

Category

Best Startup

Product/Solution Name

IMMUNA, formerly known as IMM01-STEM

Date of Approval

N/A

Indications

IMMUNA is currently in Phase 1/2a clinical trial testing for muscle atrophy related to knee osteoarthritis.

Therapeutic Categories

Cell-derived biologic; cellular secretome; exosomes

Attached Files:

- Fix et al 2021 Reversal of deficits in aged skeletal muscle durin.pdf

Background information and need for solution/product

As we age, we experience a gradual decline in immune system function and the production of its beneficial cellular secretions. These secretions are collectively known as the secretome and they orchestrate complex communication between cells. Immune dysregulation contributes to an array of degenerative illnesses within the body, including muscle atrophy, which will affect 100% of people with age. Age-related muscle atrophy, or sarcopenia, is also a major contributor to knee osteoarthritis, an inflammatory disease that is a leading cause of disability in elderly adults. There are currently no treatments to attenuate muscle loss or to enhance muscle regeneration.

Immunis created an investigational new secretome composed of natural immunomodulators to address these clinical needs. IMMUNA (formerly known as IMM01-STEM) is a novel secretome product comprised of all-natural, all-human factors that influence immune health. Preclinical data in aged mouse-models of muscle disuse and atrophy demonstrated that IMMUNA had immunomodulatory and regenerative capabilities. IMMUNA increased the number of muscle stem cells, enhanced muscle size, elevated the frequency of reparatory immune cells, and improved muscle strength. Immunis is currently conducting an FDA-approved Phase 1/2a clinical trial, where IMMUNA is injected into the quadriceps muscles of aged patients with muscle deterioration associated with knee osteoarthritis. The goal is to reverse muscle atrophy and alleviate the knee pain and stiffness of knee osteoarthritis, thereby reducing the need for surgery.

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

Attached Files:

- 2023 June Immunis.pdf
- Immunis_PitchDeck_June2023.pdf

History of the development of the solution/product

Regenerative niches containing stem cells such as mesenchymal stem cells (MSCs) and multi/pluripotent stem cells produce secretomes that demonstrate anti-inflammatory, anti-apoptotic and immunomodulatory properties. The secretome is the total set of proteins, lipids, growth factors, chemokines, cytokines, exosomes and molecules secreted by a cell. A well-functioning immune system is necessary for our health and secretomes can refine immune cell responses, meaning the immunomodulatory power of the secretome can drastically reduce susceptibility to disease.

The secretome is being studied as an alternative therapeutic approach to stem cells because the secreted bioactive molecules, and not the stem cells themselves, yield the immediate therapeutic benefits. Secretome-based therapies provide a natural, cell-free method of combating disease, thereby minimizing the risk of immune system rejection and avoiding tumorigenicity. Also, the secretome has multiple methods of administration including injection, topical application, or inhalation, providing versatile treatment options. The secretome provides incredible therapeutic advantages over traditional stem cell-based therapies and offers another treatment option in the field of biomedicine. However, secretome therapies are an underexplored and newly emerging area of research.

Immunis Chairman, Dr. Hans Keirstead, is an internationally renowned stem cell expert who has led many investigations on regenerative medicine. As a stem cell scientist, Dr. Keirstead has the expertise to cultivate specific cell types in vitro and harness their powerful secretome for clinical applications. Evidence suggests that the secretome is involved in immunomodulation, which may make it an effective therapeutic for autoimmune diseases, neurodegenerative diseases and age-related muscle-loss (sarcopenia). 100% of humans develop sarcopenia with age, which significantly impairs mobility and compromises quality of life. Preventing muscle loss and improving muscle recovery are currently unfulfilled medical needs.

Immunis has created an investigational secretome, IMMUNA, formerly known as STEM, with regenerative molecules derived from partially differentiated pluripotent cells. As age-related diseases can be exacerbated by muscle atrophy, and studying the effects of IMMUNA on muscle atrophy would produce relatively quick and measurable results, compared to long-term diseases like Alzheimer's, muscle atrophy was determined as the ideal model for investigation. Immunis' Scientific Advisory Board Member, Dr. Micah Drummond, a muscle atrophy expert at the University of Utah, published pre-clinical data of IMMUNA in aged mouse-models of muscle disuse and atrophy. The results, published in GeroScience, showed that IMMUNA increased the number of muscle stem cells, enhanced muscle size, elevated the frequency of reparatory immune cells, and improved muscle strength, highlighting IMMUNA's immunomodulatory and regenerative capabilities.

