

■ Oncology ■ Immunology ■ Neuroscience ■ Hematology ■ Ophthalmology ■ Other Diseases

Development Pipeline [Main table] (as of February 1, 2024)

Development code Origin	Generic name Product name	Indication # Additional indication (Combination drug)	Country/region	Projected submission	Mode of Action Modality (Dosage form)	Partner
Filed						
AF802/RG7853 in-house	alectinib Alecensa	NSCLC (adjuvant) #	US	November 2023	ALK inhibitor Small molecule (oral)	Roche
			EU	November 2023		
			China	November 2023		
			Japan	December 2023		
SKY59/RG6107 in-house	crovalimab -	Paroxysmal nocturnal hemoglobinuria (PNH)	China	August 2022	Anti-C5 recycling antibody Antibody (SC)	Roche
			Japan	June 2023		
			EU	June 2023		
			US	June 2023		
RG7716 Roche	faricimab Vabysmo	Retinal vein occlusion #	Japan	April 2023	Anti-VEGF/Anti-Ang-2 bispecific antibody Antibody (vitreous injection)	Roche
Phase III						
AF802/RG7853 in-house	alectinib Alecensa	Maintenance treatment of NSCLC (stage III) after chemoradiotherapy #	Global	2026 and beyond	ALK inhibitor Small molecule (oral)	Roche
RG7446 Roche	atezolizumab Tecentriq	NSCLC (neoadjuvant) #	Japan	2026 and beyond	Engineered anti-PD-L1 monoclonal antibody Antibody (IV)	Roche
		Muscle-invasive bladder cancer (adjuvant) #	Japan	2025		Roche
		Early breast cancer (neoadjuvant) #	Japan	2026 and beyond		Roche
		Hepatocellular carcinoma (HCC) (adjuvant) # (Avastin) #	Japan	2024		Roche

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		HCC (intermediate stage) # (Avastin) #	Japan	2025		Roche
		HCC (2nd Line) # (lenvatinib or sorafenib)	Japan	2026 and beyond		Roche
		Prostate cancer (2nd Line) # (cabozantinib)	Japan	-		Takeda
RG435 Roche	bevacizumab Avastin	Small cell lung cancer (SCLC) (1st Line) # (Tecentriq)	Japan/ China	2024	Anti-VEGF (Vascular Endothelial Growth Factor) humanized monoclonal antibody Antibody (IV)	Roche (China)
RG6058 Roche	tiragolumab -	NSCLC (1st Line) (Tecentriq)	Japan	2025	Anti-TIGIT human monoclonal antibody Antibody (IV)	Roche
		NSCLC (stage III) (Tecentriq) #	Japan	2025		Roche
		Non-squamous NSCLC (1st Line) (Tecentriq)	Japan	2026 and beyond		Roche
		Esophageal cancer (Tecentriq) #	Japan	2026 and beyond		Roche
		HCC (1st line) (Tecentriq/Avastin)	Japan	2026 and beyond		Roche
RG6171 Roche	giredestrant -	Breast cancer (adjuvant)	Japan	2026 and beyond	SERD (Selective Estrogen Receptor Degrader) Small molecule (Oral)	Roche
		Breast cancer (1st Line) (palbociclib + letrozole)	Japan	2026 and beyond		Roche
		Breast cancer (1st Line-3rd Line) (everolimus)	Japan	2025		Roche
RG7828 Roche	mosunetuzumab -	Follicular lymphoma (2nd Line) (lenalidomide)	Japan	2026 and beyond	Anti-CD20/CD3 bispecific antibody Antibody (IV)	Roche
		Relapsed or refractory aggressive B-cell non- Hodgkin's lymphoma (Polivy) #	Japan	2025	Anti-CD20/CD3 bispecific antibody Antibody (SC)	Roche

