Coya Therapeutics, Inc. and Dr. Reddy's Laboratories enter into an Exclusive Collaboration for Development and Commercialization of COYA 302, an Investigational Combination Therapy for Treatment of Amyotrophic Lateral Sclerosis (ALS)

- *Under the Agreement, Dr. Reddy's will obtain commercialization rights for COYA 302 in the United States, Canada, the European Union and the United Kingdom, for patients with ALS*
- *COYA will be responsible for development, including the conduct of the Phase 2 clinical trial and for obtaining regulatory approval in the United States*
- *COYA 302 is an investigational combination biologic for subcutaneous administration, comprised of low-dose IL-2 and CTLA4-Ig (abatacept). COYA 302 has a dual mechanism of action intended to suppress the chronic and sustained inflammation underlying certain neurodegenerative diseases.*
- *In early 2023, Coya entered into an in-licensing agreement with Dr. Reddy's to license its proposed biosimilar abatacept for the development and commercialization of COYA 302*

HOUSTON, TEXAS; HYDERABAD, INDIA; BASEL, SWITZERLAND. December 6, 2023 — Dr. Reddy's Laboratories SA, wholly-owned subsidiary of Dr. Reddy's Laboratories Ltd. (BSE: 500124, NSE: DRREDDY, NYSE: RDY, NSEIFSC: DRREDDY, along with its subsidiaries together referred to as "Dr. Reddy's"), and Coya Therapeutics, Inc. (NASDAQ: COYA) ("Coya"), today announced that they have entered into a development and license agreement (the "Agreement") for the development and commercialization of COYA 302, an investigational combination therapy for the treatment of Amyotrophic Lateral Sclerosis (ALS).

Under the terms of the Agreement, Coya has granted Dr. Reddy's an exclusive license to commercialize COYA 302, a proprietary co-pack kit containing combination of low dose IL-2 and CTLA-4 Ig (abatacept) in the United States, Canada, the European Union and the United Kingdom for ALS. This Agreement is in addition to the in-licensing agreement with Dr. Reddy's signed in early 2023[1]. Coya retains the right to commercialize COYA 302 for patients with amyotrophic lateral sclerosis (ALS) in Japan, Mexico, and each country in South America. Coya will have responsibility for the clinical development of COYA 302 and for seeking regulatory approval for

[1] https://www.businesswire.com/news/home/20230317005028/en/Coya-Therapeutics-Inc.-Announces-an-Agreement-with-Dr.-Reddy%E2%80%99s-Laboratories-Ltd.-to-License-its-proposed-biosimilar-Abatacept-for-the-Development-and-Commercialization-of-COYA-302-for-the-Treatment-of-Neurodegenerative-Diseases

COYA 302 for patients with ALS in the United States.

Dr. Reddy's will make a USD 7.5 million upfront payment to Coya. Upon the first FDA acceptance of an investigational new drug (IND) application for COYA 302 for the treatment of ALS, Dr. Reddy's will pay Coya an additional USD 4.2 million. Upon dosing of the first patient in the first Phase 2 trial of COYA 302 for the treatment of ALS in the United States, Dr. Reddy's will pay Coya an additional USD 4.2 million. Coya anticipates that the IND filing will be made in the first half of 2024. The Agreement also includes development and regulatory milestones up to USD 40 million should all such development and regulatory milestones be achieved. Additionally, Coya is eligible to receive sales-based milestone payments of up to USD 677.25 million linked to tiers of cumulative net sales being achieved over several years (over the term of the agreement subject to product commercial exclusivity). In addition, Dr. Reddy's will pay Coya royalties based on a percentage net sales of COYA 302 ranging from low to middle teens. Coya is not a related party to Dr. Reddy's or its promoters/promoter group.

Marc Kikuchi, Chief Executive Officer of Dr. Reddy's North America, said: "Patients with ALS, commonly known as Lou Gehrig's disease, have very few treatment options. We are pleased to partner with Coya Therapeutics on this investigational therapy which may have a unique place in treating patients with this progressive neurodegenerative disease. With this promising biologic product, we hope to reach many more patients around the world in keeping with our aim of serving over 1.5 billion patients by 2030. Dr. Reddy's biosimilars/biologics business is part of our key strategic initiatives expected to drive both near-term and long-term growth."

