TEZEPELUMAB: A DIFFERENTIATED, FIRST-IN-CLASS INVESTIGATIONAL THERAPY FOR A BROAD POPULATION WITH SEVERE UNCONTROLLED ASTHMA

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AGENDA

Introduction and NAVIGATOR Data Summary	**David Reese, M.D.—Executive Vice President, Research and Development**
Q&A	**David Reese** **Andrew Menzies-Gow, Ph.D., F.R.C.P.—Consultant in Respiratory Medicine and Director of the Lung Division at Royal Brompton Hospital; Professor of Practice (Respiratory Medicine) at Imperial College, London, England** **Michael Wechsler, M.D., M.M.Sc.—Director, The Cohen Family Asthma Institute; Professor of Medicine, Division of Pulmonary, Critical Care and Sleep Medicine at National Jewish Health, Denver, Colorado**

ASTHMA IS A CHRONIC, SERIOUS DISEASE OF AIRWAY INFLAMMATION[1-3]

- Affects more than 25 million people in the United States
- Complex, heterogeneous disease involving diverse environmental triggers and activation of multiple inflammatory pathways
- Hallmark symptoms include cough, chest tightness and shortness of breath
- Exacerbations or “asthma attacks” may require systemic/oral corticosteroids, emergency department visits and hospitalizations
- ~ 5%–10% of patients have severe asthma
  - Requires high-dose inhaled corticosteroids plus another asthma controller medication, and potentially oral corticosteroids
  - Many patients have inadequate responses to, or are ineligible for, currently available biologics and fail to achieve asthma control

New therapies that are effective irrespective of phenotype and biomarker status are needed for patients with severe uncontrolled asthma

1. National Institute of Environmental Health Sciences. www.niehs.nih.gov/health/topics/conditions/asthma/index.cfm. Accessed February 3, 2021; 2. National Heart, Lung, and Blood Institute. www.nhlbi.nih.gov/health-topics/asthma. Accessed February 3, 2021; 3. American Lung Association. www.lung.org/lung-health-diseases/lung-disease-lookup/asthma/learn-about-asthma/what-is-asthma. Accessed February 3, 2021.

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SIGNIFICANT UNMET NEED IN PATIENTS WITH SEVERE UNCONTROLLED ASTHMA

- **Uncontrolled asthma occurs when asthma symptoms persist despite treatment**
- **Patients with severe uncontrolled asthma may experience[1]**
  - **Daytime asthma symptoms**
  - **Acute reliever use > 2x per week**
  - **Waking at night due to symptoms**
  - **Limitations on daily activities**
  - **Frequent exacerbations requiring systemic/oral corticosteroids**
  - **Serious exacerbations requiring emergency department visits and hospitalization**
- **Uncontrolled patients with continued exacerbations are at highest risk of mortality due to a severe asthma attack[2]**
- **Severe uncontrolled asthma accounts for 50% of asthma-related costs[2]**

~ 2.5 million* severe uncontrolled asthma patients are potential candidates for biologics therapy; ~ 1 million in the U.S.

*U.S., EU5, China, Japan; 1. American Lung Association. www.lung.org/lung-health-diseases/lung-disease-lookup/asthma/learn-about-asthma/what-is-asthma. Accessed February 3, 2021; 2. Nunes C, et al. *Asthma Res Pract.* 2017;3:2-11.