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RG6396 Blueprint Medicines	pralsetinib -	NSCLC (1st Line) (pembrolizumab)	Japan	-	RET inhibitor Small molecule (Oral)	Roche
RG7159 GlycArt Biotechnology	obinutuzumab Gazyva	Lupus nephritis #	Japan	2026 and beyond	Glycoengineered type II anti-CD20 monoclonal Antibody Antibody (IV)	Nippon shinyaku
		Pediatric nephrotic syndrome #	Japan	2026 and beyond		Nippon shinyaku
		Extra renal lupus #	Japan	2026 and beyond		Nippon shinyaku
SA237/RG6168 in-house	satralizumab Enspryng	Generalized myasthenia gravis (gMG) #	Global	2024	pH-dependent binding humanized anti-IL-6 receptor monoclonal antibody Antibody (SC)	Roche
		Myelin oligodendrocyte glycoprotein antibody- associated disease (MOGAD) #	Global	2026 and beyond		Roche
		Autoimmune encephalitis (AIE) #	Global	2025		Roche
RG6356/ SRP-9001 Sarepta	delandistrogene moxeparovvec -	Duchenne muscular dystrophy (DMD)	Japan	2024	Microdystrophin gene therapy Gene therapy (IV)	Sarepta*
SKY59/RG6107 in-house	crovalimab -	Atypical hemolytic uremic syndrome (aHUS)	Global	2025	Anti-C5 recycling antibody Antibody (SC)	Roche
RG7716 Roche	faricimab Vabysmo	Angiod streaks #	Japan	2025	Anti-VEGF/Anti-Ang-2 bispecific antibody Antibody (vitreous injection)	-
RG6179 Roche	- -	Noninfectious uveitic macular edema	Japan	2026 and beyond	Anti-IL-6 monoclonal antibody Antibody (vitreous injection)	Roche
SA237/RG6168 in-house	satralizumab Enspryng	Thyroid eye disease (TED)	Global	2026 and beyond	pH-dependent binding humanized anti-IL-6 receptor monoclonal antibody Antibody (SC)	Roche

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Development code Origin	Generic name Product name	Indication # Additional indication (Combination drug)	Country/region	Projected submission	Mode of Action Modality (Dosage form)	Partner
Phase II/III						
GYM329/ RG6237 in-house	- -	Spinal muscular atrophy (Evrysdi)	Global	2026 and beyond	Anti-latent myostatin sweeping antibody Antibody (SC)	Roche
Phase II						
RG6396 Blueprint Medicines	pralsetinib -	NSCLC (2 nd Line)	Japan	-	RET inhibitor Small molecule (Oral)	Roche
		Solid tumors	Japan	-		Roche
GYM329/ RG6237 in-house	- -	Facioscapulohumeral muscular dystrophy (FSHD)	Global	2026 and beyond	Anti-latent myostatin sweeping antibody Antibody (SC)	Roche
RG6042 Ionis Pharmaceuticals	tominersen -	Huntington's disease	Japan	-	Antisense oligonucleotide targeting <i>HTT</i> mRNA Nucleic acid (IV)	Roche
SKY59/RG6107 in-house	crovalimab -	Sickle cell disease (SCD)	US · EU	2026 and beyond	Anti-C5 recycling antibody Antibody (SC)	Roche
AMY109 in-house	- -	Endometriosis	Global	-	Anti-IL-8 recycling antibody Antibody (SC)	-
Phase I/II						
RG6102 MorphoSys	trontinemab —	Alzheimer's disease	Japan	-	Anti-amyloid beta/TfR1 fusion protein Antibody (IV)	Roche
NXT007/ RG6512 in-house	- -	Hemophilia A	Global	-	Anti-coagulation factor Ixa/X bispecific antibody Antibody (SC)	Roche
RG6321 Roche	ranibizumab (Port delivery system) -	Neovascular age-related macular degeneration	Japan	2025	Humanized anti-VEGF monoclonal antibody Fragment Fab Antibody (injection via implant)	Roche
		Diabetic macular edema	Japan	2025		Roche

