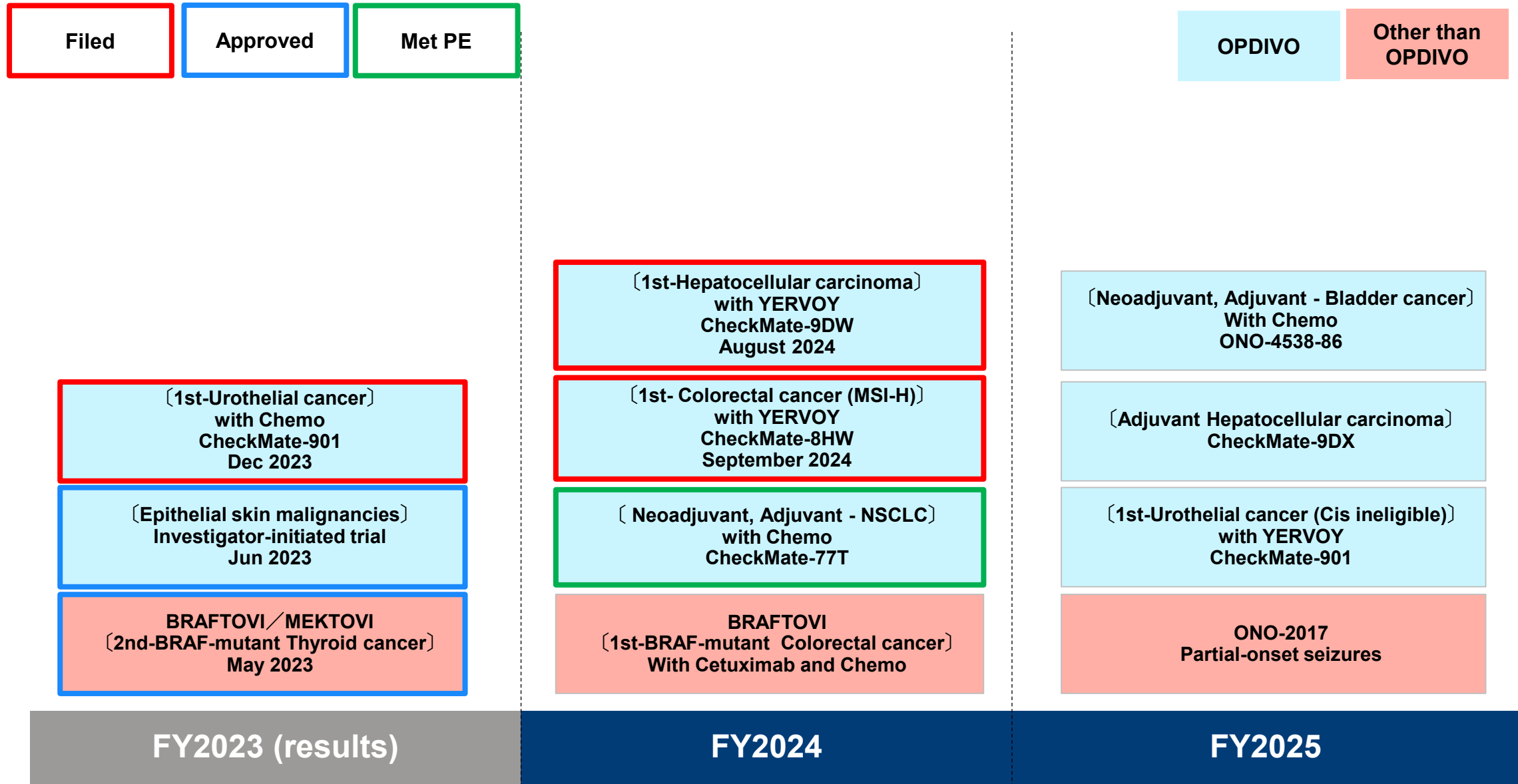


Development Pipeline Progress Status

Status of regulatory filing for approval in Japan

As of October 24, 2024



PE : Primary endpoint

Development status of OPDIVO (1)



