Overview

Pluristyx Inc., and panCELLa are merging together to become the new Pluristyx, which will combine the competencies, technologies and operating capabilities of the original companies to create an emerging leader in the cell therapy solutions sector. The company was formed to specifically provide a true streamlined end-to-end solution to customers, thereby increasing the speed and efficiency of bringing potentially life-changing cell therapies to patients afflicted by various diseases.

Merger details/logistics

Why are Pluristyx and panCELLa merging?

We want to remove the speed bumps and obstacles in the development of safe, cost-effective, and "off-the-shelf" cell therapies so that these much-needed medicines can reach waiting patients. The Pluristyx and panCELLa merger is an exciting development for both companies, and a big step in achieving this ultimate vision.

Pluristyx's well-established cell line distribution and manufacturing expertise combine synergistically with panCELLa's genetic editing, hypoimmunogenic, and safety switch technologies. Merging together under the new Pluristyx banner, we are now able to help our customers from beginning to end — from process development and raw materials to investigational new drug submission and beyond — with an enlarged portfolio of products and services that enable the fastest speed to the clinic and commercialization.

Pluristyx and panCELLa will retain their staff and the services with which their customers are already familiar.

How does this merger and end-to-end solutions benefit customers?

This merger allows us to achieve our vision of making the process of developing and bringing cell therapies forward into clinical trials and commercialization faster and more efficient for our customers.

Through the new Pluristyx, customers can have easy access to fully consented, high-quality induced pluripotent stem cell (iPSC)-based raw materials with freedom to operate, optimized manufacturing, and genetically engineered iPSCs with built-in safety and hypoimmunogenic properties, all in one place. We aim to provide a true end-to-end solution, giving cell therapy developers the option to have a single partner with all the tools, technologies, and processes needed to go from discovery to commercialization.

Plusristyx provides its services in a standardized modular format, which can then be further fine-tuned to suit the needs of customers. Our entire suite of solutions is available for evaluation in research-grade format generated from Good Manufacturing Practice (GMP)-amenable starting material, which allows for a simpler transition from development to investigational new drug (IND)-enabling studies and clinical trials. This makes it possible for us to offer services with a phase-appropriate quality level while also providing a straightforward licensing and pricing model.

Additionally, Pluristyx is dedicated to ensuring the success of our customers' therapies. We offer consultation and process planning for projects at various stages – from raw material procurement to IND filing and beyond – and guide you through the many known and unforeseen challenges that may arise during the product life cycle.

What happens to the customer licensing agreements that are already set in place before the merger?

There will be no disruption in current activities and licensing agreements. However, current customers of Pluristyx and panCELLa now have the option to make use of complementary services and new cell line products that were not available to them before.

How can existing Pluristyx customers add panCELLa services and vice versa?

Existing customers of either Pluristyx or panCELLa can seamlessly add complementary services available from the new Pluristyx. For example, Pluristyx customers can add panCELLa's technologies that enable next-generation cell therapies to their existing Pluristyx products, while panCELLa customers can access Pluristyx's cell expansion and banking services, or panCella cell lines packaged in Pluristyx's proprietary Ready-to-Differentiate® format that requires no pre-expansion prior to differentiation.

Our current customers now have the option to remain with us from the procurement of starting materials all the way through to manufacturing, potentially simplifying their reliance on multiple suppliers to achieve their goal.

To explore what services or products can be added to your existing agreement, please contact Brian.Hawkins@pluristyx.com or Jake.krembil@pancella.com.

Corporate/general

What is unique about the new Pluristyx?

The new Pluristyx combines the synergistic strengths of the original Pluristyx's induced pluripotent stem cell (iPSC) reprogramming technology and banking expertise with panCELLa's

genetic engineering technologies that differentiate them from the other players in the industry. Now, customers can seamlessly access and evaluate high quality cell banks of genetically edited iPSCs at both research and clinical grade for suitability from a single source, which effectively accelerates research and development of their cell therapy programs.

Pluristyx offers a portfolio of technologies, products and complementary expertise that provides unparalleled support during early product development. This includes providing well-characterized and Ready-to-Differentiate® cell lines that lower the barrier to obtaining and evaluating iPSCs for use in clinical products. Plursityx also offers manufacturing, banking, scaling, and cryopreservation services, alongside process development and consultation to seamlessly incorporate iPSCs into existing product workflows.

panCELLa offers a wide array of unique and effective technologies, with particular strength in gene editing. Its FailSafe™ safety switch technology enables iPSC-based therapies with unparalleled control by allowing the ability to stop uncontrolled proliferation or kill dividing cells within patients after transplantation. Its induced allogeneic cell tolerance stealth cell technology can create hypoimmunogenic cells from donors, which paves the way for universal "off-the-shelf" cell therapies.

What is the long-term vision for the new Pluristyx?

Pluristyx's vision is to provide researchers and drug developers with an efficient route to creating therapies using induced pluripotent stem cells (iPSCs) and other types of cells, whether for novel CAR-T and CAR-NK therapies or the next generation of regenerative medicine cures. Pluristyx and panCELLa merged for this very reason. As a combined company, they can provide customers a single point of access for the necessary technology, cell lines and adjacent services, including the ability to successfully freeze and thaw cells for global distribution.

The combined companies want to expedite and simplify the process of procuring starting materials and cells that meet the high bar of Good Manufacturing Practice (GMP), so that customers can rapidly advance through the typical bottlenecks of iPSC-based therapies and focus their resources and attention on bringing much-needed solutions to patients.