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Phase I						
LUNA18 in-house	- -	Solid tumors	Global	-	RAS inhibitor Mid-size molecule (Oral)	-
GC33 in-house	codrituzumab -	HCC	Global	-	Anti-Glypican-3 humanized monoclonal antibody Antibody (IV)	-
ERY974 in-house	- -	Solid tumors	Global	-	Anti-Glypican-3/CD3 bispecific antibody Antibody (IV)	-
STA551 in-house	- -	Solid tumors	Global	-	Anti-CD137 agonistic Switch antibody Antibody (IV)	-
SOF10/RG6440 in-house	- -	Solid tumors	Global	-	Anti-latent TGF-β1 monoclonal antibody Antibody (IV)	Roche
ALPS12/RG6524 in-house	- -	Solid tumors	Global	-	Anti-DLL3/CD3/CD137 trispecific antibody Antibody (IV)	Roche
SAIL66 in-house	- -	CLDN6 positive solid tumors	Global	-	Anti- CLDN6/CD3/CD137 trispecific antibody Antibody (IV)	-
ROSE12 in-house	- -	Solid tumors	Global	-	- Antibody (IV)	-
SPYK04 in-house	- -	Solid tumors	Global	-	- Small molecule (Oral)	-
RG7828 Roche	mosunetuzumab -	Follicular lymphoma (3 rd Line)	Japan	2024	Anti-CD20/CD3 bispecific antibody Antibody (IV)	Roche
RG7421 Exelixis	cobimetinib -	Solid tumors	Japan	-	MEK inhibitor Small molecule (Oral)	Roche
RG6026 Roche	glofitamab -	Hematologic tumors	Japan	-	Anti-CD20/CD3 bispecific antibody Antibody (IV)	Roche

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RG6194 Roche	runimotamab -	Solid tumors	Japan	-	Anti-HER2/CD3 bispecific antibody Antibody (IV)	Roche
RG6160 Roche	cevostamab -	Relapsed or refractory multiple myeloma	Japan	-	Anti-FcRH5/CD3 bispecific antibody Antibody (IV)	Roche
RG6330 Roche	divarasib -	Solid tumors	Japan	-	KRAS G12C inhibitor Small molecule (Oral)	Roche
RG6433 Relay Therapeutics	- -	Solid tumors	Japan	-	SHP2 inhibitor Small molecule (Oral)	Roche
RG6139 Roche	tobemstomig —	Solid tumors	Japan	—	Anti-PD-1/LAG-3 bispecific antibody Antibody (IV)	Roche
SKY59/RG6107 in-house	crovalimab -	Lupus nephritis	Global	-	Anti-C5 recycling antibody Antibody (SC)	Roche
DONQ52 in-house	- -	Celiac disease	Global	-	Anti-HLA-DQ2.5/gluten peptides multispecific antibody Antibody (SC)	-
RAY121 in-house	- -	Autoimmune disease	Global	-	- Antibody (-)	-
RG7935 Prothena	prasinezumab -	Parkinson's disease	Japan	-	Anti- α -synuclein monoclonal antibody Antibody (IV)	Roche
REVN24 in-house	-	Acute diseases	Global	-	- Small molecule (IV)	-
Development discontinued						
RG7446 Roche	atezolizumab Tecentriq	Head and neck carcinoma (adjuvant) #	Japan	-	Engineered anti-PD-L1 monoclonal antibody Antibody (IV)	Roche
RG6100 AC Immune	semorinemab -	Alzheimer's disease	Japan	-	Anti-tau humanized monoclonal antibody Antibody (IV)	Roche

In principle, completion of first dose is regarded as pipeline entry into each phase of clinical studies.

* Sarepta manages the global study including Japan

Changes from the last announcement on October 24, 2023

Oncology

- AF802/RG7853 Phase III (Non-small cell lung cancer (adjuvant)) → Filed (US)
- AF802/RG7853 Phase III (Non-small cell lung cancer (adjuvant)) → Filed (EU)
- AF802/RG7853 Phase III (Non-small cell lung cancer (adjuvant)) → Filed (CHN)
- AF802/RG7853 Phase III (Non-small cell lung cancer (adjuvant)) → Filed (JP)
- RG7446 Phase III (Head and neck carcinoma (adjuvant): development discontinued)

Neuroscience

- RG6100 Phase I (Alzheimer's disease: development discontinued)

Ophthalmology

- SA237/RG6168 Phase III (Thyroid eye disease: development started)

Other Diseases

- AMY109 Phase I (Endometriosis) → Phase II
- REVN24 Phase I (Acute diseases: development started)

R&D Activities

For the changes during the FY2023 (January 1 – December 31), please refer to page 5 of “CONSOLIDATED FINANCIAL STATEMENTS (IFRS) (Non-Audited) (for the fiscal year 2023).”

