News Release

Edgewise Receives U.S. FDA Fast Track Designation for EDG-5506 for the Treatment of Individuals with Becker Muscular Dystrophy (BMD)

– EDG-5506, a drug candidate designed to arrest muscle fiber breakdown in BMD and Duchenne muscular dystrophy (DMD), continues to advance in Phase 1 –

Boulder, Colo., *(August 16, 2021)* – Edgewise Therapeutics, Inc., (NASDAQ: EWTX), a clinical-stage biopharmaceutical company focused on developing orally bioavailable, small molecule therapies for rare muscle disorders, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for EDG-5506 for the treatment of individuals with BMD. EDG-5506, a selective, small molecule myosin inhibitor designed to protect injury-susceptible fast skeletal muscle fibers in DMD and BMD, is advancing in a Phase 1 clinical trial.

"The FDA's decision to grant EDG-5506 Fast Track designation underscores the urgency to address a significant unmet medical need for individuals with Becker muscular dystrophy," said Kevin Koch, Ph.D., President and Chief Executive Officer of Edgewise. "Becker is a serious, progressive disease that leads to severe disability, including loss of ambulation and heart disease that has substantial impact on day-to-day function in many individuals. We look forward to working closely with the FDA towards establishing EDG-5506 as the potential first muscle-directed therapy for individuals with Becker."

"I am pleased to see that the FDA recognizes Becker muscular dystrophy as a serious disease and that the team at Edgewise is acknowledging the important unmet need in Becker," said Craig McDonald, M.D., Professor and Chair, Department of Physical Medicine & Rehabilitation, University of California Davis.

The FDA Fast Track Program is designed to facilitate the development and expedite the review of new therapeutics that are intended to treat serious conditions and fill an unmet medical need. The Fast Track Program supports important new therapeutics to reach patients earlier. The designation is granted to therapeutics that offer potential to meaningfully impact survival, day-to-day functioning, or if left untreated, progression of the condition. Therapeutics that receive this designation receive a number of benefits that include more frequent meetings with the FDA to discuss development of the drug candidate and, if relevant criteria are met, eligibility for Accelerated Approval and Priority Review.

The decision to give EDG-5506 Fast Track designation was supported by a robust preclinical data package and an ongoing Phase 1 clinical trial (NCT04585464). The Company expects to have Phase 1 topline Multiple Ascending Dose (MAD) data in healthy volunteers and in individuals with BMD later in 2021.

About Becker Muscular Dystrophy

BMD is a serious, progressively debilitating, and potentially fatal inherited neuromuscular disorder. BMD results from truncation or mutation of the X-linked dystrophin gene yielding unstable and/or dysfunctional dystrophin expression in muscles. Individuals with BMD, typically males, have ongoing muscle fiber (myofiber) degeneration that eventually leads to fibrosis, progressive loss of skeletal muscle function, and that can lead to severe disability and early death. BMD typically presents with juvenile onset of muscle wasting and progressive

symmetrical, proximal muscle weakness, calf hypertrophy, activity-induced muscle cramping and elevated creatine kinase (CK) activity. While the course of BMD is variable, it is unidirectional in terms of the inevitable progressive limb weakness resulting in severe disability. BMD is also associated with early mortality from cardiac disease that is disproportionately severe compared to that seen in DMD. The incidence of BMD is approximately 1 in every 18,450 live male births. It is estimated that there are between 4,000–5,000 individuals with BMD in the U.S., with similar numbers of individuals living with BMD in Europe. Despite the seriousness of the disease, for many with BMD, the disease remains one of considerable unmet medical need as there are no approved therapies in the U.S.

About EDG-5506 for DMD and BMD

EDG-5506 is an orally administered small molecule designed to address the root cause of dystrophinopathies including DMD and BMD. EDG-5506 presents a novel mechanism of action to selectively limit injurious hypercontraction stress caused by the absence of functional dystrophin. EDG-5506 has the potential to benefit a broad range of patients suffering from debilitating rare neuromuscular disorders. It is anticipated to be used as a single agent therapy but it may also provide a synergistic or additive effect in combination with available therapies and therapies currently in development.

The Phase 1 study of EDG-5506 is designed to evaluate safety, tolerability, pharmacokinetics (PK) and pharmacodynamics (PD) in adult healthy volunteers (Phase 1a) and in adults with BMD (Phase 1b). EDG-5506 is advancing in the Multiple Ascending Dose (MAD) portion of the study. The Company expects to have topline MAD data in healthy volunteers and in individuals with BMD later in 2021. Go to clinicaltrials.gov to learn more about this study (NCT04585464).

About Edgewise Therapeutics

Edgewise Therapeutics is a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of innovative treatments for severe, rare muscle disorders for which there is significant unmet medical need. Guided by its holistic drug discovery approach to targeting the muscle as an organ, Edgewise has combined its foundational expertise in muscle biology and small molecule engineering to build its proprietary, muscle focused drug discovery platform. Edgewise's platform utilizes custom-built high throughput and translatable systems that measure integrated muscle function in whole organ extracts to identify small molecule precision medicines regulating key proteins in muscle tissue, initially focused on addressing rare neuromuscular and cardiac diseases. To learn more, go to: www.edgewisetx.com or follow us on LinkedIn, Twitter and Facebook.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements as that term is defined in Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Statements in this press release that are not purely historical are forward-looking statements. Such forward-looking statements include, among other things, statements regarding the potential of, and expectations regarding, Edgewise's drug discovery platform, product candidates and programs, including EDG-5506; the expected timing of reporting topline data from Edgewise's Phase 1 clinical trial of EDG-5506; statements regarding Edgewise's pipeline of product candidates and programs; and statements by Edgewise's chief executive officer. Words such as "believes," "anticipates," "plans," "expects," "intends," "will," "goal," "potential" and similar expressions are intended to identify forward-looking statements. The forward-looking statements contained herein are based upon Edgewise's current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results could differ materially from those projected in any forward-looking statements due to numerous risks and uncertainties, including but not limited to: risks associated with the process of discovering, developing and commercializing drugs that are safe and effective for use as human therapeutics and operating as an early

clinical stage company including the potential for Edgewise's product candidates to cause serious adverse events; Edgewise's ability to develop, initiate or complete preclinical studies and clinical trials for, obtain approvals for and commercialize any of its product candidates for muscular dystrophy patients or other patient populations; the timing, progress and results of preclinical studies and clinical trials for EDG-5506 and Edgewise's other product candidates; Edgewise's ability to raise any additional funding it will need to continue to pursue its business and product development plans; negative impacts of the COVID-19 pandemic on Edgewise's operations, including preclinical and clinical trials; the timing, scope and likelihood of regulatory filings and approvals; the potential for any clinical trial results to differ from preclinical, interim, preliminary, topline or expected results; Edgewise's ability to develop a proprietary drug discovery platform to build a pipeline of product candidates; Edgewise's manufacturing, commercialization and marketing capabilities and strategy; the size of the market opportunity for Edgewise's product candidates; the loss of key scientific or management personnel; competition in the industry in which Edgewise operates; Edgewise's reliance on third parties; Edgewise's ability to obtain and maintain intellectual property protection for its product candidates; general economic and market conditions; and other risks. Information regarding the foregoing and additional risks may be found in the section entitled "Risk Factors" in documents that Edgewise files from time to time with the Securities and Exchange Commission. These forward-looking statements are made as of the date of this press release, and Edgewise assumes no obligation to update the forward-looking statements, or to update the reasons why actual results could differ from those projected in the forward-looking statements, except as required by law**.**

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