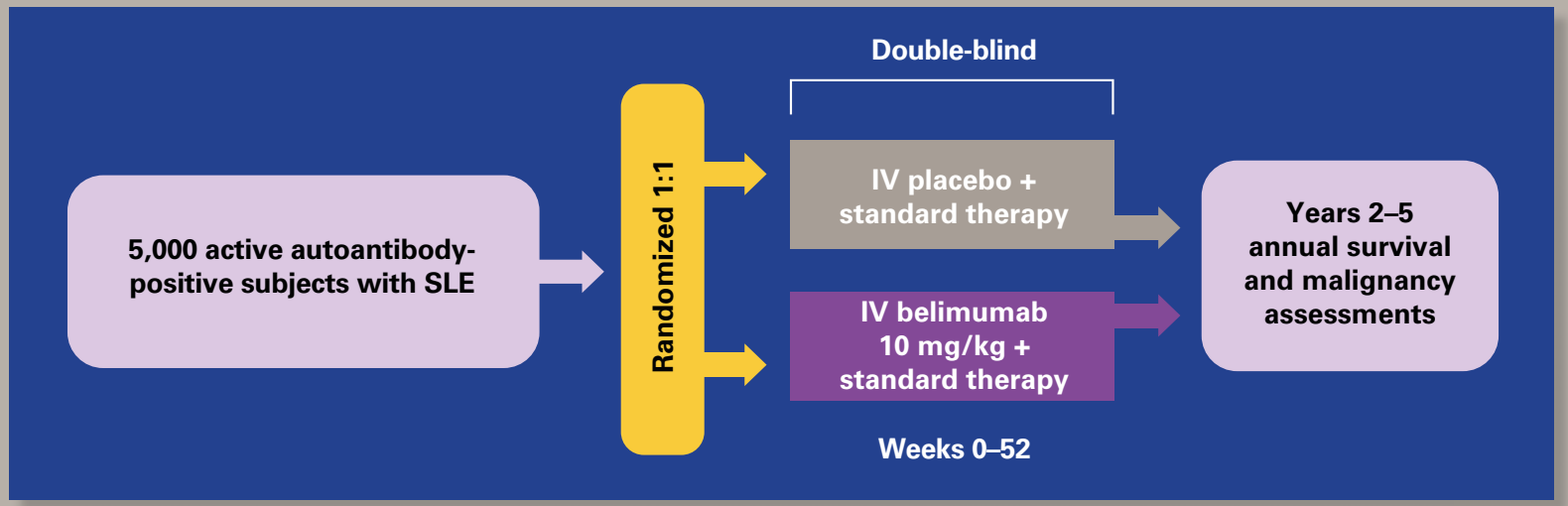
BASE (Belimumab Assessment of Safety in SLE)

A Randomized, Double-Blind, Placebo-Controlled, 52-Week Study to Assess Adverse Events of Special Interest in Adults With Active, Autoantibody-Positive Systemic Lupus Erythematosus Receiving Belimumab



Study design

- 5,000 belimumab-naïve subjects randomized to one of two blinded treatment groups: belimumab 10 mg/kg (2,500 subjects) or placebo (2,500 subjects)
- Subjects will receive intravenous study agent on Days 0, 14, 28, and every 28 days thereafter through Week 48 (14 total doses) and assessed at Week 52
- Subjects will be contacted annually from Years 2–5 for survival and malignancy assessments

Key inclusion criteria

- Males or females age 18 years or older and have a clinical diagnosis of active SLE
- Active, autoantibody-positive SLE

Key exclusion criteria

- Prior treatment with belimumab, either as a marketed product or investigational agent
- Prior treatment with B-cell targeted therapies within one year of enrollment

Safety endpoints

- Mortality
- Serious infections
- Opportunistic infections
- Malignancies
- Non-melanoma skin cancers
- Psychiatric events
- Serious infusion and hypersensitivity reactions

Additional assessments

- SLICC/ACR damage index
- Steroid reduction
- Hospitalizations

For information about participating as a clinical site or referring a potential patient, please contact:

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