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

Description: 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?

Contents:
- Executive Summary
- Strategic scoping and focus
- Datamonitor key findings
- Related reports
- OVERVIEW
- Catalyst
- Summary
- CLINICAL PIPELINE OVERVIEW
- Lupus pipeline
  - Notable movements in the SLE pipeline
  - Overall increase in the number of late-stage candidates
  - 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)

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
Bortezemib: 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
Physician research methodology
The survey questionnaire

APPENDIX B
Contributing experts
Report methodology

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