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Peptilogics Begins Pivotal Trial of First-Ever Drug Designed to Cure Medical Device-Related Infections

First Patient Enrolled in RETAIN Phase 2/3 Registration Trial of PLG0206, a First-in-Class Anti-Biofilm Drug Initially Targeting Prosthetic Joint Infection

PITTSBURGH – March 10, 2026 – ***Peptilogics***, a surgical therapeutics company dedicated to curing and preventing devastating medical device-related infections (MDRI), has announced the enrollment of the first patient in the ***RETAIN*** Phase 2/3 registration trial by Dr. Toan Le at the University of Cincinnati Medical Center. The trial is evaluating ***PLG0206***, a first-in-class anti-biofilm drug candidate, in patients with prosthetic joint infection (PJI), the first of multiple potential MDRI indications. PJI represents the largest unmet need in orthopedics and a significant entry point into a broader MDRI market that affects millions of patients annually.

Approximately five million joint replacements are performed each year across the U.S., the U.K., and Europe.[1] In two percent of cases, a protective matrix called biofilm forms on implant surfaces, shielding bacteria from antibiotics and the immune system and resulting in PJI.[2] The condition can occur quickly or even years after surgery. The current standard of care for PJI calls for two-stage revision surgery, where the infected prosthesis is removed. This approach carries a 15–25 percent failure rate, subjects patients to multiple procedures and leads to 25 percent five-year mortality.[3,4,5] The estimated total economic burden of PJI is $20 billion annually in the U.S. alone.[1,2,6] These outcomes persist in PJI – and across all MDRI – because existing treatments consistently fail to eradicate the persister bacteria protected by the biofilm.

“RETAIN is a landmark trial that will determine whether PLG0206 can provide surgeons a proven, durable cure for prosthetic joint infection,” said Javad Parvizi, MD, FRCS, Professor of Orthopedic Surgery, Acibadem University, Istanbul, and past president of the American Association of Hip

and Knee Surgeons. “Total joint arthroplasty is very successful in restoring function, mobility, and quality of life, but infection after joint replacement is a truly devastating complication that robs patients of that outcome and, in far too many cases, their lives. I’m excited about the promise of PLG0206 as a first-in-class treatment for patients with PJI, and as a potential solution for all medical device-related infections in the future.”

RETAIN is a randomized, double-blind, placebo-controlled, multi-center Phase 2/3 registration trial evaluating PLG0206 in patients undergoing DAIR (Debridement, Antibiotics, and Implant Retention) surgery to treat PJI following total knee arthroplasty (TKA). The study is designed to assess superiority versus standard of care, with a primary endpoint of treatment failure at 12 months and a key secondary endpoint of PJI-related surgical intervention at 12 months. The trial is anticipated to enroll up to 240 patients across up to 50 planned clinical sites.

The RETAIN trial builds on an earlier Phase 1 study establishing the safety profile of PLG0206 and a Phase 1B study demonstrating safety and preliminary efficacy in patients with PJI where only one of thirteen PLG0206-treated patients had a recurrence of infection by 12 months (a seven percent failure rate).[7,8] In contrast, a 12-month failure rate of 35 to 55 percent has been reported with current standard of care.[9,10]

“Biofilm is the root cause of medical device-related infections, and no approved therapy has ever been designed to target it,” said Jonathan Steckbeck, Ph.D., Peptilogics CEO. “We built PLG0206 from the ground up as the first drug to penetrate biofilm and eradicate the persister bacteria protected by it. PJI is our first indication because it is the largest and most acute unmet need, but the biofilm biology is identical across all device categories. If we are successful in RETAIN, we will have demonstrated a platform with the potential to cure and prevent infections wherever a medical device is implanted – a multi-billion dollar category-defining therapeutic.”

There are 55 million people in the U.S. alone living with medical devices and implants which span joint replacements, cardiovascular assist devices,

spinal fusion hardware, trauma fixation, hernia mesh, breast implants post mastectomy, and vascular grafts.[10,11,12] Across these categories, bacterial biofilm is the primary driver of serious device-related infections. No approved therapy has been specifically designed to target biofilm, leaving clinicians reliant on systemic antibiotics, repurposed generics, and surgical revision to manage infections that frequently recur.

PLG0206 acts against a broad range of bacteria including multi-drug-resistant pathogens, fits into existing surgical workflows, and offers low resistance potential. PLG0206 has received Qualified Infectious Disease Product (QIDP) designation, which provides five additional years of market exclusivity upon approval, as well as Orphan Drug and Fast Track designations from the U.S. Food & Drug Administration (FDA) for the treatment of Prosthetic Joint Infections (PJIs), reflecting the severity of the unmet need and the potential for an expedited path to market.

For more information on PLG0206 and the RETAIN trial, please visit ***https://peptilogics.com/pipeline/***.

Presight Capital, Thiel Bio, and Founders Fund led the round, with participation from new investors AMR Action Fund, Narya Capital, and Beyond Ventures. This brings Peptilogics' total equity funding to approximately $120 million, along with substantial grant support from CARB-X.

"What these investors understood is that hardware-related infections like PJI are different from other common infections. We chose to focus on this huge unmet need because the lack of effective therapeutic options alters the commercial landscape that has made antibiotic development difficult," said Peptilogics' CEO Jonathan Steckbeck, PhD. "Developing treatments for these infections allows us to create a new category of surgical therapeutics for patients who currently have to undergo multiple life-changing surgeries to eliminate the infection."

About the RETAIN Trial

(NCT07214311)

RETAIN is a Phase 2/3, randomized, double-blind, placebo-controlled clinical study evaluating the efficacy and safety of PLG0206 in patients undergoing Debridement, Antibiotics, and Implant Retention (DAIR) for the treatment of periprosthetic joint infection (PJI) following Total Knee Arthroplasty (TKA). The trial is expected to enroll approximately 240 participants. The primary endpoint is treatment failure, assessed 12 months after DAIR. A key secondary endpoint is the need for PJI-related surgical intervention, also evaluated at 12 months post-treatment. For more information, visit ***https://clinicaltrials.gov/study/NCT07214311#study-overview***.

About Peptilogics

Peptilogics is a surgical therapeutics company dedicated to curing and preventing devastating medical device-related infections (MDRI). Peptilogics' lead candidate, PLG0206, is a first-in-class drug that targets biofilm, a protective bacterial matrix that is the root cause of device infections across surgical categories, and has no approved cure to date. PLG0206 is currently being evaluated in a Phase 2/3 registration trial for the treatment of prosthetic joint infection (PJI), the first of multiple potential indications to treat and prevent MDRI.

Forward-Looking Statements

This press release contains "forward-looking statements" that involve substantial risks, assumptions and uncertainties. Forward-looking statements are often identified by words such as, but not limited to, "believe," "estimate," "intend," "may," "plan," "potentially," "will," "expect," "enable," "likely" or the negative of these terms or other similar expressions. All statements, other than statements of historical facts, regarding management's expectations, beliefs, goals, plans or Peptilogics, Inc. prospects should be considered forward-looking statements. Readers are cautioned that actual results may differ materially from projections or estimates due to a variety of important factors. These forward-looking

statements are made as of the date of this press release, and Peptilogics, Inc. assumes no obligation to update the forward-looking statements, or to update the reasons why actual results could differ from those projected in the forward-looking statements, except as required by law.

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