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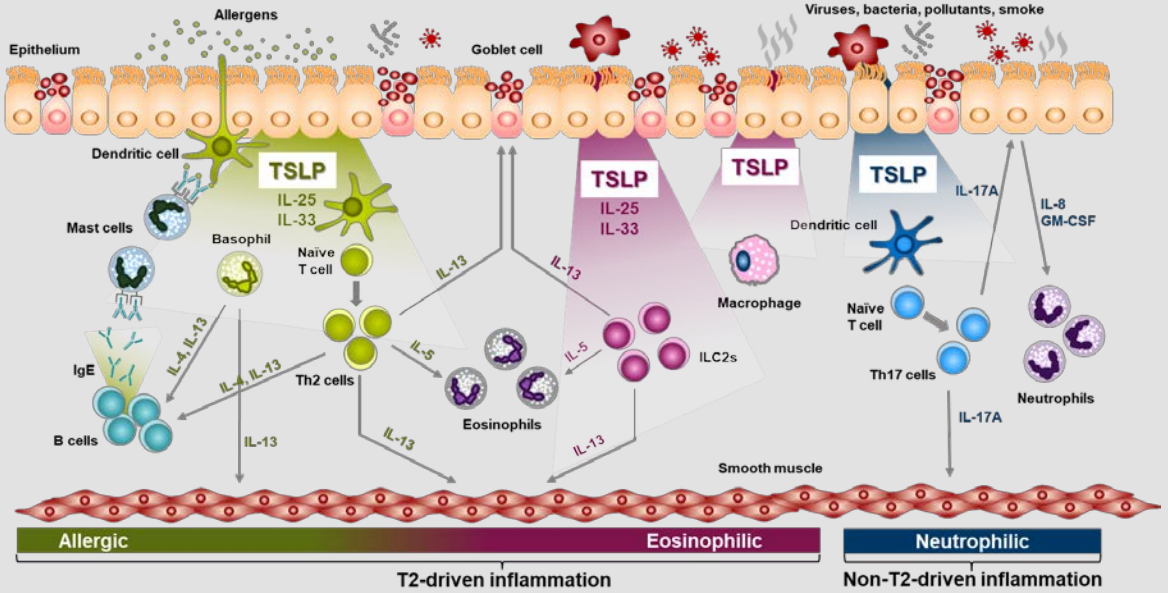
TEZEPELUMAB: A DIFFERENTIATED, FIRST-IN-CLASS INVESTIGATIONAL THERAPY FOR SEVERE ASTHMA

- **The first human monoclonal antibody that specifically blocks TSLP, a key epithelial cytokine at the top of the inflammatory cascade that activates multiple downstream pathways, including IL-4, IL-5, IL-13 and IgE**
- **The first and only biologic to reduce exacerbations in a broad population of patients with severe asthma, irrespective of eosinophil levels**



Differentiated clinical profile supports tezepelumab's potential as a first-line biologic for a broad population of patients with severe uncontrolled asthma

TSLP = thymic stromal lymphopoietin; IL = interleukin; Ig = immunoglobulin

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EFFICACY AND SAFETY OF TEZEPELUMAB IN ADULTS AND ADOLESCENTS WITH SEVERE, UNCONTROLLED ASTHMA: RESULTS FROM THE PHASE 3 NAVIGATOR STUDY

Andrew Menzies-Gow,[1] Jonathan Corren,[2] Arnaud Bourdin,[3] Geoffrey Chupp,[4] Elliot Israel,[5] Janet M Griffiths,[6] Åsa Hellqvist,[7] Karin Bowen,[8] Primal Kaur,[9] Gun Almqvist,[10] Sandhia Ponnarambil[11] and Gene Colice[12]

[1]Royal Brompton Hospital, London, UK; [2]David Geffen School of Medicine, University of California, Los Angeles (UCLA), Los Angeles, CA, USA; [3]PhyMedExp, University of Montpellier, CNRS, INSERM, CHU Montpellier, Montpellier, France; [4]Yale School of Medicine, New Haven, CT, USA; [5]Pulmonary and Critical Care Medicine, Allergy and Immunology, Brigham and Women's Hospital, Harvard Medical School, Boston, MA, USA; [6]Translational Science and Experimental Medicine, Research and Early Development, Respiratory and Immunology, BioPharmaceuticals R&D, AstraZeneca, Gaithersburg, MD, USA; [7]Biometrics, Late-stage Development, Respiratory and Immunology, BioPharmaceuticals R&D, AstraZeneca, Gothenburg, Sweden; [8]Biometrics, Late-stage Development, Respiratory and Immunology, BioPharmaceuticals R&D, AstraZeneca, Gaithersburg, MD, USA; [9]Global Development, Amgen, Thousand Oaks, CA, USA; [10]Late-stage Development, Respiratory and Immunology, BioPharmaceuticals R&D, AstraZeneca, Gothenburg, Sweden; [11]Late-stage Development, Respiratory and Immunology, BioPharmaceuticals R&D, AstraZeneca, Cambridge, UK; [12]Late-stage Development, Respiratory and Immunology, BioPharmaceuticals R&D, AstraZeneca, Gaithersburg, MD, USA.