Will Pluristyx add new capabilities or services in the future?

The newly combined company will be focused on providing a seamless experience for both existing and future Pluristyx customers. We strive to stay ahead-of-the-curve by investing in our induced pluripotent stem cell (iPSC) pipeline to introduce next-generation products and services following full integration.

Technology/programs

What cell lines and therapeutic areas does Pluristyx specialize in?

Pluristyx provides a variety of stem cell lines:

- Induced pluripotent stem cells (iPSCs) developed using our proprietary mRNA-based reprogramming technology
- Genetically modified iPSCs containing FailSafe™ and hypoimmunogenic technologies
- Conditionally-immortalized iPSCs
- 49 disease-affected human embryonic stem Cells (hESCs) lines for primary research, including hypertrophic cardiomyopathy, Huntington's Disease, and Duchenne Muscular Dystrophy genetically that can be paired with 22 matched control hESCs
- 6 clinical grade hESC lines for product development

All hESC lines are compliant with global ethical standards and clinical cell regulations and have also been approved by the National Institutes of Health. iPSCs and hESCs are available in standard and Ready-to-Differentiate® format of 25 and 100 million cells per vial that require no further expansion. These cells can be used in a variety of studies – including kidney, liver, heart, and oncology indications – with a particular strength in differentiation into T cell and natural killer (NK) cell lineages.

What kinds of modifications can Pluristyx make to cells?

Pluristyx's first proprietary technology, FailSafe™, can edit and engineer cells for increased safety by adding a "kill switch" to cells that can stop uncontrolled proliferation. This patented technology acts on cell division loci and does not interfere with the biological properties of the edited cells.

The second technology platform, induced allogeneic cell tolerance (iACT) Stealth Cells®, enables the creation of induced pluripotent stem cells (iPSCs) that are able to avoid provoking an immune response in the recipient and help ensure long-term allograft tolerance. By targeting eight specific cell-surface and local-acting genes that modulate the immune response, iACT Stealth Cells function as universal donors well suited for off-the-shelf regenerative medicine therapies without the need for patients to undergo immunosuppressive treatments in advance.

Besides FailSafe and iACT Stealth Cells, Pluristyx can also make other types of edits, which can range from knocking in/out genes, gene insertion, conditional regulation of expression, immortalization, and specific differentiation. We use many different types of gene editing

technologies to achieve these results, and all edits are assessed with whole genome sequencing to ensure quality.

How do your cell lines and services compare to other providers?

Pluristyx's goal is to help clients easily transition from research to clinical trials by adhering to regulatory guidelines and industry best practices during all stages of development, which can prove costly and time-consuming and could result in a clinical hold and project termination.

Pluristyx's clinical-grade cell lines and services are all held to Good Manufacturing Practice (GMP) standards. We also conduct extensive validation and quality assurance procedures to ensure the viability and performance of our products. Our induced pluripotent stem cells (iPSCs) are manufactured using well defined and reproducible processes that ensure highly repeatable differentiation and development, so that cells remain reliable and perform consistently in all manufacturing locations and workflows.

To ensure the highest likelihood of success, Pluristyx provides advanced cell therapy expertise from start to finish through consultation services, tailored process development, and customer service.

How does Pluristyx ensure quality control across its end-to-end technology portfolio?

Pluristyx's goal is to ensure that quality control regulations aren't a hindrance or bottleneck in moving promising cell therapies from preclinical studies to clinical trials. The combined company adheres to strict internal and external quality measures, across all its products and services, including compliance to Good Manufacturing Practices (GMP) for our clinical cell lines. Pluristyx's high bar starts with GMP-compliant starting material for induced pluripotent stem cell (iPSC) reprogramming, with regular testing and checkpoints throughout the entirety of the gene-editing and banking process.

Pluristyx has developed a variety of standardized modular services that meet our high bar for quality, which can be selected and then further tailored to meet the specific needs of our customers. We also place great emphasis on ensuring reduced lot-to-lot variability and the repeatability of our products and processes for downstream research and development. Pluristyx assesses manufactured cell lines using the most current testing methods available, such as whole genome sequencing to ensure proper edits have been made to FailSafe™ and induced allogeneic cell tolerance cells. Additionally, we have invested in strengthening the traceability of our cells through Short Tandem Repeat sequencing.

Pluristyx's clients can also take advantage of our Research Evaluation Agreement – a unique "try-before-you-buy" program – to assess the quality and performance of our products and technology before making a commitment.

Is there a way I can try Plursityx's products and/or services before making a commitment?

Yes, there is. Pluristyx has a unique "try-before-you-buy" Research Evaluation Agreement (REA). The REA model involves a nominal upfront fee for a predetermined evaluation period,where customers can test multiple cell lines and/or processes to evaluate and find the most effective fit for their own purpose Once the REA is completed and the customer is ready to move forward, standard licensing of the selected products and services is available and is handled by Pluristyx directly, without the need to negotiate with multiple licensing partners. All of Pluristyx's services, from cell lines and processes to gene editing services, qualify for the program. Additionally, Pluristyx provides a price quote upfront.

panCELLa developed the REA program prior to the merger due to the variety of cell lines and modifications available for any single purpose. The model allows customers to assess the performance, quality and viability of multiple products before making a final selection for their programs and commitment to a licensing agreement.

This arrangement is unique to Pluristyx, especially in an industry where the traditional model requires a large upfront payment and may lock customers to a particular cell line that may not be the best fit, with no easy path to change course. To date, companies and organizations of all sizes – from early-stage startups to established biopharma – have taken advantage of our REA.