

Pharmaceuticals: major clinical and regulatory news flow in 2015

Compound	Indication	Milestone	
Cotellic + Zelboraf	BRAF V600 mutation-positive metastatic melanoma	FDA priority review	Q1✓
Avastin + chemotherapy	Advanced cervical cancer	EU approval	Q1✓
Lucentis	Diabetic retinopathy	FDA approval	Q1✓
Atezolizumab	PD-L1 positive non-small cell lung cancer (NSCLC)	FDA Breakthrough Therapy Designation	Q1✓
Gazyva/Gazyvaro	Refractory indolent non-Hodgkin lymphoma (iNHL)	Phase III results (GADOLIN)	Q1✓
Venetoclax	17p deletion relapsed-refractory chronic lymphocytic leukemia	FDA breakthrough therapy designation	Q2✓
Avastin	Mesothelioma	Phase III results (MAPS, independent study)	Q2✓
Atezolizumab + chemotherapy	NSCLC	Phase Ib results	Q2✓
Atezolizumab	NSCLC	Phase II interim results (POPLAR)	Q2✓
Alecensa (alectinib)	ALK-positive NSCLC	Pivotal phase I/II results	Q2✓
Emicizumab (ACE910)	Hemophilia A	Phase I results	Q2✓
Cotellic + Zelboraf	BRAF V600 mutation-positive metastatic melanoma	Phase III results (coBRIM)	Q2✓
Actemra/RoActemra	Systemic sclerosis	FDA breakthrough therapy designation	Q2✓
Ocrelizumab	Relapsing forms of multiple sclerosis	Phase III results (OPERA I and OPERA II)	Q2✓
Atezolizumab	Urothelial bladder cancer	Pivotal phase II results	Q3✓
Emicizumab (ACE910)	Hemophilia A	FDA breakthrough therapy designation	Q3✓
Esbriet	idiopathic pulmonary fibrosis	Pooled analysis three phase III studies (ASCEND, CAPACITY I and II)	Q3✓
Ocrelizumab	Primary progressive multiple sclerosis	Pivotal phase III results (ORATORIO)	Q3✓
Cotellic + Zelboraf	BRAF V600 mutation-positive advanced melanoma	CHMP recommendation for EU approval	Q3✓
Atezolizumab	NSCLC	Pivotal phase II study results (BIRCH)	Q3✓
Venetoclax	Chronic lymphocytic leukemia	Phase II results	Q3✓

Perjeta	Early HER2-positive breast cancer neoadjuvant (pre-surgical) treatment	EU approval	Q3✓
Alecensa	Second-line ALK-positive NSCLC	Filed in US and EU	Q3✓
Avastin	Recurrent/advanced cervical cancer	Filed in Japan	Q3✓
Xeloda	Gastric cancer, adjuvant treatment	Approved in Japan	Q4✓
Cotellic + Zelboraf	BRAF V600 mutation-positive advanced melanoma	Phase III overall survival results (coBRIM)	Q4✓
Cotellic + Zelboraf	BRAF V600 mutation-positive advanced melanoma	FDA and EU approval	Q4✓
Gazyva/Gazyvaro	Chronic lymphocytic leukemia	Updated data from CLL11 study	Q4✓
Venetoclax	17p deletion relapsed-refractory chronic lymphocytic leukemia	Phase II results (M13-982 study)	Q4✓
Alecensa	ALK-positive metastatic NSCLC	FDA approval	Q4✓