

Cirius Therapeutics Completes \$40 Million Series A Financing to Fund Phase 2b Study of MSDC-0602K in NASH, Adds to Executive Team

Frazier Healthcare Partners and Novo A/S lead new investment

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SAN DIEGO and KALAMAZOO, Mich., April 11, 2017 /PRNewswire/ -- Cirius Therapeutics, previously known as Octeta Therapeutics, announced today the completion of a Series A financing of up to \$40 million led by Frazier Healthcare Partners and Novo A/S. Cirius will use the proceeds to complete the ongoing EMMINENCE trial, a Phase 2b study of MSDC-0602K, a next-generation insulin sensitizer, for the treatment of patients with non-alcoholic steatohepatitis (NASH) and liver fibrosis. In addition, the company announced the appointment of Bob Baltera as chief executive officer, Howard Dittrich, M.D., as chief medical officer and Brian Farmer as chief business officer. With the additions to the management team, the company will open an office in San Diego while retaining its R&D operations in Kalamazoo.

NASH is a severe, rapidly progressive form of nonalcoholic fatty liver disease (NAFLD), which untreated can progress to cirrhosis and liver cancer. Approximately 16 million Americans suffer from NASH, which is strongly associated with insulin resistance. MSDC-0602K addresses insulin resistance, which is considered to be a key factor in the initiation and perpetuation of NASH.

First-generation insulin sensitizers have shown promising activity in NASH studies, including showing significant improvements in fibrosis and inflammation in patients with advanced disease, but their use has been limited due to safety concerns. Jerry Colca, Ph.D., Cirius' co-founder and vice president of research and development, was involved in the early development of the first-generation insulin sensitizer pioglitazone, and has conducted decades of research into discovering next-generation approaches for overcoming insulin resistance. MSDC-0602K resulted from Dr. Colca's efforts to identify new insulin sensitizers with an improved safety profile compared to previous insulin sensitizers.

"We believe MSDC-0602K has the potential to be a critical therapeutic tool for treating patients with NASH," said Baltera. "A great deal of experimental data, including results from a Phase 2 trial in patients with Type 2 diabetes, has been generated demonstrating that these next-generation insulin sensitizers act in a novel way to positively impact the underlying metabolic parameters that drive NASH."

Baltera, Dittrich and Farmer have each successfully built venture-backed companies, including Amira Pharmaceuticals for which Baltera served as CEO and was acquired by Bristol-Myers Squibb and NovaCardia, for which Dittrich served as chief medical officer and Farmer led corporate development, acquired by Merck. Dr. Colca's industry experience in metabolic disease research began with The Upjohn Company and continued with the company through its mergers with Pharmacia, Monsanto-Searle and Pfizer.

Joining Frazier Healthcare Partners and Novo A/S in the financing were new investors Adams Street Partners and Renaissance Venture Capital Fund, as well as existing investors including Hopen Life Sciences Ventures. In conjunction with the financing, Dan Estes, Ph.D., from Frazier Healthcare and Nilesh Kumar, Ph.D., of Novo A/S will join Baltera in Board positions and, along with existing representatives David Van Andel, Mike Jandernoa and Robert Zerbe, M.D., will comprise the Cirius Board of Directors.

"At Frazier, we believe the future of NASH therapies will be a multi-drug approach, with a need for therapies that address the underlying metabolic drivers of disease, as well as resultant fibrosis and inflammation," said Dr. Estes. "We see a distinct opportunity for MSDC-0602K to become a cornerstone therapy in NASH, both as monotherapy but ultimately as part of combination approaches."

About MSDC-0602K

MSDC-0602K is an oral, once-daily next-generation insulin sensitizer that avoids safety liabilities known with first-generation approaches. MSDC-0602K has the potential to correct the metabolic disturbance that is a proximate cause of NASH, building upon multiple positive studies of first-generation insulin sensitizers in NASH. Cirius is currently enrolling the EMMINENCE trial (identifier NCT02784444), a Phase 2b study of MSDC-0602K in NASH. This randomized study is comparing three doses of MSDC-0602K to placebo in NASH patients with fibrosis, and the study includes endpoints identified as suitable for registration studies based on current FDA guidelines.

About Cirius Therapeutics

Cirius Therapeutics, formerly known as Octeta Therapeutics, is a clinical-stage pharmaceutical company focused on developing therapies to treat liver disease. The company's lead product is MSDC-0602K, a second-generation insulin sensitizer for the treatment of NASH. Cirius is actively enrolling patients in a Phase 2b clinical trial called the EMMINENCE trial, to evaluate MSDC-0602K in patients with NASH and liver fibrosis. For additional information on the EMMINENCE trial, please visit clinicatrials.gov using the identifier NCT02784444. For more information about Cirius Therapeutics, visit www.ciriustx.com.

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