Pharmaceuticals Division: Major clinical and regulatory news flow in 2016

Compound	Indication	Milestone	
Tecentriq	locally advanced or metastatic urothelial carcinoma	Pivotal phase II updated results (Imvigor 210, in first-line and platinum-refractory)	Q1/Q2
Venclexta+ MabThera/Rituxan	Relapsed or refractory CLL	US FDA breakthrough therapy designation	Q1
Venclexta	untreated acute myeloid leukemia	US FDA breakthrough therapy designation	Q1
Alecensa	Advanced or recurrent, ALK-positive NSCLC	Phase III results (J-Alex)	Q1/Q2
Ocrelizumab	Primary progressive multiple sclerosis	US FDA breakthrough therapy designation	Q1
Lebrikizumab	Severe asthma	Phase III results (Lavolta I/II)	Q1
Gazyva/Gazyvaro	MabThera/Rituxan-refractory follicular lymphoma	US FDA approval	Q1
Tecentriq	locally advanced or metastatic urothelial carcinoma	US FDA priority review	Q1
Tecentriq	locally advanced or metastatic NSCLC, PD-L1-positive	US FDA priority review	Q2
Venclexta	17p deletion relapsed-refractory CLL	US FDA accelerated approval (following priority review)	Q2
Tecentriq	Locally advanced or metastatic urothelial carcinoma	US FDA accelerated approval	Q2
Avastin	Advanced or recurrent cervical cancer	Approval Japan	Q2
Gazyva/Gazyvaro	Previously untreated FL	Phase III results (Gallium)	Q2
Tecentriq	Advanced NSCLC, second- and third-line treatment	Phase II results (Poplar, updated survival data)	Q2
MabThera (subcutaneous formulation)	Previously untreated CLL	EU approval	Q2
Actemra/RoActemra	Giant cell arteritis	Phase III results (Giacta)	Q2
Avastin + Tarceva	Unresectable advanced, metastatic or recurrent non-squamous NSCLC with EGFR-activating mutations	EU approval	Q2
Gazyva/Gazyvaro	MabThera/Rituxan-refractory follicular lymphoma	EU approval	Q2

Compound	Indication	Milestone	
Ocrelizumab	Relapsing and primary progressive MS	Filing acceptance in US, validation in EU	Q2
Gazyva/Gazyvaro	Previously untreated diffuse large B-cell lymphoma	Phase III results (Goya)	Q3
Emicizumab	Severe haemophilia A	Phase I/II follow-up results	Q3
Tecentriq	Locally advanced or metastatic NSCLC	Phase III results (Oak)	Q3
Ocrelizumab	Relapsing and primary progressive MS	Phase III post-hoc analyses of Oratorio, Opera I and II	Q3
Alecensa	ALK-positive NSCLC, first-line treatment	US FDA breakthrough therapy designation	Q4
Actemra/RoActemra	Giant cell arteritis	US FDA breakthrough therapy designation	Q4
Alecensa	ALK-positive NSCLC, second-line treatment	CHMP positive opinion on EU conditional approval	Q4
Lucentis	Myopic choroidal neovascularisation	US FDA priority review	Q4
Venclyxto	17p deletion relapsed-refractory CLL	CHMP positive opinion	Q4
Lucentis (prefilled syringe formulation)	wet age-related macular degeneration, macular edema after retinal vein occlusion	US FDA approval	Q4
Tecentriq	previously treated recurrent metastatic NSCLC	US FDA approval	Q4
Avastin	Platinum-sensitive recurrent ovarian cancer	US FDA approval	Q4
Venclyxto	17p deletion relapsed-refractory CLL	EU approval	Q4
Emicizumab	Severe haemophilia A	Phase III results (Haven 1)	Q4

US FDA: United States Food and Drug Administration
CHMP: European Medicines Agency for Medicinal Products for Human Use
CLL: Chronic lymphocytic leukemia
FL: follicular lymphoma
NSCLC: Non-small cell lung cancer
MS: Multiple sclerosis