MarketVue® Idiopathic inflammatory myopathies (IIMs)

January 2023



info@reachmr.com I www.reachmr.com

MarketVue®: Idiopathic inflammatory myopathies

UNDERSTAND THE IIMS MARKET

MarketVue market landscape reports combine primary (KOL interviews and survey data) and secondary market research to empower strategic decision-making and provide a complete view of the market.

Every **MarketVue** includes a disease overview, epidemiology (US and EU5), current treatment, unmet needs, pipeline and access and reimbursement chapter.

Methodology: Research is supported by 5 qualitative interviews with key opinion leaders (3 U.S. Rheumatologists and 2 U.S. Neurologists), a quantitative survey with 26 physicians (U.S. Rheumatologists and Neurologists) and secondary research.

Geographies covered: United States plus epidemiology for EU5 (France, Germany, Italy, Spain, United Kingdom)

EPIDEMIOLOGY: Understand prevalence, diagnosed and drug-treated prevalence of the population and key market segments ш Ľ CURRENT TREATMENT: Understand the treatment decision tree and strengths and ш weaknesses of current on-label and off-label treatment > 0 **UNMET NEEDS:** Identify opportunities to address treatment or disease management gaps Ö PIPELINE ANALYSIS: Compare current and emerging therapy clinical development ູ strategy; their performance on efficacy, safety, and delivery metrics; and their potential to С С С address unmet needs VALUE AND ACCESS: Review the evidence needed to assess and communicate value to 0 key stakeholders (e.g., providers, payers, regulators) and learn what competitors have done or are doing

Why MarketVue?

- PMR-Driven Insights informed by qualitative interviews and/or quantitative surveys
- Senior Team Experienced team members (10+ years in pharma market research) lead the research
- Strategic Delivered in a concise and strategic report template vetted by pharmaceutical industry professionals
- Fresh New reports or report refreshes delivered in as little as 15 business days





MarketVue®: Idiopathic inflammatory myopathies

UNDERSTAND THE IIMS MARKET

COMPANIES MENTIONED

- Priovant
- CSL Behring
- Janssen
- Argenx
- Alexion / AstraZeneca
- Pfizer

- Horizon Therapeutics / Amgen
- Paean Biotechnology
- EMD Serono

DRUGS MENTIONED

- IVIg (Octagam)
- Rituximab
- Azathioprine
- Methotrexate
- Mycophenolate mofetil
- Tofacitinib (Xeljanz)
- Etanercept (Enbrel)
- Adalimumab (Humira)
- Brepocitinib

- lgPro20
- Nipocalimab
- Efgartigimod (Vyvgart)
- Ravulizumab (Ultomiris)
- Zilucoplan (Zilbrysq)
- PF-06823859
- Daxdilimab
- PN-101M5049

REACH

MarketVue[®]: Idiopathic inflammatory myopathies Table of Contents

1.	DISEASE OVERVIEW	4 - 5
	A heterogenous group of chronic, autoimmune disorders marked by inflammation and weakness of the skeletal muscle	4
	Figure 1.1. Immune system involvement and druggable therapeutic targets in IIM	4
	There are no standardized classification criteria for IIMs	5
	Figure 1.2. Clinical manifestations in the IIM sub-types	5
2.	EPIDEMIOLOGY & PATIENT POPULATIONS	6
	Disease Definition	6
	Figure 2.1. Diagnosed prevalent cases of DM, ASyS, and IMNM by region	6
	Table 2.1. Diagnosed prevalent and drug-treated patients in the US and EU5	6
3.	DIAGNOSIS & CURRENT TREATMENT	7 – 16
	Overview	7
	Figure 3.1. Referral and diagnostic pathway for IIM patients	7
	Autoantibody testing is useful in predicting the severity and disease course of IIM patients	8
	Table 3.1. Clinical presentation of IIM subtypes and associated antibodies	8
	All IIM patients need to be on drug therapy during the course of their disease	9
	Table 3.2. Treatment goals for DM, ASyS, and IMNM patients	9
	Figure 3.2. Physician-reported percentage of IIM patients receiving some form of drug therapy	9
	Treatment flow for DM, ASyS, and IMNM	10
	Immune suppression is the current backbone of IIM treatment	11
	Figure 3.3. Current treatment share for DM, IMNM, and ASyS patients	11
	Figure 3.4. Physician-reported rating of current therapy effectiveness in DM, IMNM, and ASyS	11
	Upsides and downsides of current IIM treatments	12
	Physicians' perspectives on current treatment use in DM, ASyS, and IMNM	13
	Octagam 10% is the only FDA-approved treatment for DM; there are no approved therapies for other subtypes	14
	Table 3.3. Summary of the PRODERM trial results	14
	IIMs are characterized by frequent occurrences of remission and relapse	15
	Key treatment dynamics that will shape disease management and drug use in DM, ASyS, and IMNM	16
	Figure 3.5. Important dynamics of IIM market evolution	16



