Rancho Santa Fe Bio, Inc. Enters into Worldwide Exclusive License Agreement with Sanofi for Ataciguat

San Diego, CA/Paris, France (June 17, 2021). Rancho Santa Fe Bio, Inc. ("RSF Bio" or the "Company"), a San Diego, California-based clinical-stage cardiovascular platform company, today announced that it has entered into an exclusive worldwide license agreement with Sanofi, a global biopharmaceutical company. This agreement provides RSF Bio with Sanofi's rights to Ataciguat. With this license, RSF Bio will have the rights it needs to continue development of Ataciguat through clinical trials in the United States and potentially in select international countries.

Before signing this license agreement, RSF Bio entered into a worldwide exclusive license agreement in December 2019 with Mayo Clinic for the use of Ataciguat in the treatment of patients with calcific aortic valve stenosis ("CAVS"). Under that license, Mayo Clinic assigned to RSF Bio its US IND No. 119,829 along with additional patents, patent applications and know-how.

CAVS is a progressive disease that afflicts predominately the older populations with a prevalence of 2% in patients over the age of 55 years. Its prevalence increases with age to approximately 12% or higher in populations >75 years of age. (Osnabrugge et al., J Am Coll Cardiol. 2013 and Faggiano et al., Am J Cardiol. 2003). CAVS is characterized by hardening of the aortic leaflets, which progresses over years and is predominately due to a maladaptive process of calcium deposition in the valves. CAVS is often fatal within a few years from symptom onset, if untreated. Currently, no medical treatment has been proven to be effective, and the treatment of choice for severe disease is aortic valve replacement, either by surgical aortic valve replacement ("SAVR") or transcatheter aortic valve replacement ("TAVR"). RSF Bio is currently in an advanced stage of development of a novel pharmaceutical treatment with the drug Ataciguat, building upon a Phase IIb clinical trial. RSF Bio is also in the early planning stages of studying application for Ataciguat in certain other uses and indications.

Sanofi originally investigated Ataciguat in numerous preclinical studies and conducted clinical trials with the drug involving over 1,000 patients in total for three different indications: (a) stable angina, (b) peripheral arterial disease and (c) neuropathic pain. Following a reprioritization of its research and development pipeline, Sanofi provided Ataciguat to the New Therapeutic Uses ("NTU") program at the U.S. National Institutes of Health's National Center for Advancing Translational Sciences Program ("NCATS"). This program is designed to encourage the application of repurposed drugs into other clinical trials. The laboratory of Jordan Miller, Ph.D., at Mayo Clinic focuses on mechanisms underlying the progression of calcium build-up in CAVS. He was awarded a grant through the NCATS program to conduct preclinical studies with Ataciguat in CAVS, followed by Phase I and Phase II clinical trials at Mayo Clinic.

"The NCATS New Therapeutic Uses program developed and disseminated innovative approaches to three-way collaborations between government, pharmaceutical companies and academic medical centers to accelerate treatment development," said Christine Colvis, Ph.D., Director of Drug Development Partnership Programs at NCATS. "The negotiation process to set up collaborative research agreements is a bottleneck in the establishment of public-private partnerships. The NTU template legal agreements provided a strong launching point for the negotiations, speeding the process," she added. "We are excited to see the goals of the program being realized through the successful progression of this project by RSF Bio to potentially Phase III clinical testing and the promise it holds to deliver better treatment options to patients suffering from CAVS."

"We are pleased about the potential of Ataciguat and the benefit it may offer to people suffering from CAVS," said Alban de La Sablière, Senior Vice President, Head of Sanofi Partnering. "After a reprioritization of our portfolio, we made a decision to repurpose this asset with NCATS and Mayo Clinic for Phase I and Phase II clinical trials and now with RSF Bio in order to advance science and bring treatment options to patients with this unmet medical need."

"This has been an exciting journey so far, from the support we received from NCATS, to our extensive interactions and close partnerships with Sanofi, and now continuing advancement of Ataciguat towards clinical use with RSF Bio," says Dr. Jordan Miller, the Chair of the Scientific Advisory Board of RSF Bio. "I am confident that the RSF Bio team will continue the advancement of therapies for CAVS and investigating applications of Ataciguat in other indications."

"We are excited about adding the Sanofi rights to those which we have already received from Mayo Clinic through its NCATS funding," said Randy Berholtz, the Chair and Chief Executive Officer of RSF Bio. "We believe we now have all of the pieces necessary to move Ataciguat along to the next level of clinical trials in the United States and internationally. We are happy to work with Mayo Clinic Venture's team and to have Dr. Miller as Chair of our Scientific Advisory Board. We look forward to collaborating with them and him on this effort involving Ataciguat in CAVS," he continued.

About Ataciguat

Ataciguat is a novel anthranilic acid derivative that belongs to a structural class of sGC activators that can activate the oxidized form of sGC. Ataciguat has been developed through a collaboration involving Sanofi, NCATS and Mayo Clinic. Ataciguat has undergone extensive pre-clinical and clinical development including Phase I and Phase II clinical trials at Mayo Clinic for treatment of the progression of CAVS. The drug and its application in CAVS is now licensed to RSF Bio for further development through clinical trials and if successful, for future commercialization.

About Rancho Santa Fe Bio, Inc.

RSF Bio is a San Diego, California clinical stage cardiovascular platform company. RSF Bio has exclusively licensed from the Mayo Clinic and from Sanofi Ataciguat for the treatment of the progression of CAVS. RSF Bio is also involved in developing additional indications for Ataciguat, developing AVS biomarkers and in conducting research and development of additional small molecules drugs in the cardiovascular and other fields. RSF Bio's website is www.rsfbio.com and for more information please contact the Company at info@rsfbio.com.