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Sanofi, Regeneron reform global Immuno-Oncology Partnership

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Sanofi able to independently pursue own immuno-oncology programs; Regeneron retains full rights to all its other investigational immunooncology programs

Sanofi and Regeneron Pharmaceuticals, Inc. have restructured their global Immuno-oncology Discovery and Development Agreement for new immunooncology cancer treatments. The 2015 Agreement was scheduled to end in approximately mid-2020, and this revision provides for ongoing collaborative development of two clinical stage bispecific antibody programs.

This provides Sanofi increased flexibility to advance its early-stage immuno-oncology pipeline independently while Regeneron retains all rights to its other immuno-oncology discovery and development programs.

Under the terms of the restructured Agreement:

- Sanofi will pay Regeneron $462 million representing the balance of payments due under the original Immuno-oncology Agreement, which covers the Sanofi share of the immuno-oncology discovery program costs for the last quarter of 2018 and up to $120 million in development costs for the two selected clinical-stage bispecific antibodies, plus the termination fee for the other programs under the original immuno-oncology agreement.
- Sanofi secures the right to opt-in to the BCMAxCD3 and MUC16xCD3 bispecific programs when proof of concept is achieved or when the allocated funding is expended.
- Regeneron will commit up to $70 million to further develop the BCMAxCD3 bispecific antibody for multiple myeloma and up to $50 million to further develop the MUC16xCD3 bispecific for mucin-16 expressing cancers.
- Post-opt-in, Sanofi will lead development and commercialization of the BCMAxCD3 bispecific and fund 100 percent of development costs, with Regeneron reimbursing up to 50 percent out of its share of collaboration profits. Sanofi and Regeneron will share global profits equally.
- Post-opt-in, Regeneron will lead MUC16xCD3 bispecific development and lead commercialization in the U.S. The companies will share development costs and global profits equally. Sanofi will lead commercialization outside the U.S.
- The companies' ongoing collaboration for the development and commercialization of Libtayo® (cemiplimab-rwlc), a PD1 antibody, is unaffected by the amended Discovery and Development Agreement.

- Regeneron retains full rights to its other immuno-oncology programs.

Under the Immuno-Oncology License and Collaboration Agreement, the companies have developed and received U.S. Food and Drug Administration approval of Libtayo for advanced cutaneous squamous cell carcinoma (CSCC). A regulatory application for Libtayo has also been submitted in the EU. An ongoing joint clinical program is investigating Libtayo in multiple other cancers, and includes potentially pivotal trials in lung, cervical and skin cancers. Libtayo’s safety and efficacy has not been fully evaluated by any regulatory authority for indications beyond advanced CSCC.