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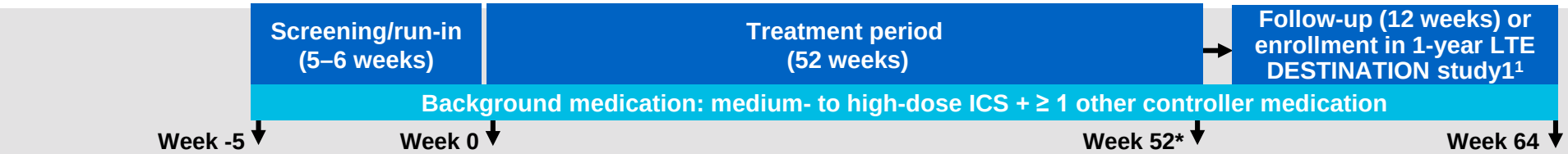
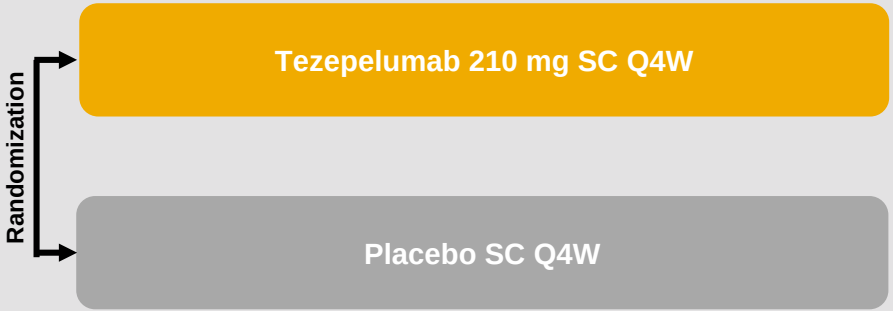
NAVIGATOR ENROLLED A SEVERE ASTHMA POPULATION



Study population:

- Age 12–80 years, non-smokers
- Uncontrolled asthma
  - Mean ACQ-6 score 2.8
- Medium- or high-dose ICS plus at least one additional controller medication with or without OCS
  - ~ 75% on high-dose ICS
- ≥ 2 exacerbations in previous 12 months
  - 40% > 2 exacerbations
- Mean baseline eosinophil counts of 340 cells/uL



Medium- or high-dose ICS (≥ 500 µg fluticasone DPI equivalent total daily dose)

*Patients received IP until week 48; ACQ-6 = Asthma Control Questionnaire-6; DPI = dry powder inhaler; ICS = inhaled corticosteroids; IP = investigational product; LTE = long-term extension; OCS = oral corticosteroids; SC = subcutaneous; Q4W = every 4 weeks; 1. Study NCT03706079. ClinicalTrials.gov website.

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TEZEPELUMAB MET ALL PRIMARY AND KEY SECONDARY ENDPOINTS IN NAVIGATOR

Primary Endpoint

- **Significantly reduced AAER over 52 weeks**
  - **56% ($p < 0.001$) in the overall population**
  - **41% ($p < 0.001$) in patients with a baseline blood eosinophil count of < 300 cells/µL**

Key Secondary Endpoints

- **Significantly improved pre-bronchodilator FEV_1 at week 52 by 0.13 L ($p < 0.001$)**
- **Significantly improved ACQ-6, AQLQ(S)+12 and ASD quality-of-life scores**

Additional Endpoints

- **Reduced AAER irrespective of baseline eosinophil count, FeNO level and allergic status**
- **Reduced AAER associated with hospitalization or emergency department visit by 79% (95% CI: 63, 88)**

AAER = annualized asthma exacerbation rate; FEV_1 = forced expiratory volume in 1 second; ACQ-6 = Asthma Control Questionnaire-6; AQLQ(S)+12 = Asthma Quality of Life Questionnaire (standardized) for patients aged 12 years and older; ASD = asthma symptom diary; FeNO = fractional exhaled nitric oxide