Changes from January 1, 2024 to February 1, 2024 are as follows:

Oncology

- We decided to discontinue the development of an engineered anti-PD-L1 monoclonal antibody RG7446 (Product name: Tecentriq) for head and neck

carcinoma (adjuvant) in consideration of the result of global Phase III study IMvolve010.

Neuroscience

- We decided to discontinue the development of an engineered anti-tau humanized monoclonal antibody RG6100 for alzheimer's disease in consideration of the result of overseas clinical studies conducted by Roche.

Other Diseases

- We started Phase II study for anti-IL-8 recycling antibody AMY109 for the treatment of endometriosis in January 2024.

Development Pipeline [Attached table] (Major Chugai originated developments licensed out to 3rd parties excluding Roche)

Development code licensee/in-house	Generic name Product name	Indication # Additional Indication (combination)	Stage Country/region	Mode of Action Modality (Dosage form)	Licensee (Granted rights)
VS-6766/CKI27	avutometinib —	Recurrent LGSOC (defactinib)	Phase III Global	RAF/MEK inhibitor Small molecule (Oral)	Verastem Oncology (exclusive global license for the manufacturing, development and marketing)
		NSCLC (defactinib)	Phase II Global		
- /CIM331	nemolizumab Mitchga (Japan)	Prurigo nodularis #	Filed Japan	Anti-IL-31 receptor A humanized monoclonal antibody Antibody (SC)	Maruho (rights for development and marketing in the skin disease area for the Japanese market)
		Pruritus associated with atopic dermatitis (pediatric) #	Filed Japan		Galderma (exclusive global license for the development and marketing excluding Japan and Taiwan)
		Atopic dermatitis	Phase III Global		
		Prurigo nodularis	Phase III Global		
		Chronic kidney disease associated pruritus	Phase II/III Global		
LY3502970/OWL833	orforglipron —	Type 2 diabetes	Phase III Global	Oral non-peptidic GLP-1 receptor agonist Small molecule (Oral)	Eli Lilly and Company (worldwide development and commercialization rights)
		Obesity	Phase III Global		

Progress made in R&D activities of major Chugai originated developments licensed out to 3rd party excluding Roche during the period from January 1, 2023 to February 1, 2024 was as follows.

- In Japan, Maruho filed for the anti-IL-31 receptor A humanized monoclonal antibody CIM331 (Product name: Mitchga) for the treatment of prurigo nodularis and pruritus associated with atopic dermatitis (pediatric) in Q2 2023.
- Eli Lilly and Company started global Phase III studies for the oral non-peptidic GLP-1 receptor agonist LY3502970/OWL833 for the treatment of type 2 diabetes and obesity in Q2 2023, respectively.

- Verastem Oncology started global Phase III study for the RAF/MEK inhibitor VS-6766/CKI27 for the treatment of recurrent LGSOC in combination with defactinib in Q4 2023.

Response to Requests from the MHLW Review Committee on Unapproved Drugs and Indications with High Medical Needs (As of February 1, 2024)

Development Request	Product	Indication	Development Status
Fourth development request	Xeloda	Neuroendocrine tumor	Submitted company opinion and waiting for evaluation by committee
	Avastin	Cerebral edema induced by radiation necrosis	Submitted company opinion and waiting for evaluation by committee
	CellCept	Systemic sclerosis with interstitial lung disease (SSc-ILD)	Waiting for prior evaluation of public knowledge-based sNDA filing by the Second Committee on Drugs
	CellCept	Remission maintenance therapy following rituximab therapy for refractory nephrotic syndrome (frequently relapsing or steroid-dependent nephrotic syndrome)	Submitted company opinion and waiting for evaluation by committee

