Expected 2021 R&D key timelines

Pipeline charts as communicated at Q2 2021 Results Meeting dated JULY 29, 2021

	Product	Milestones	Comment	Achieved / Missed(1)
H1 2021	avalglucosidase alfa	U.S. regulatory decision, PDUFA May 18 (Pompe disease)	Fast track designation, BTD, Priority review	✗ H2 2021(3)
	Libtayo®(2)	U.S. regulatory decision, PDUFA Feb 28 (1L NSCLC PD-L1 ≥50%)	Priority review	✓
	Libtayo®(2)	U.S. regulatory decision, PDUFA March 3 (advanced BCC)	Priority review	✓
	Sarclisa®	U.S. regulatory decision PDUFA July 18 (RMM-IKEMA)		✓
	amcenestrant	Pivotal data from AMEERA-3 in 2/3L mBC	Fast track designation	✗ H2 2021(4)
	Libtayo®(2)	Pivotal data in 1L NSCLC combo with chemotherapy		✗ H2 2021(4)
	Libtayo®(2)	Pivotal data in 2L Cervical Cancer		✓
	amcenestrant	Phase 3 decision for early breast cancer	Fast track designation	✓
H2 2021	avalglucosidase alfa	EU regulatory decision (Pompe disease)		
	Dupixent®(2)	U.S. regulatory decision (Asthma 6 to 11-year)		
	Sarclisa®	EU regulatory decision (Relapsed Multiple Myeloma - IKEMA)		✓
	Dupixent®(2)	Pivotal trial read-out (Chronic Spontaneous Urticaria – CSU)		✓
	Dupixent®(2)	Pivotal trial read-out (Prurigo Nodularis – PN)		
	rilzabrutinib	Pivotal trial read-out (Pemphigus)	U.S. and EU orphan designation	
	Sarclisa®	Pivotal trial read-out (1L TiMM– IMROZ)		
2021	Adding multiple NMEs in Immunology, Oncology, and RBD in 2021 to the clinical pipeline			

NMEs: new molecular entities; RBD: Rare blood disorder; Ti: transplant ineligible; RMM: Relapsed or refractory multiple myeloma; BCC: basal cell carcinoma; BC: breast cancer

(1) Achieved: on-time readout of data, irrespective of trial outcome

(2) Developed in collaboration with Regeneron

(3) FDA PDUFA 3-month extension to August 18, 2021

(4) Event driven trial

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