

Caladrius Biosciences Inc

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Caladrius Biosciences shares pop after FDA bestows favourable designation on its chronic coronary artery disease treatment

Investors sent shares of Caladrius Biosciences Inc (NASDAQ:CLBS) flying Tuesday after the US Food and Drug Administration bestowed a regenerative medicine advanced therapy (RMAT) designation on its late-stage CD34+ cell therapy program for the treatment of chronic coronary artery disease.

By the closing bell, Caladrius Biosciences finished up a whopping 67% to US\$6.61. Investors continued to rally the shares in extended trading, adding another 60% to US\$10.60.

The FDA grants the RMAT designation to regenerative medicine therapies that intend to treat serious conditions and show considerable potential. RMAT includes all the benefits of the FDA's fast track and breakthrough designations, including early-stage discussions between the FDA and the pharma company involved.

"We are delighted and encouraged that the FDA has recognized our CD34+ cell therapy program with an RMAT designation," said David Mazzo, Caladrius's president and chief executive officer. "Refractory angina is a serious condition with high morbidity and no known effective treatments. We look forward to working with the FDA to define a path to registration for our therapy with the aim of providing expeditious treatment to patients suffering from this condition," he added.

Caladrius acquired an exclusive international license to the late-stage CD34+ program from the pharmaceutical group Shire Plc in March of this year. This acquisition included Phase 1, 2 and 3 clinical study data of CD34+ cell therapy as a treatment for no-option refractory angina, along with the related regulatory filings.

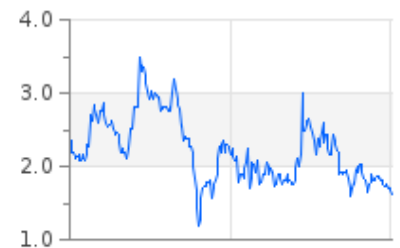
As many as 1 million people in the US have chronic symptomatic coronary artery disease, (also known as refractory angina), that is stubbornly difficult to treat with medical therapy. The symptoms of the disease include chest pain, shortness of breath and fatigue.

--Updates share price--

Price: 1.69

Market Cap: \$31.88 m

1 Year Share Price Graph



October 2019 April 2020 October 2020

Share Information

Code: CLBS

Listing: NASDAQ

| 52 week | High | Low |
|---------|------|------|
| | 3.58 | 1.15 |

Sector: Pharma & Biotech

Website: www.caladrius.com

Company Synopsis:

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.

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