As of October 24, 2024

Target disease	Treatment Line	Treatment	Phase				
			Japan	Korea	Taiwan	US	EU
Melanoma	Adjuvant · 1st · 2nd	Monotherapy, with Ipi (1st only)	Approved	Approved	Approved	Approved	Approved
	1st	Combination drug★ (relatlimab)	–	–	–	Approved	Approved
Non-small cell lung cancer	Neo-adjuvant	with Chemo	Approved	Approved	Approved	Approved	Approved
	Neo-adjuvant · Adjuvant	with Chemo	III	III	III	Approved	Filed
	1st	with Ipi	Approved	Approved	Approved	Approved	–
		with Ipi/Chemo	Approved	Approved	Approved	Approved	Approved
		with Chemo	Approved	–	–	–	–
		with Chemo (NSQ)	Revision of labeling	Approved	Approved	–	–
	2nd	Monotherapy	Approved	Approved	Approved	Approved	Approved
Hodgkin's lymphoma	Relapsed /Refractory	with Brentuximab	III	–	–	III	–
		Monotherapy	Approved	Approved	Approved	Approved	Approved
Head and neck cancer	2nd	Monotherapy	Approved	Approved	Approved	Approved	Approved
Malignant pleural mesothelioma	1st	with Ipi	Approved	Approved	Approved	Approved	Approved
	Standard of care refractory	Monotherapy	Approved	–	–	–	–
Malignant mesothelioma (Excluding Pleura)	1st or 2nd	Monotherapy	Approved				

★Combination drug (Relatlimab) : ONO-7121(Opdivo+Relatlimab (ONO-4482)

※Red: Update after announcement of FY 2023 financial result in May 2024 ※Red: Update after Q1 FY2024 in July

Development status of OPDIVO (2)



As of October 24, 2024

Target disease	Treatment Line	Treatment	Phase				
			Japan	Korea	Taiwan	US	EU
Gastric cancer	1st	with Chemo	Approved	Approved	Approved	Approved	Approved
		with Ipi/Chemo	III	III	III	—	—
	3rd	Monotherapy	Approved	Approved	Approved	—	—
Esophageal cancer	Adjuvant	Monotherapy	Approved	Approved	Approved	Approved	Approved
	1st	with Ipi, with Chemo	Approved	Approved	Approved	Approved	Approved
	2nd	Monotherapy	Approved	Approved	Approved	Approved	Approved
Colorectal cancer	MSI-H/dMMR (1st)	with Ipi	Filed	—	—	III	Filed
	MSI-H/dMMR (3rd)	Monotherapy	Approved	—	Approved	Approved	-
		with Ipi	Approved	Approved	Approved	Approved	Approved★★
Hepatocellular carcinoma	Adjuvant	Monotherapy	III	III	III	III	III
	1st	with Ipi	Filed	III	III	Filed	Filed
	2nd	with Ipi	II	II	Approved	Approved	II

★★2nd Line

※Red: Update after announcement of FY 2023 financial result in May 2024 ※Red: Update after Q1 FY2024 in July

Development status of OPDIVO (3)

As of October 24, 2024

Target disease	Treatment Line	Treatment	Phase				
			Japan	Korea	Taiwan	US	EU
Renal cell carcinoma	1st	with Ipi	Approved	Approved	Approved	Approved	Approved
		with TKI	Approved	Approved	Approved	Approved	Approved
		with Ipi/TKI	–	III	III	III	III
	2nd	Monotherapy	Approved	Approved	Approved	Approved	Approved
Urothelial cancer / Bladder cancer	Neo-adjuvant · Adjuvant	with Chemo	III	III	III	III	III
	Adjuvant	Monotherapy	Approved	Approved	Approved	Approved	Approved
	1st	with Chemo	Filed	Approved	Approved	Approved	Approved
		with Ipi	III	III	III	III	III
	2nd	Monotherapy	II	Approved	Approved	Approved	Approved
Cancer of unknown primary	–	Monotherapy	Approved	–	–	–	–
Epithelial skin malignancies	1st	Monotherapy	Approved	–	–	–	–
Rhabdoid tumor	2nd	Monotherapy	II	–	–	–	–
Flat dose	240 mg (every 2 weeks)		Approved	Approved	Approved	Approved	Approved
	360 mg (every 3 weeks)		Approved	Approved	Approved	Approved	Approved
	480 mg (every 4 weeks)		Approved	Approved	Approved	Approved	Approved
Solid tumor	–	ONO-4538HSC (Combination with vorhyaluronidase alfa)	I	–	–	Filed	Filed

Development pipeline (Oncology)