Major Clinical Trials

Project	Expected Indication	Study design	Study name	Stage	CT information
Oncology					
RG7446 (Tecentriq)	NSCLC (neoadjuvant)	Chemo ± Tecentriq	IMpower030	Phase III	NCT03456063
	SCLC [1st line]	Tecentriq + chemo ± Avastin	BEAT-SC	Phase III	JapicCTI-195034 (Japanese only)
	Muscle-invasive bladder cancer (adjuvant)	Tecentriq vs. placebo	IMvigor011	Phase III	NCT04660344
	Prostate cancer [2nd line]	Tecentriq + cabozantinib vs. novel hormonal therapy	CONTACT-02	Phase III	NCT04446117
	Early breast cancer	TNBC (neoadjuvant): nab-paclitaxel ± Tecentriq	IMpassion031	Phase III	NCT03197935
	HCC (adjuvant)	Tecentriq + Avastin vs. active surveillance	IMbrave050	Phase III	NCT04102098
	HCC (intermediate stage)	Tecentriq + Avastin + TACE vs. TACE	TALENTACE	Phase III	NCT04803994
	HCC [2nd line]	Tecentriq + lenvatinib or sorafenib vs. lenvatinib or sorafenib	IMbrave251	Phase III	NCT04770896
RG6058	NSCLC [1st line]	PD-L1 positive: Tecentriq ± RG6058	SKYSCRAPER-01	Phase III	NCT04294810

Project	Expected Indication	Study design	Study name	Stage	CT information
(tiragolumab)	NSCLC [stage III]	Tecentriq + RG6058 vs. durvalumab	SKYSCRAPER-03	Phase III	NCT04513925
	Non-squamous NSCLC [1st line]	Tecentriq + RG6058 + Pemetrexed + Carboplatin/Cisplatin vs. Pembrolizumab + Pemetrexed + Carboplatin/Cisplatin	SKYSCRAPER-06	Phase III	NCT04619797
	Esophageal cancer	Tecentriq + RG6058 vs. Tecentriq vs. placebo	SKYSCRAPER-07	Phase III	NCT04543617
	HCC (1st line)	Tecentriq + Avastin ± RG6058	IMbrave152/SKYSCRAPER-14	Phase III	NCT05904886
AF802 (Alecensa)	Maintenance treatment of NSCLC (stage III) after chemoradiotherapy	ALK fusion-positive: Alecensa vs. durvalumab	HORIZON01	Phase III	NCT05170204
RG6171/SERD (giredestrant)	Breast cancer (adjuvant)	HR positive: RG6171 vs. endocrine therapy	lidERA	Phase III	NCT04961996
	Breast cancer [1st line]	HR positive: RG6171 + palbociclib ± Letrozole	persevERA	Phase III	NCT04546009
	Breast cancer [1st line-3rd line]	HR positive: RG6171 + everolimus vs. endocrine therapy+ everolimus	evERA	Phase III	NCT05306340
RG7828 (mosunetuzumab)	Follicular lymphoma [2nd line]	RG7828 + lenalidomide vs Rituxan + lenalidomide	CELESTIMO	Phase III	NCT04712097
	Relapsed or refractory aggressive B-cell non-Hodgkin's lymphoma	RG7828 + Polivy vs Rituxan + chemotherapy	SUNMO	Phase III	NCT05171647
	Follicular lymphoma [3rd line]	RG7828 + tocilizumab + lenalidomide	Mosun	Phase I (domestic)	JapicCTI-183857 (Japanese only)
RG6396 (pralsetinib)	NSCLC [1st line]	RG6396 vs. platinum-based chemotherapy ± pembrolizumab	AcceleRET-Lung	Phase III	NCT04222972
	Solid tumors	RG6396 (single arm)	TAPISTRY	Phase II	NCT04589845
	NSCLC [2nd line]	RG6396 (single arm)	-	Phase II (domestic)	jRCT2021210074 (Japanese only)
Immunology					
RG7159 (Gazyva)	Lupus nephritis	standard treatment ± Gazyva	-	Phase III (domestic)	jRCT2011210059 (Japanese only)
	Pediatric nephrotic syndrome	Gazyva vs. MMF	INShore	Phase III	NCT05627557
	Extra renal lupus	Gazyva vs. Placebo	-	Phase III (domestic)	jRCT2071230031
Neuroscience					
SA237 (Enspryng)	Generalized myasthenia gravis (gMG)	Enspryng vs. Placebo	Luminesce	Phase III	NCT04963270
	Myelin oligodendrocyte glycoprotein antibody-associated disease (MOGAD)	Enspryng vs. Placebo	METEOROID	Phase III	NCT05271409

