



Product brief for veterinarians

We're developing
the first longevity
drugs for dogs.

Overview

Our aging thesis

Aging is the most significant modifiable risk factor for most degenerative and chronic diseases in adult dogs. Targeting the ways dogs age and decline over time may be one of the most effective and practical ways for veterinarians to increase the healthy lifespan of their canine patients.

At Loyal, our approach is to help dogs live longer and stay healthier as they age by targeting the underlying drivers of aging. Our drugs aim to extend lifespan and quality of life by reducing the incidence and severity of age-related diseases.

Products in development

We have three lifespan extension drugs in development, targeting two aging pathways.

LOY-002 is intended for dogs age 10 or older and weighing at least 14 lb. It aims to extend healthy lifespan by improving insulin sensitivity and reducing insulin in senior dogs.

LOY-001 is intended for dogs age 7 and older and weighing 40 lb or more, while LOY-003 is intended for dogs age 5 and older and weighing at least 60 lb. Both target the overexpression of IGF-1, a hormone that we believe is associated with large dogs’ shorter lifespan relative to small dogs.

	LOY-002	LOY-001 LOY-003	
	For senior dogs	For large dogs	
Purpose	Intended to extend lifespan and healthspan for older dogs of nearly every shape and size	Intended to extend lifespan and healthspan for large and giant dogs	
Description	As dogs age, their metabolic health declines, leading to disease and poorer quality of life. By increasing insulin sensitivity and lowering insulin levels, LOY-002 aims to improve metabolic health, thereby reducing age-associated disease and extending healthy lifespan.	As a result of selective breeding, large dogs have a lifelong overexpression of the hormone IGF-1. This is believed to reduce their lifespan relative to smaller dogs. LOY-001 and LOY-003 intend to lower IGF-1 levels in adult dogs with the aim of reducing age-associated disease and extending healthy lifespan.	
Target population	LOY-002: Dogs age 10 or older and weighing at least 14 lb	LOY-001: Dogs age 7 or older and weighing at least 40 lb	LOY-003: Dogs age 5 or older and weighing at least 60 lb
Dosage	LOY-002: Prescription flavored daily pill	LOY-001: Prescription injection	LOY-003: Prescription flavored daily pill
Major FDA technical sections	LOY-002: 2 of 3 complete	LOY-001: 1 of 3 complete	LOY-003: 1 of 3 complete

Milo
Age 10



Lifespan extension for senior dogs

LOY-002

Mechanism of action

Disclaimer: Our products are still in development, so the drugs and exact mechanisms of action are currently confidential. We'll continue to publish our preclinical research data, and more detailed information will be made available to veterinarians if the drug is approved by the FDA.

LOY-002 is a daily flavored tablet that aims to lower insulin levels and improve insulin sensitivity in senior dogs. By improving metabolic health in these ways, LOY-002 intends to extend lifespan and mitigate the decline in health and quality of life associated with aging.

Insulin resistance and circulating insulin levels increase with aging and have been associated with increased disease burden, frailty, and mortality in dogs. We believe that by improving insulin sensitivity and reducing insulin levels, we can extend senior dogs' quality of life and consequently extend their lifespan. The landmark Purina Institute lifespan study found that caloric restriction lowered dogs' insulin levels by 32% and extended life by an average of 1.8 years.¹ It also found that caloric restriction could delay the onset of common age-associated disease like osteoarthritis, cancer, and neoplasia.^{1,2}

While caloric restriction itself is not a practical way to extend lifespan in pet dogs, this study showed that improving metabolic health and reducing insulin can have a direct impact on canine lifespan. We believe drugs will offer a more targeted and pragmatic approach to achieving similar benefits without requiring the weight loss or extreme diet needed for caloric restriction.

