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28 Oct 2016 |

PIPELINE WATCH: Phase III Trials Start In Atypical HUS, Fabry Disease And Colorectal Cancer

by John Davis

Pipeline Watch has been updated to bring greater depth and detail to a potential therapeutic product's progress through the R&D pipeline. The table brings you a snapshot of selected late-stage clinical trial events in the pharma and biotech industries.

The table records clinical developments using data from Informa Pharma Intelligence's Biomedtracker. It lists drugs for which an important event was recorded between October 21 and October 27, 2016, divided by event type.

Events can include Phase II and Phase III trial initiations, development discontinuations, and the release of top-line and full clinical trial results. A brief summary of product approvals is also included.

A companion resource, The Pink Sheet's regulatory-focused FDA Performance Tracker, follows regulatory milestones such as new submissions and user fee calculations, complete response letters and breakthrough therapy designations.

PIPELINE WATCH – October 21 to October 27, 2016

Lead company/partner	Compound	Indication	Comments
Phase III Suspended			
Dipexium Pharmaceuticals Inc.	*Locilex* (pexiganan) cream	diabetic foot ulcer infections	OneStep-1 and -2; did not meet primary endpoint.
Inovio Pharmaceuticals	VGX-3100	cervical dysplasia	FDA clinical hold on

Inc.			proposed trial due to concerns about delivery device.
AstraZeneca PLC	durvalumab	head and neck cancer	FDA partial clinical hold due to bleeding events. New patient enrolment halted.
Phase III Results			
Janssen Pharmaceutical Cos. /Bayer AG	*Xarelto* (rivaroxaban)	treating and preventing venous thromboembolism	Real world data confirms safety and efficacy.
Sunovion Pharmaceuticals Inc.	*Latuda* (lurasidone)	schizophrenia in adolescents	Safe and effective, supplemental NDA submitted.
Vertex Pharmaceuticals Inc.	*Okambi* (lumacaftor,ivacaftor) and *Kalydeco* (invacaftor)	cystic fibrosis	They modify progression in long-term data.
Chimerix Inc.	brincidofovir	adenovirus infection	AdVise; viremia declined in blood cell transplant patients.
Gilead Sciences Inc.	*Descovy* (emtricitabine and tenofovir alafenamide)	HIVAIDS	Switching from *Truvada* (emtricitabine and tenofovir disoproxil fumarate)
Phase III Interim/Top-line Results			
Merck & Co. Inc.	*Keytruda* (pembrolizumab)	advanced bladder cancer	KeyNote-045; improved overall survival.
AstraZeneca PLC	*Lynparza* (olaparib)	ovarian cancer	SOLO-2, Significant improvement in PFS.
Boehringer Ingelheim GMBH	biosimilar adalimumab (BI 695501)	rheumatoid arthritis	Pivotal study, showed equivalence to AbbVie's Humira.
ProMetic Life Sciences Inc. /Hematech Biotherapeutics Inc.	plasma-derived plasminogen	plasminogen deficiency	US BLA filing to start within weeks.
Eli Lilly & Co.	*Taltz* (ixekizumab)	psoriatic arthritis	SPIRIT-P2; positive results, 2017 supplemental filings.
Roche /Genentech Inc.	*Lucentis* (ranibizumab)	polypoidal choroidal	EVEREST II; an

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		vasculopathy	additional indication.
Daiichi Sankyo Co. Ltd./Eli Lilly & Co.	*Effient* (prasugrel)	ischemic stroke	PRASTO-1 and 2; an additional indication in Japanese patients.
Aerie Pharmaceuticals Inc.	*Rhopressa* (netarsudil) ophthalmic solution	glaucoma, ocular hypertension	Rocket 4; achieves endpoint, NDA to be resubmitted.
GlaxoSmithKline PLC	*Shingrix* vaccine	shingles	ZOSTER-004; supports flexible dosing, and using with flu vaccine.
Gilead Sciences Inc.	sofosbuvir, velpatasvir and voxilaprevir	hepatitis C	POLARIS-1,2,3,4; once daily single tablet.
Theravance Biopharma Inc. /Mylan NV	revefenacin	chronic obstructive pulmonary disease	Met primary endpoint and well tolerated.
Phase III Initiated			
Alexion Pharmaceuticals Inc.	ALXN1210	atypical hemolytic uremic syndrome and paroxysmal nocturnal hemoglobinuria	A longer-acting anti-C5 antibody, given every eight weeks.
Maruishi Pharmaceutical Co. Ltd./Faron Pharmaceuticals Oy	*Traumakine* (FP-1201-lyo)	acute respiratory distress syndrome	A European study is already underway.
Ultragenyx Pharmaceutical Inc. /Kyowa Hakko Kirin Co. Ltd.	KRN23	pediatric X-linked hypophosphatemia	A fully human IgG1 Mab.
Protalix BioTherapeutics Inc.	PRX-102	Fabry disease	A modified human alpha-GAL-A protein.
Sumitomo Dainippon Pharma Co. Ltd.	napabucasin	colorectal cancer	The CanStem303C study.
Phase II Suspended			
Aduro Biotech Inc.	CRS-207, ADU-623	ovarian, brain, and pancreatic cancer	FDA partial clinical hold due to Listeria infection.
GlaxoSmithKline PLC	losmapimod	chronic obstructive pulmonary disease	Development stopped by company.
Phase II Results			
Minerva Neurosciences Inc. /Mitsubishi Tanabe Pharma Corp.	MIN-101	schizophrenia, negative symptoms	Six-month extension study; improved symptoms.
ChemoCentryx Inc.	avacopan (CCX168), a	C3 glomerulopathy	A patient with this rare

