ONO PHARMACEUTICAL CO.,LTD.

September 23, 2020

Opdivo® (nivolumab) in Combination with CABOMETYX® (cabozantinib) Demonstrates Significant Survival Benefits in Patients with Advanced Renal Cell Carcinoma in Pivotal Phase 3 CheckMate -9ER Trial

This information is intended to notify the press release issued on September 19 by Bristol-Myers Squibb and Exelixis, Inc. Please click the following links for the original press release.

https://www.bms.com/media/press-releases.html (Bristol Myers Squibb)
https://ir.exelixis.com/press-releases (Exelixis Inc.)

First paragraph extracted from the original press release:

(PRINCETON, NJ, September 19, 2020) – Bristol Myers Squibb Company (NYSE: BMY) and Exelixis, Inc. (NASDAQ: EXEL) today announced the first presentation of results from the pivotal Phase 3 CheckMate -9ER trial, in which Opdivo® (nivolumab) in combination with CABOMETYX® (cabozantinib) demonstrated significant improvements across all efficacy endpoints, including overall survival (OS), in previously untreated advanced renal cell carcinoma (RCC). Opdivo in combination with CABOMETYX reduced the risk of death by 40% vs. sunitinib (Hazard Ratio [HR] 0.60; 98.89% Confidence Interval [CI]: 0.40 to 0.89; p=0.0010; median OS not reached in either arm). In patients receiving Opdivo in combination with CABOMETYX, median progression-free survival (PFS), the trial's primary endpoint, was doubled compared to those receiving sunitinib alone: 16.6 months vs. 8.3 months, respectively (HR 0.51; 95% CI: 0.41 to 0.64; p<0.0001).

About CheckMate -9ER

CheckMate -9ER is an open-label, randomized, multi-national Phase 3 trial evaluating patients with previously untreated advanced or metastatic renal cell carcinoma (RCC). A total of 651 patients (23% favorable risk, 58% intermediate risk, 20% poor risk; 25% PD-L1≥1%) were randomized to *Opdivo* plus *CABOMETYX* (n=323) vs. sunitinib (n=328). The primary endpoint is progression-free survival (PFS). Secondary endpoints include overall survival (OS) and objective response rate (ORR). The primary efficacy analysis is comparing the doublet combination vs. sunitinib in all randomized patients. The trial is sponsored by Bristol Myers Squibb and Ono Pharmaceutical Co and co-funded by Exelixis, Ipsen and Takeda Pharmaceutical Company Limited.

Contact:
Ono Pharmaceutical Co., Ltd.
Corporate Communications
public_relations@ono.co.jp