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KANTAR HEALTH DISCUSSES THE PIVOTAL CLINICAL TRIALS PRESENTED AT THE 2017 AMERICAN SOCIETY OF CLINICAL ONCOLOGY (ASCO) GASTROINTESTINAL (GI) ANNUAL MEETING

MARCH 2017
VOLUME 13, ISSUE 2

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OPDIVO SHOWS APPETITE FOR GASTRIC CANCER

by TARI AWIPI and JAY GRISOLANO

Before Cyramza® (ramucirumab, Eli Lilly and Company) was approved by the U.S. Food and Drug Administration (FDA) in 2014, no targeted therapy regimens were approved for use in relapsed/refractory gastric cancer. Cyramza's approval as a monotherapy or in combination with paclitaxel after prior fluoropyrimidine- or platinum-containing systemic therapy was based on the positive results of two Phase III studies in relapsed gastric patients: the REGARD trial, which showed a significant overall survival (OS) benefit of 5.2 months for Cyramza versus 3.8 months for placebo,[1] and the RAINBOW trial, which compared Cyramza plus paclitaxel versus paclitaxel alone, demonstrating a significant progression-free survival (PFS) and OS benefit for the Cyramza combination (median PFS of 4.4 months versus 2.9 months and median OS of 9.6 months versus 7.4 months in Cyramza plus paclitaxel arm versus paclitaxel alone arm, respectively).[2] In the U.S., Cyramza had a significant first-to-market advantage in this indication and is currently highly utilized in this space (30.4% and 39.6% as monotherapy or with paclitaxel in second-line and third line, respectively[3]). However, given the limited number of treatment options, new agents still have a lot of potential, including immunotherapies, which have already made a splash in other solid tumor types.

While gastric cancer is a relatively rare tumor type in the U.S. (ranks 16th in terms of incidence), it is the most commonly diagnosed tumor type in Japan.[3] In part due to this, Ono Pharmaceuticals took the lead in evaluating immunotherapy in gastric cancer in the Asia Pacific region. In 2014, Ono Pharmaceuticals, which is co-developing Opdivo along with Bristol-Myers Squibb (BMS), initiated a randomized (2:1), double-blind, Phase III trial of Opdivo® (nivolumab, BMS/Ono Pharmaceuticals) in gastric and gastroesophageal junction (GEJ) cancer patients in Japan, Korea and Taiwan (ONO-4538-12; NCT02267343). In this trial, Opdivo (3 mg/kg q2w) was compared against placebo in patients refractory or intolerant to standard therapies, with OS as the primary endpoint. In an oral abstract session at the 2017 American Society of Clinical Oncology (ASCO) Gastrointestinal (GI) Cancers Symposium, positive data from this trial were presented.[4] The trial enrolled 493 patients with unresectable advanced or recurrent gastric/GEJ adenocarcinoma who had failed two or more previous chemotherapy regimens, including Cyramza. As of the data cut-off on August 13, 2016, 5.6 months after the last patient was randomized, median OS was 5.32 months with Opdivo versus 4.14 months with placebo (hazard ratio [HR]=0.63; 95% confidence interval [CI], 0.50-0.78; p<0.0001), and OS rates at six and 12 months were 46.4% versus 34.7% and 26.6% versus 10.9%, respectively. The objective response rate (ORR) was 11.2% with Opdivo versus 0% with placebo (p<0.0001). Median PFS was 1.61 months with Opdivo versus 1.45 months with placebo (HR=0.60; 95% CI, 0.49-0.75; p<0.0001). Grade ≥ 3 treatment-related adverse events (TRAEs) occurred in 10.3% of Opdivo-treated patients and in 4.3% of placebo-treated patients; 2.7% and 2.5% of patients, in the respective arms, discontinued study treatment due to TRAEs (any grade). The most common AEs were pruritus, diarrhea, rash, fatigue, and decreased appetite. These data were well received by the conference audience. Of particular excitement was the characteristic

OS plateau or "tail" in the Kaplan-Meier curve that we have come to expect from the checkpoint inhibitor class of immunotherapy agents; while the OS difference at the median was modest (1.18 months), a strong separation between the two curves that appears to be maintained long-term. Biomarker analysis was not reported, but is under investigation as an exploratory endpoint.

