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CollPlant's Collink.3D® BioInks and Technologies Offer a Relevant and Timely Solution to FDA's Plan to Reduce Animal Testing in Preclinical Safety Studies

CollPlant's novel rhCollagen BioInks are an available solution aligned with FDA's plan announced last week to phase out the animal testing requirement for the development of monoclonal antibody therapies and other drug candidates

REHOVOT, Israel, April 15, 2025 /PRNewswire/ -- CollPlant Biotechnologies (NASDAQ: CLGN), or "CollPlant", a regenerative and aesthetics medicine company developing innovative technologies and products based on its non-animal-derived, rhCollagen for tissue regeneration and medical aesthetics, commented today, following the United States Food and Drug Administration (FDA)'s groundbreaking step announced last week to advance public health by replacing animal testing in the development of monoclonal antibody therapies and other drug candidates with more effective, human-relevant methods. Importantly, CollPlant's Collink.3D® portfolio of rhCollagen-based BioInk products can be utilized for the biofabrication of tissue-on-a-chip or organ-on-a-chip systems, which serve as alternatives to animal testing. These systems can expedite the gap between benchtop studies and clinical trials, as well as be more economical and enable a reduced time to market.



Yehiel Tal, CollPlant's Chief Executive Officer, commented, "The FDA's new approach to develop alternatives for use in place of traditional animal testing, often referred to as 'New Approach Methodologies', or NAMs, is designed to improve drug safety and accelerate the evaluation process, while reducing animal experimentation, lowering research and development costs, and ultimately, drug prices. CollPlant's novel rhCollagen-based Collink.3D portfolio of BioInk products supports the FDA's NAMs since they can be used in a wide variety of non-animal testing applications. For example, CollPlant's BioInk products are ideal for the biofabrication of tissue-on-a-chip or organ-on-a-chip systems used for drug discovery and regenerative medicine applications and are designed to be compatible with *in-vitro* human-based systems like organoids. We anticipate that our BioInks will be instrumental to enable alternatives for achieving the goal of phasing out animal testing in five years."

Mr. Tal added, "CollPlant has also developed Computational Modeling and Simulation (CM&S) methodologies to assist in the development of its regenerative breast implant product candidate. Mimicry of the implant and human body interaction using CM&S, enables precise prediction of mechanical behavior of the implants in the body, as well as provides information about degradation kinetics, tissue remodeling and interaction with the host tissue. These smart tools are reducing the need for animal studies and are accelerating the development of safer and more effective human-specific solutions. The same development tools can be applied to any other soft or hard tissue type to optimize the development of regenerative implants."

About Collink.3D BioInk

CollPlant's **Collink.3D** BioInk pipeline consists of the first and only line of human collagen BioInk products based on chemically modified plant-derived rhCollagen that is mass-produced with high purity and consistency.

CollPlant's BioInk **Collink.3D** pipeline of products are based on a methacrylated form of its rhCollagen which can be used for 3D bioprinting of tissues and organs. CollPlant's BioInk is currently being utilized for the printing of its regenerative breast implants in development. By combining biomaterials and synthetic polymers, CollPlant Collink.3D can be utilized for tissue-on-a-chip or organ-on-a-chip systems, which enable real-time, human-relevant assessment of immune responses, degradation, and tissue remodeling.

Collink.3D enables scalable and reproducible biofabrication of tissue models, tissues, and organ transplants, while perfectly mimicking the native properties of tissues and organs. Additionally, it provides the advantage of being animal-free, has the properties of optimal rheology at room temperature, supports high viability of different cell types and is biocompatible and non-immunogenic.

About the U.S. FDA Announcement to Phase Out Animal Testing

On April 10, 2025, the FDA [announced](#) a plan to phase out animal testing as a requirement for the pre-clinical development of monoclonal antibodies and other drugs.

The FDA's statement specifies that within 3–5 years, animal testing may become the exception. Incentives and collaborative efforts across industry and government are accelerating this shift. This is intended to be the road to safer drugs, reduced development timelines and ethical research practices.

About CollPlant

CollPlant is a regenerative and aesthetic medicine company ushering in a new era of medical solutions with a focus on 3D bioprinting of tissues and organs, tissue repair and medical aesthetics. The Company's products are based on its rhCollagen (recombinant human collagen) produced with CollPlant's proprietary plant-based genetic engineering technology. These products address indications for the diverse fields of tissue repair, aesthetics, and organ manufacturing.

In 2021, CollPlant entered into a development and global commercialization agreement for dermal and soft tissue fillers with Allergan, an AbbVie company, the global leader in the dermal filler market.

For more information about CollPlant, visit <http://www.collplant.com>

Forward-Looking Statements

This press release includes forward-looking statements. Forward-looking statements include, but are not limited to, statements relating to CollPlant's objectives plans and strategies, as well as statements, other than historical facts, that address activities, events or developments that CollPlant intends, expects, projects, believes or anticipates will or may occur in the future. These statements are often characterized by terminology such as "believes," "hopes," "may," "anticipates," "should," "intends," "plans," "will," "expects," "estimates," "projects," "positioned," "strategy" and similar expressions and are based on assumptions and assessments made in light of management's experience and perception of historical trends, current conditions, expected future developments and other factors believed to be appropriate.

Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statements. Many factors could cause CollPlant's actual activities or results to differ materially from the activities and results anticipated in forward-looking statements, including, but not limited to, the following: the Company's history of significant losses, its need to raise additional capital and its inability to obtain additional capital on acceptable terms, or at all, including uncertainties surrounding the methods of fundraising and the Company's preferences regarding such methods; the Company's expectations regarding the costs and timing of commencing and/or concluding pre-clinical and clinical trials with respect to breast implants, tissues and organs which are based on its rhCollagen based BioInk and other products for medical aesthetics, and specifically the Company's ability to initiate its next large-animal study for its breast implants in a timely manner, or at all; the Company's or Company's strategic partners' ability to obtain favorable pre-clinical and clinical trial results; regulatory action with respect to rhCollagen-based BioInk and medical aesthetics products or product candidates including, but not limited to, acceptance of an application for marketing authorization review and approval of such application, and, if approved, the scope of the approved indication and labeling; commercial success and market acceptance of the Company's rhCollagen based products, in 3D Bioprinting and medical aesthetics; the Company's ability to establish sales and marketing capabilities or enter into agreements with third parties and its reliance on third party distributors and resellers; the Company's ability to establish and maintain strategic partnerships and other corporate collaborations, including its partnership with AbbVie and its ability to continue to receive milestone and royalties payments under the AbbVie agreement; the Company's reliance on third parties to conduct some or all aspects of its product development and manufacturing; the scope of protection the Company is able to establish and maintain for intellectual property rights and the Company's ability to operate its business without infringing the intellectual property rights of others; current or future unfavorable economic and market conditions and adverse developments with respect to financial institutions and associated liquidity risk; the impact of competition and new technologies; general market, political, and economic conditions in the countries in which the Company operates, including, with respect to the ongoing war in Israel, projected capital expenditures and liquidity, changes in the Company's strategy and development plans and projects, and litigation and regulatory proceedings. More detailed information about the risks and uncertainties affecting CollPlant are contained under the heading "Risk Factors" included in CollPlant's most recent annual report on Form 20-F filed with the SEC, and in other filings that CollPlant has made and may make with the SEC in the future. The forward-looking statements contained in this press release are made as of the date of this press release and reflect CollPlant's current views with respect to future events, and CollPlant does not undertake and specifically disclaims any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

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