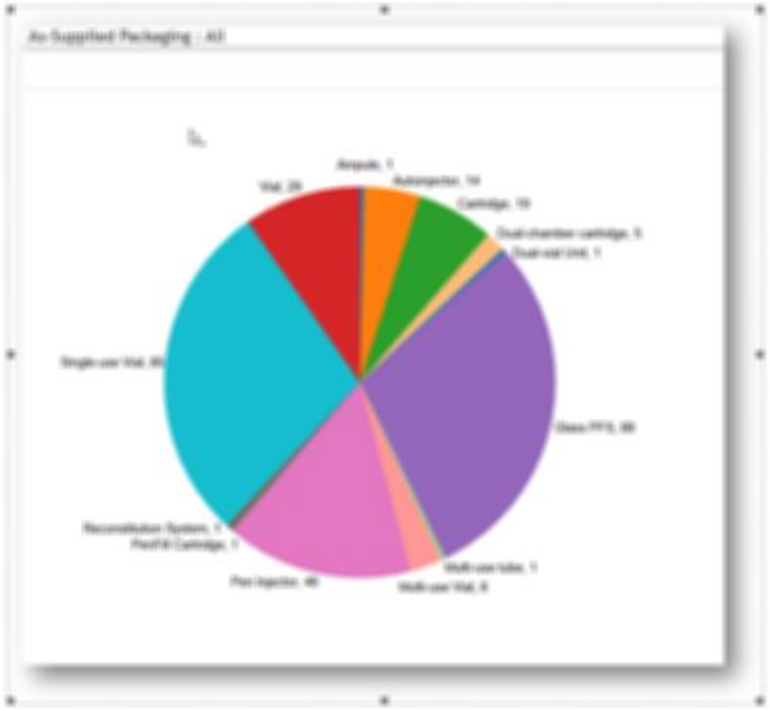
For self-administration, adherence with drug therapy and disease management protocols has become a primary concern within the healthcare and pharmaceutical industries. New generation drug injection devices are being created to address the patient compliance issues by making the delivery of injectable drugs less complicated and intimidating. Efforts to enhance adherence to dosing schedules have a non-negligible effect on drug formulation and delivery decisions and are a significant factor in the prescribing decisions of most physicians……..

Product Landscape

As more biosimilars enter the U.S. market, analysts expect to see U.S. price reductions similar to those that have occurred in Europe. However, of the seven biosimilars approved by FDA, sales of five biosimilars have been delayed, or (allegedly) adversely impacted, by actions of the brandname manufacturers. Three biosimilars (Erelzi, Amjevita, and Cyltezo) have had their marketing launch delayed by patent infringement lawsuits filed by brand-name manufacturers. In addition, Pfizer has sued Johnson & Johnson (J&J) alleging that J&J has entered into anticompetitive contracts with insurers that prevent coverage of Pfizer's biosimilar (Inflectra), a less expensive substitute for Remicade……

As-Supplied Packaging and Administration

Currently, eighty percent of monoclonal antibodies indicated for autoimmune conditions are self-administered subcutaneously by via prefilled devices. Fusion proteins represent a special class of engineered biologicals that are designed to generate a highly specific therapeutic effect at a well-defined physiological site. The current generation of FDA-approved fusion proteins addresses indications in a range of conditions, led by autoimmunity. More than half of approved fusion proteins are currently administered subcutaneously and supplied in prefilled devices.



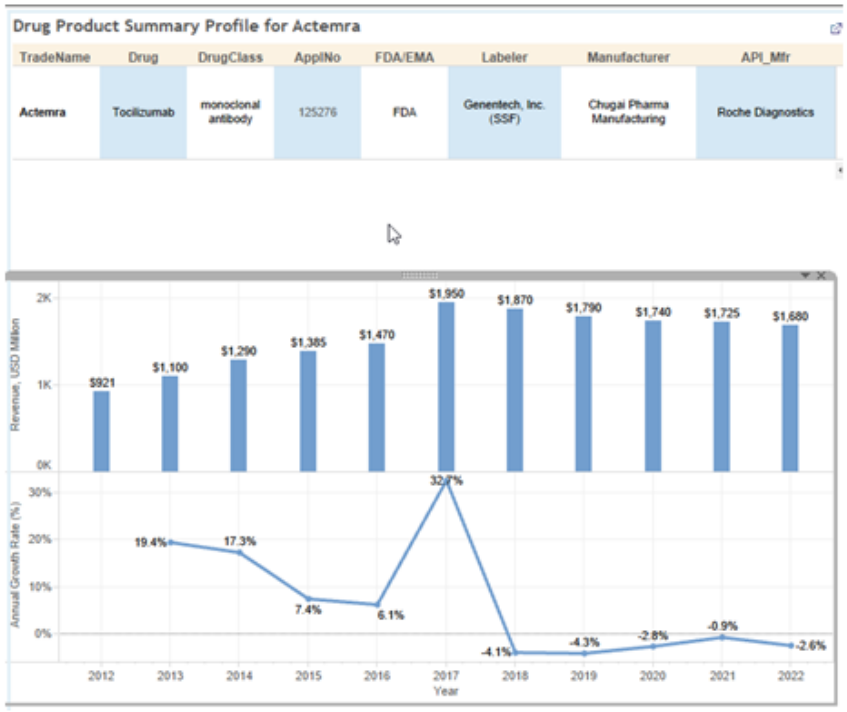
As the administration of injectables moves increasingly from practitioner offices and healthcare facilities to patient homes, decisions regarding as-supplied packaging that were once considered boilerplate have moved to the early stages of the development process. A wide spectrum of device attributes, including form factor, device-patient interaction, security and safety, dosing, activation, off-device communication, and drug formulation factors have been incorporated into drug injection devices……