The STAY study

We've completed enrollment and are actively running the STAY study, our randomized, placebo-controlled, double-blind effectiveness study intended to assess the effect of LOY-002 on lifespan and healthspan in treated dogs versus placebo. The STAY study will be conducted over several years in partnership with approximately 70 veterinary clinics across the country. 1,300 companion dogs, 10 years and older and 14 pounds and over, are participating.

Over the course of STAY, we'll collect extensive data on health, quality of life, and lifespan in dogs receiving LOY-002 and those receiving a placebo. The results of the study will support our application for full FDA approval of the drug for lifespan extension and will also be shared with veterinarians.

Working toward FDA approval

Our lifespan extension drugs are all being developed under the FDA Center for Veterinary Medicine's expanded conditional approval (XCA) pathway, which is meant for animal drugs that address an unmet medical need and require long or complex studies to collect all of the effectiveness data needed for full approval. XCA has the same high bar for safety and manufacturing quality requirements as full approval, but it allows qualifying novel drugs to come to market upon demonstrating a reasonable expectation of effectiveness (RXE). While we pursue XCA for LOY-002, we're running the STAY clinical trial to collect the effectiveness data needed for full approval.

To date, LOY-002 has completed two of three major technical sections required by the FDA. These acceptances are critical steps towards bringing the first lifespan extension drug approved by the FDA to veterinarians and dog owners in 2027:

- Reasonable Expectation of Effectiveness (RXE): In February 2025, the FDA agreed that LOY-002 can reasonably be expected to be effective at extending senior dog lifespan.
- Target Animal Safety (TAS): In December 2025, the FDA accepted LOY-002's safety package, signaling that the data submitted supports the safety of the drug when used as intended.

Loyal is committed to following the rigorous scientific and manufacturing standards set by the FDA, and product timelines will depend on our ongoing work with the agency to satisfy these requirements. The final major technical section, which covers manufacturing, is currently in progress.

Safety

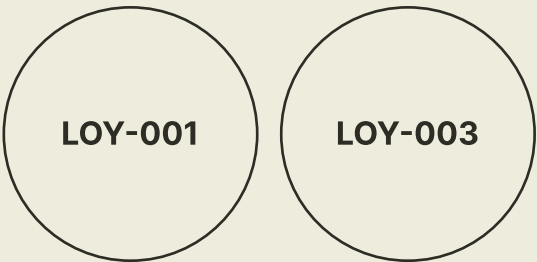
LOY-002 is part of a preventive medicine approach to aging, not a treatment for a particular disease. While even serious side effects may be tolerable with a medication intended to treat a severe or life-threatening disease, we believe that preventive treatments such as LOY-002 require an exceptionally high safety bar.

We have extensive evidence from safety studies of the active ingredient in LOY-002, and the FDA has accepted LOY-002's safety package. This included:

- Safety study conducted at standard target dose multiples (1x, 3x, and 5x the intended clinical dose), with no clinically significant adverse events observed at these doses
- Field safety data from more than 400 client-owned animals in the STAY studies taking LOY-002 for varying durations, including up to one year, that also showed no clinically significant adverse events

**FDA approval not guaranteed*

Lifespan extension for large and giant dogs



Mechanism of action

LOY-001 and LOY-003 both address the premature morbidity and mortality of large dogs. LOY-001 will be an injectable administered by veterinarians. LOY-003 will be a daily pill developed through our partnership with human biopharma company Crinetics Pharmaceuticals.

It is well-known that body size and lifespan are related in dogs and that larger dogs often have substantially shorter lifespans than smaller dogs. Larger body size is predominantly determined by the levels of certain hormones during development, including growth hormone (GH) and insulin-like growth factor 1 (IGF-1). However, these hormones have other effects on metabolism that can reduce quality of life and lifespan.

There is extensive evidence in many species, including dogs, that demonstrates a correlation between high IGF-1 levels and shorter lifespan. We believe that sustained higher levels of GH and IGF-1 in larger dogs are partly responsible for shorter lifespan and the earlier development of age-associated disease and disability. LOY-001 and LOY-003 aim to extend lifespan and preserve quality of life by reducing IGF-1 levels and delaying the onset of age-associated metabolic dysfunction and disease. These drugs will be administered only to skeletally mature dogs, so they will not affect body size.

