Inflammatory Disorders: Therapies That Suppress or Balance the Immune Response

Lucy J. Sannes, PhD, MBA

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About the Author

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Executive Summary

The immune system is a complex biological process that protects the body from infectious pathogens such as bacteria, viruses, parasites, and fungi, as well as from cells which have transformed into cancer cells but have not yet escaped the immune system. However, sometimes this process goes awry and the immune system behaves as if the individual’s own body is “foreign.” This condition can result in an autoimmune disease, or, an overreaction or exaggerated response to a foreign substance that is normally harmless, leading to an allergic response. Also, in transplantation medicine, when an organ or tissue from one individual is transferred to another, the recipient’s immune system will recognize that organ or tissue as foreign and activate the immune process, leading to subsequent rejection. In each of these settings, therapies are needed to suppress the unwanted and harmful immune response.

A number of drugs are available today to treat these disorders, but they are not always effective. In addition, early immunosuppressive therapies to reach the market suppress much of the immune response and can lead to serious adverse events such as increased risk of infection and possibly an increased risk of cancer development. This has led to an interest in identifying approaches to balance the immune system—to suppress the part of the immune response that is causing the disease while maintaining or enhancing other parts of the immune system.

This report focuses on immunotherapies that suppress or balance the immune response for selected autoimmune diseases, asthma, allergies, and prevention of organ transplant rejection. The autoimmune diseases discussed in this report include rheumatoid arthritis, type 1 diabetes, Crohn’s disease, ulcerative colitis, psoriasis, psoriatic arthritis, and systemic lupus erythematosus.

Chapter 2 discusses each of these autoimmune diseases, asthma, allergies,
Executive Summary

and prevention of organ transplant. This discussion includes information on the pathology and epidemiology of each disorder. Chapter 3 discusses the current pharmacological treatment options for these diseases.

The major focus of this report is on emerging candidate therapies for these autoimmune and inflammatory disorders and for prevention of organ transplant rejection. Approximately 400 product candidates and development programs are identified herein. A wide range of putative targets have been identified for potential new therapies being developed to treat autoimmune or inflammatory disorders or to prevent rejection of organ transplants. In Chapter 4, Table 4.1 summarizes current and emerging therapies that are directed against many of these molecular targets. Even though a large number of potential therapeutic targets have been identified, many of the emerging therapies are directed against the same or related molecular targets. This issue is highlighted in Table 4.1, and the need for companies to differentiate their emerging therapies is discussed in this chapter as well as in Chapter 9.

Chapters 5–8 discuss many of the emerging therapies that are in development for the eight autoimmune diseases included in this report, asthma, allergies, and prevention of organ transplant rejection, respectively. These are all crowded and highly competitive fields, but this is especially true for the field of autoimmune disease. More than 300 emerging autoimmune disease therapies are included in this report. These include:

- More than 100 emerging therapies for rheumatoid arthritis
- Fifteen emerging therapies for type 1 diabetes
- More than 35 emerging therapies for inflammatory bowel disease (Crohn’s disease and ulcerative colitis)
- More than 50 emerging therapies for multiple sclerosis
- 50 emerging therapies for psoriasis
- Four emerging therapies for psoriatic arthritis
- More than 25 emerging therapies for lupus (systemic lupus erythematosus and lupus nephritis)
- More than 30 early-stage therapies and programs for autoimmune disease (disease targets not specified).

The totals of each disease add up to more than 300 emerging autoimmune therapies, because many emerging therapies are being developed for treatment of more than one autoimmune disease. In
addition, this report includes more than 80 emerging therapies in development for treatment of asthma, 50 examples of emerging therapies for treatment of allergies, and nearly 30 emerging new therapies in development for prevention of organ transplant rejection.

This intense competition creates a number of additional issues and hurdles for companies developing therapies for these diseases. These are discussed in Chapter 9. The report also includes interviews with three experts in the fields of autoimmune and inflammatory disease, who discuss the progress, challenges, and hurdles faced by researchers and companies working in this field.
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manufactured for Novartis by Bayer. Extavia was FDA approved for treatment of relapsing forms of multiple sclerosis, and for treatment of patients who have had a first clinical episode of multiple sclerosis and have features consistent with the disease as shown by magnetic resonance imaging (MRI).

