

SFA Therapeutics, Inc.

Category:

Best Startup

Company Name:

SFA Therapeutics, Inc.

Turnover and/or Funding:

\$8.8M raised to-date.

(assets.

SFA-002 just completed phase 1b in autoimmune disease

No revenue yet.

Sub-Category:

Biotechnology

Corporate history (creation, key milestones, main funding,...)Information on Condition / Disease and need for solution / product (prevalence, existing treatments / solutions):

SFA Therapeutics aims to change the treatment of autoimmune disease from immunosuppression to returning the immune system to normal.

SFA was formed based on basic research at the Feitelson Laboratory at Temple University. Dr. Mark Feitelson was conducting research on the use of short chain fatty acids as possible treatments to block the progression of hepatitis B to hepatocellular carcinoma, the primary form of liver cancer. This is an extension of Mark's post-doctorate research under Dr. Baruch Blumberg, a Nobel-laureate, who discovered hepatitis B and developed the first hepatitis B vaccine.

SFA is pioneering the use of these biosynthetic metabolites that mimic substances found in healthy humans but are missing in patients with autoimmune diseases. Similar to the development of insulin for type 1 diabetics, SFA has isolated natural substances that modulate the immune system and return it to normal function, and has developed biosynthetic drugs tailored to specific immune diseases. This discovery has been tested

in 40 patients and in two clinical trials, in psoriasis as a proof of concept, in uveitis, Bullous Pemphigoid, IBS, MASH/NASH, and inoperable Stage 4 pancreatic cancer; with each case showing remarkable results.

This patented platform has potential therapeutic application across over 40 autoimmune diseases, including rheumatoid arthritis, multiple sclerosis, and inflammatory bowel disease. Its unique mechanism of action- modulating HDAC activity to maintain immune homeostasis, differentiates it clearly from current treatments that are often limited by systemic toxicity or insufficient efficacy.

Four functional cures have been observed in patients; two in psoriasis one in Stage 3 MASH/NASH, and one in IBS. SFA has nine drugs in their pipeline. The data show remarkable ability to immunomodulate the immune system to normal without immunosuppression and its associated side effects.

Autoimmune disease affects over 350 million people per year globally, and is growing at over 9% per year. There are over 100 types of autoimmune diseases. Many of these patients suffer from MAS, or multiple autoimmune syndrome. SFA Therapeutics believes that a common link among many of these diseases is a deficiency of these key metabolites, which we are replacing with our drug. By replacing the missing metabolites with our drug, we have observed patients' immune systems return to normal, and after long-term treatment (> 2 years), we have been able to withdraw the drug and observe patients being able to make these substances on their own, effectively providing a functional cure.

A phase 1b clinical trial in 28 patients with psoriasis has just been completed in the US, and the clinical study report has been submitted to the FDA. The results were World-class. There were no serious adverse events after two years of study. A major journal article is pending publication.

More information and the interim analysis data can be found at the SFA Therapeutic website at <https://www.sfatherapeutics.com/>

SFA Therapeutics aims to change the treatment of autoimmune disease from the current standard of care, immunosuppression, to immunomodulation and returning the immune system to normal. This is a radical goal- to change Medicine by curing autoimmune disease.

History of the development of the solution/product (Intellectual Property, preclinical and clinical data, development collaborations):

SFA Therapeutics has 17 global patents and 34 patents pending, including Composition of Matter and 2 NCEs. These patents cover over 40 autoimmune diseases. The patents

are grouped into three categories: Liver Disease and Hepatocellular Carcinoma, Psoriasis and Autoimmune disease, and Systemic Inflammatory Response Syndrome.

Six preclinical studies have been conducted; 2 in psoriasis in the IMQ model, 2 in MASH/NASH in mice, and 2 in pancreatic cancer.

An ex-vivo study in human skin has also been completed, which validated the preclinical results and corresponded with the changes in cytokines observed during the phase 1b clinical trial.

A phase 1a clinical trial in 6 human subjects with mild to severe psoriasis was completed in 2018. 6/6 patients in this trial showed Psoriasis Area of Severity Index (PASI) improvements of over 85%.

A phase 1b clinical trial in 28 human subjects with mild-moderate psoriasis was completed in May of 2025. Over 61% of patients in the phase 1b clinical trial showed greater than PASI 75 improvements, and 31% exhibited 100% clearance of lesions. There are no marketed oral drugs with this efficacy and safety. No treatment-related adverse events were observed.

Further, two subjects have shown durable responses, that is, after long-term treatment (> 2 years), these subjects are 100% disease-free, and have shown no return of disease, despite having previously had significant disease for many years. These patients have been off of drug treatment for over four years with no return of symptoms.

A variant of this drug, SFA-001N, was tested in a single-subject compassionate-use trial, in a patient with Stage-3 MASH/NASH that was told to prepare for a liver transplant. After 3 years, that subject is now disease-free, with their liver going from having 8 lesions, abnormal liver functionality, reduced elasticity, and an enlargement to 22.5 cm, to zero lesions (confirmed by before and after MRIs), normal liver functionality, normal liver elasticity (confirmed by Fibroscan) and a high-normal liver size of 16.5cm. This patient continues to be monitored and is showing a functional cure.