Working toward FDA approval

As with LOY-002, we are planning to seek full approval for LOY-001 and LOY-003, which would include conducting large, long-term field effectiveness trials similar to the STAY study.

We’re also seeking conditional approval for these drugs to address early mortality in large dogs due to age-associated disease.

- In November 2023, the FDA accepted LOY-001’s RXE package. We believe this to be the FDA’s first-ever formal acceptance that a drug can be developed and approved to extend lifespan.
- In June 2026, the FDA also accepted LOY-003’s RXE package, marking three efficacy acceptances for Loyal’s portfolio of drugs.

Safety

Both LOY-001 and LOY-003 are earlier in development, and safety data is being gathered for both of these drugs. As with LOY-002, continued development of these products and potential FDA approval will require equally robust evidence ensuring safety as well as efficacy.

**FDA approval not guaranteed*

Akila
Age 7



FAQs

What are the potential benefits of your drugs?

The goal of all our programs is to develop FDA-approved drugs that extend healthy lifespan in dogs. By targeting underlying pathways of aging, we believe we can delay age-associated disease and disability and give dogs more time with good health, physical function, and quality of life. The STAY study and our other clinical trials will provide much more detail about the impacts of our drugs on health and lifespan.

What are the active pharmaceutical ingredients in your drugs?

Because our products are still in development, the drugs and their exact mechanisms of action necessarily remain confidential. We'll release these details, along with safety and efficacy data, as we get closer to launching each product.

Do your drugs treat specific cancers or other age-related diseases?

Our goal is to develop medications that preserve health and broadly delay or prevent age-associated disease rather than focusing on treating specific diseases after they have already developed.

Do dogs need to be healthy when taking your drugs?

We expect dogs with many pre-existing conditions will be able to take our drugs and benefit from them, but any specific guidelines will be based on the results of our clinical and safety studies.

What about younger or smaller dogs?

We expect to support the following populations with our drugs:

- For LOY-002, dogs 10 years and older and weighing at least 14 pounds
- For LOY-001, dogs 7 years and older and weighing at least 40 pounds
- For LOY-003, dogs 5 years and older and weighing at least 60 pounds

Clinical studies are designed to measure effectiveness among a target population, and for our lifespan extension drugs, this means choosing a population that's most likely to benefit over the duration of our clinical studies. If approved, our drugs will be intended for use in the same populations studied in the clinical effectiveness trials.

Our goal is to help as many dogs as possible live longer, healthier lives. In the future, we hope to develop more therapies and serve a larger population of dogs with them.

Why develop both an injection and daily pill to treat overexpression of growth hormone in large dogs?

Our goal is to offer a range of options to suit the needs of veterinarians and dog owners.

An injectable formulation offers convenience and improved compliance, while a daily pill may be preferred by some owners.

What about cats?

We love cats too, but we're focused on helping dogs live longer, healthier lives first.

Sources

1 Lawler DF, Larson BT, Ballam JM, Smith GK, Biery DN, Evans RH, Greeley EH, Segre M, Stowe HD, Kealy RD. Diet restriction and ageing in the dog: major observations over two decades. Br J Nutr. 2008 Apr;99(4):793-805. doi: 10.1017/S0007114507871686. Epub 2007 Dec 6. Erratum in: Br J Nutr. 2009 Apr;101(7):1112. PMID: 18062831.

2 Kealy, R.D., Lawler, D.F., Ballam, J.M., Lust, G., Smith, G.K., Biery, D.N., & Olsson, S.E. (1997). Five-year longitudinal study on limited food consumption and development of osteoarthritis in coxofemoral joints of dogs. Journal of the American Veterinary Medical Association, 210(2), 222-225.

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