Caladrius Biosciences and Cognate BioServices Establish Manufacturing Agreement for Phase 3 Confirmatory Pivotal Clinical Trial of CLBS14 in No-option Refractory Disabling Angina

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BASKING RIDGE, NJ, AND MEMPHIS, TENN. (August 7, 2019) – Caladrius Biosciences, Inc. (Nasdaq: CLBS) ("Caladrius" or the "Company"), a late-stage therapeutics development biopharmaceutical company pioneering advancements of cell therapies in select cardiovascular and autoimmune diseases, and Cognate BioServices, Inc. ("Cognate"), a leading contract development and manufacturing organization in the global cellular therapies industry, announced today that they have entered into a manufacturing agreement for the production of CLBS14, Caladrius' CD34+ cell therapy. Under the terms of the agreement, Cognate will manufacture CLBS14 for Caladrius' Phase 3 confirmatory pivotal clinical trial in subjects with no-option refractory disabling angina ("NORDA").

"Selecting the right company for the manufacturing and supply of CLBS14 is critical to the success of this study. Cognate has a track record of producing personalized cellular therapy products reliably and cost-efficiently and we are excited to be working with them as we take this next step toward getting this important product to patients suffering from this terrible disease," said David J. Mazzo, PhD, Chief Executive Officer of Caladrius. "In addition to Cognate's capabilities to support our Phase 3 program, Cognate has experience as a commercial manufacturer of cell therapies and Cognate's facility has passed multiple FDA inspections."

In Spring 2018, Caladrius applied for, and was subsequently granted by the U.S. Food and Drug Administration ("FDA"), Regenerative Medicine Advanced Therapy ("RMAT") designation for CLBS14. Since then, the Company has worked closely with the FDA to finalize details of a Phase 3 trial that would satisfy the requirements, in combination with previously submitted Phase 1, 2 and 3 clinical data, for filing a biologics license application ("BLA") for CLBS14 in NORDA.

"We are incredibly excited to be selected as the manufacturer of CLBS14 at this important phase of clinical development," commented J. Kelly Ganjei, Chief Executive Officer of Cognate. "With patients at the heart of Cognate's mission and culture, we believe our teams will deliver high quality products for Caladrius. Our U.S. and EU cell therapy experience, and the recent investments in capacity and quality are nicely aligned with Caladrius' commercial goals."

About CLBS14

CLBS14 is a proprietary formulation of autologous G-CSF mobilized peripheral blood derived CD34+ cells – endothelial progenitor cells that reside naturally in the bone marrow. Among the functions of these cells is the preprogrammed ability to induce capillary growth to regenerate microcirculation in damaged tissue experiencing microvascular insufficiency. CLBS14, administered via intramyocardial injection, is formulated specifically to enhance the potency of the natural process whereby CD34+ cells repair and regenerate microvasculature.

About No-Option Refractory Disabling Angina (NORDA)

Nearly 100,000 refractory angina patients in the United States are categorized as "no-option and disabled" resulting in disease that is recalcitrant to medical therapy and not amenable to conventional revascularization procedures. Patients have recurring lifestyle-limiting symptoms such as chest pain and shortness of breath and are easily fatigued. These symptoms are often due to totally occluded coronary arteries or to diffuse coronary atherosclerosis that makes revascularization problematic. As the population ages and the incidence of diabetes mellitus increases, this clinical condition is expected to become more prevalent. Patients with this condition have significant morbidity and experience a lower quality of life.[1]

About Caladrius Biosciences

Caladrius is a late-stage therapeutics development biopharmaceutical company pioneering advancements of cell therapies for select cardiovascular and autoimmune diseases. Our leadership team collectively has decades of biopharmaceutical development experience and world-recognized scientific achievement in the fields of cardiovascular and autoimmune disease, among other areas. Our current product candidates include three developmental treatments for cardiovascular diseases based on our CD34+ cell therapy platform: CLBS12, recipient of a SAKIGAKE designation in Japan and advanced therapy medicinal product classification ("ATMP") in Europe, eligible for early conditional approval for the treatment of critical limb ischemia in Japan based on an ongoing clinical trial; CLBS16, subject of the proof-of-concept ESCaPE-CMD clinical trial in the U.S. for the treatment of coronary microvascular dysfunction; and CLBS14, recipient of a RMAT designation in the U.S. and for which we are in preparation to commence a Phase 3 clinical trial in no option refractory disabling angina. For more information on the company, please visit www.caladrius.com.

About Cognate BioServices

Cognate is a results-driven contract development and manufacturing organization (CDMO) specializing in cell and cell-mediated gene therapy products. Since 2002, Cognate has serviced autologous and allogeneic products in various stages of development from preclinical to Phase 3, and most recently in pivotal Phase 3 with FDA pre-approval inspection preparation. With development and manufacturing at our core, Cognate made significant investments in infrastructure and quality systems; and we have developed a broad range of commercialization services that facilitate logistics, supply chain planning, and capacity planning to bridge clinical to commercial manufacturing. Cognate provides and develops commercially scalable solutions so that our clients are able to offer safe and high-quality products to as many patients as possible. Please visit www.cognatebioservices.com to find out more about us.

Safe Harbor for 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 including, without limitation, all statements related to any expectations of revenues, expenses, cash flows, earnings or losses from operations, cash required to maintain current and planned operations, capital or other financial items; any statements of the plans, strategies and objectives of management for future operations; any plans or expectations with respect to product research, development and commercialization, including regulatory approvals; any other statements of expectations, plans, intentions or beliefs; and any statements of assumptions underlying any of the foregoing. Without limiting the foregoing, the words "plan," "project," "forecast," "outlook," "intend," "may," "will," "expect," "likely," "believe," "could," "anticipate," "estimate," "continue" or similar expressions or other variations or comparable terminology are intended to identify such forward-looking statements, although some forward-looking statements are expressed differently. Factors that could cause future results to differ materially 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 14, 2019 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. You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date of this Press Release. Caladrius does not intend, and disclaims any obligation, to update or revise any forward-looking information contained in this Press Release or with respect to the matters described herein.

[1]Grise MA and Verma A. Ochsner J. 2009 Winter; 9(4): 220–226.

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