

Category

Best Startup

General Information**Company Name ***

Immunis, Inc.

Turnover and/or Funding

Immunis has raised a total of \$38 Million, including a \$10 Million Series A and \$25 Million Series A-1 fundraising round.

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479

Sub-Category *

Biotechnology

Background

**Corporate history (creation, key milestones, main funding,...)Information on Condition / Disease and need for solution / product (prevalence, existing treatments / solutions)
(please be as specific as possible in your description; limit 500 words)**

Immunis is a private, clinical-stage biotech founded in 2019 in Irvine, California by Chairman Dr. Hans Keirstead, an internationally recognized stem cell scientist and serial entrepreneur. Immunis has raised \$38 million total from a Series A and Series A-1 fundraising round to fund a Phase 1/2a clinical trial targeting muscle atrophy associated with knee osteoarthritis (NCT05211986) and a Phase 2 clinical trial (NCT06600581) targeting muscle loss in obese elderly individuals.

Achievements:

2025

"Biotech Company of the Year," and "Most Innovative Investigational Therapy," Global Health & Pharma (GHP) Biotech and Lifesciences Awards

2024

"Best Immune Dysregulation Treatment Developers," and "Innovation in Age-related Disease R&D," GHP Healthcare and Pharma Awards

"Innovator of the Year: Dr. Keirstead," Orange County Business Journal (OCBJ)

"Best Technology Company CEO: Dr. Keirstead," Octane's HighTech Awards

"Immune Dysfunction Treatment Developers of the Year," and "Innovation Award in Age-Related Disease R&D," GHP Biotech and Lifesciences Awards

2023

"Innovator of the Year: Dr. Keirstead," OCBJ

"Innovation and Excellence Award," Corporate LiveWire

"Best Immune Deficit Treatment Development Firm," GHP Biotech and Lifesciences Award

"Best Small Business," and "Best Entrepreneur: Dr. Hans Keirstead," Best of America Small Business Awards

2022

"Innovator of the Year: Dr. Keirstead," OCBJ

2021-2024

Dr. Keirstead listed as one of OCBJ's Influential OC500

Reversing Age-Related Muscle Atrophy is a Clinical Need

Immune dysregulation contributes to an array of degenerative illnesses within the body, including muscle atrophy, which affects 100% of people with age. A majority of the population loses 5-15% of their skeletal muscle mass per decade after the age of 50, with accelerated loss after age 70 (von Haehling et al., 2010). Muscle atrophy (i.e., induced by disuse, disease, age) leads to reduced strength, endurance and metabolic and physical function, all of which can drastically reduce quality of life. Age-related muscle atrophy, or sarcopenia, is a leading contributor to falls, fractures, hospitalization, and comorbidities, accounting for more than \$40 billion in annual health care costs in the United States alone (Bahat & Ozkok, 2024). Additionally, sarcopenic obesity is a global health phenomenon due to both the rapid increase in the elderly population and the obesity epidemic. Sarcopenic obesity is characterized by the coexistence of excess fat mass and sarcopenia, which correlates with adverse cardiometabolic effects and contributes to poor health outcomes. Many sarcopenia therapeutics that progressed to early-stage clinical trials were discontinued due to lack of efficacy. Despite intensive efforts and a clear need, there are no pharmaceutical agents available to reverse muscle atrophy and improve functionality with age.

Complex, age-related diseases require a multifaceted therapeutic solution.

The current medical approach to manage chronic conditions in aging is to treat individual manifestations of aging in isolation using single active ingredients, with little focus on prevention, and without addressing the underlying age-related biological changes that drive health dysfunction and

increase the risk of chronic conditions. A multi-active treatment that could prevent or reverse the underlying age-related biological drift would improve health in aging, reduce risk of chronic conditions, reduce medical costs, and improve quality of life.

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

(please be as specific as possible in your description; 500 words)

Aging results in a gradual decline in immune system function and its associated beneficial cell secretions such as proteins, lipids and growth factors. Collectively known as the secretome, these secretions provide essential cell stimulation to promote health. Immunis aims to harness the immunomodulatory power of stem cell-derived secretomes to refine immune cell responses and reduce susceptibility to age-related disease. We developed a human stem cell-derived secretome (IMM01-STEM) to address the clinical need of reversing muscle atrophy associated with obesity.

IMM01-STEM Efficacy Data

Our published nonclinical data show that IMM01-STEM has immunomodulatory and regenerative capabilities in aged mouse-models of muscle disuse and atrophy. IMM01-STEM increases the number of muscle stem cells, enhances muscle size, elevates the frequency of reparatory immune cells and improves muscle strength (Fix et.al, 2021). Immunis' subsequent publication shows that the physical and physiological benefits in aged mouse muscle correlate with decreased muscle fat, increased whole-body lean mass and overall reduced fat mass (Fennel et., 2024). These data provide a promising basis for therapeutic developments of IMM01-STEM in targeting metabolic dysfunction and sarcopenia in aged populations.

Immunis completed a Phase 1/2a clinical trial monitoring the safety and tolerability of IMM01-STEM in sarcopenic individuals with knee osteoarthritis and reported no serious adverse events (NCT05211986). Our unpublished data support that IMM01-STEM improves the patients' ability to walk via a 6-minute walk test, a functional measurement of gait speed. Participants also reported decreased pain in their leg muscles (WOMAC scale) and a decrease in pain that interferes with daily activity (PROMIS-PI scale). A manuscript of the trial results is in progress.