Project	Expected Indication	Study design	Study name	Stage	CT information
	Autoimmune encephalitis (AIE)	Enspryng vs. Placebo	CIELO	Phase III	NCT05503264
RG6356/SRP-9001 (deelandistrogene moxeparvovec)	Duchenne muscular dystrophy (DMD)	RG6356 vs. Placebo	EMBARK	Phase III	NCT05096221
GYM329/RG6237	Spinal muscular atrophy (SMA)	GYM329 ± Evrysdi	MANATEE	Phase II/III	NCT05115110
	Facioscapulohumeral muscular dystrophy (FSHD)	GYM329 ± Placebo	MANOEUVRE	Phase II	NCT05548556
Hematology					
SKY59/RG6107 (crovalimab)	Atypical hemolytic uremic syndrome (aHUS)	crovalimab (single arm)	COMMUTE-a	Phase III	NCT04861259
			COMMUTE-p	Phase III	NCT04958265
	Sickle cell disease (SCD)	crovalimab vs. Placebo	CROSSWALK-c	Phase IIa	NCT05075824
Ophthalmology					
RG7716 (Vabysmo)	Angiod streaks	Vabysmo (single arm)	NIHONBASHI	Phase III (domestic)	jRCT2071220090 (Japanese only)
RG6179	Noninfectious uveitic macular edema	RG6179 (single arm)	Sandcat	Phase III	NCT05642325
SA237 (Enspryng)	Thyroid eye disease (TED)	Enspryng vs. Placebo	SatraGo 1/ Satra Go 2	Phase III	NCT05987423
RG6321 (ranibizumab (Port delivery system))	Neovascular age-related macular degeneration / Diabetic macular edema	RG6321 (single arm)	-	Phase I/II (domestic)	jRCT2071210073 (Japanese only)

FoundationOne CDx Cancer Genomic Profile: companion diagnostic indications (as of February 1, 2024)

Alterations	Cancer type	Relevant drugs
Activated EGFR gene alterations	NSCLC	afatinib dimaleate, erlotinib hydrochloride, gefitinib, osimertinib mesilate, dacomitinib hydrate
EGFR exon 20 T790M alterations		osimertinib mesilate
ALK fusion genes		alectinib hydrochloride, crizotinib, ceritinib, brigatinib
ROS1 fusion genes		entrectinib
MET exon 14 skipping alterations		capmatinib hydrochloride hydrate
BRAF V600E and V600K alterations	Malignant melanoma	dabrafenib mesilate, trametinib dimethyl sulfoxide, vemurafenib, encorafenib, binimetinib

<i>ERBB2</i> copy number alterations (HER2 gene amplification positive)	Breast cancer	trastuzumab (genetical recombination)
<i>KRAS/NRAS</i> wild-type	Colorectal cancer	cetuximab (genetical recombination), panitumumab (genetical recombination)
Microsatellite instability-high		nivolumab (genetical recombination)
Microsatellite instability-high	Solid tumors	pembrolizumab (genetical recombination)
Tumor mutational burden-high		pembrolizumab (genetical recombination)
<i>NTRK1/2/3</i> fusion gene		entrectinib, larotrectinib sulfate
<i>RET</i> fusion genes		<u>selengcatinib</u>
<i>BRCA1/2</i> alterations	Ovarian cancer	olaparib
<i>BRCA1/2</i> alterations	Prostate cancer	olaparib, <u>talazoparib tosilate</u>
<i>FGFR2</i> fusion genes	Biliary Tract Cancer	pemigatinib

* Underlined are the companion diagnostic features and relevant drugs currently under application for regulatory approval

FoundationOne Liquid CDx Cancer Genomic Profile: companion diagnostic indications (as of February 1, 2024)

Alterations	Cancer type	Relevant drugs
Activated <i>EGFR</i> gene alterations	NSCLC	afatinib dimaleate, erlotinib hydrochloride, gefitinib, osimertinib mesilate
<i>EGFR</i> exon 20 T790M alterations		osimertinib mesilate
<i>ALK</i> fusion genes		alectinib hydrochloride, crizotinib, ceritinib
<i>ROS1</i> fusion genes		entrectinib
<i>MET</i> exon 14 skipping alterations		capmatinib hydrochloride hydrate
<i>NTRK1/2/3</i> fusion gene	Solid tumors	entrectinib
<i>BRCA1/2</i> alterations	Prostate cancer	olaparib