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PRESS RELEASE

Joint Press Release by Caeregen and WACKER

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Caeregen Therapeutics and Wacker Biotech announce collaboration agreement to produce the regenerative medicine clinical candidate CTR-107 (Noregen™) for Retinal Diseases

Rochester, Michigan, USA and Halle, Germany, June 28, 2023 – Caeregen Therapeutics, a regenerative medicine therapeutics company and Wacker Biotech, a contract development and manufacturing organization (CDMO), will collaborate on the development and production of CTR-107 (Noregen™), a novel regenerative therapeutic for the treatment of retinal-related vision loss. As Caeregen's CDMO partner for CTR-107, Wacker Biotech will produce drug substance at its site in Halle, Germany, and complete clinical trial drug product production at its site in Amsterdam, the Netherlands, to support Phase I/II clinical study initiation in 2024. CTR-107 is the first program to obtain U.S. FDA Rare Pediatric Disease Designation for treatment of Familial Exudative Vitreoretinopathy (FEVR).

CTR-107 is a synthetic targeted growth-factor that mimics the properties of norrin, a naturally occurring human protein that promotes development of normal, organized blood vessels and neurons in the human eye, ear, and central nervous system. CTR-107 is first being developed for the treatment of Familial Exudative Vitreoretinopathy (FEVR), a genetic disorder of retinal blood vessel formation, resulting in partial or complete vision loss. When injected

into the eye, CTR-107 may regenerate retinal blood vessels and neurons restoring normal retinal function and counteracting vision loss due to FEVR. Caeregen intends to subsequently advance Noregen for other critical retinal disease indications including retinal vein occlusion (RVO), diabetic retinopathy (DR) and age-related macular degeneration (AMD). In December 2022, Noregen received Rare Pediatric Disease designation from the U.S. Food and Drug Administration (FDA) for treatment of Familial Exudative Vitreoretinopathy (FEVR) rendering Caeregen eligible to obtain a Priority Review Voucher at the time of marketing approval. This RPD designation for Noregen™ is the first to be granted by FDA for children with FEVR and follows the attainment of Orphan Drug Designation (ODD) by both the FDA and European Commission European Medicines Agency (EMA).

Caeregen first contracted with Wacker Biotech in 2022 to support initial manufacturing and process development for CTR-107 and has now partnered with Wacker Biotech to manufacture active CTR-107 drug substance at its site in Halle, Germany, for the first planned Phase I/II clinical study. Finished CTR-107 clinical study drug product manufacturing will be completed at Wacker Biotech's site in Amsterdam, the Netherlands. The production in compliance with pharmaceutical GMP (Good Manufacturing Practice) requirements is scheduled to start in early 2024.

"As a potential break-through program for a rare, devastating retinal disease with no therapeutic options for patients, we selected Wacker Biotech as our CDMO partner for CTR-107 development because of their long-standing experience and deep understanding of protein chemistry, and shared urgency in advancing transformative science,"

says Walter Capone, CEO of Caeregen Therapeutics. The companies' shared goal is to initiate clinical development which will support progression to regulatory submission as an approved product for patients experiencing progressive vision loss leading to blindness. "Through its unique structure, CTR-107 has the potential to repair and regenerate the neurovasculature to restore vision, with possible application to as well as reverse hearing loss and neurodegenerative diseases. We are pleased to support Caeregen Therapeutics in the development of this revolutionary regenerative drug candidate and product platform," says Guido Seidel, Vice President Business Unit BioPharma at WACKER.

Wacker Biotech, a wholly owned subsidiary of Munich-based Wacker Chemie AG, uses its proprietary FOLDTEC® technology in the production of CTR-107. With this refolding technology, microbially produced pharmaceutical proteins which tend to form inclusion bodies during production can be manufactured cost-effectively and reliably in high yields and extremely high purity. The patented process utilizes specifically developed and optimized *E.coli* bacterial strains, a patented, antibiotic- and phage free plasmid maintenance system, and comprehensive refolding know-how.

About CTR-107 (Noregen™)

CTR-107 (Noregen™) is a synthetic targeted growth-factor for retina-related vision loss modeled after norrin, a naturally occurring human protein that guides retinal formation in fetal development. CTR-107 may promote development of normal, organized blood vessels and neurons in the human eye, ear, and central nervous system for individuals with inherited or acquired retinal diseases and potential applications in other neurosensory diseases. As a first-in-class

therapeutic candidate to regenerate and repair the retinal vasculature to restore and preserve vision in patients with ischemic vitreoretinopathies, CTR-107 is currently being developed for Familial Exudative Vitreoretinopathy (FEVR), a rare disease of urgent, unmet medical need. For more information, visit: www.caeregen.com.

About Caeregen Therapeutics

Caeregen Therapeutics, LLC, based in Rochester, MI with offices in Chapel Hill, N.C., is a regenerative medicines company developing therapeutics for neurosensory diseases. By exploiting biological pathways and signaling related to cellular and organ development, Caeregen is focused on advancing targeted therapies with the ability to repair, restore and protect neurosensory tissues affected by inherited or acquired diseases. Caeregen is currently developing Noregen, a unique, novel, recombinant protein mimetic of human norrin-derived growth factor for the potential treatment of retinal-related vision loss. For more information, visit: www.caeregen.com.

About Wacker Biotech

Wacker Biotech GmbH, Wacker Biotech B.V. and Wacker Biotech US Inc. are full-service contract manufacturers of therapeutic proteins, live microbial products (LMPs), plasmid DNA (pDNA), messenger ribonucleic acid (mRNA) and vaccines based on microbial systems. Wacker Biotech's portfolio extends from strain/process development and analytical testing through to production for clinical and commercial applications. Wacker Biotech operates four GMP-compliant (Good Manufacturing Practice) production plants at its Jena and Halle sites in Germany, in Amsterdam in the Netherlands and in San Diego (USA). The production plants in Jena, Halle and

Amsterdam are FDA- and EMA-certified. Wacker Biotech GmbH, Wacker Biotech B.V. and Wacker Biotech US Inc. are wholly owned subsidiaries of Munich-based Wacker Chemie AG. For more information, visit: wacker.com/biologics

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