ENDPOINT	OPDIVO (N=330)	PLACEBO (N=163)	
Median OS	5.32 months	4.14 months	HR = 0.63 p < 0.0001
6-month OS	46.4%	34.7%	
12-month OS	26.6%	10.9%	
ORR	11.2%	0%	p < 0.0001
Median PFS	1.61 months	1.45 months	HR = 0.60 p < 0.0001

Table 1: Efficacy of Opdivo versus Placebo in Relapsed/Refractory Gastric Cancer (Asia Pacific) – ONO-4538

Not surprisingly, Ono has already filed for approval of Opdivo in gastric cancer in Japan with this data (Ono Press Release, December 27, 2016). Despite the Japanese filing, BMS has not stated that it has plans to file in the U.S. based on this data, perhaps given the enrollment was limited to Asian patients. Indeed during the discussion, Dr. Heinz-Josef Lenz of the University of Southern California's Norris Comprehensive Cancer Center took care to point out the molecular differences in gastric cancer between Asian and non-Asian populations citing reported differences in immune signatures related to T-cell function.[5] Furthermore, subgroup analysis of the ONO-4538 trial showed a stronger magnitude of benefit (HR=0.59) in patients with intestinal histologic type (a better prognostic subset that is more common in Asian gastric cancer patients) compared with patients with diffuse histology type (HR=0.82; a worse prognostic subset that is more common in Caucasian gastric cancer patients). Together, this information raise doubts about the translatability of these data in Asian patients to a broader U.S. population. During the question-and-answer portion of the session, however, the issue of U.S. filing based on Asian data was raised, and some felt that, rather than wait for a new Phase III trial readout, a confirmatory Phase II trial in a U.S. population could warrant filing. Although not discussed, an alternative scenario could be the National Comprehensive Cancer Network (NCCN) recommending Opdivo for use in relapsed/refractory gastric/GEJ. Such action (NCCN guideline recommendation for U.S. patients based strictly on data from Asian countries) has not previously occurred, but might not be entirely outside the realm of possibility given the unmet needs in gastric cancer and the well-established safety profile for Opdivo in other indications, even if balanced against the histologic subgroup data from the Japanese trial. In the absence of accelerated filing or NCCN recommendation, filing with the FDA may need to await the results of the ongoing global Phase III CheckMate-649 trial (NCT02872116) that is being conducted in the first-line setting and is investigating the combination of Opdivo plus Yervoy® (ipilimumab, BMS/Ono), data from which is not expected for several years.

Opdivo is not the only immunotherapy under late-stage development in gastric cancer. Keytruda® (pembrolizumab, Merck/MSD) has multiple Phase III trials underway in first-line and relapsed/refractory disease, was given sakigake fast-

track designation status by Japan's Ministry of Health, Labour and Welfare (MHLW) in October 2015, and may be the first immunotherapy agent to enter the gastric cancer market in the U.S. In addition, Pfizer and Merck KGaA are also developing their PD-L1 inhibitor avelumab in relapsed/refractory gastric cancer. And of course non-immunotherapy approaches are also under late-stage development, including napabucasin (BBI608, Boston Biomedical/Sumitomo Dainippon) in second-line (NCT02178956), Lonsurf® (trifluorothymidine/tipiracil hydrochloride, Taiho) in third-line, GS-5745 (Gilead) in first-line, and Cyramza in first-line. Although the results of this Asian Phase III trial may not have an immediate impact in the U.S. gastric cancer market, these remain highly impactful results globally. Opdivo could gain approval in this indication in Japan as early as late 2017, putting it well-ahead of other competitors in this setting and bringing a new option to this population of high unmet need.