Dr. Howard Berman, Chief Executive Officer of Coya, observed: "The Coya team is delighted to enter this exciting partnership with Dr. Reddy's, a world class organization that defines excellence in innovation and commercialization. While the agreement provides the financial resources to execute on the Phase 2 clinical program for COYA 302 in ALS, the strategic value of the partnership contributes much more than capital. We will benefit from and leverage Dr. Reddy's manufacturing expertise and growing commercial infrastructure both in the USA and worldwide as we plan together for the future of COYA 302 in ALS, a devastating disease with a high unmet need."

COYA 302 was developed out of the multi-year translational research collaboration between Coya and Houston Methodist in the laboratory of Dr. Stanley Appel, an internationally renowned

researcher and clinician. Houston Methodist is one of the leading hospital and academic research facilities.

About Coya 302:
COYA 302 is an investigational and proprietary biologic combination therapy with a dual immunomodulatory mechanism of action intended to enhance the anti-inflammatory function of regulatory T cells (Tregs) and suppress the inflammation produced by activated monocytes and macrophages. COYA 302 is comprised of proprietary low dose interleukin-2 (LD IL-2) and CTLA-4 Ig, and is being developed for subcutaneous administration for the treatment of patients with ALS. These mechanisms may have additive or synergistic effects.

In February of 2023 Coya announced results from a proof-of-concept, open-label clinical study evaluating LD IL-2 and CTLA-4 Ig in small cohort of patients with ALS, conducted at the Houston Methodist Research Institute (Houston, Texas) by Stanley Appel, M.D., Jason Thonhoff, M.D., Ph.D., and David Beers, Ph.D. This study was the first-of-its-kind evaluating this dual-mechanism immunotherapy for the treatment of ALS. Patients in the study received investigational treatment for 48 consecutive weeks and were evaluated for safety and tolerability, Treg function, serum biomarkers of oxidative stress and inflammation, and clinical functioning as measured by the ALSFRS-R scale.

During the 48-week treatment period, the therapy was well tolerated. The most common adverse event was mild injection-site reactions. No patient discontinued the study, and no deaths or other serious adverse events were reported.

Patients' disease progression was measured using the ALSFRS-R scale, a validated rating tool for monitoring the progression of disability in patients with ALS. The mean (±SD) ALSFRS-R scores at week 24 (33.75 ±3.3) and week 48 (32 ±7.8) after initiation of treatment were not statistically different compared to the ALSFRS-R score at baseline (33.5 ±5.9), suggesting significant amelioration in the progression of the disease over the 48-week treatment period.

Treg suppressive function, expressed as percentage of inhibition of proinflammatory T cell proliferation, showed a statistically significant increase over the course of the treatment period and was significantly reduced at the end of the 8-week washout post-treatment period. Treg suppressive function at 24 weeks (79.9±9.6) and 48 weeks (89.5±4.1) were significantly higher compared to baseline (62.1±8.1) ($p<0.01$), suggesting enhanced and durable Treg suppressive function over the course of treatment. In contrast, Treg suppressive function (mean ±SD) was significantly decreased at the end of the 8-week washout period compared to end-of-treatment at week 48 (70.3±8.1 vs. 89.5±4.1, $p <0.05$).

The study also evaluated serum biomarkers of inflammation, oxidative stress, and lipid peroxides. The available data up to 16 weeks after initiation of treatment suggest a decrease of these biomarker levels, which is consistent with the observed enhancement of Treg function. The evaluation of the full biomarker data is ongoing.

Coya 302 is an investigational product not yet approved by the U.S. Food and Drug Administration or any other regulatory agency.

About Dr. Reddy's biosimilars/biologics programme:
A part of its key strategic initiatives, it is expected to drive both near-term and long-term growth. Over the last 20 years, the team has developed into a fully integrated organisation with robust capabilities in the development, manufacture and commercialisation of a range of biosimilar products in oncology and immunology. The portfolio currently has six commercial biosimilar products marketed in India and over 27 Emerging Markets. In addition, there are several products in the pipeline in oncology and auto-immune diseases in various stages of development for global launches across regulated as well as emerging markets. Coya has successfully completed the Phase 2 study and initiated the Phase 3 study of DRL_TC, its proposed biosimilar of tocilizumab via both the subcutaneous and intravenous routes, for global markets. Dr. Reddy's proposed rituximab biosimilar application has been accepted for review by the USFDA, EMA and MHRA. Coya has also ramped up manufacturing capacity to support its global expansion plans.

