



Origin™ Announces Positive Interim Results from Phase IIb Dose-Ranging Study for Diabetic Foot Ulcers

- Interim results demonstrate strong evidence of healing and favorable safety profile
- Highest-performing arm (4X per week, 12 minutes):
 - 95% mean wound-size reduction in 12 weeks
 - 71% of wounds achieved complete healing in 12 weeks
- Goals of dose-ranging study on track to be fully met
- All arms outperformed standard of care industry average for complete wound closure
- Full results expected to serve as the basis for the pivotal trial study design

Princeton, New Jersey - October 26, 2017 - Origin, Inc. (formerly Advanced Plasma Therapies, Inc.), a Princeton, NJ based clinical-stage biotechnology company, today announced positive interim results from its “GENESIS” dose-ranging (Phase IIb) trial of plasma-generated nitric oxide in patients with chronic diabetic foot ulcers (DFUs). In addition to meeting its primary outcome measure of safety, interim results from the “GENESIS” trial demonstrated strong evidence of healing. Origin has developed a proprietary technology which, for the first time, generates and delivers therapeutic quantities of plasma-generated nitric oxide (NO) into the tissue, potentially addressing a wide range of unmet medical needs.

Key interim results from GENESIS include 95% average wound-size reduction at 12 weeks with 71% of wounds achieving complete closure (12-minute dose of NO treated 4 times per week, along with SOC).

“These are excellent early results. They suggest that our NO therapy compares favorably to the average 55% closure rate of a number of other approved advanced wound products,¹⁻⁹” said Michael Preston, Chairman and CEO of Origin. “A comparison of our results with data available from other studies suggests that our strongest performing arm healed chronic DFUs better than almost all currently available or well-publicized products.¹⁻⁹”

Dr. Patrick Briggs of Texas Gulf Coast Medical Group, and a GENESIS investigator, said the innovative therapy was far different from any other therapy for foot and ankle wounds.

“I am excited about this therapy because it’s new, different, and outside anything else I’ve seen. We have nothing today to deal with the microvascular issues that are associated with diabetic foot wounds. I’m really looking at that vasodilatory effect that you can get with nitric oxide,” Dr. Briggs commented.

Origin’s technology enables the physician to generate and deliver a high-quality therapeutic dose of plasma-streamed NO at the point of care. This unique system ensures that each patient consistently receives the intended treatment directly into the affected wound tissue.

Mr. Preston added: “With our novel therapy, we expect to address a critical unmet need for the approximately two million people in the U.S. currently suffering from chronic DFUs¹¹⁻¹². The development of a safe and effective wound-closure treatment for chronic DFUs, which frequently lead to limb amputation, represents an increasing medical need and significant market opportunity. The full study results are expected to serve as the basis for the pivotal trial study design.”

In GENESIS, patients are treated for up to 12 weeks and then monitored with regular follow-up visits for another 12 weeks post treatment. This planned interim analysis includes patients who either healed within 12 weeks or completed the treatment phase of the trial. An additional 11 subjects remain in the treatment phase and will be included in ongoing analysis of the data. A total of 18 patients dropped out of the trial, with no device-related adverse events reported at this time.

Study Design

GENESIS is a 27-week study recruiting up to 100 patients across 15 clinical sites in the U.S. designed to demonstrate safety and healing, and determine the optimal treatment regimen for chronic diabetic DFUs. After a two-week run-in period, patients are randomized into one of four different dosing regimens or a SOC-only treatment arm. Wound sizes range from 1.0 – 9.9 cm².

- Arm 1: SOC alone, including dressing changes, wound cleansing, pressure relief (off-loading) and wound debridement.
- Arm 2: 6-minute dose of plasma-generated nitric oxide, 2 times per week, along with SOC.
- Arm 3: 6-minute dose of plasma-generated nitric oxide, 4 times per week, along with SOC.
- Arm 4: 12-minute dose of plasma-generated nitric oxide, 2 times per week, along with SOC.
- Arm 5: 12-minute dose of plasma-generated nitric oxide, 4 times per week, along with SOC.

“DFUs affect as many as 15%¹³ of the 30 million diabetic patients¹¹ in the U.S. and are responsible for more hospitalizations than any other diabetic complication, thereby representing a significant cost to the healthcare system,” said Dr. David Dantzker, Vice Chairman and CMO of Origin, and former Chairman of the American Board of Internal Medicine. “We believe that NO has the potential to change not only the trajectory of wound healing, but also the underlying biology by which wounds heal. Furthermore, our therapy has the potential to address additional sizeable markets, including unmet needs in other areas of wound care, dermatology, dental, skin infection, and inflammation and pain.”