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ABOUT THE EXPERTS

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OPDIVO MAKING STRIDES IN ADVANCED HEPATOCELLULAR CARCINOMA

by EMILY BENESH and STEPHANIE HAWTHORNE

It is an exciting time for patients and their doctors fighting advanced hepatocellular carcinoma (HCC). In mid-2016 the HCC community witnessed the first randomized trial to successfully improve survival outcomes in Nexavar® (sorafenib, Onyx/Amgen/Bayer) -pretreated HCC when the multi-kinase inhibitor Stivarga® (regorafenib, Bayer) demonstrated a 37% reduction in the risk of death (HR=0.63; 95% CI, 0.50–0.79; p < 0.001) compared with placebo in the Phase III RESORCE trial.[1] This led to submission of a supplemental new drug application (NDA) with the FDA in November 2016. Additionally, Opdivo® (nivolumab, BMS/Ono Pharmaceuticals) is showing very promising activity as treatment of advanced HCC, and the excitement around these results was palpable at the 2017 ASCO GI Cancers Symposium in San Francisco.

Historically, the unmet needs in HCC have been insurmountable. Even with the best therapeutic options available, the prognosis for advanced HCC has been quite poor; first-line patients receiving the standard of care, Nexavar, have a median overall survival of 10.7 months.[2] In 2007, Nexavar, a multi-tyrosine kinase inhibitor, was established as the first targeted agent FDA-approved in this indication. It achieved this by besting a placebo control with a 2.8-month improvement in OS, although patients did not experience improvements in time to symptomatic progression or complete responses with use of this agent.[2] Additionally, in the SHARP trial (NCT00105443), 80% of Nexavar-recipient patients experienced any-grade treatment-related adverse events, with the most common Grade 3 adverse events being diarrhea (8%) and hand-foot skin reaction (8%).[2]

The last nine years have seen novel therapeutic contenders struggle to improve outcomes and unseat Nexavar as front-line therapy. This is due, in part, to liver dysfunction (cirrhosis) present in many HCC patients as well as other comorbidities resulting from infection with hepatitis B or hepatitis C, and/or occurrence of non-alcoholic fatty liver disease. In practice, systemic therapies such as Nexavar are limited to patients with the least degree of cirrhosis (Child-Pugh A). Those with greatly impaired liver function (Child-Pugh C) are often unable to tolerate current therapeutic options and generally receive only best supportive care. Even those with reasonable liver function may struggle to tolerate combination therapies that include Nexavar as a backbone.

Thus, a novel agent is greatly needed that makes strides in both efficacy and tolerability in order to encompass more patients in the treatable population. Such an agent would find an open market with a reasonable patient base; in 2016 HCC ranked as the 14th most commonly diagnosed cancer in the U.S. with an incidence of roughly 30,000 newly diagnosed patients.[3] In Eastern countries the population suffering from HCC is slightly larger; it ranked ninth in Japan with nearly 36,000 new cases reported in 2016.[3]

Against this backdrop of high unmet need and reasonable opportunity, BMS/Ono entered the HCC competitive landscape in 2012 with Opdivo. Results of Opdivo trials have shown incredible promise with OS gains and remarkably durable responses in multiple tumors, leading to its FDA approval in metastatic melanoma (alone or in combination with Yervoy® (ipilimumab, BMS/Ono), metastatic non-small cell lung cancer, advanced renal cell carcinoma, classical Hodgkin lymphoma and squamous cell carcinoma of the head and neck.

The CheckMate-040 Phase I/II trial (NCT01658878) was initiated to evaluate the safety, tolerability, dose-limiting toxicities and maximum tolerated dose of Opdivo in 1) uninfected HCC subjects, 2) HCC patients with hepatitis B, and 3) HCC patients with hepatitis C. Enrolled patients had unresectable advanced HCC, with a Child-Pugh score of ≤7 (dose escalation) or ≤6 (dose expansion). Patients could not have active HBV or HCV and were required to be on concomitant antiviral therapy with a viral load of <100 IU/mL. Subpopulations of patients were Nexavar-naïve (31% of enrolled patients) and Nexavar-experienced (69% of enrolled patients).

