

Pharmaceuticals: major clinical and regulatory news flow in the first nine months 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 (anti PD-L1)	PD-L1 positive non-small cell lung cancer	FDA Breakthrough Therapy Designation	Q1✓
Gazyva/Gazyvaro	Refractory indolent non-Hodgkin's lymphoma	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	Non-small cell lung cancer	Phase Ib results	Q2✓
Atezolizumab	Non-small cell lung cancer	Phase II interim results (POPLAR)	Q2✓
Alectinib	ALK-positive non-small cell lung cancer	Pivotal phase I/II results	Q2✓
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✓
ACE910	Haemophilia 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	Non-small cell lung cancer	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✓
Alectinib	Second-line ALK-positive non-small cell lung cancer	Filed in US and EU	Q3✓
Cotellic + Zelboraf	BRAF V600 mutation-positive advanced melanoma	Phase III overall survival results (coBRIM)	Q4✓