SFA has affiliations with Temple University in Philadelphia, LSU in New Orleans, and Einstein/Jefferson Hospital in Philadelphia.

The preclinical studies show a decrease in TNF α , IL-17, IL-23 and IFN γ . The clinical studies showed an increase in anti-autoimmune IL-10, and then a cascade of decreases in TNF α , IL-17, IL-23 and IFN γ .

SFA-002 has the potential to become an oral Enbrel or oral Humira, with the potential to create durable responses, e.g., functional cures. The Method of Action has been elucidated, and two students have earned PhDs in our laboratory working on the

proteomics and pathways associated with this drug.

Patient before and after pictures and interim analysis data can be found at:
<https://www.sfatherapeutics.com/>

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

SFA Therapeutics aims to completely change the treatment of autoimmune disease, from the treatment of symptoms to the treatment of a root cause of disease, with the potential to effect functional cures.

Autoimmune Disease

SFA Therapeutics' lead asset, SFA-002 demonstrates exceptional promise. SFA-002 targets mild-to-moderate psoriasis, representing an underserved patient population where existing treatments, notably Otezla, have shown substantial limitations. Clinical data from Phase 1 trials indicate that SFA-002 surpasses current oral competitors, demonstrating statistically significant efficacy and an outstanding safety profile, with no treatment-emergent adverse events reported. This positions SFA-002 to rapidly capture substantial market share in a global psoriasis market projected to reach \$52 billion by 2030.

The compelling efficacy and safety profile observed in clinical trials positions SFA-002 as a potential best-in-class and first-in-class oral immunomodulator. Furthermore, SFA Therapeutics has successfully navigated pre-clinical and clinical validations for its NASH treatment candidate, SFA-001N, which has demonstrated the ability to significantly delay and partially reverse fibrosis in animal models, with early compassionate-use human data affirming these effects. The global NASH treatment market is poised for remarkable expansion. Valued at \$7.75 billion in 2024, it is projected to reach approximately \$92.5 billion by 2034, growing at a CAGR of 28.14% between 2025 and 2034. This growth is driven by the increasing prevalence of obesity and related metabolic disorders.

Moreover, SFA Therapeutics has showcased remarkable versatility and scalability of its platform, extending potential therapeutic applications across over 40 autoimmune diseases, including rheumatoid arthritis, multiple sclerosis, and inflammatory bowel disease. Its unique mechanism of action-modulating HDAC activity to maintain immune homeostasis-differentiates it clearly from current treatments that are often limited by systemic toxicity or insufficient efficacy.

Oncology

The unique mode of action in SFA's platform technology has shown promise in liver and pancreatic cancers. The global liver cancer drug market was valued at approximately

\$4 billion in 2024 and is anticipated to grow at a CAGR of 18% from 2025 to 2030. Pancreatic cancer is considered the deadliest cancer, killing over 50,000 people in the United States each year. The global pancreatic cancer treatment market was valued at approximately \$3 billion in 2024 and is projected to grow at a compound annual growth rate (CAGR) of 12% from 2025 to 2030, reaching an estimated \$6 billion by 2030.

SFA has the potential to completely change the way that autoimmune diseases and cancers that develop on an inflammatory background are treated. In autoimmune disease, the standard of care is immunosuppression. This treats the symptoms but not the disease. Current drugs can cause significant side-effects, including cancer, TB, infections and antibodies. SFA's approach replaces substances that patients cannot make with biosynthetic compounds that mimic substances that are missing in patients. This represents a potentially historic shift in the medical treatment of these patients.

In oncology, the progression of hepatitis to HCC and pancreatitis to pancreatic cancer is well documented. In cancers that have an inflammatory basis, SFA-001 can revolutionize treatment by preventing the progression of the underlying inflammatory condition to cancer.

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

SFA Therapeutics website: <https://www.sfatherapeutics.com/>

American Association of Dermatology, 2025

Abstract #60220 - \"Profiling of Apremilast and SFA-002 in an Imiquimod (IMQ) Mouse Model of Psoriasis\"

<https://eposters.aad.org/s3/AM2025/poster/60220/Profiling+of+Apremilast+and+SFA002+in+an+Imiquimod+Mouse+Model+of+Psoriasis.pdf>

Abstract #60227 - \"Effectiveness of SFA-002 to inhibit TH1/TH17 inflammation in an experimental skin model\"

<https://eposters.aad.org/s3/AM2025/poster/60227/Effectiveness+of+SFA002+to+inhibit+TH1TH17+inflammation+in+an+experimental+skin+model.pdf>

References File Document upload:

[SFA Scientific White Paper July 2023 1.pdf](#)

SFA002 Key Differentiators.pdf

SFA Therapeutics Investor Deck 6 25.pdf

SFA Therapeutics Publications 7 18 24.docx

AAD abstract.docx

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