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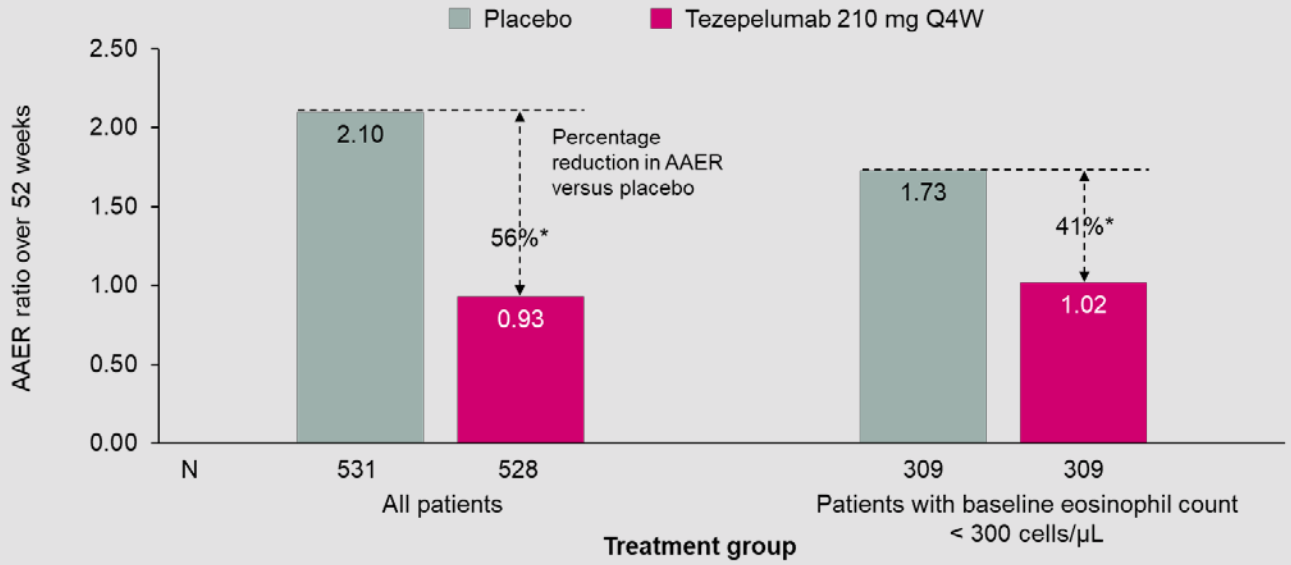
TEZEPELUMAB REDUCED EXACERBATIONS INDEPENDENT OF BASELINE EOSINOPHIL LEVELS

Primary endpoint

AAER ratio over 52 weeks



***p < 0.001 compared with placebo group**

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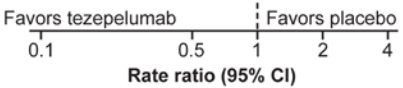
TEZEPELUMAB REDUCED EXACERBATIONS INDEPENDENT OF BASELINE BIOMARKER LEVELS

AAER over 52 weeks

	Tezepelumab 210 mg Q4W n/estimate	Placebo n/estimate	Rate ratio (95% CI)
Overall	528/0.93	531/2.10	0.44 (0.37, 0.53)
Eosinophils at baseline (cells/μL)			
< 300	309/1.02	309/1.73	0.59 (0.46, 0.75)
≥ 300	219/0.79	222/2.66	0.30 (0.22, 0.40)
Eosinophils at baseline (cells/μL)			
< 150	138/1.04	138/1.70	0.61 (0.42, 0.88)
150 to < 300	171/1.00	171/1.75	0.57 (0.41, 0.79)
300 to < 450	99/0.92	95/2.22	0.41 (0.27, 0.64)
≥ 450	120/0.68	127/3.00	0.23 (0.15, 0.34)
Eosinophils at baseline (cells/μL)			
< 150	138/1.04	138/1.70	0.61 (0.42, 0.88)
≥ 150	390/0.89	393/2.24	0.39 (0.32, 0.49)
FeNO at baseline (ppb)			
< 25	213/1.07	220/1.57	0.68 (0.51, 0.92)
≥ 25	309/0.82	307/2.52	0.32 (0.25, 0.42)
FeNO at baseline (ppb)			
< 25	213/1.07	220/1.56	0.68 (0.51, 0.92)
25 to < 50	158/0.87	151/2.20	0.40 (0.28, 0.56)
≥ 50	151/0.75	156/2.83	0.27 (0.19, 0.38)
Baseline perennial specific IgE status (FEIA)			
Any perennial FEIA-positive	339/0.85	341/2.03	0.42 (0.33, 0.53)
All perennial FEIA-negative	184/1.09	177/2.21	0.49 (0.36, 0.67)



CI = confidence interval; FEIA = fluorescence enzyme immunoassay; Ig = immunoglobulin; ppb = parts per billion

