

NOVN AMGN 23/02/2020

Original call Outcome date Months ahead Report title

FOVEAL RESEARCH TRACK RECORD 2020-2024

NOVN: ORION 4 likely morbidity benefit

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NOVN		13/11/2024			NOVN/APLS: Fabhalta Oral route opens the possibility of preventing AMD		
AZN	NOVN	13/11/2024			AZN/NOVN: Myasthenia Refractory population and only partial inhibition of complement leaves Fabhalta likely in third place		
NOVN	AZN	13/11/2024			$NOVN/AZN: A typical\ Haemolytic\ Uraemic\ syndrome: Fabahlta\ or al\ formulation\ differentiation\ should\ be\ a\ winner$		
NOVN	AMGN	13/11/2024			NOVN/AMGN: pelacarsen may be the first cardiovascular breakthrough in decades by lowering unconventional Lp(a) cholesterol to prevent heart attacks		
ALPS	NOVN	13/11/2024			APLS/NOVN:C3G Fabhalta playing second fiddle to Empaveli		
NOVN		13/11/2024			NOVN: Remibrutinib's clear path to \$4bn monopoly in Urticaria with a better BTK		
NOVN	JNJ	13/11/2024			NOVN/JNJ/AMGN: lanalumab distinctive Sjögren's syndrome data, now first mover		
SMMT	MRK	23/09/2024			SMMT: Hold your HARMONIs: VEGF in Asian lung cancer always did better		
ROG	NOVN	21/08/2024			ROG/NOVN: Factor B lacking the X Factor in IGaN		
NOVN		29/07/2024			NOVN/ROG/APLS: Fabulous Fabhalta in PNH halts Piasky blue skies		
ROG	MRK	09/07/2024			ROG/MRK/PFE: Roche's RVT3101 similar to incumbents in Ulcerative Colitis		
SRPT	ROG	29/05/2024	Jun-24	1	ROG/SRPT: Duchenne EMBARK likely enough to lessen FDA age restrictions	FDA full approval and no age restriction	Wide label FDA approval of Duchenne Gene Rx June 24
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CYTK	BMY	29/02/2024	May-24	2	CYTK: Africamten approvable, may not outshine BMY's Camzyos	Africapmten underlying data not better than Camzyos	Take out premium lost after royalty deal
MRK		15/01/2024	Mar-24	2	MRK: Pul HT: High chance FDA, major share of high-priced orphan market; trial in heart failure could open huge market	FDA approval in Group 1. Chance in lareg Group 2 market	FDA approval of Pulmonary HT drug
MRK		15/01/2024			MRK: TL1A: PRA023 despite 1st in class, may struggle to take significant share in ulcerative colitis, based on current phase II data		
MRK	AMGN	15/01/2024			MRK:MK0616 oral PCSK9 headline benefit came in undertreated patients, suggesting it may struggle to break into the large, now generic primary prevention market		
MRK	AZN	15/01/2024			MRK: crashing the ADC party late with an attempt at differentiation that may not better competitors		
MRK		15/01/2024			MRK: Sotatercept: Pulmonary HT CADENCE-PH trial in heart failure could open huge market		
BMY	BAY	21/11/2023			BMY/JNJ/BAYN: Bayer AF failure does not reduce chances of success for ischaemic stroke trials for BMY/JNJ		
AZN	GILD	31/10/2023	Sep-24	10	AZN/GILD/Daiicii- ADCs in Lung cancer face steep hurdles after ESMO23	Dato will miss OS in 2L and in 1L NSCLC	Dato-DXD misses OS in Lung and Breast
PTGX	JNJ	14/08/2023			PTGX/JNJ: Oral IL23 dosing faces hurdles of new rival oral classes and psoriasis in ulcerative colitis		
MRNA	MRK	19/04/2023			MRK/MRNA: mRNA-PD1 cancer vaccine trial control arm may have underperformed		
MRK		20/03/2023	Dec-23	9	MRK: Little hope in TIGIT trials to date	TIGIT class will fail	TIGIT fails