Immunis is currently testing IMMUNA in an FDA-approved Phase 1/2a clinical trial in aged patients with muscle atrophy associated with knee osteoarthritis to research safety and tolerability. IMMUNA is also being investigated in numerous preclinical research studies on metabolism, wound healing, arterial stiffness, insulin sensitivity, neurogenesis, cognitive decline, neuroinflammation, immune dysfunction, liver and fat pathology, and multisystem senescence. Secretome therapeutics are a unique biomedical tool and IMMUNA is a testament to the presumably diverse applications of the secretome in addressing inevitable and currently, untreatable age-related diseases.

Our experienced leadership and knowledgeable Advisory Board members afford Immunis the advantage of developing all intellectual property including product design, development, manufacturing, quality assurance, quality control, and clinical operations. At Immunis, we take an in-

house approach when it comes to making IMMUNA. We have a fully functioning Good Manufacturing Practice laboratory in our facility where we produce IMMUNA without the need for a third-party manufacturer. Our scientists scale-up the growth of cells in vitro using a proprietary media. Over time, the cells release their secretome into the media, which we then collect and process. After filtering out the cellular debris, we concentrate the secretome and run several quality control tests to verify batch consistency and sterility. Once verified, we bottle and package our secretome product for clinical and pre-clinical testing. We are confident in our technology as no secretome clinical trial to our knowledge has ever reported a serious adverse event when administered in humans.

Attached Files:

- Prix Galien Awards 2023 Immunis Supplemental Business Information.pdf

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

Our immune system is the most critical determinant of our health, affecting our susceptibility to disease and ultimately, quality of life as we age. Immune dysregulation is at the root of numerous age-related diseases. Since 2019, there has been a steady increase in scientific publications on the secretome ameliorating diseases. Secretomes are an emerging class of biologics, rich in active biomolecules secreted by a cell. They play significant roles in cell communication, development, and immune responses, meaning they can potentially address complex, age-related diseases. However, secretome therapies are still a newly emerging area of research.

The secretome has recently been studied as an alternative therapeutic approach to administering stem cells directly, which have a controversial history as a biomedical treatment. Interestingly, scientists are discovering that the secreted bioactive molecules from stem cells, and not the stem cells themselves, are what yield the immediate therapeutic benefits. IMMUNA is an innovative, investigational secretome therapy with regenerative molecules harvested from partially differentiated pluripotent stem cells. Secretome-based therapies like IMMUNA provide a natural, cell-free method of combating disease, thereby minimizing the risk of immune system rejection and avoiding tumorigenicity. Other advantages of the secretome are the ease of manufacturing and scalability for mass production, making secretomes off-the-shelf-ready therapies. Similarly, producing a secretome is more cost-effective than growing large numbers of stem cells for a particular treatment. Also, the secretome has multiple methods of administration including injection, topical application, or inhalation, providing versatile treatment options. The secretome provides incredible therapeutic advantages over traditional stem cell-based therapies and offers another treatment option in the field of biomedicine.

Secretomes have a wealth of potential for reversing the effects of age-related diseases and improve overall quality of life as we age. Immunis is currently conducting an FDA-approved Phase 1/2a clinical trial to assess the safety and tolerability of IMMUNA in patients with muscle atrophy related to knee osteoarthritis, an inflammatory disease contributing to age-related disability. Age-related muscle atrophy, or sarcopenia, is a major contributor to knee osteoarthritis, an inflammatory disease that is a leading cause of disability in elderly adults. There are currently no treatments to attenuate muscle loss or to enhance muscle regeneration and knee surgery requires an extensive recovery process. IMMUNA was created to address these clinical needs in the hopes of reversing muscle atrophy and alleviating the knee pain and stiffness, thereby reducing the need for surgery.

Secretome therapies are advantageous because they can be easily modified to suit the needs of 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. In addition to muscle atrophy, variations of IMMUNA are also being investigated in numerous pre-clinical research studies on metabolism, wound healing, arterial stiffness, insulin sensitivity, neurogenesis, cognitive decline, neuroinflammation, immune dysfunction, liver and fat pathology, and multisystem senescence. Thus, secretomes are a powerful tool for modulating the immune system and maintaining human health with age.

Attached Files:

- Immunis Spotlight_V4FINAL.mp4

Please provide appropriate references (ie Pubmed links)

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

<https://pubmed.ncbi.nlm.nih.gov/35285638/>

<https://pubmed.ncbi.nlm.nih.gov/30816242/>

<https://pubmed.ncbi.nlm.nih.gov/28191785/>

<https://pubmed.ncbi.nlm.nih.gov/33359378/>

<https://pubmed.ncbi.nlm.nih.gov/31527327/>

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