INNOVATION FOR REGENERATION

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Executive Summary

On recombinant TLR5 agonist

Global markets

· Global GvHD market is expected to reach US$ 640 million in 2026 with the annual average growth rate of 6.0%.
- The growth of global GvHD markets is caused by the increase in cancer patients as well as by the increase in HSCT (Hematopoietic Stem Cell Transplant).
- There are approved pharmacologic therapies for the treatment of Acute GvHD following allogeneic HSCT (one for adults and one for pediatric population).
- However, there are currently no approved pharmacologic therapies for the prevention or prophylaxis of Acute GvHD following allogeneic HSCT.

· The global market size of mucositis reached US$ 2.3 billion in 2018, and is expected to grow at a 2019-2025 CAGR of 7.1%.
- According to the National Center for Biotechnology Information, oral mucositis occurs in 40% of cancer patients receiving chemotherapy, and 100% in head and neck cancer patients.
- There are currently no approved pharmacologic therapies for prevention or prophylaxis of severe mucositis due to combined radiation and chemotherapy in head and neck cancer.

· The global cancer immunotherapy market is expected to grow from US$ 16.9 billion to US$ 75.8 billion in 2025.

Value Proposition of TLR5 agonist Pipelines (First-in-Class)

With dual mechanisms of action, a TLR5 agonist, when used prophylactically, may alleviate side effects such as mucositis and GvHD during chemo/radiation therapy, and simultaneously enhance anti-cancer treatments.

· The efficacy of the treatment for ARS (Acute Radiation Syndrome) caused by total body irradiation has been proved by the Non-human primate (NHP) testing. Our recombinant TLR5 agonist (KMRC011) suppresses gastrointestinal damage caused by radiation exposure, ensuring high survival rate.
· KMRC011 is under development for the prophylaxis of intestinal acute GvHD, which could improve the quality of patients' life better than the existing treatment therapeutics.
· KMRC011 can be developed as a therapeutic agent for a number of indications such as oral mucositis by protecting tissues from radiation exposure and toxic anticancer agents.
· Based on its own immune modulation activities, KMRC011 can be used in combination with other cancer treatments including immune checkpoint inhibitors.

Our Current Needs

To expedite the commercialization of TLR5 agonist therapeutics, we are looking to find capable partners interested in co-developing TLR5 agonist therapeutics in terms of clinical studies and regulatory affairs. Preferably, Connext will manufacture and supply recombinant collagenase drug products under the future business collaboration.

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On Collagenase

Global markets

· Approved therapies exist for several indications in the major markets.
- Injectable brand: Xiaflex™ (Peyronie's disease/Dupuytren's contracture), Qwo™ (cellulite)
- Topical brand: Santyl™ (wound debridement)
- Sales of Xiaflex™ have recently skyrocketed in the US at the 2012-2020 CAGR of 29%. In 2012, the sales revenue of Xiaflex™ was US$ 32 million. In 2020 it was US$ 316 million.
- Qwo™ for cellulite treatment was approved in 2020 in the US and can be classified similarly with aesthetic products like botulinum toxin. The commercial potential for cellulite treatment is great, with approximately six million potential patients in the US.

Value Proposition of Our Collagenase Pipelines

Connext is the only company in the world capable of manufacturing *high quality recombinant enzymes applicable to therapeutic purposes using proprietary methods for enhanced productivity and efficiency.* These enzymes include class I collagenase, class II collagenase, and thermolysin, critical components for tissue dissociation.

Xiaflex™, an existing commercially available collagenase therapy, is produced from a wild-type pathogenic bacterial strain (Clostridium histolyticum). However, Connext can produce high-purity recombinant enzymes using genetically engineered E. coli, which provides important advantages:

· Pathogenic Clostridium wild-type strain produces several toxins, ultimately generating safety concerns. However, recombinant enzymes are entirely free from toxic impurities, ensuring the safety of an injectable drug product.
· The upstream bioprocess using a recombinant strain is highly efficient and can produce enzymes with consistent productivity at a lower up-front cost than our competitors. Connext's proprietary downstream process purifies enzymes to ensure high-quality enzymes appropriate for therapeutic use.