The patient characteristics between the dose escalation and expansion cohorts were well balanced; both cohorts favored male subjects (75% and 80%, respectively) and were enriched for Asians (38% and 47%, respectively). Seventy-six percent of all patients were systemic therapy-experienced, slightly more than two-thirds of whom had received prior Nexavar. In October 2016, interim data were presented for 48 patients treated in the dose escalation cohort and 214 patients in the dose-expansion cohort,[4] and on January 20th at the ASCO GI Cancers Symposium in San Francisco updated results from this trial were presented.[5] As of interim analysis data cut-off date (August 8, 2016), investigators had treated 262 patients across the dose escalation (0.1-10 mg/kg) and expansion phases (3 mg/kg) of the trial. In the dose-escalation phase (n=48), twenty-five percent of patients experienced Grade 3/4 or greater TRAEs, including aspartate transaminase (AST) increase (10%), alanine transaminase (ALT) increase (6%), and lipase increase (13%). While hematologic liver parameters are of particular concern to the HCC patient population, these were considered manageable and did not result in hepatitis. Health-related quality of life outcomes, as measured by EQ-5D VAS and index scores, did not show differences in first- or second-line patients and were stable from baseline to week 25. Thus, the relatively mild toxicity profile of Opdivo monotherapy in these pretreated HCC patients was encouraging.

In second-line Nexavar-experienced patients, 37 patients were evaluable in the escalation cohort and 145 were evaluable in the expansion cohort. Investigator assessed ORR were 16.2% and 18.6% in the escalation and expansion phases, respectively, including complete response (CR) rates of 8.1% and 2.1%. Blinded independent central review (BICR) noted lower rates of CR (2.7% and 0.7%, respectively), but the ORR was only slightly lower than that reported by investigators (18.9% and 14.5, respectively). The duration of response (DOR) was 17.1 months in the dose escalation cohort and had not been reached in the dose expansion cohort. The median OS of the dose escalation cohort was 15.0 months and 13.2 months in the dose expansion cohort. At a nine-month follow-up, 67% and 71% of patients were alive in the escalation and expansion cohorts, respectively. In the escalation cohort, 46% of patients were alive at 18 months. In the dose expansion Nexavar-naïve cohort (n=69), 21.7% of patients had a partial objective response. Six- and nine-month OS rates were 87% and 77%, respectively. Expression of PD-L1 did not correlate with response to Opdivo in either patient population. Despite PD-L1 level appearing inconsequential to outcomes in this population, the discussant, Dr. Milind Javle from

the UT-MD Anderson Cancer Center, stated that detailed biomarker analyses (e.g., mutational burden, tumor-infiltrating lymphocytes, or immune gene signatures) would further enrich the population for responders and improve survival rates even more, emphasizing the need for predictive biomarkers for immunotherapy.[6]

ENDPOINT	DOSE ESCALATION NEXAVAR-EXPERIENCED, 2L (N=37)	DOSE EXPANSION NEXAVAR-EXPERIENCED, 2L (N=145)	DOSE EXPANSION NEXAVAR-NAIVE, 1L (N=69)
Median OS	15.0 months	13.2 months	—
6-month OS	67%	82%	87%
9-month OS	67%	71%	77%
ORR	16.2%	18.6%	21.7%
Complete Response	8.1%	2.1%	0%
Partial Response	8.1%	16.6%	21.7%
ORR PD-L1 < 1%	15.4%	17.2%	—
ORR PD-L1 ≥ 1%	22.2%	32.0%	—

Table 2: Investigator-Assessed Efficacy with Opdivo in Advanced Hepatocellular Carcinoma-CheckMate-040

Results from the CheckMate-040 trial were very promising. Cross-trial comparisons of Opdivo and Nexavar suggest that Opdivo far outstrips efficacy numbers obtained by Nexavar in previous trials (in the SHARP trial, ORR was 2% and median OS was 10.7 months).[2] Based on these encouraging results, BMS is pursuing several avenues to establish and expand the reach of Opdivo in this space. In November 2015, BMS initiated a randomized global Phase III head-to-head trial (CheckMate-459; NCT02576509) of Opdivo versus Nexavar. The trial is recruiting treatment-naïve, Child-Pugh A advanced HCC patients in the U.S., Europe, Asia, and Australia. According to the presenter, Dr. Ignacio Melero, patient recruitment for CheckMate-459 is almost finished. In addition, BMS is exploring Opdivo use as a monotherapy and in combination with Yervoy or other novel agents in Phase I and II trials in various HCC treatment settings.