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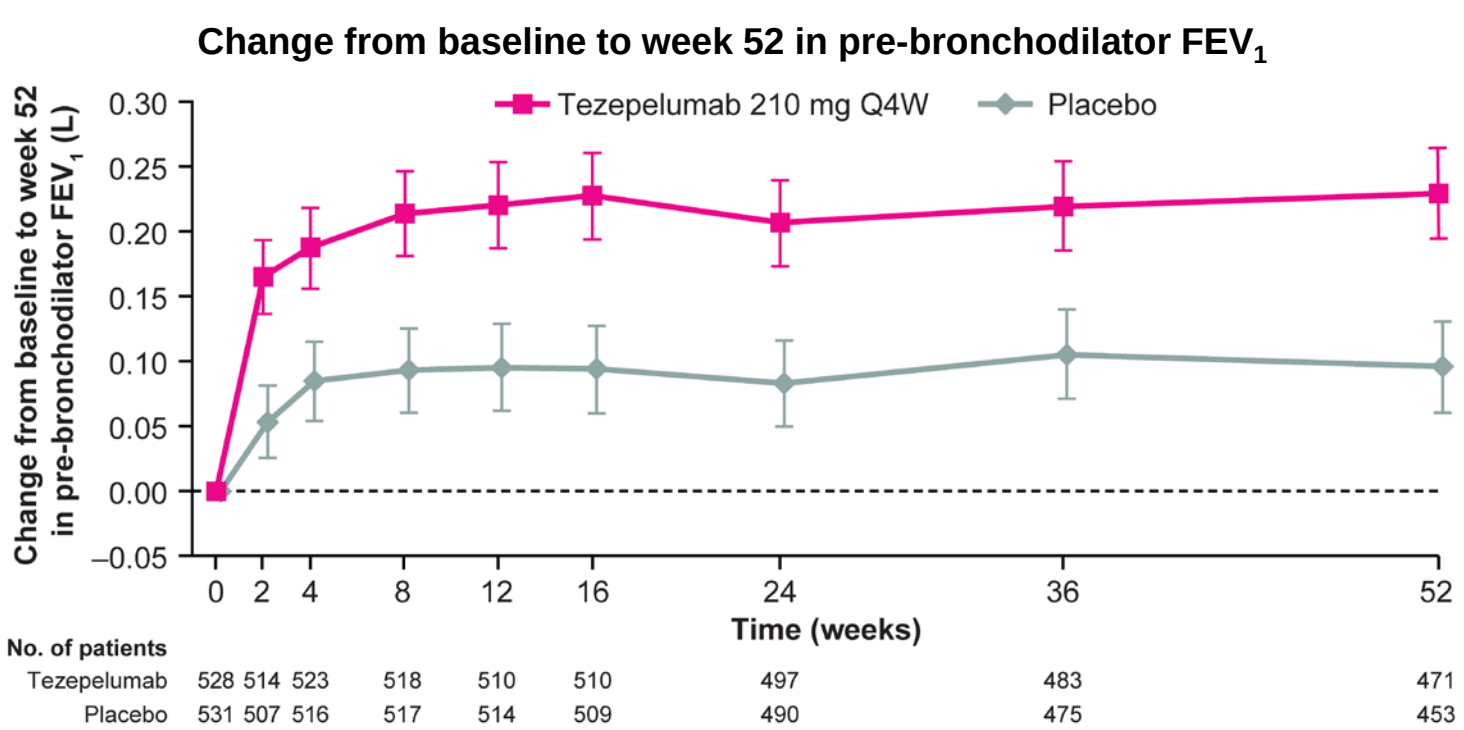
TEZEPELUMAB IMPROVED PULMONARY FUNCTION AS EARLY AS TWO WEEKS



FEV_1 = Forced Expiratory Volume in 1 Second

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NO CLINICALLY MEANINGFUL DIFFERENCES IN SAFETY RESULTS BETWEEN THE TEZEPELUMAB AND PLACEBO GROUPS

Adverse Event (AE) No. of patients (%)	Tezepelumab (N = 528)	Placebo (N = 531)
Any AE	407 (77.1)	422 (79.5)
Serious AEs (SAEs)	46 (8.7)	70 (13.2)

- The most common adverse events (occurring in ≥ 3% of patients) were nasopharyngitis, upper respiratory tract infection, headache
- No treatment-related anaphylactic reactions or cases of Guillain-Barré syndrome were reported