Xiaflex™ is provided with a separate vial for a dedicated diluent. However, with the advanced, novel formulation technology that Connext has developed, there is no need for a separate diluent, thus maximizing user convenience.

Our Current Needs

To expedite the commercialization of collagenase therapeutics, we are seeking capable partners interested in establishing business development opportunities, including, but not limited to, co-development and marketing partners in EU, Japan, and Oceania. Preferably, Connext will manufacture and supply recombinant collagenase drug products under any business collaboration to be established.

Executive Summary

On Connext

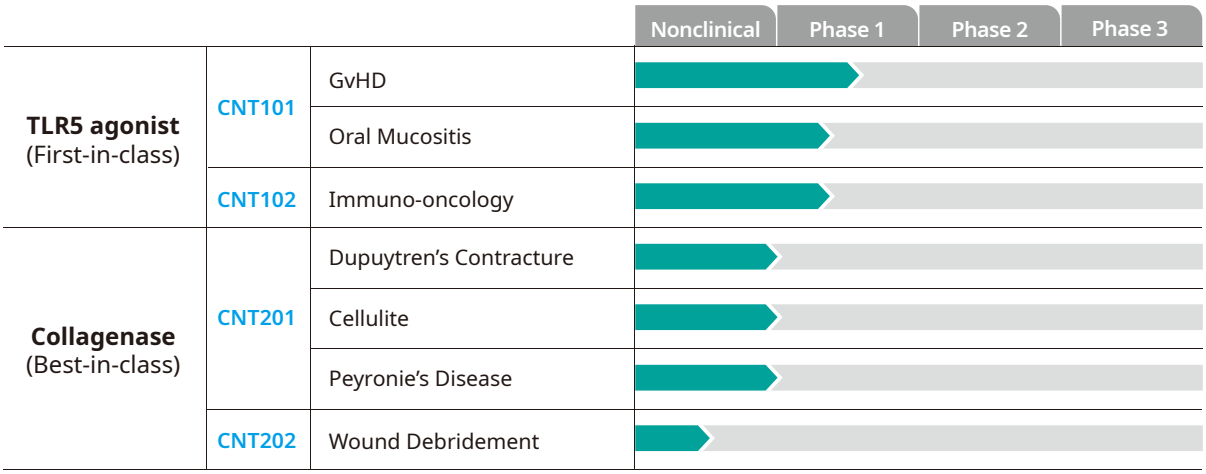
Founded in 2017, Connext is a clinical-stage biotechnology company spun-off from a government-funded research institute. Connext aims to improve quality of life by rapidly delivering innovative medicines and technologies to patients. Connext's pipeline includes a recombinant TLR5 agonist for radiation-induced diseases (first-in-class), and recombinant collagenase for musculoskeletal diseases (best-in-class). Connext is expanding indications to cover a wide range of therapeutic areas and is seeking opportunities to collaborate with partners globally.

Portfolio & Pipeline

Our portfolio consists of 2 proprietary technology platforms:

TLR5 agonist: TLR5 agonists have been previously demonstrated to control inflammation and promote regeneration of damaged tissues by activating innate immunity. Connext has developed TLR5 agonist technology as a therapeutic solution for Acute Radiation Syndrome (ARS), and completed a first-in-human study. Based on the therapeutic potential, Connext is expanding indications to include mucositis, and GvHD (Graft versus Host Disease).

Collagenase: Collagen is a fibrous component in connective tissues and the most abundant protein in mammals. Collagenase is an enzyme derived from microorganisms which breaks down collagen. Connext has developed a cutting-edge manufacturing process using genetically engineered E. coli to ensure product stability, high-quality, and safety. Utilizing this technology, Connext is currently developing therapeutic agents for diseases caused by collagen-related disorders.



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