As of October 24, 2024

Code (Generic name)MOA, Modality	ID/Area	Target Indication	PI	PI/II	PII	PIII	Filed	Approval
Braftovi Capsule (Encorafenib) BRAF inhibitor	jRCT2011200018/JP	BRAF-mutant thyroid cancer						
								FY2024.5 Approval
Mektovi Tablet (Binimetinib) MEK inhibitor	jRCT2011200018/JP	BRAF-mutant thyroid cancer						
								FY2024.5 Approval
ONO-4059 (tirabrutinib) BTK inhibitor	NCT04947319/US	Primary central nervous system lymphoma						
								FY2025 Primary Completion (Part A)
ONO-4482 (relatlimab) Anti-LAG-3 antibody	NCT05337137 /JP, US, EU, KR, TW	Hepatocellular carcinoma*						
	NCT01968109/JP, US, EU	Melanoma*						FY2024 Primary Completion (Actual)
ONO-7427 Anti-CCR8 antibody	NCT04895709/JP, US, EU	Solid tumor*						
								FY2025 Primary Completion
ONO-4578 PG receptor (EP4) antagonist	NCT06256328/JP, KR, TW	Gastric cancer*						
								FY2025 Primary Completion
	NCT06547385/JP	Colorectal cancer*						FY2027 Primary Completion
	NCT06538207/JP	Pancreatic cancer*						FY2024 Primary Completion
	NCT06542731/JP	Non-small cell lung cancer*						FY2026 Primary Completion
ONO-7475 (tamnorzatinib) Axl/Mer inhibitor	NCT06570031/JP	Hormone receptor-positive, HER2-negative breast cancer						FY2025 Primary Completion
	NCT06532331/JP	Pancreatic cancer*						FY2027 Primary Completion
	NCT06525246/JP	EGFR-mutated non-small cell lung cancer						FY2025 Primary Completion
ONO-7913 (magrolimab) Anti-CD47 antibody	NCT06532344/JP	Pancreatic cancer*						FY2025 Primary Completion
	NCT06540261/JP	Colorectal cancer*						FY2024 Primary Completion
ONO-7914 STING agonist	NCT06535009/JP	Solid tumor						FY2026 Primary Completion
ONO-4685 PD-1 x CD3 bispecific antibody	NCT05079282/US	T-cell lymphoma						FY2025 Primary Completion
	NCT06547528/JP							FY2028 Primary Completion
ONO-7018 MALT1 inhibitor	NCT05515406/US	Non-Hodgkin lymphoma, Chronic lymphocytic leukemia						FY2027 Primary Completion
	NCT06622226/JP							FY2027 Primary Completion
ONO-8250 iPSC-derived HER2 CAR T-cell therapy	NCT06241456/US	HER2-expressing Solid tumor						FY2029 Primary Completion

* : Combination with Opdivo, Estimated study completion date shown in jRCT or ClinicalTrials.gov

MoA : Mode of Action ※Red: Update after announcement of FY 2023 financial result in May 2024 ※Red: Update after Q1 FY2024 in July

Development pipeline (Non-oncology)

As of October 24, 2024

Code (Generic name) MOA, Modality	ID/Area	Target Indication	PI	PI/II	PII	PIII	Filed	Approval	
ONO-2017(cenobamate)Inhibition of voltage-gated sodium currents/positive allosteric modulator of GABAA ion channel	NCT06579573 /JP	Primary generalized tonic-clonic seizures	→						
	NCT04557085/JP	Partial-onset seizures	→						
Velexbru Tablet (ONO-4059 : tirabrutinib) BTK inhibitor	jRCT2031220043/JP	Pemphigus	→						
ONO-2910 Enhancement of Schwann cell differentiation	NCT06538272 /JP	Chemotherapy-Induced Peripheral Neuropathy	→						
ONO-2808 S1P5 receptor agonist	NCT05923866/JP, US	Multiple System Atrophy	→						
ONO-4685 PD-1 x CD3 bispecific antibody	jRCT2071220081/JP	Autoimmune disease	- - - - - →						
	NCT05332704/EU		→						
ONO-2020 Epigenetic Regulation	NCT05507515/US	Neurodegenerative disease	- - - - - →						
ONO-1110 Endocannabinoid regulation	jRCT2071220100/JP	Pain	- - - - - →						
ONO-4915 PD-1 x CD19 bispecific antibody	jRCT2071240056 /JP	Autoimmune disease	- - - - - →						

