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Apimeds Pharmaceuticals and Lōkahi Therapeutics Announce FDA Type C Meeting Scheduled for LT-100 (Apitox)

MATAWAN, N.J. & LA JOLLA, Calif.--(BUSINESS WIRE)-- Apimeds Pharmaceuticals US, Inc. and Lōkahi Therapeutics, Inc. today announced that the U.S. Food and Drug Administration (FDA) Division of Anesthesiology, Addiction Medicine and Pain Medicine (DAAP) has confirmed a Type C meeting to discuss LT-100 (Apitox), a non-opioid biologic candidate being developed for the treatment of the signs and symptoms of osteoarthritis (OA). The meeting will be conducted via teleconference on Monday, May 4, 2026.

The scheduled interaction follows the recent submission of a Type C meeting request and represents an important step in the coordinated U.S. regulatory strategy for LT-100. The meeting is intended to support alignment with the FDA on key development considerations and the overall path forward for the program in the U.S.

LT-100 is pure honeybee venom, with a long history of clinical investigation. The product was originally developed and approved in South Korea, where it was approved for marketing in South Korea by the Korean Food and Drug Administration (KFDA; now the Ministry of Food and Drug Safety [MFDS]). Apimeds and Lōkahi Therapeutics are now advancing the program in the U.S. by integrating its historical data with rigorous development standards.

“LT-100, which is currently undergoing manufacturing process enhancements, is taking an important next step toward clinical advancement as we work to align with the FDA on future development strategies,” said Erik Emerson, President of Apimeds and Chief Executive Officer of Lōkahi Therapeutics. “LT-100 has broad therapeutic potential, and we believe that updating the route of administration to reflect current clinical best practices, while reducing burden for patients and providers, positions the program well for continued progress.”

“This meeting reflects the extensive analytical and development work undertaken to prepare LT-100 for continued advancement,” said Susan Kramer, DrPH, SVP of Development at Lōkahi Therapeutics. “Our team has carefully evaluated the nonclinical, clinical, and manufacturing components of the program to ensure a cohesive and scientifically rigorous development plan. Early and constructive engagement with the FDA is a critical step in responsibly advancing this asset.”

About Apimeds Pharmaceuticals US, Inc

Apimeds Pharmaceuticals US, Inc. (NYSE American: APUS) is a clinical-stage biopharmaceutical company focused on developing non-opioid, biologic-based therapies for pain management. For more information visit www.apimedsus.com.

About Lōkahi Therapeutics

Lōkahi Therapeutics is focused on advancing innovative therapeutic opportunities through disciplined evaluation, strategic development, and collaborative discovery. Through initiatives like the ai² Futures Lab, Lōkahi integrates emerging talent into real-world problem-solving to help shape the future of healthcare. For more information visit www.lokahithera.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Statements contained in this news release that are not statements of historical fact may be deemed to be forward-looking statements. Without limiting the generality of the foregoing, words such as “anticipate”, “believe”, “expect”, “plan” and “will” are intended to identify forward-looking statements. Such forward-looking statements are based on the beliefs of management, as well as assumptions made by, and information currently available to, management. These statements relate only to events as of the date on which the statements are made, and Apimeds undertakes no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law. All of the forward-looking statements made in this press release are qualified by these cautionary statements, and there can be no assurance that the actual results anticipated by Apimeds will be realized or, even if substantially realized, that they will have the expected consequences to or effects on the company or its business or operations. Readers are cautioned that certain important factors may affect Apimeds’ actual results and could cause such results to differ materially from any forward-looking statements that may be made in this press release. Factors that may affect Apimeds’ results include, but are not limited to, the ability of Apimeds to raise additional capital to finance its operations (whether through public or private equity offerings, debt financings, strategic collaborations or otherwise); risks relating to Apimeds’ ability to advance its product candidate and successfully complete clinical trials; risks relating to its ability to hire and retain qualified personnel; and the additional risk factors described in Apimeds’ filings with the U.S. Securities and Exchange Commission (the “SEC”), including its Annual Report on Form 10-K for the year ended December 31, 2024 as filed with the SEC on April 15, 2025 (as amended on May 2, 2025).

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