

Newsletter October 2021 – An exciting kick-off to Autumn

The Cline Scientific team hopes you have had a great summer and would like to share with you the exciting things going on and what's happening soon. The upcoming period is going to be an eventful time for the team as we take significant steps towards bringing both our StemCART and CellRACE products to clinical phases by carrying out key testing and product development activities.

Cline's goal of bringing new possibilities to healthcare

Our work is motivated by improving healthcare and the lives of patients worldwide. Cline sees our approach to diagnosing and treating diseases as being a part of a rapidly changing paradigm shift in healthcare. Over the years, advances in science, medicine and technology have allowed leaps in what is possible to be understood, overcome, and managed in a way that has never been possible.

However, there is still a long way to go in addressing some of the most important health challenges that impact patients' lives. Breast cancer with distant metastasis has a survival rate of just 27%¹. Osteoarthritis, which can severely limit a patient's life and mobility, is estimated to affect 10% of people over 60².

There is light at the end of the tunnel and the emerging areas of precision medicine and cell therapy aim to get to the root cause of disease, looking at cells at an individual level to best understand and use them for good. Scientists, clinicians, and R&D companies, such as Cline, are working on the breakthroughs that will bring new possibilities to patients.

The value and future plans of our projects

In September, Cline CEO Patrik Sundh took part in a video interview with Analyst Group as part of their latest analysis connected to Cline's recent half-yearly report. You can watch the short interview [here](#). See the full updated analysis [here](#).

StemCART

This newsletter will dive into the progress towards our first ex vivo testing for StemCART and other activities. Upcoming milestones include receiving ethical approval for collecting patient material (Q4 2021), the commencement of ex vivo testing (Q4 2021), development

¹ American Cancer Society. 2020. Cancer Facts & Figures 2020

² Zhang Y, Jordan JM. Epidemiology of osteoarthritis. Clinics in geriatric medicine. 2010

of method in the cell viability project (Q4 2021), project with Chalmers University on matrix formulation findings (Q1 2022) and the initial results from ex vivo testing (Q2 2022).

Submitted ethical application

Last week, Cline applied to gain an ethical permit from the Swedish Ethical Review Authority. As communicated earlier in the first half of the year, this step is necessary to begin the planned ex-vivo study in late 2021. Obtaining this means Cline can collect the necessary patient tissue material and conduct the study in a safe and ethical manner. The study has been planned and will be carried out together with Cline's clinical and academic collaborators.

The goal is to test the StemCART prototype's performance and healing ability with human joint cartilage. These tests will help the team validate the StemCART concept and refine the product. These results will then contribute to the planning and obtaining of permission to start the clinical Phase 1 in humans.

Optimization of the matrix formulation

This autumn, Cline will be conducting a project together with Chalmers University of Technology. The project will work with the formulation and methods of the StemCART supporting matrix. The matrix, which was developed during the Spring of 2021, will form an essential component of the StemCART cartilage repair implant, housing and supporting the cells. The goal of the project is to optimize the StemCART matrix material to maximize cellular viability and response. This is important to ensure cells can perform effectively in the joint and guarantee biological compatibility. The project will continue into the first half of 2022.

Development of quality testing procedure project

In the Cline cell labs, the team has initiated a project to develop a method to test cell viability within the various stages of the cells' development, from differentiation on our nanotechnology surfaces to when the cells are encapsulated within the matrix. The aim is to have a rigorous, quantifiable, and straightforward way to measure cell viability. This will both allow the team to test different methods and compositions as well as their effect on cells during product development. It will also serve as a quality control method, so Cline can ensure cells are alive and healthy (viable). Methods to evaluate quality is a central part of developing a cell-based product.

Knee injuries in the news

Over the summer, and notably during the Euro 2020 soccer championships, the public attention has turned to knee injuries and knee surgeries, an area where the StemCART-product could have a great impact in the future. Articular cartilage injury in athletes can be due to either injury or the high demands of loading on the joint leading to accelerated degradation of cartilage³. Knee injuries sustained in sports often involve cartilage damage

³ Mithoefer K, Peterson L, Zenobi-Wong M, Mandelbaum BR. Cartilage issues in football—today's problems and tomorrow's solutions. British journal of sports medicine. 2015

such as of the meniscus and lead to chondral or osteochondral defects. These injuries and knee surgery can often lead to knee osteoarthritis, which was found to be present in up to 32% of players, or a 12-fold risk increase³. Surgery options can restore some function and decrease pain, do not result in the production of hyaline cartilage³.

A recent example is Zlatan Ibrahimovic who has been out of action in the Swedish team due to a knee injury and arthroscopic lavage procedure, where the knee joint is “cleaned” of blood, fluid, and debris. This recent injury follows knee issues throughout his career which is very common to happen for football players ⁴.

Scientists, clinicians, and soccer associations are working together to bring better options for athletes, to restore their ability to play, and their long-term health. Newer techniques that utilize stem cells and tissue-engineered neocartilage present exciting future strategies for sport-associated cartilage repair³ and StemCART has the potential to offer new and better treatment for cartilage repair.

Positive trend for SMEs at the EMA

On the regulatory side of the StemCART project, the European Medicines Agency (EMA) has released a [new report](#) highlighting the Agency's support for SMEs. The EMA is responsible for the evaluation and supervision of medicinal products in the European Union. The EMA has a dedicated office responsible for the support of SME companies and provides regulatory, financial, and administrative assistance to companies such as Cline. This support can come in the form of fee exemptions, direct consultation, and training/workshops. As an advanced medicinal therapy product (ATMP) in development, StemCART will need to gain marketing authorization from EMA in the future to launch in the EU. Cline is registered as an SME to take advantage of this support.

The short report features key figures of companies that are registered as SMEs with EMA from 2016 to 2020. Some highlights include that the success rate of marketing authorization applications for human medicines submitted by SMEs has more than doubled, reaching 89% in 2020. In 2020, SMEs were behind 16 recommendations for approval. This accounted for almost 20% of all medicines for human use recommended for approval by EMA last year. These positive trends show the rising value and impact that small companies are able to make within the pharmaceutical industry.

CellRACE

The cancer diagnostic project has been continuing well since the last newsletter. Work at the lab has been focused on the refinement of gradient surface and the automating cell analysis method and establishing algorithms to predict metastasis. A new collaboration to develop such algorithms is underway and we hope to be able to present this soon. Stay tuned for the next newsletter where we will dive deeper into the current work and plan forward for our cancer diagnostics project.

⁴ https://www.eurosport.com/football/zlatan-ibrahimovic-has-keyhole-surgery-on-knee-and-expected-to-make-a-full-recovery-within-eight-wee_sto8380725/story.shtml



We will continue to keep you updated on all the above activities, keep an eye on the website and other communication channels to follow the development. Feel free to contact us if you have questions or suggestions, and do not forget to subscribe to our newsletter!

Warmest regards,

The Cline Team

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About Cline Scientific

Cline Scientific develops advanced cancer diagnostics and regenerative medicine treatments. The company is working heavily with R&D through joint collaborations with pharmaceutical companies and academic researchers around the world. The focus is on projects in the cancer diagnostic and stem cell therapy fields since Cline's nanotechnology here provides unmet solutions to critical challenges and functions. The unique patented surface nanotechnology is used in cell-based products and processes to drive projects within Life Science into and through the clinical phase.

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