Category

Best Digital Health Solution

General Information

Company Name *

Mymee

Number of employees *

1-10

Turnover and/or Funding

NA

words remaining :

499

Product/Solution Name *

Mymee's product is a proprietary personalized trial & care platform for rheumatic autoimmune patients who can no longer control disease flares with prescription therapies.

Corporate Name *

Mymee

Date of Approval *

Indications *

Autoimmune rheumatic diseases and disorders including:

Rheumatoid arthritis
Psoriatic arthritis
Ankylosing spondylitis
Lupus
Mixed connective tissue disorder
IBD, Psoriasis, MS and long COVID with rheumatic symptoms

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474

Therapeutic Areas *

Rheumatology

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*Kindly clearly label your files with company name and asset name.

Background information and need for drug / device
(please be as specific as possible in your description; limit 500 words)

While the introduction of new FDA-approved medications over the past two decades has transformed the lives of countless autoimmune patients, others do not achieve or sustain remission with prescribed treatment and continue to suffer from disease flares and disability. Those who are autoimmune Rx "non-responders" - as they are defined in clinical trials and real-world evidence literature - continue to struggle with uncontrolled flares including pain and swelling in joints, stiffness and limitation of movement, fatigue, and other debilitating rheumatic symptoms, impacting their quality of life and ability to work.5 In a 2020 patient survey conducted by the American College of Rheumatology, 44% rheumatic patients said they face work limitations.

In clinical trials, an average of >40% of Lupus (SLE), rheumatoid arthritis (RA) psoriatic arthritis (PsA) and ankylosing spondylitis (AS) patients are non-responders to autoimmune biologics and targeted therapies [ABTT] as defined by inadequate response or intolerance. Real world studies estimate the non-responder population in year one at 65-75% as defined by analysis of pharmacy (switching, additions, non-adherence) and healthcare claims data. Over 90% of non-responders in the real world did not meet entry criteria for the new targeted therapies introduced in the last 5 years.

It is estimated 4 million patients diagnosed with autoimmune diseases face uncontrolled rheumatic flares annually, assuming 40% annual incidence among RA, PsA, AS, SLE, as well as 10% incidence among IBDs and Psoriasis. The numbers are set to rise, with multiple recent studies finding that COVID increases the likelihood of an RA, AS, SLE or Spondylitis diagnosis by 40%.

Patients who do not respond to ABTT remain vulnerable to the complex variables that make up their exposome (e.g. food, drugs, supplements, excipients, climate, stresses, toxins, allergens, pathogens, vaccines and other variables). Compounding the complexity for patients is the elevated risk of drug-supplement-food interactions and side effects associated with polypharmacy that rises with the pain of uncontrolled flares. Going through trial and error in search of solutions can alleviate or exacerbate flares while patients remain in the dark as to which exposures or health interventions correlate to positive or negative symptoms response.

The healthcare costs associated with non-responders to ABTT is an estimated $120B/ year, including ABTT drug and delivery costs, conventional Rx, diagnostic monitoring, emergency room visits, specialist visits and inpatient stays (including surgery).

The final challenge facing non-responders is the scarcity of rheumatologists, who are the center point of care and monitoring for any patient taking ABTTs. By 2025, the patient demand is expected to rise to 7k patients per rheumatologist, up from 4k patients per rheumatologist in 2020, limiting their time availability to spend with autoimmune Rx non-responders beyond prescriptions of concomitant medications and diagnostic monitoring.

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*Kindly clearly label your files with company name and asset name.

Attached Files:

- BACKGROUND_Galien submission for Mymee.pdf

**History of the development of the solution/product *
(please be as specific as possible in your description; 500 words)**

Mymee completed its first study evaluating efficacy of its personalized trial & care platform in SLE in 2018, which demonstrated patients were able to achieve significant reduction in flares as measured by clinically validated PROMIS® scores in an average 17 weeks. In 2020, Mymee initiated its personalized trial & care research for Long COVID patients in collaboration with the Mt Sinai Hospital Center for Post COVID Care in response to the "mystery" health crisis in New York City, before Long COVID had an official name.

