

Colorectal Cancer [2017]

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Abstracts

Will new targeted therapies transform the treatment of colorectal cancer?

Checkpoint inhibitors continue their march into multiple areas of oncology, and are now approved as treatments for colorectal cancer. But while Keytruda (pembrolizumab; Merck & Co.) and Opdivo (nivolumab; Bristol-Myers Squibb) represent the most recent additions to the CRC treatment armamentarium, do KOLs believe they'll make an impact? An array of programmes are in late-stage development, including other PD-1/PD-L1 inhibitors, BRAF/MEK inhibitors, and cancer vaccines. All are vying for patients and the all-important seal of approval from key opinion leaders. But how will these products fare in a highly competitive space? And what will be the key to clinical and commercial differentiation? KOLs provide candid insights on these and other new therapies, their likely use, and how they'll affect current mainstays such as anti-VEGFs and anti-EGFRs, in KOL Insight: Colorectal Cancer.

Ten North American and European KOLs provide their insight on 8 marketed/registered products, 7 pipeline programmes, 3 early-stage mechanisms of action and the potential for bevacizumab biosimilars.

Top takeaways

It's about to get personal. As gene mapping becomes more common in the diagnosis of CRC, what impact will this have on treatment selection and sequencing of current and future treatment options?

Outlook unclear for checkpoint inhibitors. KOLs are split on whether these new additions will have a significant impact on CRC treatment outcomes. What could drive higher rates of adoption in the treatment algorithm?



New treatment guidelines on the horizon? Data on left side vs. right side tumours could usher in significant changes in the treatment algorithm for CRC. Do KOLs believe treatment guidelines will evolve, and what impact will this have on treatment selection?

Combination regimens to lead the charge. KOLs agree that combination regimens will become an increasingly important part of the CRC treatment algorithm in the near future. But which regimens are the best, and what clinical trials are needed to support their approval?

KOLs warming to bevacizumab biosimilars, but concerns still remain. With over a dozen Avastin biosimilars on the way, and one already approved in the US, KOLs are cautiously optimistic. What are their concerns, and what will biosimilars have to show to achieve widespread uptake?

The bar has been set, and it's high. KOLs believe that novel therapies for CRC will be held to higher safety and efficacy standards in the future. How will this impact clinical development and investment in an area which still has significant levels of unmet need?

Quote

"Personally, I'm not 100 percent comfortable with that because with statistics you have to make some assumptions that things are close enough, but not exactly the same. When you say, 'no clinically meaningful difference,' that's in one tumour type and in one study. One study in lung cancer doesn't necessarily tell you that it's going to have the same [efficacy] in colon cancer."US Key Opinion Leader

"From a philosophical point of view, this is an interesting strategy. But I don't see the point to go in a Phase III trial, which is very costly and very difficult to run, when the Phase II trial is negative. What is the point? You should move to another target or modify something. I have worked on colorectal cancer for 15 years more or less. I have never seen any Phase II negative trial which converted into a positive Phase III trial, never in my life. I would not bet any money on this trial." European Key Opinion Leader

Sample of therapies covered

Marketed/Registered Therapies



Aflibercept (Zaltrap; Regeneron/Sanofi)

Bevacizumab (Avastin; Roche)

Ramucirumab (Cyramza; Eli Lilly)

Cetuximab (Erbitux; Eli Lilly/Merck Group)

Panitumumab (Vectibix; Amgen)

Regorafenib (Stivarga; Bayer)

Nivolumab (Opdivo; BMS)

Pembrolizumab (Keytruda; Merck & Co.)

Pipeline (P3) Therapies

Atezolizumab (Tecentriq; Roche)

Lefitolimod (Mologen)

Binimetinib (Array Biopharma/Pierre Fabre)

Cobimetinib (Cotellic; Exelixis)

Nintedanib (Boehringer Ingelheim)

Napabucasin (Boston Biomedical/Sumitomo Dainippon Pharma)

OncoVAX (Vaccinogen)

Early Stage MOAs (P1/P2)

Veliparib (ABT-888; AbbVie)

Entinostat (Syndax Pharmaceuticals)



SYM004 (futuximab/modotuximab; Symphogen)

KOLs interviewed

KOLs from North America

Johanna Bendell. Director of GI Cancer Research Program at Sarah Cannon Research Institute, Nashville, TN

Thomas Cartwright. Co-Chairman US Oncology Gastrointestinal Research, Ocala, FL

Mike Morse. Professor of Medicine, Professor in the Department of Surgery, Member of the Duke Cancer Institute, Duke University School of Medicine, Durham, NC

Bert O'Neil. Joseph W. and Jackie J. Cusick Professor of Oncology, Indiana University of Medicine, Indianapolis, IN

Bassel el-Rayes. Chief Clinical Research Scientist, Winship Cancer Institute, Emory University Hospital and Grady Memorial Hospital, Atlanta, GA

KOLs from Europe

Guiseppe Aprille. Department of Oncology, University Hospital, Udine, Italy

Khurum Khan. Locum Consultant GI and Acute Oncology, The Royal Marsden NHS Foundation Trust, Sutton, UK

Jaafar Bennouna. Professor, Medical Oncology, University of Nantes, France and Institut de Cancérologie de l'Ouest, Nantes, France

John Bridgewater. Clinical Researcher, University College London Cancer Institute, London, UK

Anonymous German KOL. Head of Oncology/Haematology Department, large



teaching hospital in Germany

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competitors and your markets. Covering biosimilars, market access, medical affairs, sales & marketing, technology and therapy areas, FirstWord Reports provide expert views and intelligence on the challenges facing pharma today.



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