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Sanofi and Regeneron announce positive results for PD-1 antibody

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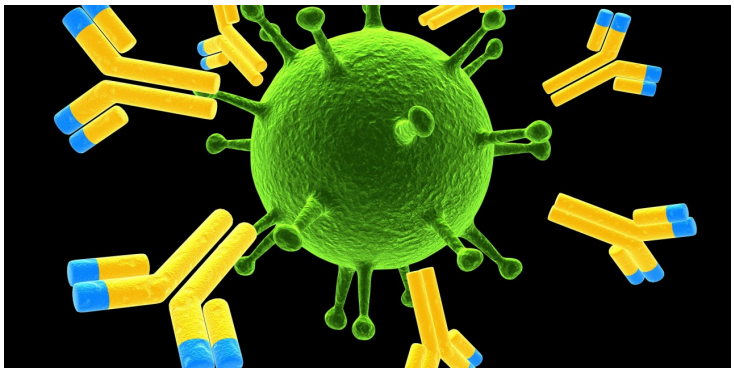
High and durable response rate in disease without any FDA-approved therapies



Sanofi and Regeneron has announced positive topline pivotal results for PD-1 antibody cemiplimab in advanced cutaneous squamous cell carcinoma.

High and durable response rate in disease without any FDA-approved therapies

Cemiplimab rolling BLA submission initiated per FDA Breakthrough Therapy Designation, with completed submission expected in Q1 2018

Sanofi and Regeneron Pharmaceuticals, Inc. has announced positive topline results from a pivotal Phase 2 clinical study of cemiplimab in 82 patients with advanced cutaneous squamous cell carcinoma (CSCC) which is the second deadliest skin cancer after melanoma.

Cemiplimab is an investigational human antibody targeting PD-1 (programmed cell death protein 1), demonstrated an overall response rate (ORR) of 46.3%, as determined by independent review. The median duration of response had not yet been reached at the data cut-off point (32 of 38 responses are ongoing). At the time of this analysis all patients had a minimum of 6 months of follow up.

The safety profile in this study was generally consistent with approved anti-PD-1 agents.

These pivotal data will form the basis of a rolling Biologics License Application (BLA) submission to the U.S. Food and Drug Administration (FDA), which has been initiated and is expected to be completed in the first quarter of 2018.

Elias Zerhouni, M.D., President, Global R&D, Sanofi said, “EMPOWER-CSCC 1 was initiated in 2016 and has enrolled rapidly, underscoring the serious unmet need in advanced CSCC. We look forward to working with regulatory agencies globally to bring this important therapy to advanced CSCC patients as quickly as possible. We continue to rapidly advance a broad development program to evaluate cemiplimab both as monotherapy and combination across a number of solid tumor and blood cancers.”

Israel Lowy, MD, PhD, Vice President of Global Clinical Development and Head of Translational Science and Clinical Oncology, Regeneron said, “For patients with CSCC that cannot be cured by surgery or radiation, there are no FDA-approved treatment options, and advanced CSCC is responsible for 3,900 to 8,800 deaths per year in the U.S. This is the largest prospective study ever conducted in this disease, and we are pleased that many people were able to achieve deep

and durable responses with cemiplimab monotherapy. The high and durable response rates seen in this study are particularly notable given that the study enrolled patients regardless of biomarker status.”

EMPOWER-CSCC 1 is a single-arm, open-label clinical trial and remains active. Enrollment is complete in the study arm of patients with metastatic CSCC receiving a 3 mg/kg dose of cemiplimab every two weeks. Enrollment continues in the remaining two study arms of patients with metastatic CSCC receiving a 350 mg flat dose of cemiplimab every three weeks and patients with locally advanced and unresectable CSCC receiving a 3 mg/kg dose of cemiplimab every two weeks.

Updated results from both the EMPOWER-CSCC 1 Phase 2 trial and the Phase 1 clinical trial will be submitted for presentation at a 2018 medical congress.

Cemiplimab is being jointly developed by Regeneron and Sanofi under a global collaboration agreement. Cemiplimab is currently under clinical development, and its safety and efficacy has not been fully evaluated by any regulatory authority.