Intelligencia AI

May: Lupus Awareness Month

As May marks lupus awareness month, we studied our data at Intelligencia AI to better understand the current and potential future state of drug development for this disease.

Lupus is a chronic autoimmune disease that can be debilitating to a patient's quality of life or even prove fatal, mainly due to heart disease, cancer and infections.

Due to the periodic nature of the disease (flares-remission), as well as the similarity of its symptoms to other diseases, **lupus is notoriously difficult to diagnose**.

Systemic Lupus Erythematosus (SLE) is the most common and most serious type of lupus, which can affect any organ.

Reported global SLE incidence ranges from **1.5 to 11 per 100,000 person-years**, while prevalence ranges from 13 to 7,713.5 per 100,000 individuals[1].

Based on pooled results from multiple studies, **estimated survival for SLE patients is >95% over a 5-year observation period since diagnosis**[2].

HOW IS LUPUS CURRENTLY TREATED?

As there is no cure, treatments aim to improve symptoms and reduce organ damage.

Commonly used types of treatment[3]:

- Nonsteroidal anti-inflammatory drugs
- Corticosteroids
- Antimalarial drugs
- Biological therapies
- Immunosuppressive agents/chemotherapy

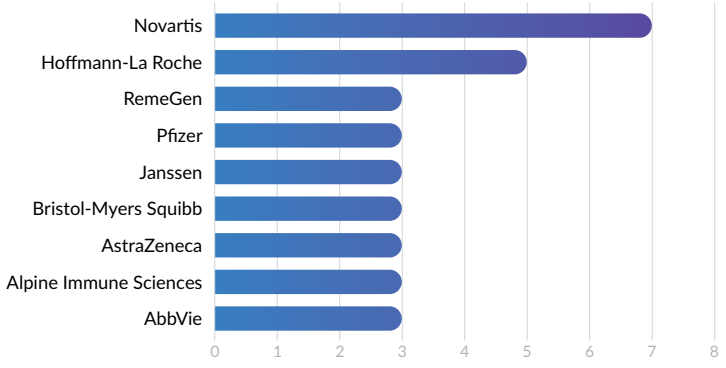
Only two drugs have received FDA approval in the past 15 years. Both work by reducing excessive autoimmune response, either indirectly reducing autoantibody levels (Belimumab, GSK) or inhibiting immune signaling pathways (Anifrolumab, AstraZeneca).

DETAILS IN THE DATA: HERE'S WHAT WE UNCOVERED

In our data[4], we identified:

- 90 ongoing industry-led, FDA-regulated interventional clinical development programs* among which:
  - *46 are in Phase 1, 1b or 1/2*
  - *29 are Phase 2 and*
  - *15 are in Phase 3.*
- The 90 programs noted above are being conducted by 60 different primary sponsors, and correspond to 78 investigational drugs/drug combinations, covering over 26 different drug modalities/modality combinations.

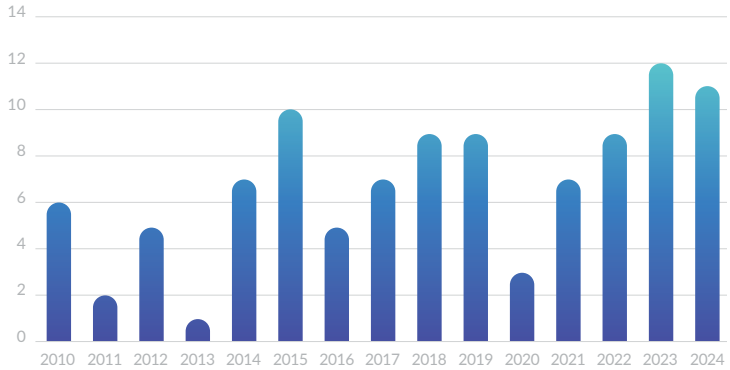
Sponsors With Highest Number of Active SLE Clinical Programs



These are the top-ranking sponsors based on the number of ongoing SLE clinical programs, all of which currently have a total of 3-7 programs each.

