

## Oncology Development News Bulletin

REGULATORY EVENTS		
<b>Astrazeneca</b>	Fulvestrant (SERD)	sNDA/MAA filed in US/EU for 1 <sup>st</sup> -line breast cancer HR+/HER2- (SAG vs anastrozole)
<b>Astrazeneca</b>	Osimertinib (EGFRmut TKI)	sNDA/MAA filed in US/EU for 2 <sup>nd</sup> -line NSCLC-T790M+ (SAG vs CT)
<b>Eisai</b>	Bendamustine	NDA approved in JP for 1 <sup>st</sup> -line NHL-low grade and for 1 <sup>st</sup> -line MCL
<b>BMS</b>	Nivolumab (Mab PD-1)	sBLA approved in US (accelerated) for 2 <sup>nd</sup> -line urothelial cancer (SARM SAG)
<b>Merck &amp; Co</b>	Pembrolizumab (Mab PD-1)	sBLA filed in US for 1 <sup>st</sup> -line urothelial cancer –cisplatin ineligible (SARM SAG)
<b>Merck &amp; Co</b>	Pembrolizumab (Mab PD-1)	sBLA filed in US for 2 <sup>nd</sup> -line urothelial cancer (SAG vs Inv. Choice CT)
<b>Sanofi</b>	Aflibercept (VEGF TRAP)	Positive opinion on approval in JP for 2 <sup>nd</sup> -line colorectal cancer
<b>Ariad</b>	Brigatinib (ALK I)	MAA filed in EU for 2 <sup>nd</sup> -line NSCLC-ALK+ (SARM SAG)
<b>Amgen</b>	Blinatumomab (Mab CD19 /CD3)	sBLA filed in US for R/R adult ALL –B cell precursor (SAG vs SOC CT)
PHASE 3 EVENTS		
<b>Institution</b>	Bicalutamide (Antiandrogen)	Improves OS in adjuvant prostate cancer (SAG vs placebo)
<b>Merck &amp; Co</b>	Pembrolizumab (Mab PD-1)	To enter phase 3 in 1 <sup>st</sup> -line H&N locally advanced (AO to R-CT)
<b>Kowa/Chugai</b>	Peretinoin (Retinoid)	Fails to improve RFS in adjuvant liver cancer (SAG vs placebo)
<b>Roche</b>	Bevacizumab (Mab VEGF)	Fails to improve OS in perioperative Oesophagogastric cancer (AO to CT)
<b>Roche</b>	Atezolizumab (Mab PD-L1)	Accrual ongoing in 1 <sup>st</sup> -line melanoma-BRAF+ (AO to cobimetinib/vemurafenib)
<b>Institution</b>	PEG Interferon	Accrual completed in adjuvant ulcerated melanoma (SAG vs observation)
<b>Astrazeneca</b>	Durvalumab (Mab PD-L1)	To enter phase 3 in 1 <sup>st</sup> -line SCLC-ED (AO to platinum/etoposide)

This material has been prepared specifically for the clients of on-kòs. The opinions stated here represent interpretation and analyses of information available to the public and released by the subject companies. We do not assume any liability for the accuracy, comprehensiveness or use of the information in this report.

## Oncology Development News Bulletin

<b>Otsuka</b>	Guadecitabine (HMA)	Accrual ongoing in 2 <sup>nd</sup> -line MDS (SAG vs Inv. Choice)
<b>Agios</b>	AG120 (IDH1 I)	Accrual ongoing in 2 <sup>nd</sup> -line cholangiocarcinoma -IDH1+ (SAG vs Plac)
<b>Jiangsu HengRui</b>	Apatinib (mRTKI)	Enters phase 3 in RAI- refractory thyroid cancer (SAG vs placebo)
<b>Tocagen</b>	Toca511/Toca FC (Viral therapy)	Accrual completed in 2 <sup>nd</sup> -line glioblastoma (SAG vs Inv. Choice)
<b>Sanofi / Regeneron</b>	REGN2810 (Mab PD-1)	Is in pivotal phase 2 for cutaneous squamous cell carcinoma (SARM SAG)
<b>Amgen</b>	Blinatumomab (Mab CD19/ CD3)	Accrual ongoing in 2 <sup>nd</sup> -line aNHL (SAG vs Inv. Choice)
<b>Sanofi</b>	Cabazitaxel (Chemo)	Phase 2 / 3 study in 2 <sup>nd</sup> -line urothelial cancer stopped early for futility (SAG vs vinflunine)

### PROGRESS TO PHASE 2

<b>Cellceutix RadioMedix</b>	Kevetrin (AKT I) 177Lu-PSMA-617 (Targeted Radiotherapeut.)	For ovarian cancer For prostate cancer
<b>Celldex NCI</b>	Varilumab (Mab CD27) Ad-CEA (Cancer vaccine)	For B-cell lymphomas For colorectal cancer

### NEW ENTRIES IN PHASE 1

V3-X (Vaccine for cholangiocarcinoma) Immunitor LLC  
 Karonudib (MTH1 I) Helleday Foundation  
 YH25448 (EGFRmut TKI) Yuhan Corporation  
 4SCAR19 (CAR-T Cells) Shenzhen Geno-Immune Inst.  
 BCD-100 (Mab PD-1) Biocad

### BUSINESS DEVELOPMENT EVENTS

<b>Hope Biosc. Seattle Genetics</b>	Acquires rights to Hope-777 (MERTK/AXL I, pre-clin) from Neo Pharm Co Acquires rights to IMMU-132 (Mab TROP-2 conj, in pivotal phase 2 for 3 <sup>rd</sup> -line breast cancer TN) from Immunomedics
<b>Incyte</b>	Acquires rights to INCAGN1876 (Mab GITR agonist, phase 1) and to INCAGN1949 (Mab OX40 agonist, phase 1 ) from Agenus

Main abbreviations: SAG=Single Agent; SARM=Single Arm; CO= In combination with; AO=Add On; CT=Chemotherapy; R = radiotherapy; IA = interim analysis; SOC = Standard of Care