



## Caladrius Biosciences Announces that 50% of Subjects Have Been Treated in the Phase 2 Clinical Trial of CLBS03 for Type 1 Diabetes

July 19, 2017

*Pre-specified interim analysis to occur six months post-treatment*

**BASKING RIDGE, N.J. (July 19, 2017)** – Caladrius Biosciences, Inc. (NASDAQ: CLBS) (“Caladrius” or the “Company”), a development stage biopharmaceutical company with multiple technology platforms targeting autoimmune and select cardiology indications, announces that 50% of subjects have been treated in The Sanford Project: T-Rex Study, a prospective, randomized, placebo-controlled, double-blind Phase 2 clinical trial to evaluate the safety and efficacy of the Company’s CLBS03 as a treatment for recent-onset type 1 diabetes (T1D). A pre-specified interim analysis of early therapeutic effect will occur after the six-month post-treatment follow-up visit, with results expected to be announced in late 2017 or early 2018. This complete study will enroll a total of approximately 111 subjects age 8 to 17.

CLBS03 is a personalized autologous cell therapy consisting of each patient’s own regulatory T cells, or Tregs, which have been expanded in number and functionally enhanced by a proprietary method developed through a collaboration with Jeffrey Bluestone, Ph.D. and renowned researchers at the University of California, San Francisco (UCSF). Caladrius holds exclusive rights to an international portfolio of issued and pending patents related to this method.

“We are very pleased to have reached this treatment milestone in our landmark study in T1D and look forward to having the preliminary data around year end. The T-Rex study is being conducted at 10 leading clinical centers throughout the U.S. whose strong interest has allowed us to enroll and treat patients rapidly. We are excited to be advancing this novel T1D therapeutic approach and look forward to treating the second half of study subjects, building on the encouraging earlier data and completing the interim analysis that may inform us as to the initial therapeutic effects of CLBS03 on adolescents with early onset T1D,” noted David J. Mazzo, PhD, President and Chief Executive Officer of Caladrius Biosciences.

Enrollment of the 70<sup>th</sup> subject in the study, which is expected to occur this summer, will trigger a \$2.4 million cash payment with the delivery of an additional 508,475 shares of Caladrius common stock to investors pursuant to the terms of the September 2016 private placements.

Stephen E. Gitelman, MD, a leading pediatric endocrinologist at UCSF, is chairman of the executive steering committee for the T-Rex Study. Dr. Gitelman, along with Kevan Herold, MD at Yale University, conducted a Phase 1 study funded by the Juvenile Diabetes Research Foundation on what is now known as CLBS03 that demonstrated Treg therapy to be well tolerated, durable and preserving of beta cell function in children. This study was published in *Clinical Immunology*. Two-year results from that study<sup>[1]</sup> provided evidence for safety and tolerability of autologous expanded polyclonal Treg cell therapy in 14 adults with recent-onset T1D. Additionally, the Tregs retained their T cell receptor diversity and demonstrated enhanced functional activity. These two-year data were published in November 2016 in the peer-reviewed journal *Translational Medicine*.

CLBS03 has U.S. Food and Drug Administration (FDA) Fast Track designation, European Medicines Agency’s Advanced Therapeutic Medicinal Product classification and FDA Orphan Drug designation as a potential new treatment for recent-onset type 1 diabetes.

### **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 development stage biopharmaceutical company with multiple technology platforms targeting autoimmune and select cardiology indications. The Company is investigating its lead product candidate, CLBS03, an ex vivo expanded polyclonal T regulatory cell therapy for the treatment of recent-onset type 1 diabetes in a currently enrolling Phase 2 trial. For more information on Caladrius please visit [www.caladrius.com](http://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 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.

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



Source: Caladrius Biosciences, Inc.