Pfizer	SAN	21/12/2022	Oct-24	22	PFE: pregnancy RSV vaccine: \$450m. Stiff competition from single-use antibody targeted to high-risk children limits utility.	RSV vaccine will not take share from Beyfortus	Beyfortus antibody continues to grow 382% a year later
Pfizer	07.114	21/12/2022	Oct-23	9	PFE: 2024: Etrasimod: Ulcerative colitis: Good chance of FDA approval, better practical oral efficacy in large unmet market	Etrasimod FDA approval in UC	Fda approval of Velsipity in UC
_				7	PFE: Elranatamab: Myeloma: faces stiff competition from ever rising CAR-Ts	Elranatamab undifferentiated	
Pfizer		21/12/2022	Aug-23				1 year after launch, 2024E only \$100m
Pfizer		21/12/2022	Jun-23	5	PFE: Ritlecitinib: Alopecia areata: 2023: High chance of FDA, majority share in large, high priced unmet need, despite 2nd to market with better efficacy	Ritlecitinib FDA approval	FDA approval of Litfulo in Hair Loss
CNCE		21/12/2022	Jan-23	1	CNCE: deuruxolitinib appear gain a response in more patients, and faster than baricitinib	Deuruxolitinib appears superior to baricitinib	Alopeica BuyOut by Sun
ROG		15/08/2022	Feb-23	6	ROG: Idiopathic pulmonary fibrosis: PRM-151 tepid	PRM-151 undirrefentiete to standard of care, will likley fail	STARSCAPE terminated for futility
ROG	AZN	15/08/2022			ROG: Giredestrant needs restriction to very narrow ESR1 or will likely fail breast Ca		
BMY		21/06/2022	Jun-22	1	BMY/Kite: Bristol's Breyanzi best in class	FDA approval in LBCL	Breyanzi FDA approved
BMY		21/06/2022			BMY: Bristol's Breyanzi best in class		
BAY	BMY	16/05/2022	Nov-23	18	BAY: Bayer's Factor Xia lower bleeding came with more stroke in phase II AF	Asundexian unlikely to succeed in AF or MI	Asundexian fails in AF or heart attacks
JNJ		08/03/2022	Oct-24	31	JNJ: TAR200 MIBC: High 50% repsonse rates, though only very early data	TAR-200 success in adj MIBC	MIBC: fails adj phase III vs chemoradiation
JNJ		08/03/2022	Sep-24	30	JNJ: TAR200 MIBC: High 50% repsonse rates, though only very early data	TAR-200 success in neo adj MIBC	MIBC: positive neo adj phase II vs PD1
JNJ		08/03/2022	Jun-24	27	JNJ: Nipocalimab: Likley successful phase III, less shots, longer duration, but late to market	Nipocalimab postive phase III in MG	Positive phase III MG trial
JNJ		08/03/2022	Apr-23	13	JNJ: TAR-200 likley FDA approval in NMIBC	FDA approval in NMIBC	Positive nBCG-NMIBC registrational study: FDA filed
JNJ		08/03/2022	Oct-22	7	JNJ: Teclistamab phase II similar efficacy but no G3 neurotoxicity may be competitive threat to Carvykti	FDA approval with less neurotox than Carvykti	FDA approved, but Black box neurotoxic in phase III: Black box: but less than Carvkyti
GILD		10/02/2022	Feb-23	12	GILD: Trodelcy concern: Approveable, but high risk to be able to better chemo in previously CDK treated patients	FDA approval, but no benefit in prior CDK	FDA approves Trodelvy in HER2-ER+ 2L BC, with no effect in fully CDK treated pts
BMY		11/07/2021	Oct-24	39	BMY:Cendakimab: eosinophilic oesophagitis likely successful in steroid refractory	Successful Phase III	Successful Phase III
BMY				14	BMY: Deucravacitinib: plaque psoriasis: 2022: likely FDA approval, better than Otezla, safer than JAKs, easier to take than Stelara	FDA approval of Sotyktu in psoriasis	FDA approval of Sotyktu in psoriasis
		11/07/2021	Sep-22				
