Caladrius Biosciences Announces Addition of Three Clinical Sites, Including University of California, San Francisco, for the Ongoing Phase 2 Study of CLBS03 in T1D

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BASKING RIDGE, N.J., Jan. 25, 2017 — Caladrius Biosciences, Inc. (NASDAQ:CLBS) ("Caladrius" or the "Company"), a cell therapy company combining a select therapeutic development pipeline with an industry-leading development and manufacturing services provider (PCT), announces today that three additional clinical sites, including the UCSF Benioff Children's Hospital San Francisco ("UCSF"), under the direction of investigator Stephen Gitelman, 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 University of Florida Diabetes Institute (under Michael Haller, MD) and the Harold Schnitzer Diabetes Health Center at Oregon Health & Science University (under Ines Guttman-Bauman, 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).

Dr. Gitelman is chairman of the executive steering committee for the T-Rex Study. Dr. Gitelman, along with Kevan Herold, MD, at Yale University, and Jeffrey Bluestone, PhD of UCSF (inventor of the Treg technology which comprises CLBS03) conducted a Juvenile Diabetes Research Foundation funded Phase 1 study of this technology. Two-year results[1] from that study provided evidence for safety and tolerability of autologous expanded polyclonal Treg cell therapy in fourteen adults with recent-onset T1D. Additionally, the Tregs retained their T cell receptor diversity and demonstrated enhanced functional activity..

"Related approaches with Tregs are moving forward in other autoimmune diseases and in transplantation, but type 1 diabetes is at the forefront of evaluating this cell-based therapy," said Dr. Gitelman. "We are very excited about this novel approach to treating type 1 diabetes, and look forward to expanding upon our initial findings in adults with this Phase 2 trial for adolescents."

These three 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), the Barbara Davis Center for Diabetes in Aurora, Colorado under Peter Gottlieb, MD and Indiana University under Linda DiMeglio, MD, MPH. The study is expected to include approximately 12 U.S. study sites.

"We are pleased to welcome Drs. Gitelman, Haller, Guttman-Bauman and their teams to the T-Rex Study. Dr. Gitelman has and will continue to provide valuable guidance for the trial and all of these clinical sites are expected to contribute to meeting our goals of enrollment," said David J. Mazzo, PhD, 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 infusion of capital pursuant to the terms of the recently announced private placements of Caladrius common stock.

1. Bluestone, J., et al. (2015) Type 1 diabetes immunotherapy using polyclonal regulatory T cells. *Science Translational Medicine,* 7 (315).

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 12 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. Enrollment of the first cohort of 19 subjects, designated for a preliminary safety evaluation, was completed in August 2016. The evaluation produced favorable safety data and the Company began enrollment of the second cohort of subjects in 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's subsidiary, PCT, is a leading development and manufacturing partner exclusively focused on the cell therapy industry and has served over 100 clients since 1999. PCT provides a wide range of innovative services including product and process development, GMP manufacturing, engineering and automation, cell and tissue processing, logistics, storage and distribution, as well as expert consulting and regulatory support. For more information on Caladrius please visit www.caladrius.com and for more information on PCT please visit www.pctcaladrius.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 15, 2016, 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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