R&D Trends: Sepsis

Description: Improvements in clinical trial design and advances in biomarker research hold the key to a tailored approach to sepsis therapy

Despite Eli Lilly's Xigris being the only licensed therapeutic, the sepsis market remains commercially attractive due to its large patient population and high mortality rates. However, the complexities of the disease create a number of problems in clinical development, such as enrolment of appropriate patients, difficulties in demonstrating efficacy and a high rate of product failures.

Features and benefits

- Overview of the clinical pipeline for sepsis along with an assessment of the key R&D trends
- Analysis of current clinical trial design and its impact on drug development for sepsis
- Discussion of future clinical trial design and how it will evolve with improved understanding of the disease and advances in biomarker research
- Review of feedback from key opinion leaders on the future of sepsis therapy

Highlights

- The majority of R&D activity for sepsis focuses on attenuation of the systemic inflammatory response which characterizes the disease, with a number of novel targets being investigated. The pipeline shows promise, although only one product is in Phase III, meaning that new drugs remain several years from the market.
- Eli Lilly's Xigris is currently the only marketed direct therapy for sepsis. However, its commercial performance has been disappointing due to efficacy and safety concerns and its restricted label. However, the sepsis market remains commercially attractive due to its large patient population, high mortality rates, and lack of market competition.
- In the long-term, physicians will most likely have a range of complimentary drugs at their disposal for treating sepsis. Combined with advances in biomarker research and their incorporation into diagnosis and therapy, this would aid the creation of a “personalized medicine” approach where therapy can be tailored to individual patients.

Your key questions answered

- Gain an insight into key trends in the pipeline and drug classes currently in development for sepsis
- Assess how future clinical trial design will better reflect the characteristics of sepsis and facilitate greater success in drug development
- Understand how new product approvals and developments in biomarker research will impact new treatment approaches

Contents:

Executive Summary
- Strategic scoping and focus
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OVERVIEW
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CLINICAL PIPELINE OVERVIEW
- High mortality rates and a lack of efficacious and safe marketed therapies translate into a high unmet need for new sepsis drugs
- Antibacterial therapy plays a vital role in sepsis treatment, although this does not directly translate into a high level of R&D interest
- Despite the disappointing performance of Xigris, the sepsis market remains commercially attractive
- With Xigris unavailable in Japan, physicians have turned to endotoxin removal to treat severe sepsis
- Disappointing Phase III results for Eisai's eritoran tetrasodium mean that a new marketed sepsis therapy
remains years from the market. The majority of R&D activity for sepsis targets attenuation of the characteristic systemic inflammatory response.

Biosynexus's pagibaximab is the only preventative pipeline candidate.

Mechanisms of action:
Late-stage development compounds recently discontinued.

TARGET PRODUCT PROFILE

Xigris (drotrecogin alfa [activated]; Eli Lilly)
- Target product profile versus current level of attainment.
  - The drawbacks of Xigris give considerable scope for new sepsis drugs to show advantages in efficacy, safety, and price.

CLINICAL TRIAL DESIGN IN SEPSIS

Preclinical trials:
- The heterogeneity of animal models and their lack of representation of the complexity of sepsis in humans are contributing to the poor translation of preclinical promise to clinical development.

Clinical trials:
- Inadequate clinical trial design has been identified as a contributing factor to the raft of late-stage clinical trial failures for sepsis drugs.
  - Endpoints: mortality as key focus.
  - Future developments in clinical trial design.
  - Reducing patient heterogeneity, enrolling the most appropriate patients in clinical trials, and identifying the most appropriate endpoints will enable more accurate evaluations of new sepsis drugs.

INNOVATIVE EARLY-STAGE APPROACHES

Vitamin C may represent an efficacious, safe, and cost-effective prevention for sepsis.
- Blockbuster cancer drug Avastin may have a potential role in sepsis therapy.
- Stem-cell approach showed high promise in improving survival rates for sepsis in mice.
- Targeting of free heme by hemopexin holds promise in monitoring disease progression.

THE FUTURE OF TREATMENT IN SEPSIS

In the long term, physicians could have a range of complementary treatment options at their disposal.
- The identification and use of suitable biomarkers could further contribute to a more targeted approach for treating sepsis.

BIBLIOGRAPHY

Journal papers
Websites
Datamonitor reports

APPENDIX

Contributing experts
Conferences attended
Report methodology

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