The Product Ecosystem

During 2017, the biological drug supply chain experienced significant market consolidation as CMOs and Clinical Research Organizations (CROs) built their scale and capability. Mergers and acquisitions can complicate keeping track of the functions a CMO can fulfil and the sites it can provide access to. Especially as pharmaceutical and biologics producers often work with hundreds of external partner contacts. International seminars and events help manufacturers stay up to date with these changes alongside the general advances in the global landscape.

A greater number of biologics manufacturers are seeking strategic partnerships to shrink their base of contacts, while maintaining a global reach and access to technologies they require. With this shift on the horizon, to retain market share, medical CMOs will find it necessary to enhance their capabilities in order to avoid account erosion……

Product Analysis, Financial Performance & Forecasts



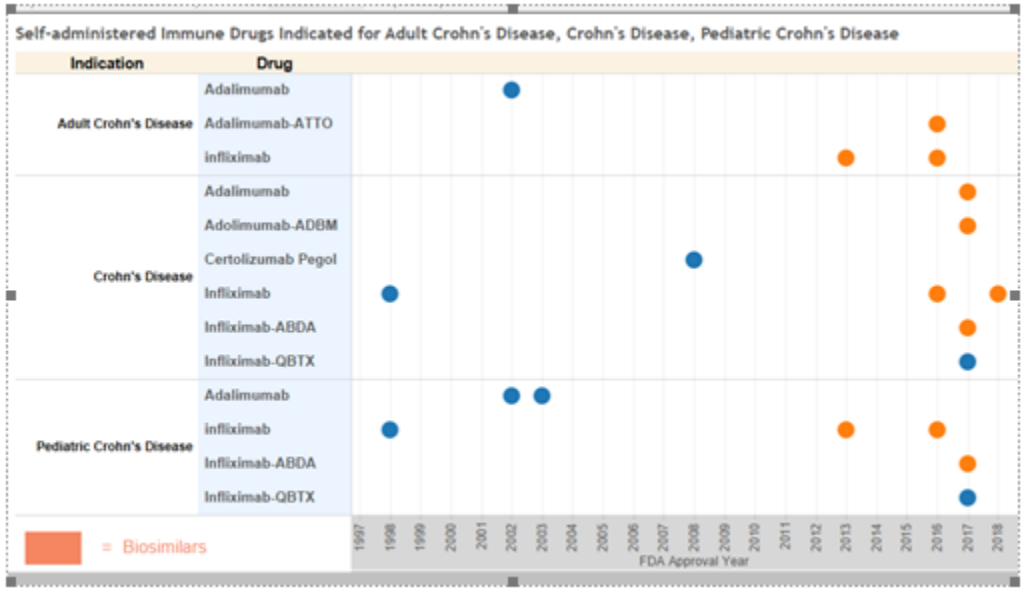
Actemra (known as RoActemra within the EU) is the result of research collaboration between Roche and Chugai. Actemra is considered the first humanized IL-6 receptor-inhibiting monoclonal antibody. In Japan, Actemra was launched by Chugai in June 2005 as a therapy for Castleman's disease; in April 2008, additional indications for RA, polyarticular-course juvenile idiopathic arthritis and systemic-onset juvenile idiopathic arthritis were also approved in Japan.

In January 2009, Roche announced that the European Commission approved RoActemra, to treat patients with rheumatoid arthritis. RoActemra, in combination with methotrexate (MTX), is indicated for the treatment of adult patients with moderate to severe RA who have either responded inadequately to, or who were intolerant to, previous therapy with one or more disease DMARDs or TNF antagonists…….

