



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

January 5, 2017

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

San Francisco – January 5, 2017 – [Spruce Biosciences](#), a clinical-stage biotechnology company developing novel therapies for rare endocrine disorders, today announced that the European Medicines Agency (EMA) has granted orphan drug designation for SPR001 for the treatment of congenital adrenal hyperplasia (CAH).

Earlier this month, Spruce [also received orphan drug designation](#) for SPR001 from the U.S. Food and Drug Administration (FDA). "The granting of orphan drug designation by both the EMA and FDA represents an important step forward for our lead product candidate, and underscores the high unmet medical need for developing new therapies that may benefit patients living with congenital adrenal hyperplasia," said Dr. Alexis Howerton, CEO, Spruce Biosciences.

Spruce is currently in a Phase 2 clinical trial to assess the safety and efficacy of SPR001 in adults with classic CAH. This study is 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](#).

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](#).

Media Contact

Sumitra Gupta
Canale Communications
619-849-6006
sumitra@canalecomm.com