

PRESS RELEASE

Number 1

Wacker Biotech Provides Active Ingredient to Treat Achondroplasia in Children for Ascendis Pharma Global Phase-2 Trial

Munich / Jena, January 8, 2020 – Wacker Biotech has reached a major milestone in supporting Ascendis Pharma’s TransCon™ CNP program. Following the success of clinical phase 1, Ascendis Pharma has completed an application in the U.S. for initiation of a global phase 2 trial for TransCon™ CNP in children with achondroplasia, the most common form of dwarfism. TransCon™ CNP drug substance, a transiently conjugated peptide using TransCon™ technology, is being made by Wacker Biotech GmbH in Jena, Germany.

Roughly 250,000 patients worldwide suffer from achondroplasia, the most common form of dwarfism, for which the FDA (U.S. Food and Drug Administration) and EMA (European Medicines Agency) have not yet approved any therapy. Danish biotech company Ascendis Pharma is working to close this gap and meet significant medical needs by developing TransCon™ CNP, which is designed to address all aspects of achondroplasia by providing continuous CNP (C-type natriuretic peptide) exposure with a once-weekly dose. Ascendis Pharma is being supported by Wacker Biotech GmbH, which Ascendis Pharma has contracted to manufacture TransCon™ CNP. Following the success of clinical phase 1, an application for initiation of a global phase 2 trial for TransCon™ CNP in children with achondroplasia has been filed at the FDA.

“We are delighted to be able to support Ascendis Pharma in supplying the clinical trials for TransCon™ CNP in children with achondroplasia. Wacker Biotech sees itself as a reliable partner to pharmaceutical and biotech companies for developing and producing biologics to international GMP standards,” said Dr. Susanne Leonhartsberger, managing director of Wacker Biotech GmbH, a WACKER Group subsidiary based in Jena. “We are expert in the bioengineered production of active ingredients on a small and large scale, for clinical development phases for approving a drug, as well as for supplying the commercial market afterward,” she added.

Wacker Biotech has been working with Ascendis Pharma since 2017. The process for making the candidate based on Ascendis Pharma’s proprietary TransCon technology was transferred successfully to Wacker Biotech GmbH in Jena at the start of this partnership. TransCon™ CNP is manufactured there in compliance with pharmaceutical GMP (Good Manufacturing Practice) requirements to ensure the high quality necessary for the approval of clinical trials or for market approval by the FDA or EMA. Wacker Biotech made the material both for the successful phase 1 trial and for the phase 2 trial that has now been applied for.

TransCon™ CNP is a long-acting prodrug of C-type natriuretic peptide (CNP) in development for children with achondroplasia. Phase 1 results demonstrated that TransCon™ CNP provided continuous exposure to CNP with a pharmacokinetic profile designed to maximize efficacy with once-weekly dosing.

The ACcomplisH trial that has now been applied for is a global, phase 2, randomized, double-blind, placebo-controlled trial that will enroll approximately 60 children, aged 2 to 10, with achondroplasia. It is designed to demonstrate the safety and efficacy of TransCon™ CNP in children with achondroplasia.

About Wacker Biotech

Wacker Biotech GmbH and Wacker Biotech B.V. are full-service contract manufacturers of biopharmaceutical proteins based on microbial systems. The companies' services range from molecular biology, analytical services and process development through to the GMP-compliant manufacture of clinical test samples and pharmaceutical actives, live microbial products and vaccines for the commercial market. Wacker Biotech has three GMP-compliant, FDA- and EMA-certified production plants in Jena and Halle in Germany and in Amsterdam in the Netherlands. Above all, Wacker Biotech offers proprietary technologies that satisfy market needs for cost-efficient production and maximum quality. Wacker Biotech GmbH and Wacker Biotech B.V. are wholly-owned subsidiaries of the Munich-based WACKER Group.

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The company in brief:

WACKER is a globally-active chemical company with some 14,500 employees and annual sales of around €4.98 billion (2018).
WACKER has a global network of 24 production sites, 22 technical competence centers and 50 sales offices.

WACKER SILICONES

Silicone fluids, emulsions, rubber grades and resins; silanes; pyrogenic silicas; thermoplastic silicone elastomers

WACKER POLYMERS

Polyvinyl acetates and vinyl acetate copolymers and terpolymers in the form of dispersible polymer powders, dispersions, solid resins and solutions

WACKER BIOSOLUTIONS

Biotech products such as cyclodextrins, cysteine and biologics, as well as fine chemicals and PVAc solid resins

WACKER POLYSILICON

Polysilicon for the semiconductor and photovoltaic industries