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## **CHAPTER 1: EXECUTIVE SUMMARY**

### **CHAPTER 2: DME IS JUST NOT A VEGF DISEASE - INFLAMMATORY CASCADE AND ANGIOGENESIS, WHAT IMPACT THE MOST?**

- Multifactorial nature of DME has become clearer, inflammation is a very early event in the development of DME
- Targeting pathways beyond VEGF such as inflammatory and oxidative pathways holds the key for future treatment success

### **CHAPTER 3: DME -AN INCREASING ECONOMIC AND QUALITY OF LIFE BURDEN GLOBALLY**

- Geographic differences with current DME related treatment burden will be diminished in the future driven with the rising rates of diabetes and ageing population globally

## **CHAPTER 4: SHIFTING TREATMENT PARADIGMS OF DME**

- Anti-VEGF treatments have replaced laser as first line therapy with proven efficacy
- A definite role of steroids in the treatment paradigm, as inflammatory pathway has a major role to play
- Large unmet need remains as half of the DME patients have sub-optimal responses with therapy, greater personalization is still in need
- Clinical data comparison of current treatments with real world data indicative of early stage treatment and optimal number of frequencies for better outcome
- Geography specific difference in the treatment of DME – availability of new treatments to change the treatment paradigm

### **CHAPTER 5: NOVEL PIPELINE CANDIDATES TO TRANSFORM THE TREATMENT PARADIGM BY ADDRESSING THE KEY UNMET NEEDS- LONGER DURABILITY AND DELIVERY PROFILES**

- Next generation anti-VEGF agents in development focus on durability with less frequent dosing than current treatments
- Drugs in clinical development with potential as a combination therapy with existing standard of care anti-VEGF-A therapies to address DME patients who respond sub-optimally or become refractory to existing therapies

- Non-VEGF targets to act upstream to address all oxidative pathways with potential to reduce treatment burden, improve visual outcomes, a solution to the sub-optimal efficacy of current treatment
- Potential of gene therapy to transform the DME treatment landscape -one-time treatment for the patients who have demonstrated a very strong dependence on frequent anti-VEGF treatments
- Novel oral and topical therapies could transform the standard of care with non-invasive and prophylactic treatment
- Sustained drug delivery treatment to address the need for frequent intravitreal injections

**CHAPTER 6: AMIDST BIOSIMILARS, HIGH-COST DME DRUG MARKET IN THE US ESTIMATE TO GROW RAPIDLY WITH THE ENTRY OF DRUGS WITH MORE DURABILITY, NON-INVASIVE TREATMENT OPTIONS AND DOWN THE LINE WITH THE ENTRY OF GENE THERAPY**

- Anti-VEGFs leads the current DME market due to its proven efficacy compared to steroids
- Off-label use of Avastin and Triamcinolone acetonide, indicative of price sensitivity influence on prescription and insurance coverage
- Current market landscape of anti-VEGF's and steroids and potential pipeline compounds to drive market growth in the DME sector
- Impact of biosimilars in the current landscape