BERLIN 2025 ESMO congress

794P

A fruquintinib expanded access program (EAP) to provide treatment for patients with metastatic colorectal cancer (mCRC)

S. Kasper-Virchow[1], H. Karachiwala[2], R. Vera[3], J. Gramaça[4], S.P. Choo[5], M.I. Meneses Medina[6], G. Bodoky[7], N. Pavlakis[8], M.P. Saunders[9], S. Clark[10], J. Peng[11], Y. Yin[11], N. Vaidya[12], L. Gagnon[13], C. Kohn[13], J. Netter-Coti[14]

[1] Department of Medical Oncology, University Hospital Essen, Essen, Germany, [2] Medical Oncology, Tom Baker Cancer Center, Calgary, Canada, [3] Medical Oncology Department, University Hospital of Navarra, Instituto de Investigación Sanitaria de Navarra, IdISNA, Pamplona, Spain, [4] Medical Oncology Unit, Centro Hospitalar Universitário Lisboa Central, Lisbon, Portugal, [5] Medical Oncology, Curie Oncology, Singapore, [6] Departamento de Hematología y Oncología, Instituto Nacional de Ciencias Médicas y Nutrición Salvador Zubirán, Mexico City, Mexico, [7] Oncology Department, Szent László Hospital, Budapest, Hungary, [8] Department of Medical Oncology, Royal North Shore Hospital, Sydney University, Sydney, Australia, [9] Clinical Oncology, The Christie NHS Foundation Trust, Manchester, United Kingdom, [10] Global Evidence and Outcomes Oncology, Takeda Development Center Americas, Inc. (TDCA), Cambridge, United States of America, [11] Statistics, Takeda Development Center Americas, Inc. (TDCA), Cambridge, United States of America, [12] Global Medical Affairs, Takeda Development Center Americas, Inc. (TDCA), Cambridge, United States of America, [13] Global Oncology Expanded Patient Access Programs, Takeda Development Center Americas, Inc. (TDCA), Cambridge, United States of America[14] Department of Hepato-Gastroenterology and Digestive Oncology, Georges Pompidou European Hospital, Paris, France

Background

Globally, colorectal cancer is the 3rd most diagnosed cancer and the 2nd leading cause of cancer death; 22% of patients (pts) are diagnosed with metastatic disease and up to 50% diagnosed at stages 1–3 progress to stage 4. Standard of care (SoC) for mCRC includes chemotherapy, trifluridine/tipiracil (FTD-TPI) and regorafenib; however, there is an unmet need for new, effective treatments for refractory mCRC. Fruquintinib (fruq), a highly selective oral inhibitor of all 3 VEGFRs, is approved, including in the US/EU, for pre-treated mCRC. We report data from an EAP (NCT06195514) initiated in 2023 outside of China, Hong Kong, and Macau to provide fruq to pts with refractory mCRC who exhausted SoC therapies and could not enter a clinical trial.

Methods

Adult pts who had progressed on, or were intolerant to, fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy and VEGF/EGFR inhibitors, as indicated, were enrolled in 26 countries. Pts had received FTD-TPI and regorafenib unless intolerant or not locally available. Baseline (BL) characteristics were collected via pt access forms; data were summarized via descriptive statistics. Fruq was initially dosed at 5 mg on days 1–21 in 28-day cycles. Treatment duration was estimated from orders (1 order = 2-month supply).

Results

From Nov 2023–Apr 2025, 1069 pts were enrolled and received a 2-month supply of fruq (BL characteristics in the table). Overall, 19.1% and 40.3% of pts did not receive prior FTD-TPI and regorafenib, respectively; common reasons for this included lack of availability or medical justification. Initial fruq dose was 5 mg in 97% of pts. 43.8% of pts received ≥1 resupply; 5.5% had ≥4 total orders (8-month supply). Of pts who received ≥1 resupply, 21.6% had a dose reduction.Table: 794P

Baseline characteristics of patients treated via the EAP

Characteristic	Enrolled patientsN=1069
Age, median (range)	65 (23–90)
Male, n (%)	580 (54.3)
Region, n (%)	
Europe (excluding Italy)	786 (73.5)
Australia	116 (10.9)
Asia	97 (9.1)
North America (excluding United States)	60 (5.6)
South America	10 (0.9)
Eastern Cooperative Oncology Group performance status, n (%)	
0	395 (37.0)
1	629 (58.8)

Characteristic	Enrolled patientsN=1069
2	45 (4.2)
Previous treatments, n (%)	
Fluoropyrimidines	935 (87.5)
Oxaliplatin	947 (88.6)
Irinotecan	861 (80.5)
VEGF inhibitor	839 (78.5)
EGFR inhibitor	353 (33.0)
FTD-TPI	864 (80.8)
Regorafenib	638 (59.7)
Both FTD-TPI and regorafenib	576 (53.9)
Either FTD-TPI or regorafenib	926 (86.6)

Conclusions

Pts in the EAP had exhausted SoC therapies. The low dose reduction rate of fruq may reflect its tolerable real-world safety profile. The demand as shown through resupplies highlights the unmet need for pts with later-line mCRC.

