Regeneron Collaboration Accounting Summary

Last Updated: September 30, 2020

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Sanofi accounting of Antibody License and Collaboration Agreement with Regeneron[1]

		U.S.	Ex-U.S.
Net sales		Sanofi consolidates worldwide net sales	
Cost of sales		Sanofi consolidates worldwide cost of sales	
R&D expense[2]		Development costs funded upfront by Sanofi until first positive Phase 3; subsequent costs funded 80% Sanofi / 20% Regeneron *Regeneron 20% reimbursement recorded as a reduction of Sanofi R&D expense*	
SG&A expense		Sanofi expenses 100% of its commercial expenses	
Other operating income and expenses	**1. Regeneron SG&A spend**	Sanofi reimburses Regeneron for 100% of Regeneron's commercial expenditures	
	2. Development balance	Regeneron reimburses 50% of cumulative development costs quarterly once collaboration profitable[3]; *Reimbursement capped at 10% of Regeneron's share of profit per quarter on all Antibody products combined[4]*	
	3. Collaboration profitable	Outflow: Sanofi expenses 50% of profit; paid to Regeneron	Outflow: Sanofi expenses 35% to 45% of profit; paid to Regeneron
	4. Collaboration in a loss	Inflow: Sanofi recognizes reimbursement of 50% loss from Regeneron	Inflow: Sanofi recognizes reimbursement of 45% loss from Regeneron
Amortization of intangibles (IFRS)	**Sales Milestones**		Regeneron entitled to receive up to $250m in milestones starting from $1bn ex-US sales[5]

(1) Following expiry of the Antibody Discovery Agreement in December 2017, Dupixent®, Kevzara® and IL-33 / SAR440340 continue to be developed and commercialized with Regeneron under the Antibody License and Collaboration Agreement (LCA) signed in November 2007, Amended and Restated November 2009 and further amended May 2013 and July 2015 and restructured in April 2020

(2) For discovery and pre-clinical activities, Sanofi funded $120m per year between 2007-2009; up to $160m per year between 2010-2014; up to $160m per year between 2015-2017, less $75m reallocated to the immunology-oncology agreement spread over 2015-2017; Discovery agreement expired December 31, 2017

(3) As of December 31, 2019, Sanofi has incurred $7.4bn; $3.0bn to be reimbursed; balance includes costs for Dupixent®, Kevzara® and IL-33 / SAR44034 as well as Praluent® through March 31, 2020

(4) Including Dupixent®, Kevzara® and IL-33 / SAR44034

(5) Praluent® removed from LCA at April 2020 restructuring, but ex-U.S. sales of Praluent® remain included in calculation of sales milestones

Sanofi Libtayo® accounting pursuant to immuno-oncology global collaboration[1,2]

		U.S.	Ex-U.S.
Net sales		Consolidated by Regeneron	Consolidated by Sanofi
Cost of sales		Consolidated by Regeneron	Consolidated by Sanofi
R&D expenses		Sanofi reimburses 50% of development expenses incurred during quarter[3]	
SG&A expenses		Sanofi expenses 100% of its commercial expenses	
Other operating Income and expenses	**1. SG&A reimbursement**	Inflow: Regeneron reimburses 100% of Sanofi's U.S. commercial expenses	Outflow: No Regeneron commercial expenses ex-US
	2. Development balance	Regeneron reimburses 50% of pre-POC development costs[4] quarterly, once collaboration profitable[5]	
	3. Collaboration profitable	Inflow: Sanofi recognizes 50% of collaboration's profits	Outflow: Sanofi expenses 50% of profits; to be paid to Regeneron
	4. Collaboration in a loss	Outflow: Sanofi expenses 50% of losses; to be paid to Regeneron	Inflow: Sanofi recognizes reimbursement of 50% of collaboration's losses
Amortization of intangibles (IFRS)	**Sales milestones**	Regeneron to receive $375m milestone when sales of Libtayo®, including sales of future opt-ins under the IO LCA[6] sold for use in combination with Libtayo®, exceed $2bn over any consecutive 12-month period	

(1) On July 1, 2015, Sanofi and Regeneron entered into an Immuno-Oncology (IO) Discovery and Development Agreement and an IO License and Collaboration Agreement (IO LCA). Sanofi made a $640m upfront payment. The companies agreed to reallocate $75m (spread over three years) to IO R&D from Sanofi's $160m annual contribution to their existing antibody discovery agreement. The companies agreed to invest $1bn from discovery through POC, to be funded 25% by Regeneron and 75% by Sanofi.

(2) Libtayo® collaboration unaffected by the Amended I-O Discovery and Development Agreement effective December 31, 2018. Revision provides for ongoing collaborative development of two clinical-stage bispecific antibody programs: (1) BCMAxCD3 and (2) MUC16xCD3 Agreement

(3) In January 2018, Sanofi and Regeneron announced the Libtayo® budget through 2022 was increased from $650m to $1.64bn, funded equally by the two companies

(4) As of December 31, 2019, amounts to $80m primarily for bi-specifics, LAG3 and CTLA-4 development programs

(5) Capped at 10% of Regeneron profit share per quarter

(6) Sanofi has opt-in rights with respect to each of the 2 bi-specifics antibodies (BCMAxCD3 or MUC16xCD3) covered by the Amended and Restated IO Discovery Agreement

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