**Copaxone (glatiramer acetate)**

Teva’s Copaxone (glatiramer acetate) has a very different mechanism of action. In Copaxone’s prescribing information, Teva reports that it may induce and activate glatiramer acetate-specific suppressor T cells, which would suppress the immune response. Glatiramer acetate is also included in the 2002 guidelines from the American Academy of Neurology.33

**Novantrone (mitoxantrone)**

EMD Serono’s Novantrone (mitoxantrone) was initially developed for treatment of certain cancers. In patients with multiple sclerosis, it inhibits B-cell, T-cell, and macrophage proliferation. It is FDA approved for reducing neurologic disability and/or the frequency of clinical relapses in patients with secondary (chronic) progressive, progressive relapsing, or worsening relapsing-remitting multiple sclerosis. Generic versions of mitoxantrone are also available.

The prescribing information for Novantrone includes a boxed warning about two serious potential side effects: cardiotoxicity and secondary acute myelogenous leukemia (AML). In 2003, the American Academy of Neurology issued a report regarding the use of mitoxantrone, with practice recommendations. These recommendations include reserving mitoxantrone for use in patients who have failed other therapies and who have rapidly advancing disease. The recommendations report that mitoxantrone reduces the clinical attack rate and related outcomes in patients with relapsing multiple sclerosis, but that the toxicity of this drug limits its use in patients with relapsing forms of multiple sclerosis. The recommendations also include routine monitoring of patients for cardiac, liver, and kidney abnormalities. These and other recommendations (and discussion of the data) can be found in the article that was published by the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology.34

**Tysabri (natalizumab)**

Biogen Idec’s and Elan’s Tysabri (natalizumab) is a monoclonal antibody that binds to the alpha4 subunit of alpha4beta1 and alpha4beta7 integrins expressed on the surfaces of leukocytes (except neutrophils).
Chapter 5

EMERGING THERAPIES IN DEVELOPMENT FOR TREATMENT OF MAJOR AUTOIMMUNE DISEASES

5.1. Introduction

As discussed in Chapter 2, autoimmune diseases are the result of an individual's immune system attacking his or her own tissues and organs. The resulting implications are often very debilitating for the patient.

This report focuses on eight autoimmune diseases: rheumatoid arthritis, type 1 diabetes, Crohn’s disease, ulcerative colitis, multiple sclerosis, psoriasis, psoriatic arthritis, and systemic lupus erythematosus. Drug development activities for these indications represent a highly competitive field: We identified more than 300 emerging therapies for treatment of autoimmune diseases (see Tables 5.1–5.8, located in Section 5.27). Tables 5.1–5.7 present emerging therapies for each autoimmune disease included in this report. A number of emerging therapies are listed in multiple tables because they are being developed for multiple autoimmune indications. Table 5.8 includes information on selected early-stage autoimmune disease programs for which the initial autoimmune disease target has not yet been revealed.

The more than 300 emerging autoimmune therapies in clinical or preclinical development included in this report are distributed within the eight subsequent tables as follows:

- Table 5.1: More than 100 emerging therapies for rheumatoid arthritis
- Table 5.2: Fifteen emerging therapies for type 1 diabetes
- Table 5.3: More than 35 emerging therapies for inflammatory bowel disease (Crohn’s disease and ulcerative colitis)
- Table 5.4: More than 50 emerging therapies for multiple sclerosis
In addition to developing Cimzia for treatment of Crohn’s disease and rheumatoid arthritis, UCB is developing epratuzumab for treatment of systemic lupus erythematosus (SLE). Epratuzumab is a humanized monoclonal antibody that targets CD22, an antigen located on the surface of B lymphocytes. Epratuzumab was originally developed by Immunomedics, which has licensed UCB the worldwide rights to epratuzumab for treatment of autoimmune disease indications. Immunomedics retained rights to epratuzumab for oncology indications and is separately developing epratuzumab for oncology. Epratuzumab is in Phase II development for treatment of systemic lupus erythematosus (SLE).