The genesis of the company began over a decade ago with founder and CEO, Mette Dyhrberg's own case. From 14 years old to adulthood, she was diagnosed with six autoimmune disorders including psoriatic arthritis and Sjogren's syndrome. Women are predominantly affected by rheumatic diseases at a rate of 2 - 9x more than men. After testing the therapies that have transformational impact on other patients, including Humira, without a reduction in flares, and hearing from experts "there is nothing more we can do," Mette took matters into her own hands to address her symptoms. As an entrepreneur and economist, she dedicated her time to analyzing her own data until she could identify triggers that correlated directly to her flares. Sixteen months later in 2012, she was able to bring herself into remission and became determined to help others do the same. She filed her first patent in 2013 - now cited by companies like Apple - and began the journey to help others, leading to her founding Mymee, Inc in 2017.

Since Mymee's last submission and nomination to Galien in 2021, Mymee completed two peer reviewed real world studies evaluating adherence, engagement, efficacy and medication reduction, as well as an independent validation study demonstrating reduction in specialty Rx among non-responders to ABTT as measured independently by a commercial insurer.

A peer-reviewed study (n=202) published in the global rheumatology research journal RMD Open (May 2022) highlighted findings demonstrating that Mymee's personalized trial and care platform can help autoimmune patients reverse disease flares. A second peer-reviewed study (n=163) focused on patients with rheumatic symptoms taking immunosuppressants, demonstrated reversal of hard-to-treat flares involving joint pain, weakness, muscle pain, fatigue, and brain fog. Among patients who experienced statistically significant improvements through the program based on Mymee's personalized trial & care platform, non-adherence to prescription therapy was ruled out as the driver of disease flares.

The target population for Mymee's proprietary personalized trial & care platform included at-risk Rx non-responders with autoimmune disease and Long COVID patients and the following characteristics:
- 68% - 73% with comorbidities
- 77% women
- Average 5 medications at baseline including biologic and/or conventional immunosuppressants.
- >30 moderate to high frequency symptoms including joint pain and swelling, limitations of movement, muscle pain, weakness, fatigue, anxiety, poor memory/confusion, headaches and diarrhea/constipation.

- Moderate to severe HRQoL as measured by PROMIS domains.

The retrospective studies (n=202; all autoimmune, n=163; only autoimmune disease and Long COVID patients with uncontrolled joint flares and systemic rheumatic symptoms) demonstrated that personalized trials & care can help 70% of at-risk non-responders to reduce the level of severity of moderate and severe autoimmune rheumatic flares and achieve statistically significant and clinically meaningful improvement in 17 weeks as measured by 10 PROMIS ® HRQoL domains.

Peer-reviewed study published in RMD Open May 2023 (n=202, all autoimmune)
https://rmdopen.bmj.com/content/9/2/e003061
https://www.ajmc.com/view/digitally-tracked-data-improve-qol-in-autoimmune-diseases-long-covid

Peer-reviewed research presented at the annual IFM 2023 (n=163, rheumatic patients)
https://posters.ifm.org/ifm/2023/eposters/384985/millennia.lytle.a.self-evidence-driven.digital.care.platform.correlates.the.html

In this study, which was presented at the IFM medical conference "Advances in Clinical Research and Innovative Practices" on June 1st, 2023, 73% had comorbidities and the majority were diagnosed with rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, lupus (SLE), MCTD, Long COVID, Psoriasis and IBD. 77% of patients were referred by payers and providers including Preferred One (UHC), Nielsen/WTW and Mount Sinai Hospital. Average autoimmune biologic and targeted therapy reductions reported in the study were validated through an independent analysis by a commercial insurer. The savings were based on current list prices (WAC) before rebates.

A critical objective was to demonstrate the complexity that non-responders face when trying to control flares with a trial & error approach based on standard drug, supplement, nutrition & health guidelines. The visual in the peer-reviewed study highlights this complexity, showing the unique associations between diverse symptoms and combinations of exposome variables (food, drugs, supplements, excipients, allergens, pathogens, stresses, climate, etc).

