BACKGROUND [Mymee, Inc, copyright 2023, publication excerpt, full source list available upon request.] Background information and need for solution/product.

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.