BMY	DAY.	11/07/2021	Aug-22	13	BMY: Mavacamten: cardiomyopathy: 2022:FDA approval very likely.	FDA approval of Camzyos in HoCM	FDA approval of Camzyos in HoCM
BMY	BAY	11/07/2021			Factor XIa inhibitor BMS-986177 ischaemic stroke prevention 2025: early data and epidemiology suggest new gold standard	504	504
BMY		28/06/2021	Mar-22	8	BMY: LAG3+Opdivo approvable, but driven by PD1-ve only	FDA approval of Opdulag	FDA appoved Opdulag
GSK	AZN	02/02/2021	Feb-23	24	GSK: Daprodustat FDA approval likely only in dialysis dependent.	Restricted FDA approval to dialysis-dependent only	FDA Daprodustat approval restricted to dialysis dependent only
JNJ		02/02/2021			Zejula in lung doubtful		
JNJ		02/02/2021	Feb-24	36	Gepotidacin good prospects of approval, though needs time for standard of care to become ineffective	Successful phase III, FDA approval	Positive phase III EAGE trial.FDA filed
AZN		02/02/2021	Dec-21	10	cabotegravir prep likely FDA approval, but faces 1st gen generics	FDA approval	Cabotegravir FDA approved
JNJ		15/10/2020	Apr-22	18	Mavacamten's potential	Successful phase III, FDA approval	FDA appoved mavacempten
ROG	JNJ	23/09/2020	Aug-24	47	JNJ: amivantamab + lazertinib combo data is supportive of first line success	Will beat Tagrisso in 1L; FDA approval	FDA approved lazertinib+ amivantamab in 1st line EGFR NSCLC with exon 19/21
JNJ	AZN	23/09/2020	Aug-23	35	JNJ: Niraparib: likely FDA (MAGNITUDE) in 1L prostate cancer, but late and undifferentiated	FDA approval, but undifferentiated to Lynparza	FDA approval of Niraparib in 1st line suspected or deleterious BRCA prostate cancer
JNJ	AZN	23/09/2020	May-23	32	AZN: Lynparza PROpel will likely lead to 1st line PFS in ITT popn	Wider FDA approval	FDA approved Lynparza in 1st line suspected or deleterious BRCA prostate cancer
JNJ	AZN	23/09/2020	May-21	8	JNJ: Amivantamab good chance of FDA success in 1st line exon 20 insertion lung cancer	FDA apporval in ex20i	Amivantamab FDA-approved Exon20i
ROG		12/06/2020	Apr-22	22	ROG.SW: TIGIT tweaks trailing Tecentriq but faces far more effective rivals	RocheTIGIT will fail	Roche TIGIT fails
Takeda		19/04/2020	Feb-24	46	Tak721: Likely Fda approval in eosinophilic oesophagitis	FDA approval on first filing	FDA approved on second filing
Takeda		19/04/2020	Sep-21	17	TAK-788: Specific mutated "I lung cancer, likely FDA approval in 2021	FDA approval	FDA approved
Takeda		19/04/2020	Nov-21	19	TAK-620: post-transplant cytomegalovirus likely FDA approval in 2021	FDA approval	FDA approved
Takeda		19/04/2020	Jul-22	27	TAK-924: Concerns over response rate data will deliver OS benefit	Phase III likley to fail	TAK-924 fails phase III
Takeda		19/04/2020	May-22	25	TAK-609: intrathecal Elaprase in Hunter's unlikely to get FDA approval	FDA failure	TAK-609 discontinued
NOVN		23/02/2020	Jun-23	40	NOVN: Kisqali's Kiss of life: Unique survival and tolerability bodes well for adjuvant	Successful phase III in adj, wider use than Verzenio; FDA adjuvant	
NOVN	ROG	23/02/2020	Aug-20	5	NOVN: Ofatumumab: best MS efficacy, Likley Fda approval, £3bn 2024 conservative estimate		FDA approves Ofatumumab (2024 sales ~\$3.6bn
NOVN	AMGN	23/02/2020	Dec-21	22	NOVN: inclisiran likely to get FDA approval this year;looks likely to easily become blockbuster		FDA approves inclisiran. Current \$1bn annual run rate
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