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Colorectal Cancer: Update Bulletin #1

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Abstracts

This edition presents the views and insights from three world leading key opinion leaders (KOLs) from North America and Europe on a variety of recent events in the colorectal cancer (CRC) market, including; Symphogen announcing detailed results from its randomised Phase II study with SYM004 compared to investigator-choice chemotherapy or best-supportive-care, in patients with advanced metastatic CRC and acquired resistance to anti-EGFR monoclonal antibodies (mAbs); Array BioPharma and Pierre Fabre announcing safety results and initial clinical activity data from the safety lead-in phase of the Phase III BEACON CRC study, which is assessing the safety and efficacy of binimetinib, encorafenib and cetuximab (BIN/ENC/CTX) in patients with BRAF-mutant CRC whose disease has progressed after one or two prior regimens in the metastatic setting; and The European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) adopting a positive opinion, recommending the granting of a marketing authorisation for Mvasi, a biosimilar version of Avastin (bevacizumab) from Amgen and Allergan, intended for the treatment of carcinoma of the colon or rectum and other indications.

Business Questions:

Are KOLs intrigued by SYM004's mechanism of action?

Were KOLs disappointed with the overall result from SYM004's Phase II study, and did they think that the positive signal in certain patients warrants further investigation?

Do KOLs believe that the design of the Phase II study for SYM004 contributed to its failure?

What are the next steps for Symphogen and SYM004? Terminate development

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or confirm the positive efficacy signal seen in the Phase II study for SYM004 in a larger Phase III study?

Where do KOLs believe that SYM004 will be used in the treatment of mCRC, and which products will it displace?

Do KOLs believe that early data from the Phase III BEACON study, which is assessing the binimetinib/encorafenib/cetuximab (BIN/ENC/CTX) triplet combination, supports previously published data from the Southwest Oncology Group?

What do KOLs think about the safety and early efficacy data for BIN/ENC/CTX; promising, or too early to tell?

What will BIN/ENC/CTX need to show in order to compete with current treatment regimens: improvements in OS, ORR, and PFS, or all of the above?

Are KOLs happy to have access to biosimilars, or will remaining concerns slow down uptake of bevacizumab biosimilars in the mCRC setting?

What do KOLs think about the non-medical switching of patients from Avastin to bevacizumab biosimilars?

Will the Centers for Medicare & Medicaid Services' (CMS) announcement that all biosimilars will receive their own J code lead to greater biosimilar uptake?

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