UCB is also developing CDP6038, a biological therapy that targets interleukin-6 (IL-6), for treatment of autoimmune diseases. CDP6038 is in Phase I development.

**5.27. Tables 5.1–5.9**

**Table 5.1. Companies Developing Therapies That Suppress or Balance the Immune System and/or Restore Balance For Treatment of Rheumatoid Arthritis**

<table>
<thead>
<tr>
<th>Company</th>
<th>Product/Technology</th>
<th>Status</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adeona Pharmaceuticals</td>
<td>Oral dnaJP1</td>
<td>Phase III</td>
<td>• An epitope-specific immunotherapy</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• A heat shock protein-derived peptide that contributes to T cell-mediated inflammation</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• For rheumatoid arthritis</td>
</tr>
<tr>
<td>Alder Biopharmaceuticals</td>
<td>ALD518</td>
<td>Phase II</td>
<td>• A monoclonal antibody that targets IL-6</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• The MAb is made in yeast.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• For rheumatoid arthritis</td>
</tr>
<tr>
<td>Amgen</td>
<td>AMG827</td>
<td>Phase I</td>
<td>• Fully human monoclonal antibody; targeted to the interleukin-17 (IL-17) receptor</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• For rheumatoid arthritis, psoriasis, and inflammatory bowel disease</td>
</tr>
</tbody>
</table>

Continued
Chapter 6
EMERGING THERAPIES FOR TREATMENT OF ASTHMA

6.1. Pipeline Overview

More than 80 candidate therapies are in development for treatment of asthma (see Table 6.1 at the close of this chapter). Most of these agents are in Phase II or earlier stages of development. Emerging therapies that are in Phase III in the United States and/or Europe for treatment of asthma include Abbott’s Flutiform (formoterol and fluticasone) and Novartis’/Schering-Plough’s MFF258 (mometasone furoate/formoterol fumarate).

The discussion in this chapter focuses on companies developing some of the more advanced novel emerging therapies for treatment of asthma. This chapter includes emerging Phase III and selected Phase II candidates.

6.2. Abbott Laboratories and SkyePharma (Also Mundipharma and Kyorin)

SkyePharma developed Flutiform, which is a fixed-dose combination of the long-acting beta agonist formoterol and the corticosteroid fluticasone. These two drugs are delivered in a metered-dose inhaler. Both formoterol and fluticasone are available individually and are included in the previous discussion of current drugs (Chapter 3).

In May 2006, Kos Pharmaceuticals and SkyePharma announced they had signed an exclusive licensing agreement granting Kos Pharmaceuticals rights to Flutiform in the United States and the right of first negotiation in Canada. At the time of the agreement, Flutiform was already in Phase III clinical trials. In December 2006, Abbott completed the acquisition of Kos Pharmaceuticals, and Abbott now has rights to
In addition, Greer has conducted a Phase IIb study of SLIT for Timothy grass. Greer has also reported that Phase I studies have been conducted evaluating sublingual-oral administration of Greer’s standardized dust mite, short ragweed, Timothy grass, and cat hair extracts.

### 7.6. Stallergenes

Stallergenes (France) specializes in desensitization, or specific immunotherapy, for allergies. Products on the market today are not included in this discussion. The company has a research program called the STALAIR program, which is a program for development of sublingual desensitization tablets.

The first product from the STALAIR program is called ORALAIR Grasses, which is a sublingual tablet for grass pollen desensitization. ORALAIR Grasses was first approved in German for treatment of adults in June 2008 and has been on the market since September 2008. In January 2009, ORALAIR Grasses was approved for pediatric indications. Stallergenes reports that a mutual recognition procedure will make it possible for Stallergenes to register ORALAIR in most countries in Europe in 2009.