Estimated study completion date shown in jRCT or ClinicalTrials.gov. Dashed lines indicate studies on healthy adults.
 MoA : Mode of Action ※Red: Update after announcement of FY 2023 financial result in May 2024 ※Red: Update after Q1 FY2024 in July

Development pipeline - Deciphera



As of October 24, 2024

Code (Generic name) MOA, Modality	ID/Area	Target Indication	PI	PI/II	PII	PIII	Filed	Approval
QINLOCK (ripretinib) KIT inhibitor	NCT03353753/NA, EU, AU, SG	GIST ≥4 th Line						FY2020 Approval
	NCT05734105/NA, SA, EU, AU, KR, TW	GIST 2nd KIT Exon 11+17/18						FY2025 Primary Completion
DCC-3014 (vimseltinib) CSF-1R inhibitor	NCT05059262/NA, EU, AU, HK	TGCT						FY2024 FDA: Filing accepted EMA: Filing accepted
DCC-3116 ULK inhibitor	NCT04892017/US	Solid tumor (with sotorasib)						FY2027 Study completion
	NCT05957367/US	Solid tumor (with ripretinib)						FY2026 Study completion
DCC-3084 Pan-RAF inhibitor	NCT06287463/US	Solid tumor						FY2026 Study completion

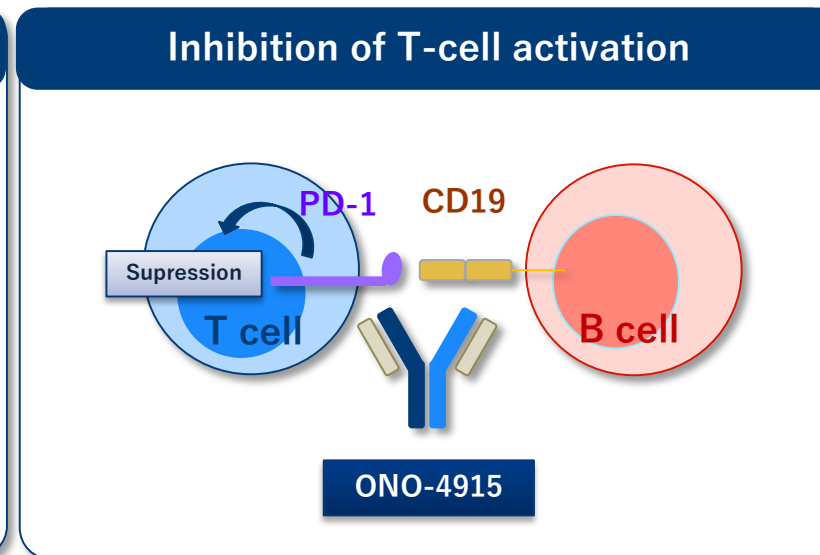
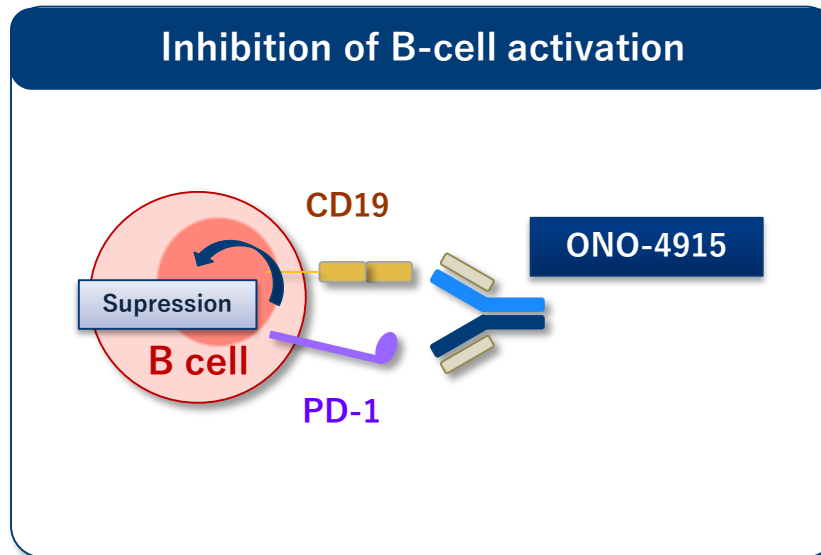
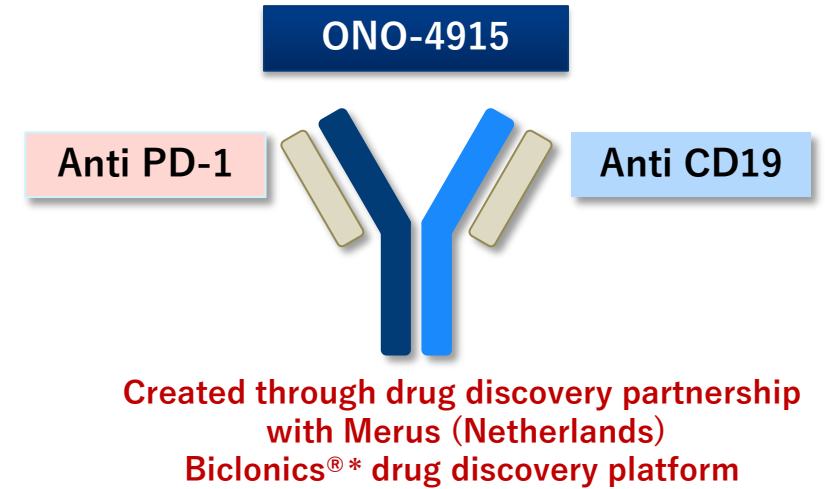
NA : North America, SA : South America, AU : Australia, SG : Singapore, HK : Hong Kong, KR : Korea, TW : Taiwan, JP : Japan

