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Comparative Efficacy: Potential Advantage of ANX005 over Intravenous Immunoglobulin in Guillain-Barré Syndrome

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Annexon Biosciences Inc., Brisbane, USA

Poster 237

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This presentation concerns drug candidates that are under clinical investigation, and which have not yet been approved for marketing by the U.S. Food and Drug Administration (FDA). These are currently limited by federal law to investigational use, and no representation is made as to their safety or effectiveness for the purposes for which they are being investigated.

This presentation also contains estimates and other statistical data made by independent parties and by us relating to market size and growth and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates or statistical data. Neither we nor any other person makes any representation as to the accuracy or completeness of such data or undertakes any obligation to update such data after the date of this presentation.

Disclosures

Henk-André Kroon, MD MBA	Employee of Annexon Biosciences

ANX005 for GBS Granted FDA Fast Track and FDA / EMA Orphan Drug Designation

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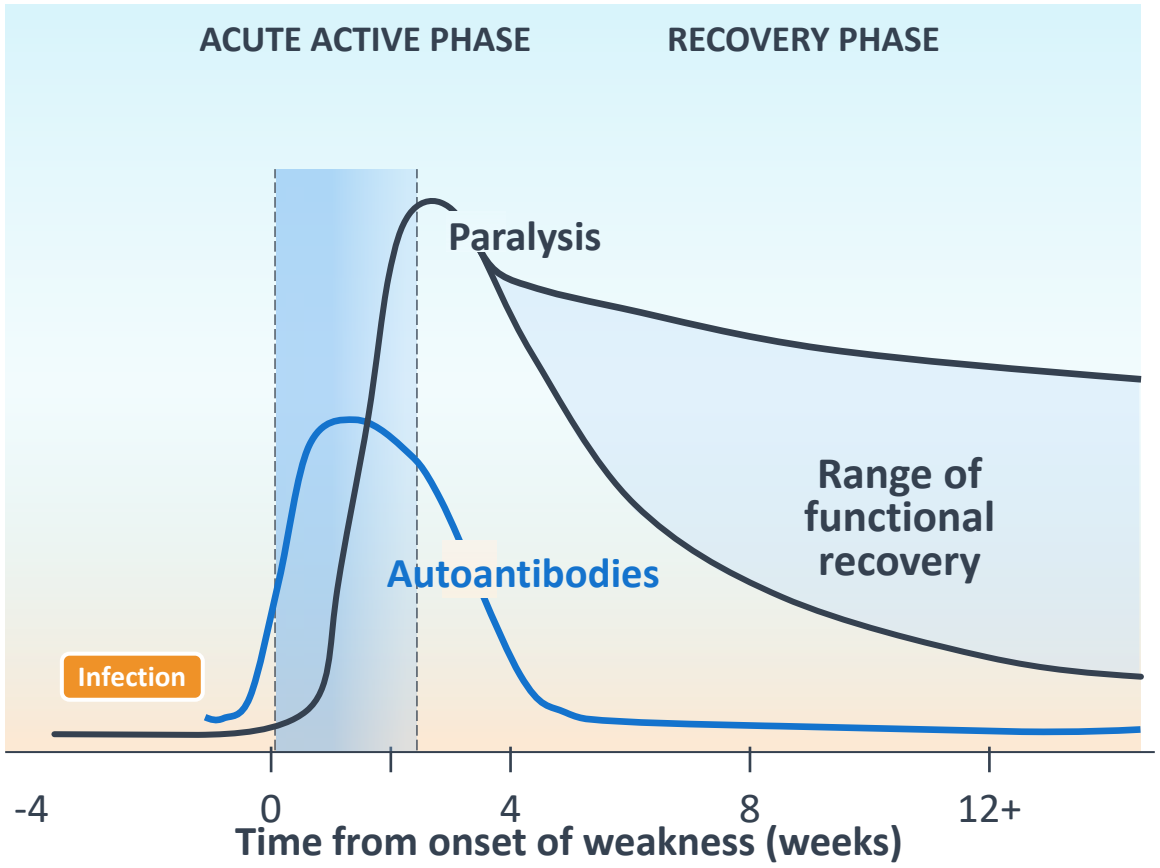
Introduction

1. In GBS, auto antibodies cross-react with the peripheral nervous system, and activate the classical complement pathway causing nerve inflammation and nerve damage
2. With IVIg, ~25% of patients show progressive muscle weakness, resulting in significant morbidity and an uncertain path to recovery
3. ANX005 is a monoclonal antibody that blocks complement mediated neuroinflammation and nerve damage immediately and completely during a single infusion
4. In a Phase 1b study ANX005 doses that inhibited complement during the acute active phase of GBS showed rapid improvement in muscle strength and function versus placebo
5. Phase 1b informed design placebo-controlled Phase 3
6. This indirect comparison evaluated the effectiveness of ANX005 versus IVIg using historical GBS study data



