Systemic Lupus Erythematosus - 2015

Last updated 30 November 2015 Historically, developers of systemic lupus erythematosus (SLE) drugs faced formidable challenges: drug development for a complex, multifaceted, poorly understood disease; regulatory hurdles; a small but heterogeneous population; and a multiplicity of manifestations. Recent positive clinical trial results and the regulatory approval of belimumab (GlaxoSmithKline’s Benlysta)—the first new agent in 50 years—have lowered some development hurdles, and a growing list of emerging agents has ushered in a new era of SLE drug development. We forecast that sales of SLE therapies will increase approximately during our 2014-2024 forecast period, driven largely by the entry and uptake of premium-priced biologics.

Questions Answered in This Report:

- The entry and uptake of premium-priced branded agents belimumab (GlaxoSmithKline’s Benlysta), blisibimod (Anthera Pharmaceuticals), rigerimod (ImmuPharma’s Lupuzor), anifrolumab (MedImmune), and abatacept (Bristol-Myers Squibb’s Orenica) during our forecast period will transform the predominantly off-label and generic SLE market. How much market growth will be driven by agents that secure regulatory approval for SLE and lupus nephritis? How do interviewed thought leaders perceive the safety and efficacy of these emerging agents?

- The regulatory approval and launch of the novel B-cell modulator belimumab make this agent the first in 50 years to secure regulatory approval for SLE. In markets where the drug has launched, how are physicians using it and what are their perceptions of its efficacy and current and future role in treating SLE? Will any agents in the SLE pipeline challenge belimumab? What reimbursement challenges does belimumab face in this largely genericized market?

- Rituximab (Biogen/Roche/Genentech/Chugai/Zenyaku Kogyo’s Rituxan, Roche’s MabThera) failed clinical trials for both SLE and lupus nephritis. Despite these failures, the agent garners significant off-label use in treatment-refractory patients. Will rituximab continue to play a role in the SLE treatment algorithm? How will the entry of biosimilar rituximab and the approval of abatacept and belimumab for lupus nephritis affect sales and use of this agent?

Scope:

Markets covered: United States, France, Germany, Italy, Spain, United Kingdom, and Japan.

Primary research: 31 country-specific interviews with rheumatologists and nephrologists.
Epidemiology: Diagnosed prevalence of SLE; diagnosed prevalence of SLE by flares and persistently active disease; diagnosed prevalent cases of SLE with lupus nephritis; diagnosed and drug-treated populations.

Population segments in market forecast: Total population.

Emerging therapies: Phase II: 16 drugs; Phase III: 5 drugs; preregistration: 0 drugs; registered: 4 drugs. Coverage of 9 select preclinical and Phase I products.

Report Details

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