EYLEA® (AFLIBERCEPT) BIOSIMILAR CMC ANALYTICAL SOLUTIONS

Pre-developed, risk-mitigated biosimilarity assessment, testing solutions, data evaluation and consultation

The successful development of a biosimilar presents unique challenges compared to that of an innovator biologic. In particular, one must prove the biosimilar candidate's structural and functional differences do not have a meaningful impact on the clinical safety and efficacy profile already established for the innovator. Comprehensive and rigorous analytical testing to assess biosimilarity is thus the foundation upon which the successful development of a biosimilar begins.

By applying knowledge accumulated from working on more than 150 unique biosimilar programs, combined with expert analysis of published research, we have identified the preliminary Critical Quality Attributes of Eylea® and thus its biosimilars. From this, we developed an analytical strategy and methodologies needed to assess them, and generated preliminary test data using the innovator to provide a reference to assess *in vitro* biosimilarity.

Compiled as an Eylea® Biosimilar CMC Analytical Master File, this resource is an invaluable and unique guide to support your biosimilar program throughout its development and product lifecycle.

Solution Highlights

- Assess biosimilarity sooner with the prospective Eylea® Biosimilar CMC Analytical Master File containing pre-established methods and preliminary reference data
- Make better decisions with rigorous and comprehensive testing methodologies designed and developed to enable an early and thorough assessment of biosimilarity
- Smarter advancement via a phase-appropriate, molecule management approach with the development and product lifecycle in mind
- Mitigate risks to safety and potency through assessment of 13 pre-identified, high-and medium-risk Critical Quality Attributes

Solution Benefits

- Three options provide you flexibility wherever your biosimilar is in the development or product lifecycle:
  - Testing solutions
  - Evaluation of your data
  - Consultative insights
- 12 months or more potential time saved to assess *in vitro* biosimilarity vs *de novo* Research & Development
- Potential increase in the probability of clinical success using an early, risk-mitigated approach
- Up to 30% or more potential increase in the value of your biosimilar by reaching the market faster and with greater probability of success

Solution Options Detail

Testing Solutions

- Critical Quality Attributes
- Physicochemical characterization
- Biological characterization
- Target Product Profile
- Structural & functional attributes
- Process validation
- GMP lot release & stability

Client Data Evaluation

- Gap analyses
- Scientific rationale (e.g. SAR)
- Review of regulatory feedback

Consultation

- Scientific
- Regulatory
- Commercial

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Eylea® (Aflibercept) Biosimilar CMC Analytical Solutions

Assess Biosimilarity Sooner

With the prospective Eylea® Biosimilar CMC Analytical Master File containing pre-established methods and preliminary reference data:

- Pre-identified preliminary Critical Quality Attributes (CQAs) of innovator provide an existing foundation to assess biosimilarity
- Pre-established, qualified methodologies provide a rigorous framework to test the CQAs of your biosimilar candidate right away
- Pre-generated preliminary reference data gives you a head start to assess biosimilarity

Make Better Decisions

Through rigorous and comprehensive testing methodologies developed to enable early and thorough assessment of biosimilarity:

- Increase the probability of your candidate progressing into clinical development with extensive early characterization to establish biosimilarity
- Tailor your program based on a broad spectrum (a specific set) of regulatory expectations
- Understand protein structure and structural characteristics relevant to function
- Understand how formulation differences might impact method development, validation and the molecule's attributes

Smarter Advancement

Via a phase-appropriate, molecule management approach with the development and product lifecycle in mind:

- Start using the end in mind with a CMC analytical strategy based on the Target Product Profile and mechanism of action (including secondary mechanism of action – ADCC, CDC)
- Access qualified methods to provide a rigorous early, traceable assessment and rapid progression path to validated status (cGMP standards, ICH requirements)
- Prepare long term for routine, global lot release and stability testing under commercial GMP conditions

Take Advantage of Related Covance Solutions for Eylea® Biosimilar Development

- Nonclinical: Animal Studies & Bioanalysis (Toxicology, PK/PD, Immunogenicity)
- Clinical: Phase I & III (PK/PD, Immunogenicity, Efficacy)
- Central Labs, Clinical Bioanalysis and Biomarkers, including Companion Diagnostics
- Regulatory Strategy
- Commercial Market Access: Value Communications, Policy Reimbursement, Patient Value and Patient Reported Outcomes

Learn more about our drug development solutions at **www.covance.com**

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