About Dr. Reddy's Laboratories Limited:
Dr. Reddy's Laboratories Ltd. (BSE: 500124, NSE: DRREDDY, NYSE: RDY, NSEIFSC: DRREDDY) is a global pharmaceutical company headquartered in Hyderabad, India. Established in 1984, it is committed to providing access to affordable and innovative medicines. Driven by its purpose of 'Good Health Can't Wait', the company offers a portfolio of products and services including APIs, generics, branded generics, biosimilars and OTC. Its major therapeutic areas

of focus are gastrointestinal, cardiovascular, diabetology, oncology, pain management and dermatology. Its major markets include – USA, India, Russia & CIS countries, China, Brazil and Europe. As a company with a history of deep science that has led to several industry firsts, Dr. Reddy's continues to plan and invest in the businesses of the future. As an early adopter of sustainability and ESG actions, we released its first Sustainability Report in 2004. Its current ESG goals aim to set the bar high in environmental stewardship; access and affordability for patients; diversity; and governance. For more information, log on to: https://www.drreddys.com/.

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About Coya Therapeutics, Inc.
Headquartered in Houston, TX, Coya Therapeutics, Inc. (Nasdaq: COYA) is a clinical-stage biotechnology company developing proprietary treatments focused on the biology and potential therapeutic advantages of regulatory T cells ("Tregs") to target systemic inflammation and neuroinflammation. Dysfunctional Tregs underlie numerous conditions including neurodegenerative, metabolic, and autoimmune diseases, and this cellular dysfunction may lead to a sustained inflammation and oxidative stress resulting in lack of homeostasis of the immune system.

Coya's investigational product candidate pipeline leverages multiple therapeutic modalities aimed at restoring the anti-inflammatory and immunomodulatory functions of Tregs. Coya's therapeutic platforms include Treg-enhancing biologics, Treg-derived exosomes, and autologous Treg cell therapy. Coya's 300 Series product candidates, COYA 301 and COYA 302, are biologic therapies intended to enhance Treg function and expand Treg numbers. COYA 301 is a cytokine biologic for subcutaneous administration intended to enhance Treg function and expand Treg numbers in vivo, and COYA 302 is a biologic combination for subcutaneous and/or intravenous administration intended to enhance Treg function while depleting T effector function and activated macrophages. These two mechanisms may be additive or synergistic in suppressing inflammation. For more information about Coya, please visit www.coyatherapeutics.com.

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Forward-Looking Statements

This press release contains “forward-looking” statements that are based on our management’s beliefs and assumptions and on information currently available to management. Forward-looking statements include all statements other than statements of historical fact contained in this presentation, including information concerning our current and future financial performance, business plans and objectives, current and future clinical and preclinical development activities, timing and success of our ongoing and planned clinical trials and related data, the timing of announcements, updates and results of our clinical trials and related data, our ability to obtain and maintain regulatory approval, the potential therapeutic benefits and economic value of our product candidates, competitive position, industry environment and potential market opportunities. The words “believe,” “may,” “will,” “estimate,” “continue,” “anticipate,” “intend,” “expect,” and similar expressions are intended to identify forward-looking statements.

Forward-looking statements are subject to known and unknown risks, uncertainties, assumptions and other factors including, but not limited to, those related to risks associated with the impact of COVID-19; the success, cost and timing of our product candidate development activities and ongoing and planned clinical trials; our plans to develop and commercialize targeted therapeutics; the progress of patient enrollment and dosing in our preclinical or clinical trials; the ability of our product candidates to achieve applicable endpoints in the clinical trials; the safety profile of our product candidates; the potential for data from our clinical trials to support a marketing application, as well as the timing of these events; our ability to obtain funding for our operations; development and commercialization of our product candidates; the timing of and our ability to obtain and maintain regulatory approvals; the rate and degree of market acceptance and clinical utility of our product candidates; the size and growth potential of the markets for our product candidates, and our ability to serve those markets; our commercialization, marketing and manufacturing capabilities and strategy; future agreements with third parties in connection with the commercialization of our product candidates; our expectations regarding our ability to obtain and maintain intellectual property protection; our dependence on third party manufacturers; the success of competing therapies or products that are or may become available; our ability to attract and retain key scientific or management personnel; our ability to identify additional product candidates with significant commercial potential consistent with our commercial objectives; ; and our estimates regarding expenses, future revenue, capital requirements and needs for additional financing.

We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy, short-term and long-term business operations and objectives, and financial needs. Moreover, we operate in a very competitive and rapidly changing environment, and new risks may emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed herein may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. Although our management believes that the expectations reflected in our forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances described in the forward-looking statements will be achieved or occur. We undertake no obligation to publicly update any forward-looking statements, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.