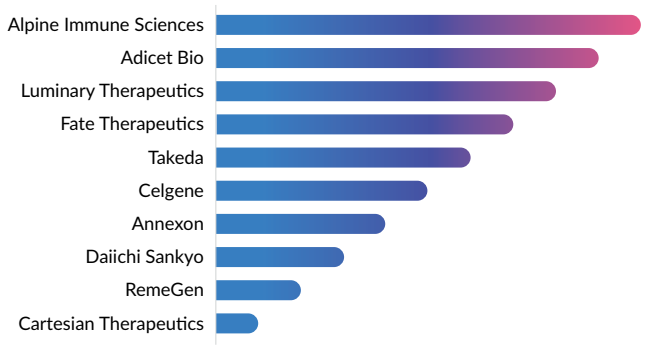
- Among our industry-led, FDA-track historical programs, 45% transitioned from Phase 1 to Phase 2, and 18% from Phase 2 to Phase 3, while a total of 2 drugs received marketing authorization, accounting for a 9% approval rate at the drug-indication level.
- Among drugs currently in Phase 3 SLE trials, there are 8 drugs (each investigated by a different sponsor) that have no prior FDA approval for lupus.
- Each of these drugs covers different modalities (small molecule inhibitor, monoclonal antibody, fusion protein, antigen-binding antibody fragment).
- In terms of mechanism of action, all eight of these drugs either deplete the number of immune cells (e.g. B-lymphocytes, plasmacytoid dendritic cells) to reduce autoantibodies, or they inhibit excessive immune signaling.

Distribution of Total SLE Clinical Programs by Year of Initiation Since 2010



For the past ten years, there has been an increase in the number of initiated clinical programs targeting SLE, with a current upward trend.

Top 10 Sponsors in SLE-Ranked by Intelligencia AI Pipeline Performance Score



Our pipeline performance score leverages our patented AI-driven probability of technical and regulatory success (PTRS) assessments.

SO WHAT DOES THIS MEAN?

While lupus has a significant survival rate, it is still debilitating to a patient's quality of life, making this an unmet need. Seeing the number of active clinical programs, the pharmaceutical industry seems to agree. Phase 3 research focuses on either reducing autoantibodies or inhibiting excessive immune signaling. Continued industry interest in these approaches emphasizes their potential and the likely direction of lupus research in the next few years.

About Intelligencia AI

Intelligencia AI™ leads the way in leveraging proprietary data, biomedical expertise and artificial intelligence (AI) with its patented technology to address significant challenges in the pharmaceutical industry. These challenges include lengthy drug development timelines, excessive costs, and unsustainable return on investment (ROI). Its suite of AI-powered solutions delivers actionable insights crucial in mitigating risks and enhancing decision-making associated with drug development by providing an accurate, unbiased assessment of a drug's probability of success. Founded in 2017, Intelligencia AI is headquartered in New York, NY, with offices in Athens, Greece, and employs 110 individuals globally. Visit intelligencia.ai to discover more.

References

1 Barber MRW, Drenkard C, Falasinnu T, Hoi A, Mak A, Kow NY, Svenungsson E, Peterson J, Clarke AE, Ramsey-Goldman R. Global epidemiology of systemic lupus erythematosus. Nat Rev Rheumatol. 2021 Sep;17(9):515-532. doi: 10.1038/s41584-021-00668-1. Epub 2021 Aug 3. Erratum in: Nat Rev Rheumatol. 2021 Sep 1;: PMID: 34345022; PMCID: PMC8982275.

2 Tektonidou MG, Lewandowski LB, Hu J, Dasgupta A, Ward MM. Survival in adults and children with systemic lupus erythematosus: a systematic review and Bayesian meta-analysis of studies from 1950 to 2016. Ann Rheum Dis. 2017 Dec;76(12):2009-2016. doi: 10.1136/annrheumdis-2017-211663. Epub 2017 Aug 9. Erratum in: Ann Rheum Dis. 2018 Mar;77(3):472. PMID: 28794077.

3 U.S. Food & Drug Administration, Minority Health and Health Equity Resources, Accessed May 2024.

4 Data as of May 16, 2024

Intelligencia AI intelligencia.ai

**A program (also known as clinical pipeline or drug pipeline) is the clinical development of a drug (or a set of drugs in case of combination therapies) by a pharmaceutical company (alone or in collaboration with other partners) for an indication. A program consists of a set of clinical trials with the ultimate goal of approval for marketing. Each program has unique and specific parameters that can potentially justify a separate regulatory approval. Specifically, the definition of a clinical program is one of unique drug(s), drug dosage, mode of administration, adjuvant state, indication, sponsor, disease severity (e.g. stage of disease), line of treatment and biomarker information used as inclusion criteria.*