26 August 2026

FDA-CVM Establishes INAD File for CannEpil® Veterinary Program

Highlights:

- **U.S. FDA Center for Veterinary Medicine establishes Investigational New Animal Drug (INAD) File No. 14145 for CannEpil®**
- **Represents the first formal FDA regulatory milestone for the CannEpil® veterinary development programme**
- **Initial development programme targeting cancer-related pain in companion animals, beginning with canine oncology**
- **Programme being advanced by Argent BioPharma's global CannEpil® licensing partner, Endovia Health Sciences, together with Lupvindol Biosciences**
- **Argent retains ownership of the underlying CannEpil® intellectual property, manufacturing participation and a perpetual 10% royalty on veterinary revenues**

Argent BioPharma Ltd. (ASX: RGT) ("**Argent BioPharma**" or the "**Company**") is pleased to advise that the U.S. Food and Drug Administration's Center for Veterinary Medicine ("**FDA-CVM**") has established Investigational New Animal Drug File No. 14145 for the CannEpil® veterinary development programme.

The establishment of the INAD file represents the first formal FDA regulatory milestone following the recent expansion of Argent BioPharma's CannEpil® global licensing agreement into veterinary applications and the subsequent appointment of Lupvindol Biosciences to lead the U.S. veterinary pharmaceutical development programme.

The INAD establishes the regulatory framework under which the CannEpil® veterinary programme can progress through formal interactions with FDA-CVM, including product development planning, required preclinical and clinical studies, manufacturing activities and regulatory submissions in support of potential future approval.

Importantly, establishment of an INAD file does not constitute FDA approval, Conditional Approval, confirmation of product safety or efficacy, or authorisation to commercially market CannEpil® in the United States.

Initial Focus on Companion-Animal Oncology

Endovia Health Sciences ("**Endovia**"), formerly Splash Beverage Group and Argent BioPharma's exclusive global CannEpil® licensing partner, has advised that the initial veterinary development programme will focus on the management of cancer-related pain in companion animals, beginning with canine oncology.

The programme is intended to progress through FDA-CVM under the Minor Use / Minor Species (MUMS) and Conditional Approval pathways, subject to ongoing regulatory engagement and the successful completion of required development activities.

Lupvindol Biosciences will lead the scientific, pharmaceutical development and FDA regulatory activities associated with the programme.

The Lupvindol programme is led by Dr Hunter Land, who was GW Pharmaceuticals' first full-time U.S. research and development employee and participated in the development of Epidiolex®, the first FDA-approved plant-derived cannabinoid medicine, as well as Sativex®.

Strategic Significance for Argent BioPharma

The establishment of INAD File No. 14145 represents an important execution milestone for Argent BioPharma following the global licensing and subsequent expansion of CannEpil® into veterinary healthcare.

Within a relatively short period, the CannEpil® veterinary strategy has progressed from expansion of the licensed field, to appointment of a dedicated development partner, and now to establishment of a formal FDA investigational regulatory file.

The Company believes that progressing CannEpil® through a defined U.S. veterinary regulatory pathway provides an additional opportunity to create value from an asset originally developed for human drug-resistant epilepsy while maintaining Argent BioPharma's capital-efficient licensing strategy.

Roby Zomer, Chairman, commented:

"The establishment of the CannEpil® INAD file is an important milestone because it moves the veterinary programme into formal regulatory engagement with the U.S. FDA Center for Veterinary Medicine.

Only recently, we expanded the CannEpil® licence into veterinary healthcare and our licensing partner appointed an experienced cannabinoid pharmaceutical development team to execute that strategy. The establishment of INAD File No. 14145 demonstrates tangible progress from commercial agreement to regulatory execution.

For Argent BioPharma, this is exactly how our licensing model is intended to work. We retain ownership of the underlying intellectual property, manufacturing participation and long-term royalty economics, while experienced partners fund and execute the development and commercialisation pathway.

There remains substantial development work ahead and the INAD does not represent FDA approval. However, we believe this first formal FDA milestone represents meaningful progress in building an additional veterinary value stream from the CannEpil® platform."

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About Argent BioPharma

Argent BioPharma Ltd. (ASX: RGT) is a revenue-generating specialty biopharmaceutical company focused on building a differentiated immune-modulation intellectual property platform through the development, commercialisation and strategic licensing of innovative therapeutics. The Company's portfolio is anchored by CimetrA®, a first-in-class immune-modulating platform targeting inflammatory and autoimmune diseases, supported by proprietary NanoBodies™ and peptide technologies, advanced nano-delivery systems and EU-GMP manufacturing capabilities. Following the global licensing of CannEpil®, Argent BioPharma has adopted a capital-efficient strategy that combines proprietary intellectual property, commercial-stage products, strategic licensing, manufacturing services and recurring royalty income to create long-term shareholder value. With a focused pipeline of immune-modulating technologies, a growing portfolio of proprietary pharmaceutical assets and an expanding commercial platform, Argent BioPharma is positioning itself as a next-generation specialty pharmaceutical company with a clear pathway toward expansion into the United States capital markets.

About CannEpil®

CannEpil® is a pharmaceutical-grade cannabinoid formulation comprising cannabidiol (CBD) and tetrahydrocannabinol (THC) isolates in a standardised oral liquid formulation manufactured under European Union Good Manufacturing Practice standards. CannEpil® was originally developed and clinically researched for the management of seizures associated with drug-resistant epilepsy in humans and has established regulated access pathways in several international markets. Following the expansion of its global licensing arrangement, CannEpil® is now also being investigated for veterinary applications through a dedicated U.S. FDA development programme. CannEpil® has not been approved by the FDA for veterinary use.