Caladrius Biosciences Announces Addition of Four Clinical Sites, Including Joslin Diabetes Center, for the Ongoing Phase 2 Study of CLBS03 in T1D

April 3, 2017

BASKING RIDGE, N.J., March 30, 2017 — Caladrius Biosciences, Inc. (NASDAQ:CLBS) (“Caladrius” or the “Company”), a cell therapy company advancing a select therapeutic development pipeline, announces today that four additional clinical sites, including Joslin Diabetes Center, an affiliate of Harvard Medical School, under the direction of investigator Jason L. Gaglia, MD, have opened to enroll subjects for the Company’s Phase 2 clinical trial of CLBS03 in type 1 diabetes, The Sanford Project: T-Rex Study. The other clinical sites include Children’s Mercy Hospital (under Mark A. Clements, MD), the University of Miami Diabetes Research Institute (under David Baidal, MD) and Vanderbilt University Hospital (under Daniel J. Moore, PhD, MD). These sites will contribute to the continued enrollment of subjects in the trial to meet the total of 111. The study is evaluating CLBS03 (the Company’s product candidate consisting of autologous expanded regulatory T cells, or Tregs) as a treatment for recent-onset type 1 diabetes (T1D).

These four clinical sites join existing clinical sites for the T-Rex Study at Sanford Research (Sioux Falls, South Dakota under Kurt Griffin, MD, PhD and Fargo, North Dakota under Luis Casas, MD), Indiana University under Linda DiMeglio, MD, MPH, UCSF Benoiff Children’s Hospital San Francisco under Stephen Gitelman, MD, the Barbara Davis Center for Diabetes in Aurora, Colorado under Peter Gottlieb, MD, the Harold Schnitzer Diabetes Health Center at Oregon Health & Science University under Ines Guttman-Bauman, MD and University of Florida Diabetes Institute under Michael Haller, MD. The study is expected to include approximately 12 U.S. study sites.

“We are pleased to welcome Drs. Gaglia, Clements, Baidal, Moore and their teams to the T-Rex Study. All of these clinical sites are expected to contribute to meeting our goals of enrollment,” said David J. Mazzo, PhD, President and Chief Executive Officer of Caladrius. “They join a geographically diverse group of clinical sites experienced in the conduct of diabetes clinical research and reinforce our expectation to meet the announced milestone achievements for the study.”

The Company expects to reach the important milestone of treating 50% of subjects by mid-2017. The results from a pre-specified interim analysis of early therapeutic effect for the study triggered after approximately 50% of subjects reach the 6-month post-treatment follow-up visit is expected to be announced late 2017/early 2018. The enrollment of the 70th subject in the study, expected to occur in mid-2017, will trigger an additional infusion of capital pursuant to the terms of the recently announced private placements of Caladrius common stock.

About The Sanford Project: T-Rex Study

The landmark study, which is being conducted in collaboration with Sanford Research, a Sanford Health subsidiary, is a prospective, randomized, placebo-controlled, double-blind Phase 2 clinical trial to evaluate the safety and efficacy of CLBS03 as a treatment for T1D, in approximately 111 subjects age 8 to 17 with recent-onset T1D. Subjects are randomized into one of three groups to receive, through a single administration, either a high dose of CLBS03, a low dose of CLBS03 or placebo. Following safety evaluations of the first cohort of 19 subjects after 1 and 3-months of treatment, the enrollment of the second cohort of subjects has continued since October 2016. The key endpoints for the trial are the standard medical and regulatory endpoints for a T1D trial and include preservation of C-peptide, an accepted measure for pancreatic beta cell function; insulin use; severe hypoglycemic episodes; and glucose and hemoglobin A1c levels. For more information on The Sanford Project: T-Rex Study, please visit https://clinicaltrials.gov/ct2/show/NCT02691247.

About Caladrius Biosciences

Caladrius Biosciences, Inc. is a cell therapy development company with cell therapy products in development based on multiple technology platforms and targeting autoimmune and cardiology indications. The Company is investigating its lead product candidate, CLBS03, for the treatment of recent-onset type 1 diabetes in a currently enrolling Phase 2 trial. The Company's subsidiary, PCT, is a well-known development and manufacturing partner exclusively focused on the cell therapy industry and has served over 100 clients since 1999. For more information on Caladrius please visit www.caladrius.com.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements reflect management's current expectations, as of the date of this press release, and involve certain risks and uncertainties. All statements other than statements of historical fact contained in this press release are forward-looking statements. The Company's actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors. Factors that could cause future results to materially differ from the recent results or those projected in forward-looking statements include the "Risk Factors" described in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission ("SEC") on March 17, 2017, and in the Company's other periodic filings with the SEC. The Company's further development is highly dependent on, among other things, future medical and research developments and market acceptance, which are outside of its control.

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