Key insights from the research:
- Research involved 121,852 patient-reported data captures and 3,391 personalized trial coach sessions delivered over an average 17 weeks.
- More than 225 symptoms and 534 triggers were tracked in patients' own words for observation and tested across the personalized trials, with correlations confirmed when modification reliably worsened or improved symptom response.
- 70% of patients with moderate to severe flares as measured by 10 PROMIS® HRQoL reversed their level of severity within 17 weeks.
- Mean reduction in moderate to high frequency symptoms, e.g.: joint pain (33%); fatigue (33%); limitation of movement (39%); muscle pain (40%); anxiety (41%), weakness (42%)
- Non-adherence to therapy was not a driver of disease flares, with 5 average medications per patient at baseline (76% ≥ 1 immunosuppressant).
- Patients cited 98% improvement in ability to work with physicians to manage symptoms.

Additional informail about these studies is available upon request.

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*Kindly clearly label your files with company name and asset name.

Attached Files:

- DEVELOPMENT CLINICAL EVIDENCES_Galien submission for Mymee_15June2023.pdf

Why this drug or device is innovative, the broad implications for future research, and/or how it will improve the human condition *

Mymee closes the gap in care for patients who have uncontrolled disease flares and inadequate response to treatments. While FDA approved autoimmune Rx and following nutrition and health guidelines help countless patients to sustain remission and minimize symptoms, others are left highly vulnerable to their exposome (food, medication, supplements, excipients, toxins, climate, stresses, pathogens, vaccines). For these patients, trial & error between drugs, diets and alternative health interventions can increase risk of exposure to hidden triggers and drug-supplement-food interactions.

Participating in a personalized trial & care program capable of identifying direct correlations between negative triggers, positive health interventions and symptoms severity, helps patients gain control of their disease flares and work with their doctor to reduce or optimize their drug regimen if needed. Testimonials from patients credit Mymee with giving them their life back,no longer being afraid of their body, being able to laugh again, going back to work, and canceling surgeries.

Mymee Inc is a pioneer in personalized trials & care for patients with uncontrolled autoimmune and long COVID disease flares. Mymee's proprietary personalized trial & care platform is clinically validated and SOC-II and HIPAA-compliant. In peer-reviewed studies, Mymee delivered statistically significant improvements in all ten HRQoL PROMIS® domains and a >40% mean reduction in 59 patient-reported symptoms. Peer-reviewed publications include Rheumatic & Musculoskeletal Disease Open Journal ('23), IFM Conf ('23 & '20), ACR Conf ('22), JMIR Lupus (SLE) Publication ('20) and IEEE conf ('20). Mymee has received industry recognition including Top 100 NY Healthcare Startups 2022 & 2023, Health 2.0 Outstanding Leadership Award: CEO & Founder 2022, Juniper Networks Awards 2022: #1 Most Innovative Precision Medicine Solution, Nominee Prix Galien Award: Digital Health, 2021, Honoree Fast Company World Changing Ideas Awards 2021.

Real world studies show personalized trial research & care delivers measurable value to providers and payers as well as patients. Non-responders to autoimmune biologics who still struggle with uncontrolled flares at the end of Step Therapy is one of the highest human & economic cost problems to solve.

Key findings demonstrate that Mymee's personalized trial & care platform enables:

- Statistically significant improvements in all 10 HRQoL PROMIS® domains and >40% mean reduction in 59 patient-reported symptoms; the more severe, the greater the improvement 1, 2 (corp 2 pager)

- >30% reduction in polypharmacy, addressing a key risk factor in rheumatic diseases..

- 98% improvement in patients' perceived ability to work with their doctor to manage symptoms.

- Average $11k Rx savings per autoimmune biologic and targeted therapy non-responder per year, as audited by a commercial insurer (based on list prices (WAC) prior to rebates).

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*Kindly clearly label your files with company name and asset name.

Attached Files:

- INNOVATION_Galien submission for Mymee_15June2023.pdf
- MYMEE COMPANY OVERVIEW.pdf

Please provide appropriate references (PubMed, Abstract, Website) *

attached

*Kindly clearly label your files with company name and asset name.

Attached Files:

- REFERENCES_Galien submission_USA_2023docx.pdf