# Codiak BioSciences Announces Program Reprioritization and Corporate Restructuring

August 30, 2022

– Enrollment continues in Phase 1 clinical trial of IV-administered exoASO™-STAT6 in patients with advanced hepatocellular carcinoma –

– Prioritizing vaccine program funded by CEPI and advancement of engEx-AAV™ for gene delivery –

– Plans to initiate Phase 2 studies of exoSTING™ and exoIL-12™ paused -

– Codiak expanding strategic discussions; aligning headcount with current priorities –

CAMBRIDGE, Mass., Aug. 30, 2022 (GLOBE NEWSWIRE) -- Codiak BioSciences, Inc. (NASDAQ: CDAK), a clinical-stage biopharmaceutical company pioneering the development of exosome-based therapeutics as a new class of medicines, today announced a reprioritization of its clinical and research initiatives, an acceleration of discussions related to potential strategic corporate and program-based partnerships, and a restructuring of operations to support a streamlined set of priorities.

"We are focused on positioning Codiak for success in the current capital markets environment, prioritizing engEx® platform programs which we believe are well-positioned to generate compelling new clinical and preclinical data in the near term. We are also accelerating strategic and collaborative discussions at both the corporate level and for specific clinical candidates and engEx® platform programs," said Douglas E. Williams, Ph.D., President and CEO of Codiak. "The preclinical and human clinical data generated to date validate our initial vision for this broad platform and support the tolerability and predictable pharmacology of exosome therapeutic candidates with early signs of clinical activity."

**Program Updates**

- **exoASO™-STAT6** is Codiak's first systemically administered exosome-based drug candidate, and its third candidate to enter clinical trials. exoASO-STAT6 is engineered to selectively deliver antisense oligonucleotides to disrupt STAT6 signaling in tumor associated macrophages (TAMs) and induce an anti-tumor immune response. Preclinical studies of exoASO-STAT6 showed single agent anti-tumor activity in models of aggressive hepatocellular carcinoma (HCC). Enrollment continues in the Phase 1 clinical trial of exoASO™-STAT6 in patients with advanced HCC, liver metastases from primary gastric cancer and colorectal cancer where high STAT6 transcript levels correlate with poor prognosis for patients. Data is expected during the first half of 2023.
- Codiak announced last month a new partnership with CEPI (Coalition for Epidemic Preparedness Innovations) to advance its **exoVACC™** pan betacoronavirus program. As part of the partnership, CEPI is providing seed funding of up to $2.5 million, which Codiak anticipates will fund the completion of preclinical development and identification of a clinical candidate by early next year.
- Preclinical data presented at ASGCT earlier this year on the Company's **engEx-AAV ™** discovery program, demonstrated efficient incorporation of AAV capsids inside exosomes where they were not subject to neutralization by antibodies against AAV. These engineered constructs efficiently transduce target cells and support the idea of engEx-AAV for repeat dosing of gene delivery constructs. Codiak's team will continue to advance this program toward generation of *in vivo* proof-of-concept data later this year.
- Codiak is pausing plans to initiate Phase 2 trials of exoSTING™ and exoIL-12™. Platform-validating data from Phase 1 trials for both programs were reported in June, demonstrating potential for best-in-class profiles, and Codiak identified a recommended Phase 2 dose for each candidate.
- Codiak is prioritizing discussions related to establishing potential new strategic and collaborative initiatives for the Company, including program-based partnerships. Codiak's existing research and business partnerships with Lonza and Jazz Pharmaceuticals are continuing, with resources committed to attain key goals.

**Organizational Updates**

Codiak BioSciences has aligned the organization to reflect its smaller, refocused pipeline. The Company's workforce will be reduced by 37%, to 53 full-time employees, to support the priority programs mentioned above.

Dr. Williams added, "We're incredibly proud of the work of our team having created, manufactured and brought into the clinic the first engineered exosomes. I would like to personally thank every Codiak employee for their trailblazing work, particularly those who are impacted by today's announcement. Together we have made great strides toward making this new modality a reality for patients, and we remain strongly committed to realizing this important goal."

**Financial Overview**

As of June 30, 2022, Codiak had cash, cash equivalents, and marketable securities of approximately $41.8 million. An essential component of the Company's strategic corporate and partnering discussions and other initiatives is exploring prospective opportunities to provide funding to enable extension of Codiak's cash runway and the potential to resource additional programs.

**About Codiak BioSciences**
Codiak is a clinical-stage biopharmaceutical company pioneering the development of exosome-based therapeutics, a new class of medicines with the potential to transform the treatment of a wide spectrum of diseases with high unmet medical need. By leveraging the biology of exosomes as natural intercellular transfer mechanisms, Codiak has developed its proprietary engEx® Platform to expand upon the innate properties of exosomes to design, engineer and manufacture novel exosome therapeutic candidates. Codiak has utilized its engEx® Platform to generate a deep pipeline of engineered exosomes aimed at treating a broad range of disease areas, spanning oncology, infectious disease and rare disease.

**Forward-Looking Statements**
This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including, among other things, statements concerning the development and therapeutic potential of the Company's portfolio, the clinical development of exoASO-STAT6, statements regarding the capabilities and potential of Codiak's engEx Platform and engineered exosomes generally, and statements regarding the program reprioritization, plans to expand discussions related to potential strategic corporate and program-based partnerships, and the restructuring of operations. Any forward-looking statements in this press release are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. In particular, the statements regarding the initiation and timing of clinical trials are dependent upon availability of sufficient cash resources, and statements regarding the restructuring are dependent on Codiak's ability to successfully implement the restructuring and the impact of the restructuring on Codiak's business, as to which the Company can make no assurances. For a discussion of these risks and uncertainties, and other important factors, any of which could cause our actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in Codiak's Annual Report on Form 10-K for the year ended December 31, 2021, and in subsequent filings with the Securities and Exchange Commission (SEC), as well as discussions of potential risks, uncertainties and other important factors in Codiak's subsequent filings with the SEC. All information in this press release is current as of the date of this report, and Codiak undertakes no duty to update this information unless required by law.

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