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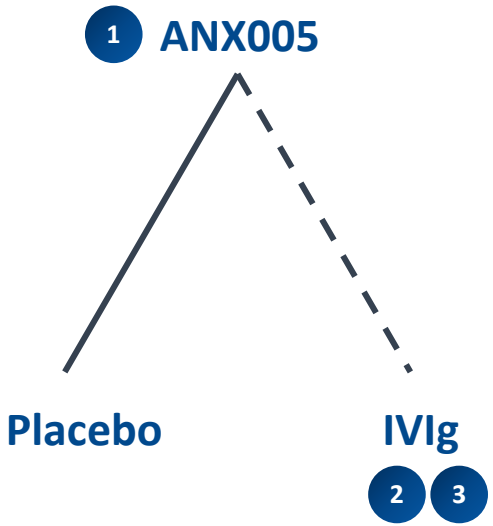
Indirect Comparisons of ANX005 Anti-C1q Therapy to IVIg



1. ANX005 Phase 1b – Bangladesh (RCT n=18)
2. IGOS-1000 – Bangladesh (RWD n=13)
3. SID-GBS (RCT n=28/44)

Direct comparison
Indirect comparison

- 1 ANX005 Phase 1b study of GBS patients from Bangladesh was used in an indirect comparison to data from two studies of IVIg-treated GBS patients in 2 different populations:
  - 2 IGOS (Bangladesh)
  - 3 SID-GBS (Netherlands)
- Patients were matched by age, GBS-Disability Score, muscle strength (MRC sumscore, range 0-60)
- Muscle strength at Week 1 was analysed using an independent t-test
- GBS-DS was analysed using proportional odds logistic regression at Week 4

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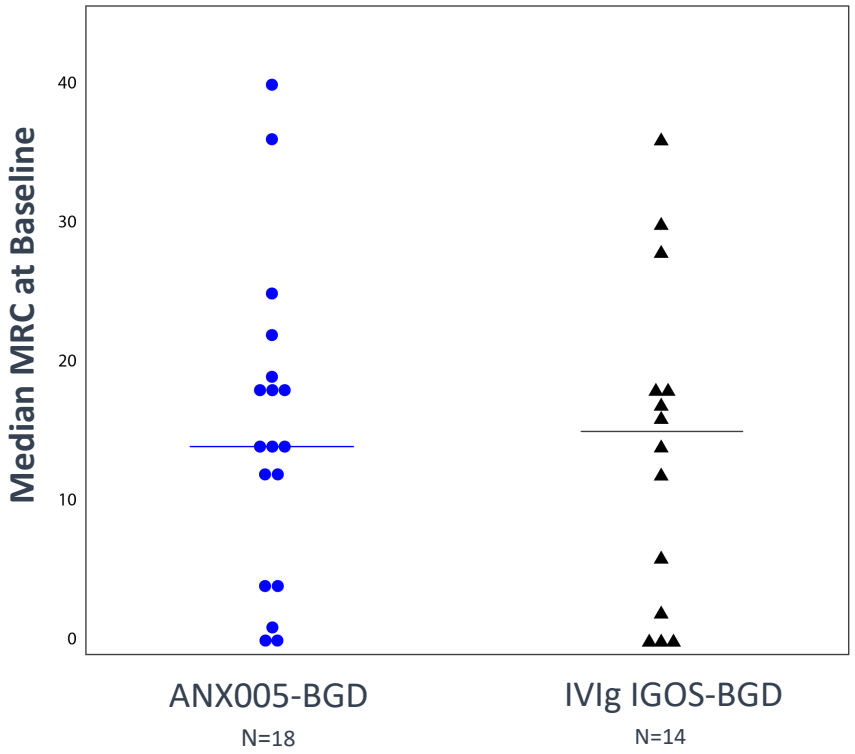
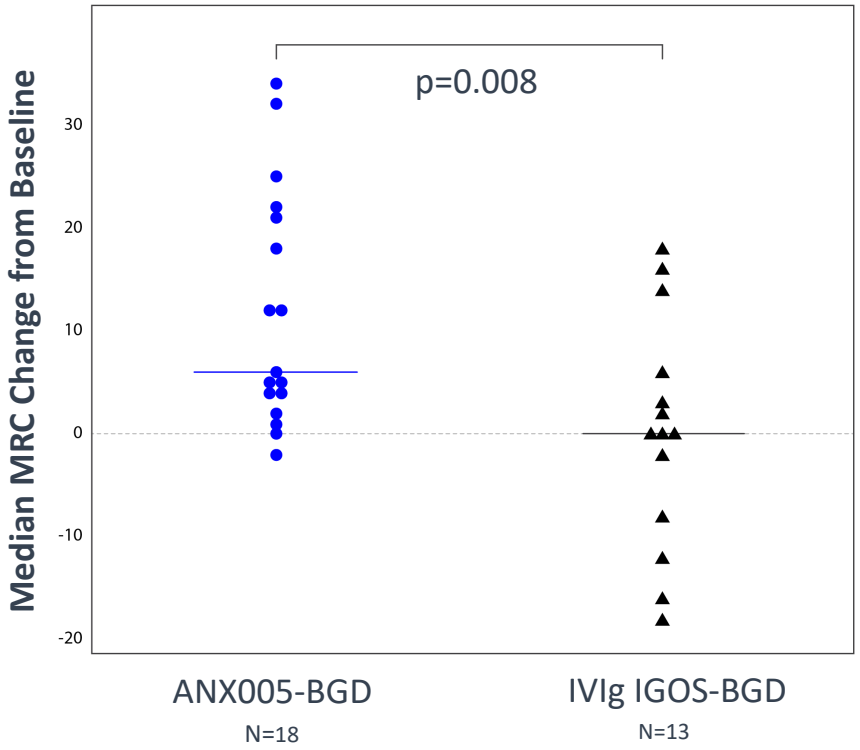
ANX005 Showed Rapid Improvement in Muscle Strength over IVIg

