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Solvias to Perform Release Testing on World's First CRISPR-based Gene-Editing Therapy

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Global Provider Signs Long-Term Agreement with Vertex Pharmaceuticals for CASGEVY™

Kaiseraugst, Switzerland – January 23, 2024 – Solvias, a global provider of chemistry, manufacturing, and control (CMC) analytics, announced today that it will perform analytical release testing services on the world's first CRISPR/Cas9 genome-edited cell therapy. The company has signed a long-term agreement with Vertex Pharmaceuticals for CASGEVY™ (exagamglogene autotemcel or exa-cel) which received U.S. Food & Drug Administration (FDA) approval for the treatment of sickle cell disease (SCD) in patients 12 years and older with recurrent vaso-occlusive crises.

Solvias and Vertex Pharmaceuticals have worked together for several years to develop and validate test methods that are critical for the final release of patients' own edited cells, so that they can be delivered back to patients. The companies' collaboration included establishing the testing methods that will be scaled for commercializing CASGEVY. Solvias also has invested significantly in preparing one of its global facilities to support the commercial release work for this transformative therapy.

Archie Cullen, Chief Executive Officer, Solvias, stated:

"Solvias is honored to be playing a critical role in delivering this breakthrough therapy to patients. Our decades of experience offering comprehensive GMP analytical services uniquely positions us to partner with companies in bringing their therapies to market. This collaboration highlights our deep scientific knowledge and creative solutions serving to advance even the most cutting-edge therapies."

In addition to gaining FDA approval, CASGEVY recently received a positive opinion from the European Medicines Agency's (EMA's) Committee for Medicinal Products for Human Use for conditional approval of the treatment of severe SCD and transfusion-dependent beta thalassemia (TDT).

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About Solvias

Solvias is a global provider of chemistry, manufacturing, and control (CMC) analytics to the pharmaceutical, biotech, material science, and cosmetic industries. Its team of scientists and regulatory experts have years of experience in small molecules, biologics, and cell and gene therapies. The company offers comprehensive solutions from raw materials to drug products to final release testing, as well as API development and manufacturing for small molecules. Headquartered near Basel, Switzerland, Solvias operates five facilities to the highest standards and in accordance with ISO, GMP, GLP and FDA regulations. For more information, visit solvias.com.

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