

Lupus (SLE)



Key facts about Lupus

- The last drug approved for SLE was GSK's Benlysta in 2011 and that was the first approved product for the indication in over 50 years meaning physicians have very few options when treating Lupus.
- SLE has been linked to contact with various occupational and environmental exposures such as silica dust, intake of certain drugs, and past infections.
- SLE patients have mortality rates twice as high as the general population and those with LN have mortality rates almost eight times higher.

What is Lupus?

- Systemic Lupus Erythematosus (SLE), also known as lupus, is a systemic inflammatory autoimmune disease in which the body's defense system acts against its own organs.
- Any organ or tissue can be affected with one of its most severe manifestations being renal (kidney) involvement, known as lupus nephritis (LN).
- SLE has a wide range of symptoms depending on the severity and the organ(s) being affected.
- Some well-known symptoms include acute and chronic rashes, oral ulcers, hair thinning or loss, swollen joints, pain and swelling in affected organs, renal malfunction and failure (LN), and anemia.
- The pathophysiology of SLE and LN is complex and not fully understood. However, tissue and organ injury is believed to be mainly driven by the production of autoantibodies and the disposition of immune complexes to the various tissues and organs.

Patient Impact

- SLE patients have higher mortality rates than the general public due to the disease causing organ impairment along with secondary infections and the development of cardiovascular disease.
- Comorbidities such as fatigue, fibromyalgia (widespread general pain), and cognitive dysfunction all negatively affect patient's quality of life.
- Patients, especially younger ones, can experience negative psychological and social effects due to the rashes associated with the disease such as the butterfly rash seen in the image above found in many lupus patients.

Treatment options

- Treatment options are very limited and most cases are treated off-label with antimalarial drugs, steroids, and other immunosuppressive therapies.
- Biologics have been used to treat the condition almost entirely off-label and generally in conjunction with one or more additional therapies.
- The steroids and other immunosuppressive drugs generally used are associated with significant side effects due to shutting down the immune system and also are not preferred in younger patients.

* GlobalData PharmaPoint: Systemic Lupus Erythematosus and Lupus Nephritis - Global Drug Forecast and Market Analysis to 2022
Image: <http://www.apolloid.com/2010%20Senior%20Projects/Jenna%20Zeigler/untitled.jpg>

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Epidemiology

In 2012 there were 452,000 prevalent cases of SLE in the 7MM growing to 488,800 in 2022 with an average annual growth rate of 0.81%.*

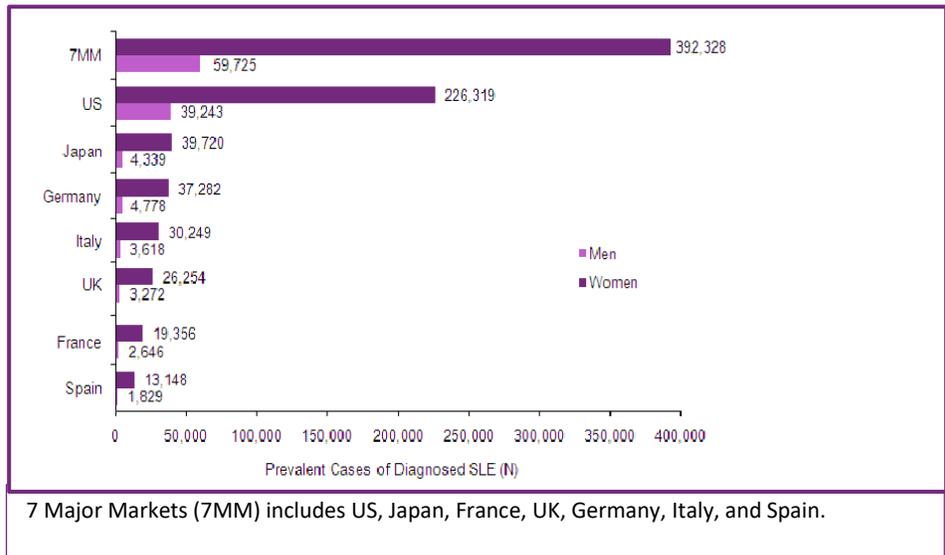
Approximately 20% of SLE patients in the 7MM will also suffer from LN.*

Prevalence of SLE in women is 5-8x higher than in men amongst the different regions thought to be caused by certain reproductive factors involving hormonal changes.

Studies have found that Caucasians have a lower risk of developing SLE than other ethnicities.

US prevalence in 2012 was 256,600 comprising almost 60% of the overall diagnosed prevalent cases of SLE in the 7MM.*

SLE has been shown to be more prevalent in patients with a family history of the condition showing an unknown, but probable genetic component.



Along with other side effects, some of the medicines used to treat lupus play a role in causing clinical depression.

With few recent improvements in care, a significant unmet need persists for lupus patients.

Unmet Needs of Lupus Patients

- Products approved for the treatment of Lupus
- Safer and more effective treatments without suppressing the immune system
- Better management of LN and comorbidities
- Improving patient mortality
- Raise disease awareness among physicians and patients*

About KPI Therapeutics™:

KPI Therapeutics is a clinical stage biotechnology company, which develops first in class therapies for unmet medical needs in autoimmunity using its novel Kv1.3 channel blocker based platform. Its lead drug, dalazatide is being clinically advanced for Inclusion Body Myositis, (IBM) an orphan disease, and for lupus. Our autoimmune platform molecules are also being developed for new therapies to address atopic dermatitis and uveitis.

Our dalazatide program is developing a biologic Kv1.3 inhibitor targeting the immune cells that cause Lupus.