

# **R&D Trends: Systemic Lupus Erythematosus - Benlysta's FDA approval provides hope for disease treatment, future trial design, and other pipeline candidates**

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## **Abstracts**

### **Introduction**

There remains considerable debate over the optimum efficacy measure and clinical trial design in SLE. While the SLE Responder Index has proved successful in demonstrating the efficacy of Benlysta (belimumab; Human Genome Sciences/GlaxoSmithKline) such that many other trials are now following suit, it is unclear if this will spur other successes.

### **Features and benefits**

Benchmark novel and existing therapies using the ideal target product profiles identified by Datamonitor and access leading rheumatologists' opinion

Support R&D decision making by evaluating lupus clinical trial designs that have set a precedent, as well as analysis of discontinued projects

### **Highlights**

Datamonitor identified 32 drug candidates in development for systemic lupus erythematosus (SLE), with four products in Phase III. Recent negative outcomes of major clinical trials threaten to move industry away from drug development in SLE, but Benlysta's recent US approval may ignite further commercial interest in this disease.

Two new B-lymphocyte stimulator (BLyS) candidates have emerged within the late-stage SLE pipeline. Eli Lilly's LY2127399 and Anthera Pharmaceuticals' A-623 are both being investigated based on the novel SLE Responder Index. While this approach was successful for Benlysta, it remains to be seen if this can be emulated by other candidates.

The FDA published its formal guidance for industry for developing a medical product for SLE in June 2010, pointing to the use of disease activity indices in clinical trials. However, many specialists believe that the answer is to move away from these kinds of instruments and to check objective measures, such as biomarkers.

### **Your key questions answered**

What lessons can be learned from past clinical trials in SLE and how can these be applied to novel pipeline candidates?

How does the recent approval of Benlysta impact the future of drug development for SLE?

What are the most promising trends seen in early stages of the SLE pipeline?

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- B-cell directed therapies are leading the way
- Lack of industry-sponsored clinical trials conducted in Japan
- Compounds recently discontinued
  - Orencia (abatacept; Bristol-Myers Squibb)
  - Apremilast (CC-10004; Celgene)
  - NNC-0152-0000-0001 (Novo Nordisk)
  - Gusperimus trihydrochloride (NKT-01; Nippon Kayaku)

#### MEDI-546

### TARGET PRODUCT PROFILE

- Off-label treatments are the gold-standard therapies for SLE
- Comparator one: Rituxan/MabThera (rituximab; Biogen Idec/Roche)
- Comparator two: CellCept (mycophenolate mofetil; Roche/Vifor Pharma)
- Target product profile versus current level of attainment

### CLINICAL TRIAL DESIGN IN SYSTEMIC LUPUS ERYTHEMATOSUS

- Regulatory guidance on clinical trial design
  - FDA finally publishes full formal industry guidance
  - Summary of formal FDA guidance for industry in SLE
  - Summary of FDA guidance for industry in lupus nephritis

EMA guidelines

Similarities can be seen in recent trial designs

Standard of care

Endpoints

Variations in disease activity create a challenge

Systemic Lupus Erythematosus Disease Activity Index (SLEDAI)

The British Isles Lupus Assessment Group (BILAG)

European Consensus Lupus Activity Measure (ECLAM)

Systemic Lupus Erythematosus Activity Index (SLAM)

Measurement of flares

Extent of organ damage is critical to assessing global systemic lupus erythematosus disease activity

Rheumatologists are only moderately satisfied with current treatment efficacy measurements

Movement towards composite endpoints

Quality of life measures used as secondary endpoints

Steroid-sparing effects

Future of lupus trial design

More stringent subsetting of patients

## **INNOVATIVE EARLY-STAGE APPROACHES**

Biologics make up the majority of the early-stage pipeline

Interferon inhibitors moving through the pipeline

Cluster of differentiation drug candidates are seen in all phases of development

CD20 product still in development for lupus

Bortozemib: proteasome inhibitor shows early potential in lupus nephritis

## **THE FUTURE OF DISEASE TREATMENT IN SYSTEMIC LUPUS ERYTHEMATOSUS**

Targeted therapies to reduce dependence on steroids

Identification of biomarkers will aid in development and treatment

## **BIBLIOGRAPHY**

Journal papers

Websites

Datamonitor reports

Other

## **APPENDIX A: SURVEY INFORMATION**

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