While the BMS/Ono developmental program has a head start, they are not alone in pursuing opportunities in the HCC space. Merck also has a strong program for Keytruda® (pembrolizumab, Merck/MSD). An ongoing Phase III trial (KEYNOTE-240; NCT02702401) is investigating Keytruda versus best supportive care in relapsed/refractory HCC. Additionally, an ongoing randomized Phase II trial is pitting the PD-L1 inhibitor durvalumab (AstraZeneca) monotherapy versus the CTLA4 inhibitor tremelimumab (AstraZeneca) monotherapy versus the durvalumab/tremelimumab combination in Nexavar-refractory patients (NCT02519348). Another agent in development is Pexa-Vec® (pexastimogene devacirepvec, SillaJen), an oncolytic virus that delivers the granulocyte-macrophage colony-stimulating factor (GM-CSF) to tumor cells. Pexa-Vec is being paired with Nexavar versus Nexavar monotherapy as first-line therapy in Child-Pugh A advanced HCC in a Phase III trial (NCT02562755). Beyond immunotherapy approaches, other targeted therapy agents are in late-stage development in HCC. Stivarga has been filed for FDA approval in second-line

HCC based on the positive RESORCE trial results and was granted priority review by the FDA in January 2017. In addition, Phase III trials are ongoing in second-line HCC for Cabometyx® (cabozantinib, Exelixis/Ipsen), which was granted Orphan Drug Designation for the treatment of HCC by the FDA in March 2017; Cyramza® (ramucirumab, Eli Lilly); and tivantinib (ArQule). In first-line HCC, Eisai recently reported that the Phase III Study 304 met its primary endpoint of showing non-inferior OS for Lenvima in comparison with Nexavar, with significant improvements in PFS and ORR (Eisai Press Release, January 25, 2017).

Thus, a host of agents are seeking entry into a space that promises to become increasingly crowded in the near future. It remains to be seen whether final results from the dose expansion cohort of CheckMate-040 might prompt an accelerated approval approach, or whether BMS will wait to file until CheckMate-459 data are reported. Nonetheless, the data that are unfolding continue to support a potential future scenario in which Opdivo emerges triumphant as a new leader in HCC management, potentially unseating Nexavar in the front-line and bringing a more effective and tolerable treatment to fuel the hope for a very ill patient population.

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CONFERENCE COVERAGE

Every year, Kantar Health sends multidisciplinary teams of oncology experts to significant oncology meetings around the world to analyze the most important clinical presentations, satellite symposia, poster sessions and floor exhibits.

Oncology Conference Insight will continue to bring you highlights and breaking news from the following 2017 oncology meetings:

Date	Meeting	Location
Jan. 19-21	Gastrointestinal Cancers Symposium 2017	San Francisco
Feb. 16-18	Genitourinary Cancers Symposium 2017	Orlando
Apr. 1-5	American Association of Cancer Research (AACR) Annual Meeting 2017	Washington D.C.
June 2-6	American Society of Clinical Oncology (ASCO) Annual Meeting 2017	Chicago
Sept. 8-12	European Society of Medical Oncology Congress (ESMO) 2017	Madrid
Oct. 26-30	AACR-NCI-EORTC International Symposium on Molecular Targets and Cancer Therapeutics Annual Meeting 2017	Philadelphia
Dec. 5-9	CTRC-AACR San Antonio Breast Cancer Symposium (SABCS) Annual Meeting 2017	San Antonio
Dec. 9-12	American Society of Hematology (ASH) Annual Meeting 2017	Atlanta

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