TEZEPELUMAB: A DIFFERENTIATED, FIRST-IN-CLASS INVESTIGATIONAL THERAPY FOR SEVERE UNCONTROLLED ASTHMA

- **Tezepelumab is a first-in-class monoclonal antibody that blocks TSLP, a key epithelial cytokine at the top of the inflammatory cascade**
- **NAVIGATOR demonstrated the potential for tezepelumab as a first-line biologic in a broad population of patients with severe uncontrolled asthma**
  - **Clinically meaningful reductions in exacerbations irrespective of EOS counts, FeNO levels and allergic status**
  - **Significant improvements in lung function, asthma control and quality-of-life measures**
  - **Substantial reductions in exacerbations associated with hospitalization or emergency department visit**
- **No clinically meaningful differences in safety results between tezepelumab and placebo groups**
- **U.S. and EU regulatory submissions planned for H1 2021**
- **Phase 2 study enrolling patients with COPD**
- **Phase 2b study initiating Q2 2021 for chronic spontaneous urticaria**
- **Amgen/AZ partnership will leverage each company's strengths towards global commercialization**

EOS = eosinophil; COPD = chronic obstructive pulmonary disease

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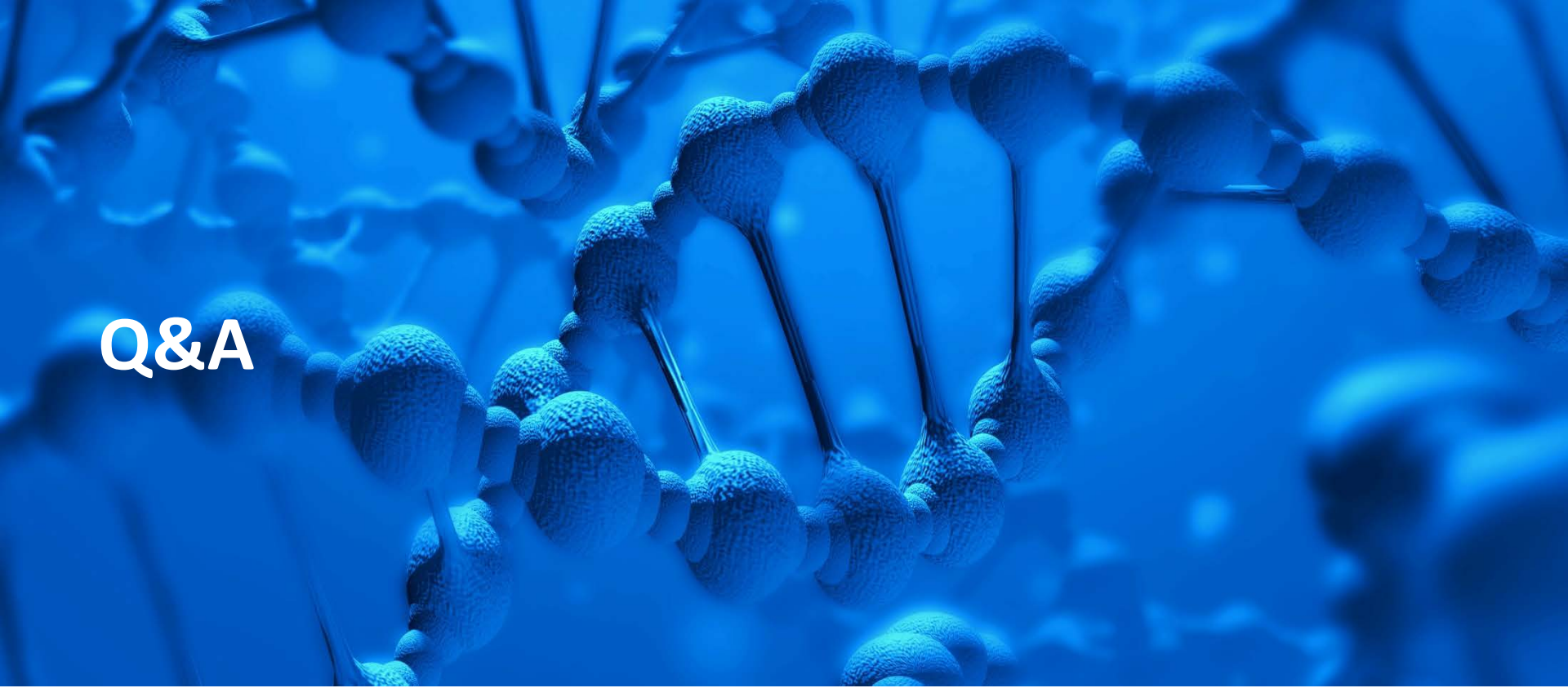
Q&A

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