Estimated study completion date shown in jRCT or ClinicalTrials.gov. Dashed lines indicate studies on healthy adults.

ONO-4915

Initiated Phase I study in Japan for the treatment of autoimmune disease

- Bispecific antibodies targeting PD-1 and CD19
- By binding to PD-1 and CD19 on B cells, ONO-4915 suppresses the activation of B cells involved in autoimmunity through PD-1 signaling
- By binding to PD-1 on T cells and CD19 on B cells, ONO-4915 suppresses the activation of T cells involved in autoimmunity through PD-1 signaling.



Key milestones in FY2024 Q2 (FY ending March 2025)



As of October 24, 2024

(Development pipeline)

	Product/ Code(Generic name)	Target indication/Study name	Progress
Product to be approved	OPDIVO	Urothelial cancer (1L with Chemo) /CheckMate-901	Approved (Oct.2024) in TW
		NSCLC (Neoadjuvant, Adjuvant) /CheckMate-77T	Approved (Oct.2024) in US
		Hepatocellular carcinoma (1st with Ipi) /CheckMate-9DW	Filed in US, EU (Aug.2024) in JP (Sep.2024)
		MSI-H Colorectal cancer (1st with Ipi) /CheckMate-8HW	Filed in JP (Sep.2024)
	Vimseltinib (DCC-3014)	TGCT	Filing accepted in EU (Jul.2024) in US (Aug.2024)
P2	OPDIVO	Rhabdoid tumor	Started in JP (Sep.2024)
	ONO-2910	Diabetic polyneuropathy	Discontinued (Sep.2024)
P1	ONO-7018	Non-Hodgkin lymphoma, Chronic lymphocytic leukemia	Started in JP (Oct.2024)
	ONO-4915	Autoimmune disease	Started in JP (Sep.2024)

Key milestones in FY2024 Q2 (FY ending March 2025)



As of October 24, 2024

(Drug discovery partnerships & Research collaborations/Licensing & Co-promotion)

Title	Progress
Ono Enters into a New Option and Research Collaboration Agreement with Monash University to Discover and Create New Anti-GPCR Antibodies in the Autoimmune and Inflammatory Diseases	Started (Aug.2024)
Ono Enters into License Agreement for LCB97, an Antibody-Drug Conjugate, and Research Collaboration and License Agreement to generate novel ADC candidates by leveraging ConjuAll™ ADC platform with LigaChem Biosciences	Started (Oct.2024)
Ono Enters into a Drug Discovery Collaboration and Option Agreement with Shattuck Labs to Generate Bifunctional Fusion Proteins	Discontinued
Ono Enters into Collaboration Agreement with Domain Therapeutics and Université de Montréal for GPCR-Targeted Drug Discovery	
Ono and Equillium Announce Exclusive Option and Asset Purchase Agreement for the Development and Commercialization of Itolizumab	Not exercising option