For the United States, in October 2008 Stallergenes announced the start of a Phase III trial in adults for treatment of allergic rhinoconjunctivitis to grass pollens. Stallergenes has also announced the start of a Phase III trial in China to evaluate STALORAL 300. In addition, a Phase II/III trial to desensitize patients to dust mites is underway. In April 2009, Stallergenes released outcome data from the first year of treatment in this study, which includes 509 patients in seven countries. The study is comparing two different treatment groups with a placebo. The endpoint is the adjusted average symptom score on nasal symptoms, which is assessed during the three last months of the year. In an April 2009 press release, Stallergenes reported that both treatment groups showed a highly significant statistical difference compared to placebo. In addition, no difference was seen between the two treatment groups. Additional data are discussed in this announcement.
Table 9.1. 2008 Sales of Selected Drugs for Treatment of Autoimmune Diseases and Asthma (cont.)

<table>
<thead>
<tr>
<th>Drug</th>
<th>Company</th>
<th>2008 Sales (in millions)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Xolair</td>
<td>Genentech and Novartis</td>
<td>$517 (Genentech)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>$211 (Novartis)</td>
</tr>
</tbody>
</table>

Note: The numbers reported in this table do not include sales of all drugs sold for treatment of autoimmune diseases and asthma. These are examples that demonstrate the large potential for drugs that succeed in this market.

(1) These sales include both oncology and autoimmune disease indications. Genentech reported US sales of $2,587 million in 2008.

Source: Sannes & Associates, Inc.

A number of factors have fueled the growth of this market, including the large number of patients with these diseases and their significant unmet needs. This large market and market potential has attracted significant interest and investment by the major pharmaceutical and biopharmaceutical companies, as well as large numbers of smaller companies. As a result, the fields of emerging therapies for many of these diseases have become highly competitive, as discussed in Section 9.2. The significant investments by major pharmaceutical companies can be seen in the discussions and tables of Chapters 5–8. Examples of companies with very large investments (at least 9 or 10 candidates in the clinic for these indications, and some with up to almost 20) are discussed in Section 9.3. There is also considerable merger and acquisition activity in this field, as discussed in Section 9.4.

There is no question that pharmaceutical and biopharmaceutical companies consider the markets for therapies that suppress or modulate the immune system (for treatment of the indications discussed in this report) to be attractive. However, companies in these fields face very significant hurdles as they develop new therapies, in addition to the usual hurdles such as determining whether the new therapy is efficacious and safe and conducting the clinical studies to address these basic questions. Many of these challenges and hurdles are, at least in part, a result of the very high level of competition. The challenges and hurdles faced by companies who are developing and commercializing novel therapies that suppress or modulate the immune system are discussed in Section 9.5.
Chapter 10

THOUGHT LEADER INTERVIEWS

10.1. Randall C. Schatzman, PhD
President and Chief Executive Officer
Alder Biopharmaceuticals

Insight Pharma Reports (IPR): Please provide a brief description of what Alder Biopharmaceuticals is doing in the field of modulating the immune system. What is novel about your technology or approach? What are the benefits?

Dr. Schatzman: Alder is developing therapeutic monoclonal antibodies for unmet needs in cancer, autoimmune disease, and anemia. We think that the whole antibody is the proven therapeutic. It is the one that is well accepted in the marketplace and by physicians.

We are trying to address some of the primary issues relating to the manufacture of monoclonal antibody therapeutics. What was clear is that cost is a barrier. Manufacturing space (meaning tank time) is a barrier. We also think that timelines are a barrier. We wanted to resolve all of those issues. Rather than sticking with a mammalian-based manufacturing system, we decided that we wanted to solve the problems of why a microbial system did not seem to express whole antibodies very well. We modified a yeast in a way that allowed it to express large quantities of intact antibodies that retain all of their activity, fold appropriately, and are secreted into the media for purification. At the end of the day, what happens is that we simplify our process moving forward. We are in the tank for about 90 hours as opposed to the more traditional 2–3 weeks in a mammalian tank. So our manufacturing campaign becomes very short. Also, the fact that none of our products are touching mammalian-derived materials means that we do not have any viral clearance issues, so our release specs and our timing for release is much faster than with a mammalian batch. Producing our master cell
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