Immunis is conducting a Phase 2 clinical trial to determine whether the positive outcomes of the secretome treatments in mouse models are also observable in obese, sarcopenic humans (NCT06600581). Concurrently, Immunis is conducting non-terminal preclinical research studies with VetBio Partners, LLC to determine the safety and efficacy of IMM01-STEM in reversing muscle atrophy in aged canines. IMM01-STEM may potentially help elderly humans and pets regain their muscle, improve muscle function and reduce fat mass thereby increasing mobility, independence and autonomy.

Collaborations

Our experienced leadership and Advisory Board afford Immunis the advantage of developing all intellectual property including product design, development, manufacturing, quality control, and clinical operations in-house. We produce IMM01-STEM within our fully functioning Good Manufacturing Practice laboratory, eliminating the need for a third-party manufacturer. We scale-up the growth of human stem cells in vitro using proprietary media and harvest the secreted factors. We filter out the cellular debris, concentrate the secretome, and run several quality control tests to verify batch consistency and sterility. Once verified, we bottle and package IMM01-STEM for clinical and pre-clinical testing.

As age-related diseases can be exacerbated by muscle atrophy, and studying the effects of IMM01-STEM on muscle produces relatively quick and measurable results, compared to long-term diseases like Alzheimer's, muscle atrophy was determined as the ideal model for investigation. Immunis leverages its partnerships within the University of California, Irvine and the University of Utah to execute thoughtfully planned pre-clinical trial experiments.

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

IMM01-STEM is a multi-active biologic

Numerous molecular pathways become altered to promote disease, but a majority of FDA-approved drugs target only a single biological disease pathway. To address this issue, Immunis developed a method to generate defined, high purity stem cell secretomes that can produce defined cocktails of pro-regenerative biologics to help restore health across diverse biological systems. There are currently no FDA-approved secretomes on the market, making IMM01-STEM the most advanced secretome in clinical trials.

IMM01-STEM has multiple therapeutic benefits

Immunis' human stem cell-derived secretome, IMM01-STEM, leverages the power of all-natural immune modulators to promote muscle regeneration, enhance metabolism, and reduce body fat. Age-related muscle loss, or sarcopenia, will affect 100% of humans with age and there are currently no pharmaceutical treatments available. Obesity is another major issue that people experience later in life and is most common in conjunction with sarcopenia. Thus, sarcopenic obesity is one of the greatest medical challenges to address. Current weight loss drugs are reported to cause unintended muscle loss, which is linked to increased disability, hospitalization, diabetes, chronic inflammation, and diminished quality of life. IMM01-STEM aims to reverse the negative effects of these age-associated conditions by boosting metabolism and increasing muscle mass and function to enhance human healthspan well into our years.

Therapeutic advantages over traditional therapies

IMM01-STEM provides advantages over traditional stem cell therapies because the bioactive molecules, and not the stem cells themselves, yield the benefits that can restore the regenerative stem cell niche long-term. Secretomes provide a natural, cell-free method of combating disease,

thereby minimizing the risk of immune system rejection and avoiding tumorigenicity. Also, multi-active secretomes are easier to manufacture and scale for mass production, making them off-the-shelf-ready therapies.

Other advantages are that secretomes can be modified for a broad range of diseases. The nature and composition of a secretome is highly complex and dependent on the environmental conditions and cell type in which it was produced, meaning an infinite number of secretomes can be fine-tuned in vitro for a specific disease or animal species. Thus, secretomes provide numerous therapeutic advantages over stem cell-based therapies and can be transformative for human healthspan.

Supporting healthspan in the growing aging population

Many elderly individuals experience weight gain and muscle loss, with their only treatment options being diet, exercise, and GLP-1 agonists, which have controversial effects. Unpublished data from our Phase 1/2a human clinical trials shows suggestive benefits of IMM01-STEM in ameliorating leg pain for those with age-related muscle loss and an improvement in quality of life. Also, Phase 2 clinical research is underway to study how IMM01-STEM may benefit overweight elderly with muscle loss. As opposed to popularized GLP-1s that decrease weight, but compromise muscle mass, IMM01-STEM has suggestive efficacy in preclinical models to reduce fat while promoting muscle regeneration and function, a revolutionary feat that is not demonstrated by any FDA-approved drug on the market. Immunis aims to support healthspan and independence in the growing elderly population by promoting muscle and metabolic health.

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

Immunis' website

www.immunisbiomedical.com

Immunis' Clinical Trials

<https://clinicaltrials.gov/study/NCT05211986>

<https://clinicaltrials.gov/study/NCT06600581>

Immunis' Publications

<https://pubmed.ncbi.nlm.nih.gov/34427856/>

<https://pubmed.ncbi.nlm.nih.gov/38500398/>

Immunis' Awards

<https://immunisbiomedical.com/awards/>

Additional References

<https://pubmed.ncbi.nlm.nih.gov/21475699/>

<https://pubmed.ncbi.nlm.nih.gov/38315328/>

*Kindly clearly label your files with company name and asset name.

Attached Files:

- [GeroScience_2021.pdf](#)
- [AgingCell_2024.pdf](#)