MarketVue[®]: Idiopathic inflammatory myopathies Table of Contents

4. UNMET NEED	
Overview	17
Figure 4.1. Top Unmet Needs in DM, IMNM, and ASyS	17
Figure 4.2. Physician-reported unmet needs in DM, IMNM, and ASyS	17
There is a high unmet need for FDA-approved treatments with fewer insurance barriers	18
Figure 4.3. Neurologist-reported proportion of DM, IMNM, and ASyS who are not well-managed with current therapy options	18
Figure 4.4. Physician-reported proportion of DM, IMNM, and ASyS patients who encounter these barriers to receiving drug therapy	18
Physician perspectives on unmet needs in the diagnosis and treatment of IIM	19
5. PIPELINE ANALYSIS	
Overview	20
Figure 5.1. Percentage of rheumatologists and neurologists (n=26) rating target as "promising" for DM, IMNM, and ASyS (score of 6 or 7)	20
The pipeline for IIM is limited with three treatments in Phase 2/3 clinical development	21
Table 5.1. Comparison of ongoing Phase 3 and Phase 2/3 trials of therapies for IIM	21
The pipeline for DM is active; currently there are no industry-funded Phase 1 trials for IIM	22
Table 5.2. Comparison of ongoing Phase 2 therapies for IIM	22
Physician perspectives on novel, upcoming therapies are largely positive	23
6. VALUE & ACCESS	24 – 25
Overview	24
Table 6.1. Current IIM therapy pricing, U.S.	24
Table 6.2. Typical U.S. commercial payer coverage of Octagam 10%	24
Key market access dynamics that will continue to shape treatment use	25
Table 6.1. IIM patients by insurance type	25
7. METHODOLOGY	26 – 27
Primary Market Research Approach	26
Epidemiology methodology	27



Meet the REACH Team









DANIELLE DRAYTON, PhD., Dr. Drayton is CEO and Founder of REACH Market Research. She is a seasoned business leader and pharmaceutical market researcher. Prior to founding REACH, Dr. Drayton led the Biopharma Market Assessment business at Decision Resources Group (DRG) comprised of market research, RWD analytics, and consulting business lines. In her 14 years at DRG, she worked with 48 of the top 50 pharmaceutical companies and countless biotech companies that involved exhaustive evaluation of unmet need, target product profiles, commercial potential and new product adoption, and company competitiveness. She also has extensive experience conducting product and market opportunity assessments, portfolio analysis, product and therapeutic area strategy, product valuation and sales forecasting, and pre-launch planning. Dr. Drayton completed a postdoctoral fellowship at the Harvard Medical School, received a Ph.D. in Immunobiology from Yale University, and earned a B.S. in Microbiology and Immunology from the University of Miami (Florida).

MELISSA CURRAN is the Director of Product Management at REACH. Melissa has over 10 years of life sciences market research and consulting experience spanning from bespoke strategy consulting to syndicated market research product development and management. Prior to joining REACH, she worked at Decision Resources Group (DRG) for 7 years assisting pharmaceutical and biotechnology commercial teams across the product lifecycle to inform strategic decision making. Melissa is particularly passionate about new product planning and portfolio management, especially in the rare disease space where data can be scarce, and decision-making can be challenging. Specific types of strategic assessments Melissa specializes in include market landscape assessments, commercial opportunity assessment, patient journey mapping, product positioning and TPP optimization, portfolio prioritization, and competitive intelligence. She also has extensive experience working across various market research methodologies including qualitative interviews, quantitative surveys, patient chart audits, real world claims and EHR data, conjoint analysis and secondary research. Melissa received her bachelor's degree in Biology and minor in Business from Providence College.

MICHAEL HUGHES, MSc, Ph.D., Dr. Hughes is the Director of Research at REACH. He has worked in academia, regulatory affairs (NICE) and in RWE and epidemiology consultancies, leading the global epidemiology team at Clarivate (previously Decision Resources Group) for many years. Over that period, he has built numerous new approaches to epidemiological forecasting and imputation, which now form industry best-practice. He has built syndicated and custom epidemiological models and forecasts for many blockbuster drugs across many therapeutic areas, often using a hybrid approach sourcing data from multiple types of dataset and primary market research. He has recently worked on projects in prostate cancer, amyloidosis, anaphylaxis and multi-drug resistant UTIs, among others. He has supported the needs of both big pharma, including Novartis, GSK and Johnson and Johnson, as well as smaller companies and biotechs.

Meet the REACH Team



TYLER JAKAB, MPH is an analyst at REACH Market Research. He is responsible for conducting both primary and secondary market research regarding rare disease therapies to be integrated into market research reports for life science clients. Tyler is a recent graduate of Boston University School of Public Health where he obtained an MPH in Epidemiology of Biostatistics. Prior to joining REACH, he held roles in which he was responsible for health policy analysis, tobacco control research, and health communication. He has extensive experience in data analysis, as well as manuscript and report writing. Tyler also earned a BS in Psychology and Anthropology from the University of North Carolina at Chapel Hill.



BAYLEY KOOPMAN is a Research Associate at REACH Market Research. At REACH, Bayley supports both primary and secondary market research through literature reviews and working with qualitative data. He recently graduated from Tufts University with a B.S. in Biology where he studied the interdisciplinary OneHealth approach for public health and the environment. During this time, Bayley founded an earlystage consumer product startup, which became a finalist team in two consecutive Tufts University Entrepreneurship Pitch Competitions. Prior to joining REACH, Bayley also held roles in regulatory affairs in the raredisease pharmaceutical industry and veterinary practice.



BRIANA MULLINS is a current PhD student At NYU School of Medicine studying the immunological progression of disease in psoriatic arthritis. She currently does both laboratory research and computational biology. Previously she earned her undergraduate degree in Biochemistry at New York University (NYU) and worked in the Blaser Lab studying the human microbiome. She also received an MSc. in Population Health at the University College London (UCL) and conducted antibiotic prescription research using the UK THIN Database. Before starting her PhD Briana worked at Decision Resources Group as an Associate Epidemiologist.

