



Morphogenesis Successfully Completes its First-in-human Phase 1 Clinical Trial for Melanoma

Tampa, FL, August 17, 2020 – Morphogenesis, Inc., a clinical-stage biotechnology company based in Tampa, Florida, developing immunotherapies to treat patients with cancer, is excited to announce the successful completion of the Company’s first-in-human Phase 1 clinical trial for its cancer immunotherapeutic (IFx-Hu2.0). During the course of the trial, the investigational product was well tolerated, and patient follow-ups demonstrated no noteworthy safety issues directly related to the therapy.

This important trial will serve as the foundation for Morphogenesis’ transition into later phase clinical trials—that further study the efficacy of IFx-Hu2.0. Phase 1’s completion and success is positive news for patients as well as Morphogenesis as the Company looks forward to furthering its clinical development goals. “This is a major milestone for Morphogenesis. As we think back to all the hard work that went into this achievement and celebrate it, we are also excited about what this means for patients moving forward as we progress through the phases of clinical development and continue on a path to providing a safe and efficacious treatment option for patients,” said Dr. Michael Lawman, President and Co-Founder.

The successful completion of this study and the continued achievements of Morphogenesis marks a significant advancement of Tampa Bay businesses, especially biotech initiatives. This has the potential to drive future funding for successive phases of clinical development. “I am extremely proud of the Morphogenesis team and what we have been able to accomplish. We would like to thank all our patients who chose to participate and were able to provide us with invaluable clinical information. We also look forward to advancing the use of our immunotherapy in larger scale studies. From a business perspective, this is a major inflection point for the Company that we intend to capitalize on by driving more investment funds to Morphogenesis,” said Dr. Kiran Patel, Chairman of the Board.

About the study:

Six patients with Stage 3 or Stage 4 metastatic melanoma who could not be treated with surgery and/or had failed or refused other treatments were enrolled in the Phase 1 clinical trial. The immunotherapeutic Morphogenesis developed (IFx-Hu2.0) was injected directly into one, two, or three melanoma skin tumors. The patients were assessed over a four-week period, primarily to establish the safety of the immunotherapy. Subsequent clinical development milestones will include larger Phase 2 studies, involving 60 to 100 patients. Dr. Patricia Lawman, CEO and Co-Founder noted, “As we celebrate this achievement, we cannot help but think of the patients’ families. When a patient is diagnosed with such a devastating disease the entire family is affected. We are extremely proud to be able to provide a promising treatment option that is both safe and simple to help cancer patients and their families through what we know to be a very challenging healing process.”

About Morphogenesis, Inc.

Founded by Drs. Michael J.P. Lawman, Ph.D. (President) and Patricia D. Lawman, Ph.D. (Chief Executive Officer) and now celebrating its 25th Anniversary, Morphogenesis, Inc. is a clinical-stage biotechnology company based in Tampa, Florida, developing immunotherapies to treat patients with cancer. The clinical Phase 1 trial of its lead biological product, IFx-Hu2.0, for the treatment of patients with cutaneous melanoma has successfully concluded at Moffitt Cancer Center ([NCT03655756](#)). In another clinical Phase 1 trial, IFx-Hu2.0 is actively being investigated for the treatment of patients with Merkel cell carcinoma or cutaneous squamous cell carcinoma across National Cancer Institute-designated Comprehensive Cancer Centers in the United States ([NCT04160065](#)).

To learn more about Morphogenesis visit morphogenesis-inc.com.

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