

Lindsay Rosenwald's Fortress Bio (NASDAQ: FBIO) Spotlight on 2024 Milestones from Subsidiaries

Fortress Biotech, a unique biotech company led by industry veteran Dr. Lindsay Rosenwald, has announced multiple new significant milestones to start 2024.

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[Fortress Biotech](#) (Fortress Bio), a unique biotech company led by industry veteran [Dr. Lindsay Rosenwald](#), focused on identifying, in-licensing and developing high-potential marketed drugs and development-stage drug candidates in-house and through its subsidiary partner companies, has announced multiple new milestones to start 2024 with a bang.



Avenue Therapeutics Finalizes Phase 3 Study for IV Tramadol with FDA

Avenue Therapeutics, a subsidiary of Fortress Bio, has reached a significant milestone in its quest to introduce new therapies for neurologic diseases. The company has finalized an agreement with the U.S. Food and Drug Administration (FDA) on a Phase 3 safety study for intravenous (IV) tramadol. This drug, currently in development, is aimed at treating acute post-operative pain in medically supervised settings.

The pivotal non-inferiority study will assess the risk of opioid-induced respiratory depression linked to opioid stacking in IV tramadol compared to IV morphine. The study will involve around 300 patients undergoing bunionectomy, comparing the effects of IV tramadol to IV morphine over a 48-hour post-operative period. This study follows the success of IV tramadol in two previous Phase 3 efficacy trials. Avenue Therapeutics' CEO, Dr. Alexandra MacLean, expressed optimism about the trial, noting the collaborative efforts with the FDA and the potential of IV tramadol in managing acute post-operative pain safely. The trial's success could lead to FDA approval of IV tramadol, offering a new pain management option for patients in the United States.

Journey Medical Corporation Submits NDA for [DFD-29](#) to Treat Rosacea

In another significant development, Journey Medical Corporation, also a Fortress Biotech subsidiary, has submitted a New Drug Application (NDA) to the FDA for DFD-29. This drug, designed for the treatment of rosacea, could revolutionize the approach to this skin condition.

DFD-29, or Minocycline Hydrochloride Modified Release Capsules (40 mg), aims to treat both inflammatory lesions and erythema (redness) associated with rosacea. This submission follows the success of two Phase 3 clinical trials, which met all primary and secondary endpoints without significant safety issues.

Claude Maraoui, Co-Founder, President, and CEO of Journey Medical, highlighted the potential of DFD-29 as a best-in-class oral treatment for rosacea, noting its superiority over existing treatments and placebo in clinical trials. The drug's approval could benefit the approximately 16 million Americans suffering from rosacea, providing a comprehensive treatment option for both inflammatory lesions and erythema.

Conclusion

These developments from Avenue Therapeutics and Journey Medical Corporation, subsidiaries of Fortress Bio, mark the start of an exciting year for the company. The progress in the development of IV tramadol and DFD-29 showcases Fortress Bio's commitment to advancing medical treatments and enhancing patient care. These milestones reflect the company's strategic direction and potential in 2024, potentially offering hope for new, effective treatment options in neurology and dermatology.

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