Lifescient's INAD Application Received FDA Clearance for LS-001, A Long-Acting Medication to Control Pain Associated with Bone Cancer in Dogs

LIFESCIENT ANNOUNCEMENT
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Lifescient, Inc., a veterinary pharmaceutical company developing long-acting injectables (LAIs) to replace daily dosing of pets with long-term medication needs, has received notification of acceptance from the Food and Drug Administration (FDA) of the company's Investigational New Animal Drug (INAD) application for LS-001, an LAI proposed for the control of pain associated with bone cancer in dogs with a subdermal injection.

In addition, the FDA has also granted a sponsor fee waiver for LS-001 based on the product being intended for Minor Use in a Major Species (MUMS). The Company is seeking a MUMS designation which will provide an extended period of exclusive marketing rights, and also be eligible for an FDA grant to support product development.

Lifescient is planning for a pre-submission conference with the FDA in the fall of 2024 following which the company plans to initiate a clinical study.

"Clearance of the INAD for LS-001 is a significant milestone in Lifescient's mission to develop convenient treatment options for our pets that will also relieve the pet owner from the burden of daily dosing with weekly or monthly dosing," said Kamalesh Rao, founder and Chief Executive Officer of Lifescient.

The company's scientific advisor Dr. Craig Miller said, "The veterinary medicines market is underserved with predominantly oral or topical formulations of pet medications which are not ideal for chronic management and treatment of pet diseases. For instance, pain management in pets is extremely challenging with burdensome twice to thrice daily dosing schedule and imposes undue burden on the pet caregiver. LS-001 is a long-acting injectable medication that is intended to bring pain relief to dogs suffering from bone cancer. In the US there are an estimated 25,000 dogs (Tufts University Report) that are newly diagnosed with bone cancer each year with an average life expectancy of approximately 2-12 months. With such a strong need in veterinary medicine, LS-001 will bring relief to both pets and their owners."

Furthermore, our LAI drug delivery platform has the potential for application across many species of animals, such as hyperthyroidism in cats and hypertension in dogs and cats.

Advantages of LAIs over pills and topicals include significantly improved prescription compliance, reduced side effects, reduced oral pill management, improved bioavailability,

elimination of drug diversion and abuse, enhanced quality of life for pet owners and superior quality of care for pets.

About LS-001

LS-001 is a subdermal long-acting injectable medication of an analgesic commonly prescribed by veterinarians. The injectable releases medication continuously in a controlled manner and is absorbed by the animal. It is formulated as a biodegradable polymer that maintains the level of drug within the therapeutic window during the course of treatment. LS-001 is the first product based on our LAI drug delivery platform which, besides bone cancer pain, has additional potential uses for the management of arthritis, palliative care, and post- surgical pain.

About Lifescient

Lifescient is reformulating FDA approved medications into LAIs using a biodegradable polymer. Kamalesh Rao, Lifescient's founder, has more than three decades of experience as a formulation scientist. He previously worked at Titan Pharmaceuticals as Director of Manufacturing whose LAI product was approved to treat opioid addiction in humans.

Cautionary Note on Forward-Looking Statements

Statements in this press release about future expectations, plans and prospects, as well as any other statements regarding matters that are not historical facts, may constitute "forward-looking statements" within the meaning of The Private Securities Litigation Reform Act of 1995. These statements include, but are not limited to, statements relating to Lifescient's business, strategy, future operations, cash runway, the advancement of Lifescient's product candidates and product pipeline, and clinical development of Lifescient's product candidates, including expectations regarding timing of initiation and results of clinical trials. The words ``anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "goals," "intend," "may," "might," "outlook," "plan," "project," "potential," "predict," "target," "possible," "will," "would," "could," "should," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

Any forward-looking statements are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in, or implied by, such forward-looking statements. These risks and uncertainties include, but are not limited to, (i) Lifescient's ability to obtain, maintain and protect its intellectual property rights related to its product candidates; (ii) Lifescient's ability to advance the development of its product candidates under the timelines it anticipates in planned and future clinical trials; (iii) Lifescient's ability to replicate in later clinical trials positive results found in preclinical studies and early-stage clinical trials of its product candidates; (iv) Lifescient's ability to realize the anticipated benefits of its research and development programs, strategic partnerships, research and licensing programs and academic

and other collaborations; (v) regulatory requirements or developments and Lifescient's ability to obtain and maintain necessary approvals from the U.S. Food and Drug Administration and other regulatory authorities related to its product candidates; (vi) changes to clinical trial designs and regulatory pathways; (vii) risks associated with Lifescient's ability to manage expenses; (viii) changes in capital resource requirements; (ix) risks related to the inability of Lifescient to obtain sufficient additional capital to continue to advance its product candidates and its preclinical programs; and (x) legislative, regulatory, political and economic developments.

Any forward-looking statements that are made in this press release speak as of the date of this press release. Lifescient undertakes no obligation to revise the forward-looking statements or to update them to reflect events or circumstances occurring after the date of this press release, whether as a result of new information, future developments or otherwise, except as required by the federal securities laws.

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