

Pan-European Pharmaceuticals

Feedback from FY24 catalysts doc series: Prostate Cancer and Multiple Sclerosis

Industry Overview

Feedback from prostate cancer / MS pipeline physician call

We provide feedback from our FY24 prostate cancer and MS pipeline physician call, hosted as part of our [FY24 pipeline doc call series](#). Key topics explored were:

Prostate cancer: Pluvicto Nubeqa Lynparza

Our KOL: 1) Is now using Pluvicto in almost all eligible PSMA-PET +ve mCRPC patients (80-90%) post-taxane therapy with no supply restrictions. Sees potential for expansion of centres (Novartis target 400 end 23E) but noted limited physicians with sufficient nuclear medicine expertise. PET scanning widely available, not a limitation; 2) Sees pre-taxane/post ARDT approval (PSMAFore trial) as likely, doubling the patient pool. Many patients not good candidates for taxane and most should have received ARDT in earlier lines of therapy. However, caveated that, although PFS primary endpoint HR0.43 was impressive, trial was poorly designed to address OS (HR1.16) due to crossover. Did not put any weight on pre-specified crossover adjusted OS (HR0.80). Expects regulators to be more focussed on HR1.16 which he thought needs to be closer to 1.0 at next interim for approval; 3) Sees HSPC (PSMAAddition data 25E) as higher hurdle given; a) PFS (not OS) primary endpoint in trial vs lots of other options with OS data; b) lack of longer term safety data (HSPC pts live longer); c) Potential low drug durability; 4) Nubeqa preferred ARDT due to safety but limited upside from ARANOTE trial (mono use vs label with chemo only) 1H24 given already using ex-chemo off-label; 5) c10% of mCRPC patients qualify for Lynparza (BRCAm/HRR+) and would still receive post PSMAFore approval.

MS: Orals, CD20, Ocrevus, Kesimpta, BTK/CD40 debate

MS takes: 1) At a high level, current treatment split roughly 50% of patients on CD20, but thinks this could increase up to 60-70% (with newer patients no prior negative experience with injectables). Within this, roughly 45%/45% Ocrevus/Kesimpta, with 10% Briumvi. Moving forward sees Kesimpta taking majority share on convenience. 2) Subcut Ocrevus largely seen as an alternative to IV Ocrevus for those with difficulty with venous access, but not seen as a competitor to Kesimpta (as more convenient still) even if nurse home administration achieved. 3) BTK evobrutinib failure likely due to milder patient population enrolled (noting teriflunomide arm relapse rate better than that seen on Ocrevus arm in its pivotal). Though still believes a delta on MRI lesions/CDP could be seen, and data may still be filable, but we see unlikely Merck would pursue. 4) Sanofi's Tolebrutinib differentiation: Better MRI data, brain penetration, CSF biomarker data (B-cell dependent CSF biomarkers on reducing innate macrophage microglia activity). Noted 50% ARR reduction vs teriflunomide would put in line with CD20s, vs 20-30% more in line with Gilenya. Greatest potential for differentiation on CDP, potentially vs both CD20 and orals. 5) Not concerned on liver tox, seeing it as no worse than that seen with teriflunomide and manageable with monthly liver monitoring. 6) Sees frexalimab PII data as exciting, with MRI lesion reduction similar to CD20, and no thrombosis (CD40L historial issue). Key differentiator being non-B-cell depleting mechanism a particular benefit in pops at risk of infection (elderly), but with trade off on frequency of dosing.

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Equity
Pan-Europe
Pharmaceuticals

Graham Parry >>
Research Analyst
MLI (UK)
+44 20 7996 0735
graham.parry@bofa.com

Sachin Jain, CFA >>
Research Analyst
MLI (UK)
+44 20 7995 9676
s.jain@bofa.com

Joe Bowden >>
Research Analyst
MLI (UK)
jbowden@bofa.com

Charlie Haywood >>
Research Analyst
MLI (UK)
charlie.haywood@bofa.com

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Glossary

1L / 2L / 3L = 1st Line / 2nd Line / 3rd Line

ARDT = Androgen Receptor directed therapy

BRCA = BReast CAncer gene

BTK = Brutons Tyrosine Kinase

CD20 = Cluster of differentiate 20 (a cell surface receptor)

CDP = Confirmed Disease Progression

CSF = Cerebrospinal fluid

HR = Hazard Ratio

HRR+ =Homologous Recombination Repair positive

IV = intravenous

KOL =Key Opinion Leader

MRI = Megnetic Resonance Imaging

MS =Multiple Sclerosis

mCRPC = metastatic Castrate Resistant Prostate Cancer

mHSPC = metastatic Hormone Sensitive Prostate Cancer

OS = Overall survival

PSMA = Prostate-specific membrane antigen

PET = Positron emission tomography

PFS = Progression free survival

SOC = Standard of care

BTK = Bruton tyrosine kinase

CSF = Cerebrospinal Fluid

MS = Multiple sclerosis

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