	complement inhibitor		disease responded.
Shire PLC	maribavir	CMV infection	Reduced viremia in transplant patients.
Trevena Inc.	oliceridine	pain	Safe and effective.
Bristol-Myers Squibb Co.	*Opdivo* (nivolumab)	heavily pretreated classical Hodgkin's lymphoma	CheckMate-205; safe and effective in an expanded cohort.
Phase II Completed			
Samumed	SM04554	androgenetic alopecia	Safe and effective.
Phase II Interim/top-Line Results			
OncoGenex Pharmaceuticals Inc./Ionis Pharmaceuticals Inc.	apatorsen; an antisense heat shock protein 27 production inhibitor	metastatic bladder cancer	Borealis-2; positive survival results.
Sanofi/Lexicon Pharmaceuticals Inc.	sotagliflozin	type 1 diabetes	inTandem4; confirms Phase III dose.
Windtree Therapeutics Inc.	*Aerosurf* (lucinactant)	respiratory distress syndrome	In premature infants.
ObsEva SA	nolasiban (OBE001); oral oxytocin antagonist	in vitro fertilization	IMPLANT; proceeding to Phase III in Europe.
Galapagos NV/AbbVie Inc.	GLPG1837	cystic fibrosis	SAPHIRA 2; well tolerated
Allergan PLC /Motus Therapeutics Inc.	relamorelin, a ghrelin agonist	diabetic gastroparesis	Safe and effective, in diabetes patients.
Advaxis Inc.	axalimogene filolisbac	cervical cancer	Increased overall survival rate
DBV Technologies SA	*Viaskin Peanut*	peanut allergy	OLFUS-VIPES; two year follow-up showed durable responses.
Gilead Sciences Inc.	selonsertib (GS-4997)	non-alcoholic steatohepatitis (NASH), pulmonary arterial hypertension, diabetic kidney disease	Showed antifibrotic activity.
Phase II Initiation			
Targovax ASA	ONCOS-102/GM-CSF gene therapy	malignant mesothelioma	Increases tumor infiltrating lymphocytes.
Selecta Biosciences Inc.	SEL-212	gout	In refractory patients.

Stealth BioTherapeutics	elamipretide	congestive heart failure	The IDDEA-HF study.
Actelion Pharmaceuticals Ltd.	ACT-541468	insomnia	In adult patients.
Theranexus	THN102	narcolepsy	Being compared with modafinil.
Sanifit	SNF472	calciphylaxis	An orphan disease.

Source: Source: Informa Pharma Intelligence's Biomedtracker.

Marketing Approvals – October 21 to October 27, 2016

Lead Company	Partner Company	Drug	Indication	Market	Comments
REGULATORY APPROVAL					
Merck & Co	-	*Zinplava* (bezolotoxumab)	recurrence of Clostridium difficile-associated diarrhea	US	*In patients receiving antibacterial drugs.*
Recordati Industria Chimica & Farmaceutica SPA	Apricus Biosciences Inc.	*Vitaros* (alprostadil) cream	erectile dysfunction	Greece	Launch expected in first half of 2017.
SUPPLEMENTAL REGULATORY APPROVAL					
Merck & Co	-	*Keytruda* (pembrolizumab)	first line non-small cell lung cancer	US	*For tumors with a high PD-L1 expression and no EGFR or ALK tumor aberrations.*
Novartis AG	-	*Cosentyx* (secukinumab)	psoriatic arthritis, ankylosing spondylitis	Switzerland	Targets IL-17.

Source: Biomedtracker.