Intelligencia AI

June: Scleroderma Awareness Month

As June marks scleroderma awareness month, we took a deep dive into our data at Intelligencia AI to better understand the current and potential future state of drug development for this disease.

Scleroderma is a chronic autoimmune connective tissue disease which causes inflammation and fibrosis (scarring/thickening) of the skin and many other organs.

The disease is categorized into **localized scleroderma, when it mostly affects the skin or tissues directly under the skin**, and **systemic scleroderma (sSc), when it also affects internal organs**. sSc can further be categorized into diffuse cutaneous systemic sclerosis (dcSSc) and limited cutaneous systemic sclerosis (lcSSc)[1,2].

sSc is usually more severe than the localized form; **reported global sSc incidence ranges from 1.8 to 23.6 per 100,000 person-years**, while prevalence ranges from 1.6 to 25.3 per 100,000 individuals[3].

dcSSc and lcSSc have the lowest 10-year survival rates among connective tissue diseases, 60% and 75% respectively[4].

HOW IS SYSTEMIC SCLERODERMA CURRENTLY TREATED?

As there is currently no cure, treatments mainly aim to improve symptoms and reduce organ damage and generally include[5]:

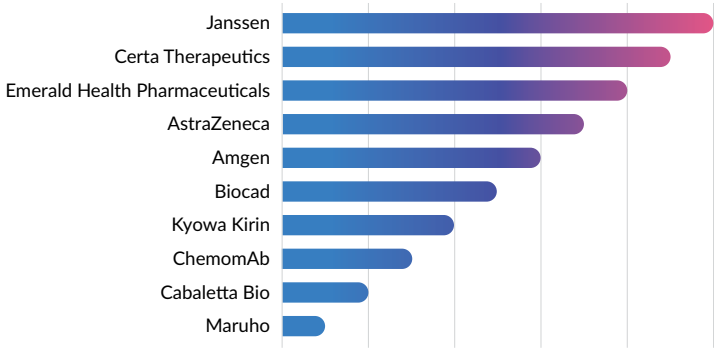
- anti-inflammatory medications
- drugs for vascular disease
- immunosuppressive therapy
- anti-fibrotic agents

DETAILS IN THE DATA: HERE'S WHAT WE LEARNED ABOUT SYSTEMIC SCLERODERMA

There is currently no FDA-approved treatment for scleroderma. Among industry-led, FDA-track clinical development programs* in our data[6] we identified:

- 22 historical (failed) programs, of which 20 programs (90.9%) failed at Phase 1 or Phase 2, while only 2 programs (9.1%) reached Phase 3.
- 16 **ongoing** programs, of which:
  - 4 are in Phase 1, 1b, or 1/2
  - 9 are in Phase 2, and
  - 3 are in Phase 3.
- The 16 mentioned programs above are being conducted by 16 different primary sponsors, and correspond to 16 investigational therapies, including small molecules, antibodies (monoclonal or other), and autologous CAR-T cells.

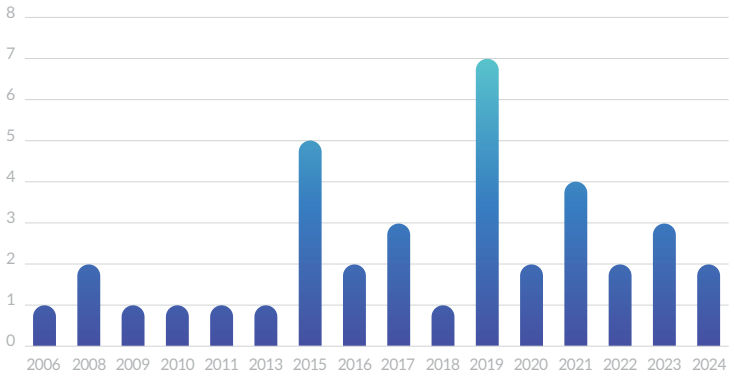
Top 10 Sponsors in Scleroderma Ranked by Intelligencia AI Pipeline Performance Score



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

- 8 of the 16 ongoing programs have received Orphan Drug designation.
- The drugs currently in Phase 3 trials comprise the B-lymphocyte antigen CD20 Binding Agent Divozilimab (Biocad), the Interferon alpha/beta receptor 1 Antagonist Anifrolumab (AstraZeneca), and the Interleukin-17 receptor A Antagonist Brodalumab (Kyowa Kirin). Divozilimab aims to achieve B-cell depletion, while Anifrolumab and Brodalumab inhibit immune signaling pathways.

Distribution of Total Scleroderma Clinical Programs by Year of Initiation Since 2006



For the past almost twenty years, there has been a consistently low annual number of initiated clinical programs targeting Scleroderma, excluding a few outlier years.

PERSPECTIVE: WHAT DOES THIS ALL MEAN?

Systemic scleroderma poses an unmet need, but it is one with significant challenges. It has a complex pathophysiology and largely unknown etiology. With the low 10-year survival rate, the lack of FDA-approved treatments, and limited industry focus (no sponsor is currently running more than one clinical program, with few initiated every year and only three currently in Phase 3), there is a huge gap. Further research is needed to improve understanding of the disease, as well as clinical studies to uncover timely interventions, tailored to each patient's profile.

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 National Institutes of Health, Health Topics, Scleroderma, Accessed 31 May 2024.
2 https://www.nhs.uk/conditions/scleroderma/; Accessed 31 May 2024.
3 Tian J, Kang S, Zhang D, Huang Y, Zhao M, Gui X, Yao X, Lu Q. Global, regional, and national incidence and prevalence of systemic sclerosis. Clin Immunol. 2023 Mar;248:109267. doi: 10.1016/j.clim.2023.109267. Epub 2023 Feb 15. PMID: 36804224.
4 Garen T, Lerang K, Hoffmann-Vold AM, Andersson H, Midtvedt Ø, Brunborg C, Kilian K, Gudbrandsson B, Gunnarsson R, Norby G, Chaudhary A, Thoen J, Forseth KØ, Fresjar K, Førre Ø, Haugen M, Haga HJ, Gran JT, Gilboe IM, Molberg Ø, Palm Ø. Mortality and causes of death across the systemic connective tissue diseases and the primary systemic vasculitides. Rheumatology (Oxford). 2019 Feb 1;58(2):313-320. doi: 10.1093/rheumatology/key285. PMID: 30281089.
5 https://www.hopkinsscleroderma.org/patients/scleroderma-treatment-options, Accessed 31 May 2024.
6 Data as of May 31, 2024.

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**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.*