Adolore BioTherapeutics Announces Issuance of First U.S. Patent Covering CA8* Gene Therapies to Treat Chronic Pain

Patent and CA8 gene therapy technology licensed by Adolore BioTherapeutics from the University of Miami*

Company advancing development of rdHSV-CA8 gene therapy for the treatment of chronic osteoarthritis (OA) knee pain toward an IND*

DELRAY BEACH, FL. – March 4, 2024 – Adolore BioTherapeutics ("Adolore" or the "Company"), a biotechnology company focused on developing breakthrough opioid-free gene therapy treatments for chronic pain, today announced the U.S. Patent and Trademark Office (USPTO) has issued patent No. 11,911,450 covering its innovative CA8* (*Carbonic anhydrase-8-like analgesic peptides, CA8 variants) gene therapies, using a state-of-the-art replication-defective disease-free HSV vector (rdHSV-CA8*). This issued patent and patent family, as well as the underlying CA8*-related technology were licensed in 2023 by Adolore BioTherapeutics from the University of Miami, Miami, FL.

"The issuance of this patent establishes a proprietary position for Adolore's highly innovative approach for treating chronic pain," commented Roelof Rongen, CEO of Adolore. "We continue to believe in the potential of this platform and building the intellectual property protection for our CA8* gene therapies is a key first-step as we progress toward clinical testing and commercialization of these novel and potentially transformational therapies."

"This important patent covers a range of CA8 variants, both as novel composition of matter as well as their novel uses, and includes technology, which holds the potential to minimize unwanted effects of avoiding biodistribution of our novel gene therapies to unaffected healthy tissues," said Dr. Roy Levitt, Inventor and Founder/Chairman of Adolore. "There is a significant and growing need to provide an alternative to the currently available and widely used oral opioid pain treatments that can adversely impact the entire body. These oral opioid-based treatments are systemic, short-acting and complicated by dependence, tolerance, abuse, addiction, death and diversion. We continue to develop our innovative approach to potentially address the significant unmet need for safe and effective locally acting pain therapies to replace opioids; and our preclinical data strongly support progression toward the clinics with continued development."

There are currently very few safe, efficacious non-opioid analgesic treatments for chronic pain on the market, leaving a large and very urgent unmet medical need. Leveraging its innovative CA8* gene therapy, Adolore is currently advancing two preclinical development programs, ADB-101 for the treatment of genetically-determined life-long recurrent severe neuropathic pain due to erythromelalgia an orphan disease where there are no approved therapies; and ADB-102 for

the treatment of patients with chronic pain caused by knee OA. Based on compelling data generated to date, the Company is progressing these programs toward an IND filing and first-in-human clinical studies.

The Company's development program for the treatment of chronic pain in knee osteoarthritis is supported by a UG3/UH3 grant awarded to the University of Miami by NIH/NINDS HEAL program to support all formal pre-clinical GLP/GMP/GCP development work through a first-in-human study in patients expected to commence in 2026.

About Carbonic Anhydrase-8 (CA8*) Gene Therapy

CA8* (*Carbonic anhydrase-8 like analgesic peptides, CA8 variants) gene therapies are a novel class of neuronal calcium channel inhibitors that activate Kv7 voltage-gated potassium channels that are long-acting when administered locally. Oral therapeutics that activate Kv7 voltage-gated potassium channels demonstrated proven analgesic efficacy before they were removed from the market due to severe adverse events related to systemic exposure. CA8* gene therapy provides for versatile dosing regimens and routes of administration, including intra-articular, intra-neuronal (nerve block) and intradermal injection. This non-opioid CA8* mechanism-of-action addresses neuropathic, inflammatory, and nociceptive pain, which apply to a broad range of chronic pain indications, including osteoarthritis pain, diabetic and other forms of peripheral neuropathy, post-herpetic neuralgia, lower back pain, and cancer pain, as well as rare pain conditions such as erythromelalgia, an orphan drug disease. Using a replication-defective HSV vector enables disease-free localized delivery to the peripheral somatosensory nervous system with an excellent safety profile. HSV vectors are known for their stability and prolonged gene-expression, providing an excellent basis for long-term treatment.

About Adolore BioTherapeutics, Inc.

Adolore BioTherapeutics, Inc., is a biotechnology company focused on developing novel therapies for the treatment of chronic pain and other pain and nervous system conditions or disorders. Our best-in-class programs are long-acting, locally acting gene-therapies that are opioid-free Disease Modifying Anti-Pain therapies (DMAPs) for the treatment of chronic pain.

The Company's two current CA8* gene therapy programs are in preclinical development for treatment of patients suffering from erythromelalgia, a life-long heritable chronic pain condition representing an orphan drug disease with no approved therapy, and chronic osteoarthritis knee pain, affecting a large number of patients that is often treated with opioids due to the lack of good alternatives, thus contributing to the ongoing opioid crisis.

For more information, visit adolore.com.

Forward Looking Statements

To the extent this announcement contains information and statements that are not historical, they are considered forward-looking statements within the meaning of the federal securities

laws. You can identify forward-looking statements by the use of the words “believe,” “expect,” “anticipate,” “intend,” “estimate,” “project,” “will,” “should,” “may,” “plan,” “intend,” “assume” and other expressions which predict or indicate future events and trends and which do not relate to historical matters. You should not rely on forward-looking statements, because they involve known and unknown risks, uncertainties and other factors, some of which are beyond the control of the Company. These risks and uncertainties include, but are not limited to, those associated with drug development. These risks, uncertainties and other factors may cause the actual results, performance or achievements of the Company to be materially different from the anticipated future results, performance or achievements expressed or implied by the forward-looking statements.

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