Significant early benefit seen with ANX005 versus IVIg in Bangladesh

Similar Baseline Muscle Strength



Significant Improvement at Week 1



BGD, Bangladesh; IVIg, intravenous immunoglobulin; MRC, Medical Research Council

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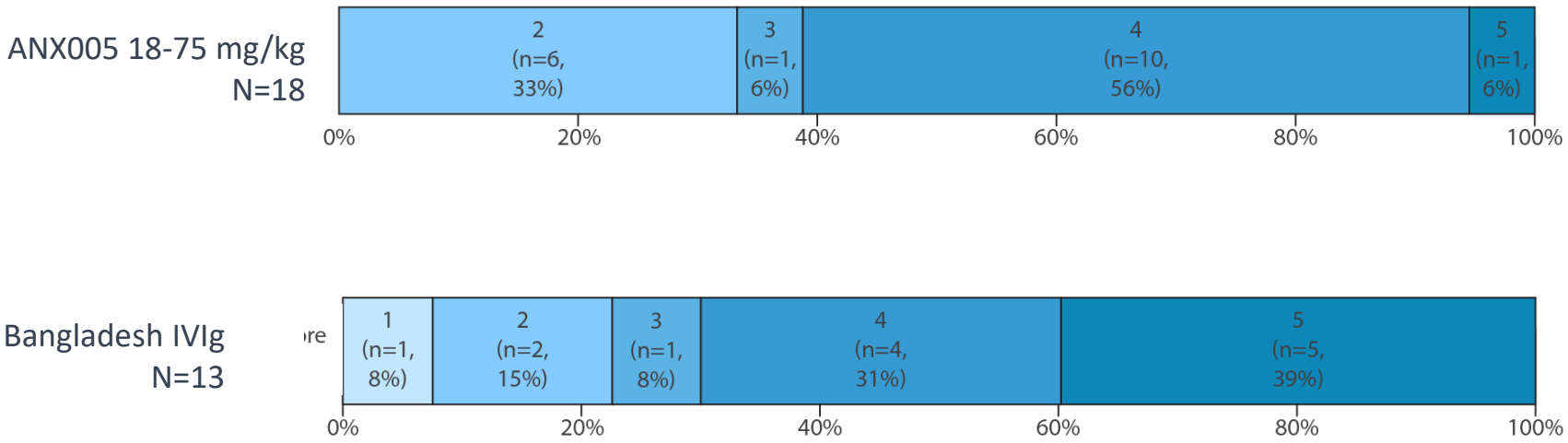
ANX005 Shift to Better vs IVIg: Improved Function at Week 4

Odds ratio of 2.5, adjusted for baseline GBS-DS



OR 2.5 (95% CI: 0.6-10), p=0.19

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Conclusion

- In a previously presented Phase 1b study ANX005 showed evidence of early improvement in muscle strength and better health status at week 8 versus placebo
- In a matched population treated with IVIg in Bangladesh, ANX005 showed the potential to be better than IVIg with early improvement in muscle strength and GBS-DS
- EMA granted Orphan Drug Designation for ANX005 in the treatment of GBS citing "evidence of substantial clinical benefit over standard of care"
- Further comparative analyses are planned with data from ANX005 pivotal phase 3 study

Results of Phase 3 trial evaluating ANX005 vs placebo will be presented during clinical highlights on 25 June

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Thank You!
Q&A

Annexon Biosciences sincerely thanks all the patients, families, and study staff who are helping make the ANX005 GBS Program possible