Autoimmune Therapeutics – Market Segment Analysis

Crohn's Disease

CD is conventionally treated with systematic or local corticosteroids and immunosuppressives. However, a significant proportion of patients fail therapy or fail to enter remission with these medications. In addition, more than 50% of patients treated acutely with corticosteroids will either become resistant or steroid-dependent. These medications are also associated with significant adverse effects. Adalimumab has been used as a treatment for moderate to severe CD and the CLASSIC I trial suggests that adalimumab may be more effective than placebo at inducing remission in these patients. The introduction of novel biologic agents has changed the landscape of the management of CD, offering effective and rapid clinical response with minimal adverse effects.



Company Profiles

Lonza Group AG (Lonza) is a Switzerland-based holding company and a supplier to the pharmaceutical, healthcare and life-science industries. The Company divides its activities into four divisions: Life Science Ingredients; Microbial Control; Custom Manufacturing, and Bioscience. The Life Science Ingredients division comprises a range of products for applications in nutrition, hygiene, preservation, water treatment, materials protection, and other industrial markets. The Microbial Control division focuses on five areas: hygiene, wood protection, water treatment, oil/gas applications, and industrial preservation and comprises products ranging from disinfectants to household cleaning products. The Custom Manufacturing division comprises products used in pharmaceuticals sector. The Bioscience division comprises bioscience products, including cell culture and molecular biology tools for research, tests for microbial detection, and media used in the production of therapeutics. In October, Lonza acquired a controlling interest in Octane Biotech, a partner company with which they were developing a closed and fully automated system for the manufacture of mesenchymal stem cells and chimeric antigen receptor (CAR) T cells. Lonza has been investing heavily in the cell and gene therapy space, with acquisition and manufacturing capacity investments……

Lonza Biological Drug Captive Supply Chain

TopLevelSupplier	Supplier	City	Country
Lonza	Lonza AG	Visp	Switzerland
	Lonza Biologics	Portsmouth	USA
	Lonza Biologics plc	Slough	UK
	Lonza Biologics Porriño, S.L.	O Porriño	Spain
	Lonza Biologics Tuas Pte Ltd.	Tuas	Singapore
	Lonza Biopharma AG	Visp	Switzerland
	Lonza Biotec SRO	Kouřim	Czech Republic
	Lonza Braine SA	Braine l'Alleud	Belgium
	Lonza Guangzhou Nansha LTD	Nansha District	China

What You Will Learn

- What are the approved biological drugs indicated for autoimmune conditions, what is the as-supplied packaging, and who markets them?
- What are the major factors driving the growth of biological drugs for treating autoimmunity?
- What is the size of the market biological autoimmune therapeutics drugs today, who are the market share leaders, and what will it be in 2022?
- How important are drug developer-device manufacturer relationships and what are the key alliances in the industry?
- What are the essential design factors, technologies and market development issues for biological autoimmune drugs?
- What are the significant economic, technology, and regulatory factors affecting the market for immunotherapeutic drugs?

Report Format and Availability

This report is available electronic format. A site license for a single physical location and a corporate license are also available. Custom licensing options to address specific company user requirements are available by calling client services at 603-595-4340, or by emailing clientservices@greystoneassociates.org.

Methodology

Research methodology is based on primary research in the form of in-depth interviews with key market participants, technology developers, distributors, industry experts, and market influencers, a list that includes regulatory officials, industry trade groups, and materials standards organizations.

Primary data is evaluated and normalized against secondary sources including trade journal articles, technical literature, industry publications, company data sheets and published information, and statistical data from government agencies and trade associations.

Forecasts and projections of market demand and future market activity are derived using standard modeling and statistical techniques.

About Greystone Associates

Greystone Associates is a medical technology consulting firm focused on the areas of medical market strategy, product commercialization, venture development, and market research. We assist medical and healthcare market participants in achieving their business objectives through the creation of detailed development strategies, product commercialization programs, and comprehensive market and technology research and analysis.

Our market research publications are designed, researched and written to provide timely and insightful information and data on focused market segments, with the aim of providing market participants with the essential knowledge to refine and execute their marketing plans and financial targets.

About Our Research

Our reports are carefully researched and written to provide timely and insightful analysis of key factors and developments shaping the commercial marketplace. The focused nature of our publications is designed to allow readers to identify emerging demand and growth opportunities in selected markets. Numerous charts, tables and graphs complement the text, with evaluations and assessments of current and probable future market developments, technology issues and business factors – information necessary to compete effectively in the global marketplace.

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