



## Caladrius Biosciences Announces Enrollment of the 70th Subject in the Phase 2 T-Rex Clinical Trial of CLBS03 for Type 1 Diabetes

September 5, 2017

*Milestone Achievement Triggered \$2.4 Million Payments to Caladrius*

**BASKING RIDGE, N.J. (September 5, 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 the 70<sup>th</sup> subject has recently been enrolled 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). Pursuant to the terms of September 2016 private placements, the achievement of this enrollment milestone triggered payments of \$2.4 million in total cash receipts, which have been received by Caladrius, with the delivery of an additional 508,475 shares of Caladrius common stock to those investors at a purchase price of \$4.72 per share.

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. Caladrius holds exclusive rights to an international portfolio of issued and pending patents related to this product.

“We are pleased that enrollment in the landmark T-Rex study continues according to plan and that we have surpassed the important milestone of treating the 70<sup>th</sup> patient, triggering a capital infusion. This capital, coupled with support from our research partner, Sanford Research, existing capital on our balance sheet as well as various grants, provides funding for this study and our current operations well beyond the end of 2018,” stated David J. Mazzo, Ph.D., President and Chief Executive Officer of Caladrius Biosciences. “We look forward to early 2018 and the expected pre-specified interim analysis of safety and potential early therapeutic effect after the six-month post-treatment follow-up visit of the first 56 subjects.”

### **About The Sanford Project: T-Rex Study**

The landmark T-rax 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. Enrollment of the first cohort of 19 subjects, designated for a preliminary safety evaluation, was completed in August 2016. The evaluation of safety data from this group was satisfactory 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.



Source: Caladrius Biosciences, Inc.