Name of Organization / 会社名

Caladrius Biosciences, Inc.

URL

www.caladrius.com

Brief Descriptions of Organization / 会社概要

Caladrius is a publicly traded (NASDAQ) clinical-stage biopharmaceutical company based in the New York City area committed to the development of innovative products in cardiovascular and autoimmune disease that have the potential to restore the health of people with chronic illnesses.

Caladrius currently has four programs in the mid to late stages of clinical development, including three cell therapies for cardiovascular diseases that are based on our autologous CD34+ cell therapy platform, and additionally, an autoimmune product candidate, CLBS03, a T regulatory cell therapy for the treatment of recent-onset type 1 diabetes.

Title of Presentation / 講演タイトル

Autologous CD34 cell therapy for critical limb ischemia: a long-term Japanese-American partnership

Abstract / 要旨

Caladrius remains committed in commercializing our Sakigake-designated autologous CD34 cell therapy product, CLBS12, for the treatment of no-option Critical Limb Ischemia (CLI) in Japan. No-option CLI refers to patients who have exhausted available treatment options and remain disabled due to severe pain and/or non-healing skin ulcers. Due to its favorable regulatory environment, Japan has emerged at the forefront of research and collaborations within regenerative medicine.

The therapeutic potential of CD34+ cells was first discovered by a Japanese scientist working at a laboratory in the US, and this discovery triggered a partnership between Japanese and American physicians and scientists which continues to this day. The effectiveness and safety of CD34 cells has now been documented in numerous human clinical trials across multiple indications. In Japan 2 prior clinical trials documented the ability of a single administration of CD34 cells to permanently reverse CLI.

In collaboration with PMDA Caladrius has designed a 30 patient pivotal clinical trial of CLBS12 for CLI, targeting conditional approval. The study is underway at 10 clinical sites in Japan. In March 2018, the CLBS12 program received Sakigake designation from PMDA.

Caladrius now seeks a Japanese pharmaceutical or biotech partner to join us in this important mission to treat this debilitating condition.

Objectives and/or Motives / 目的

We are seeking to collaborate on CLBS12 with commercial and/or development partners. The CLBS12 CLI program received Sakigake designation on March 2018. Caladrius is committed to completing the current clinical trial and prior clinical data indicates a high probability of clinical success. In order to maximize the efficiency of launching this product and serving patients in need Caladrius believes that having a Japanese partner will be essential.