Clinical trial identification

NCT06195514.

Editorial acknowledgement

Editorial support, under the direction of the authors, was provided by Christian Jones, PhD, of Ashfield MedComms, an Inizio company, funded by Takeda Pharmaceuticals, U.S.A., Inc., Cambridge, MA, and complied with GPP guidelines (DeTora LM, *et al.* Ann Intern Med 2022;175:1298–1304).

Legal entity responsible for the study

Takeda Pharmaceuticals U.S.A., Inc., Cambridge, MA, USA.

Funding

Takeda Pharmaceuticals U.S.A., Inc., Cambridge, MA, USA.

Disclosure

S. Kasper-Virchow: Financial Interests, Full or part-time Employment: University Hospital Essen; Financial Interests, Financially compensated role, Honoraria: BMS, MSD, Amgen, Merck Healthcare, Servier, Onkowissen, Lilly, AstraZeneca, Daiichi Sankyo, Takeda; Financial Interests, Advisory Role: BMS, MSD, Roche, Novartis, Merck Healthcare, Amgen, Servie, Takeda, Lilly, AstraZeneca; Financial Interests, Research Funding: BMS, Lilly, Roche; Financial Interests, Other, Travel, accommodations, expenses: MSD, Lilly, Amgen, BeiGene. H. Karachiwala: Financial Interests, Speaker's Bureau: Taiho Pharmaceutical; Financial Interests, Financially compensated role, Honoraria: Roche Canada, Eisai, Merck, BMS, Incyte, Ipsen, AstraZeneca, Amgen, Astellas Pharma, Takeda. R. Vera: Financial Interests, Advisory Role: MSD, Roche, Amgen; Financial Interests, Speaker's Bureau: Roche, Amgen, Takeda, Lilly, MSD; Financial Interests, Other, Travel, accommodations, expenses: Roche, MSD, Amgen, Takeda, Lilly. S.P. Choo: Financial Interests, Full or part-time Employment: Curie Oncology; Financial Interests, Leadership Role: Curie Oncology, Director; Financial Interests, Stocks or ownership: BMS, Agenus, Lucence diagnostics; Financial Interests, Financially compensated role, Honoraria: AstraZeneca, Pierre Fabre, Servier, BMS, MSD, Roche, Amgen, Zuellig Pharma, Gene Solutions, Juniper; Financial Interests, Advisory Role: AstraZeneca, BeiGene, Takeda, Astellas; Financial Interests, Speaker's Bureau: AstraZeneca; Financial Interests, Other, Travel, accommodations, expenses: AstraZeneca, MSD, Servier. M.I. Meneses Medina: Financial Interests, Advisory Role: BMS, MSD, Ipsen, Takeda; Financial Interests, Speaker's Bureau: BMS, MSD, Roche, Ipsen, AstraZeneca; Financial Interests, Research Funding: MSD; Financial Interests, Other, Travel, accommodations, expenses: Roche, Ipsen, Takeda, MSD. G. Bodoky: Financial Interests, Advisory Role: Roche, Pfizer, Janssen, Novartis, Bayer, Lilly, Ipsen; Financial Interests, Other, Travel, Accommodations, Expenses: Lilly, Pfizer, Roche, Janssen, Novartis. N. Pavlakis: Financial Interests, Advisory Role: Roche, Boehringer Ingelheim, AstraZeneca, Merck KGaA, Merck Serono, Amgen, Merck Sharp & Dohme, Novartis, Pfizer, Takeda, Bristol Myers Squibb, BeiGene, Gilead Sciences, Duo Oncology, Daiichi Sankyo/AstraZeneca, Zymeworks, BioNTech, Johnson & Johnson/Jan; Financial Interests, Financially compensated role, Honoraria: BeiGene, Bayer, Takeda, Pierre Fabre, Merck KGaA, Illumina, Gene Solutions, MSD Oncology; Financial Interests, Institutional, Research Funding: Bayer, Pfizer, Roche. M.P. Saunders: Financial Interests, Advisory Board: Takeda, Servier, MSD, Bayer, GSK, Incyte and NOrdic. S. Clark: Financial Interests, Full or part-time Employment: Takeda; Financial Interests, Personal, Stocks or ownership, Spouse: Pfizer. J. Peng, Y. Yin, N. Vaidya: Financial Interests, Full or part-time Employment: Takeda. L. Gagnon, C. Kohn: Financial Interests, Full or part-time Employment: Takeda; Financial Interests, Stocks or ownership: Takeda. All other authors have declared no conflicts of interest.