About DFUs

Diabetic foot ulcers are chronic, non-healing, penetrating wounds of the foot in patients with type 1 and type 2 diabetes mellitus. Over 30 million people in U.S. have diabetes¹¹ and it is estimated that at least 15%¹³ will develop a DFU resulting in \$11,000-16,000 annual incremental cost per patient¹⁴ (excluding amputation). Approximately 60% of these wounds are not healed after initial treatment with standard of care and are then considered chronic¹⁵. An estimated 85% of all diabetic lower-extremity amputations are preceded by a chronic, non-healing foot ulcer¹⁶ and approximately 15% of diabetic patients will have an amputation during their lifetime¹⁷. The five-year mortality rate for DFU patients with an amputation is estimated up to 74%, higher than that for several types of cancer including breast, colon, prostate and Hodgkin’s disease¹⁸.

About Origin

Origin, Inc. (formerly Advanced Plasma Therapies, Inc.) is a clinical-stage biotechnology company that applies its proprietary technology to generate and deliver Nitric Oxide (NO) from a defined high-energy plasma stream. This targeted, plasma-generated NO stream penetrates the tissue to achieve its therapeutic effect. NO is a biologically active agent, shown to modify disease pathways through anti-microbial, anti-inflammatory, tissue-regenerative and vasodilatory activities. Origin's technology will be initially studied in several highly unmet conditions, including the treatment of wounds, ulcers, and acute and chronic infections. Origin's first planned product is a therapy for use in treating diabetic foot ulcers (DFU), a condition that results in an estimated \$9-\$13 billion of US annual healthcare costs¹⁴. Further studies are planned outside of the US to address this global epidemic. Origin, Inc. was founded in 2010 and is based in Princeton, New Jersey.

For more information, please visit www.originww.com.

¹ BioDrugs. 2002;16(6):439-55.; ² Diabetes Care 2003 Jun; 26(6): 1701-1705.; ³ Ostomy Wound Manage. 2006 Jun;52(6):68-70, 72, 74 passim.; ⁴ Int Wound J. 2013 Oct; 10(5): 502-507.; ⁵ Int Wound J. 2009 Jun;6(3):196-208.; ⁶ <https://www.prnewswire.com/news-releases/new-study-shows-diabetic-foot-ulcers-treated-with-oasis-ultra-tri-layer-matrix-demonstrated-significantly-better-and-more-rapid-wound-closure-compared-to-standard-care-300074793.html>; ⁷ Ostomy Wound Manage. 2005 Aug;51(8):24-39.; ⁸ WOUNDS. 2013;25(12):340-344.; ⁹ Wound Repair Regen. 2015 Nov-Dec;23(6):891-900.; ¹⁰ The International Journal of Lower Extremity Wounds Vol 10, Issue 4, pp. 218 – 223.; ¹¹ <https://www.healio.com/endocrinology/diabetes/news/in-the-journals/%7B476de9eb-1079-49bc-a35a-57fa20086cfa%7D/cdc-100-million-americans-have-diabetes-or-prediabetes-accessed-07/19/17>; ¹² Margolis D, Malay DS, Hoffstad OJ, et al. Incidence of diabetic foot ulcer and lower extremity amputation among Medicare beneficiaries, 2006 to 2008 [article online], 2011.; ¹³ Singh N., Armstrong D. G., Lipsky B. A. Preventing foot ulcers in patients with diabetes. The Journal of the American Medical Association. 2005;293(2):217-228. doi: 10.1001/jama.293.2.217.; ¹⁴ Rice et al. Burden of Diabetic Foot Ulcers for Medicare and Private Insurance. Diabetes Care. 2013.; ¹⁵ Frykberg RG, Banks J. Challenges in the Treatment of Chronic Wounds. Advances in Wound Care. 2015;4(9):560-582. doi:10.1089/wound.2015.0635; ¹⁶ Deshpande et al. Epidemiology of Diabetes and Diabetes-Related Complications. Physical Therapy. 2008;88(11):1254-1264. doi:10.2522/ptj.20080020.; ¹⁷ Jonasson et al. Risks of Nontraumatic Lower-Extremity Amputations in Patients with Type 1 Diabetes. Diabetes Care 2008 Aug; 31(8): 1536-1540; ¹⁸ Robbins JM, et al. Journal of the American Podiatric Medicine. 2008; vol. 98, issue 6

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