



Spruce Biosciences Receives FDA Orphan Drug Designation for SPR001 for the Treatment of Congenital Adrenal Hyperplasia

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Clinical-stage biotech granted orphan drug designation for the treatment of CAH, a rare endocrine disease

San Francisco – December 4, 2017 – [Spruce Biosciences](http://sprucebiosciences.com), a clinical-stage biotechnology company developing novel therapies for rare endocrine disorders, today announced that the U.S. Food and Drug Administration (FDA) has granted orphan drug designation for SPR001 for the treatment of congenital adrenal hyperplasia (CAH).

Earlier this year, Spruce initiated a Phase 2 clinical trial to assess the safety and efficacy of SPR001 in adults with classic CAH. This study is currently enrolling at centers across the U.S., with topline data expected in 2018. Patients interested in seeing if they may be eligible to participate can visit the clinical trial study site [here](#).

"Receiving orphan drug designation is an important regulatory milestone, and we are pleased that SPR001 for CAH has been granted this status. We are developing SPR001 with the objective of providing individuals with CAH an effective treatment, and our team is committed to advancing the clinical development program to address this unmet need," said Dr. Alexis Howerton, CEO, Spruce Biosciences.

CAH is a rare endocrine disorder that is caused by genetic mutations resulting in the inability to produce the critical 'stress' hormone cortisol. Although CAH is part of the newborn screening program, there are currently no FDA-approved therapies for CAH. CAH is typically treated with chronic, high-dose steroids which commonly leads to significant side effects and long-term health consequences.

"Treatments to improve the lives of CAH patients are of critical interest to CARES Foundation. We applaud the work of Spruce Biosciences in this space and look forward to continuing to collaborate with Spruce to provide patients with more options," said Dina Matos, Executive Director, CARES Foundation. CARES is a non-profit organization dedicated to improving the lives of patients with CAH through community support, advocacy, education, and research.

The FDA grants orphan drug designation to promote the development of promising products for rare conditions that affect fewer than 200,000 people in the U.S. and for which significant unmet need remains. This designation provides sponsors with development and commercial incentives including market exclusivity, tax credits for clinical research costs and the waiver of certain administrative fees.

For more information on Spruce Biosciences and its lead clinical program for CAH, please visit sprucebiosciences.com.

About Spruce Biosciences

Spruce Biosciences is a clinical-stage biotechnology company developing novel therapies for rare endocrine disorders. The Spruce team is leveraging their extensive expertise in endocrinology and orphan drug development to meet the significant unmet need of patients suffering from rare endocrine diseases. Spruce's lead product candidate, SPR001, has a novel and clinically verified mechanism of action (MOA) and is currently in Phase 2 clinical trials for congenital adrenal hyperplasia, a rare disease that is screened in newborns and for which there is not yet an FDA-approved therapy. The Company is headquartered in San Francisco and closed a Series A Financing of \$20 million in 2016. For more information on Spruce, please visit sprucebiosciences.com.

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