1. Executive Summary & Key Messages

Indication: Autoimmune-A
Modality: bispecific antibody
Formulation/Route: prefilled syringe / subcutaneous
Planned regimen (synthetic): 100 mg QW

Key messages:
- Dermavax is being developed for Autoimmune-A.
- Primary endpoint: Change from baseline in Symptom Score at Week 12.
- Primary result: LS mean difference -1.00 (Drug – Placebo), p=0.049.
- Safety: common AEs include Upper respiratory infection, Fatigue, Nausea.

2. Background & Unmet Need

Autoimmune-A is associated with persistent symptoms and variable response to standard therapy.
This synthetic briefing book is structured to support retrieval-augmented generation (RAG) practice.

Document governance (synthetic):
- Document version: v2.9
- Program identifier: AMGN-D004-302
- Intended use: internal training / prototype only

3. Mechanism of Action

Proposed mechanism: targeted receptor antagonist.
MOA summary: Blocks receptor-mediated signaling to reduce disease activity.

Biology notes (synthetic):
- Target pathway is assumed disease-relevant for training purposes.
- Biomarker shifts are described as supportive evidence in later pages.

4. Study Design

Trial: AMGN-D004-302 (Phase 3), randomized, double-blind, placebo-controlled (synthetic).
Population: Adults with moderate-to-severe Autoimmune-A with inadequate response to standard therapy.

Arms:
- Arm: Dermavax 100 mg QW, n=255
- Arm: Placebo, n=254

Key inclusion criteria:
- Confirmed diagnosis per protocol definition
- Baseline disease activity above threshold
- Stable background therapy for ≥4 weeks

Key exclusion criteria:
- Severe uncontrolled comorbidity (per protocol)
- Recent major surgery within 12 weeks
- Known hypersensitivity to components

5. Endpoints & Analysis Overview

Primary endpoint: Change from baseline in Symptom Score at Week 12
Secondary endpoint: Time to flare through Week 24

Analysis notes (synthetic):
- Primary analysis uses an intention-to-treat estimand.
- Missing data handled via multiple imputation (illustrative).
- Multiplicity control via hierarchical testing (illustrative).

6. Efficacy Results

Primary outcome:
- Result: LS mean difference -1.00 (Drug – Placebo)
- 95% CI: [-1.40, -0.60]
- p-value: 0.049

Secondary outcome:
- Interpretation: Did not meet prespecified significance threshold

Discontinuations:
- Overall discontinuation rate (synthetic): 8.9%

7. Safety Summary (TEAEs)

Safety overview (synthetic):
- Serious AE rate: 1.7%
- Discontinuation due to AE: 2.3%

Common adverse events listed below.

Common TEAEs (synthetic)

Adverse Event	Rate (%)
Upper respiratory infection	6.2
Fatigue	5.4
Nausea	4.0
Elevated ALT	2.9
Injection-site reaction	2.0
Arthralgia	2.0

8. Dosing & Administration

Route: subcutaneous
Formulation: prefilled syringe
Regimen: 100 mg QW

Administration notes (synthetic):
- Missed dose: take as soon as remembered unless near next scheduled dose.
- Storage: controlled room temperature unless specified otherwise.
- Concomitant therapy: per protocol allowances.

9. Contraindications, Warnings & Monitoring

Contraindications:
- Known hypersensitivity to active substance or excipients.

Warnings/Precautions:
- Monitor for hypersensitivity reactions.
- Assess for infection risk in susceptible patients.
- Consider hepatic monitoring if clinically indicated.

Monitoring recommendations (synthetic):
- Baseline labs per protocol (CBC, CMP)
- Periodic assessment of liver enzymes
- Clinical monitoring for infections

10. Appendix: Abbreviations & Traceability

Abbreviations:
- AE: Adverse event
- SAE: Serious adverse event
- TEAE: Treatment-emergent adverse event
- ITT: Intention-to-treat

Traceability fields (synthetic):
- Drug ID: D004
- Trial ID: AMGN-D004-302
- Document version: v2.9
- Date: 2025-12-26

Note: This document is synthetic and intended only for RAG/agent practice.