Bristol Myers Squibb Research at ASCO Demonstrates Diverse Approaches in Treating Cancer to Improve Outcomes for Patients

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Cell Therapy  CheckMate  chemotherapy  colorectal  doctor  hematology  I-O  Immuno-Oncology
Immunotherapy  ipilimumab  KarMMa  kidney  Leukemia  lung  lymphoma  melanoma  Multiple Myeloma
nivolumab  nurse  Oncology  Opdivo  pancreatic  patients  PD-1  RCC  Research  Squibb  treatment  tumor
Yervoy

Dateline City:
PRINCETON, N.J.

Overall survival results from CheckMate-9LA and CheckMate-227 (three-year follow-up) in first-line lung cancer

New data from CAR T and CELMoD trials, including KarMMa (ide-cel), demonstrate sustained leadership in multiple myeloma

New efficacy and safety analyses of pivotal data for oral hypomethylator CC-486 in acute myeloid leukemia

Wide range of research platforms across immunotherapy, cell therapy and protein degradation underscore commitment to advancing cancer research and treatments

PRINCETON, N.J.--(BUSINESS WIRE)--Bristol Myers Squibb (NYSE: BMY) today announced the presentation of data across its portfolio, aimed at addressing solid tumor and hematologic malignancies in 28 types of cancer, at the upcoming American Society of Clinical Oncology 2020 (ASCO20) Virtual Scientific Program, which will take place from May 29 to May 31, 2020.

Presentations will feature clinical and non-clinical studies highlighting the potential role of immunotherapy, including combination approaches, to deliver durable treatment outcomes in multiple hard-to-treat solid tumors. In hematology, presentations will demonstrate the company’s innovative research in multiple myeloma, through both BCMA-targeted CAR T and proof-of-concept CELMoD data, suggesting targeted protein degradation as a potential new treatment approach. In addition, precision treatment approaches will explore how new biomarker insights may aid in the selection of optimal therapies for patients based on disease biology.

Accepted abstracts will be available on the ASCO conference website on Wednesday, May 13 at 5 p.m. EDT and the embargo will lift for all data included in these presentations at that time. Overall, data from more than 50 company-sponsored studies and collaborations will be featured at the meeting:

Solid Tumor

- First presentation of results from CheckMate-9LA evaluating Opdivo (nivolumab) plus Yervoy (ipilimumab) with limited chemotherapy, and three-year follow-up data from CheckMate-227 evaluating Opdivo plus Yervoy combination in first-line metastatic non-small cell lung cancer
- Treatment-free survival data from analyses of Opdivo plus Yervoy in advanced melanoma and new data in patients with immunotherapy-resistant renal cell carcinoma (RCC)
- Analyses of multiple biomarkers associated with Opdivo plus Yervoy or Opdivo in patients with RCC

Cell Therapy

- Pivotal trial results from KarMMa study of idecabtagene vicleucel (ide-cel; bb2121), a potential first-in-class BCMA CAR
T in multiple myeloma being developed with bluebird bio

- Updated data from EVOLVE Phase 1 study of orva-cel (orvacabtagene autoleucel), a fully human BCMA CAR T being developed by Juno Therapeutics, a Bristol-Myers Squibb Company, in heavily pre-treated multiple myeloma patients

**Hematology**

- First clinical disclosure for CC-92480, a novel CELMoD agent evaluated in combination with dexamethasone in patients with relapsed and refractory multiple myeloma
- Multiple analyses from the QUAZAR-001 pivotal Phase 3 study evaluating CC-486 maintenance therapy in acute myeloid leukemia

“This year’s ASCO meeting underscores the science-driven approach of our development program in solid tumor and hematologic malignancies, our dedication to precision medicine, as well as our commitment to helping to deliver durable improvement in patient outcomes through potentially transformative therapies,” said Samit Hirawat, M.D., executive vice president, chief medical officer, global drug development, Bristol Myers Squibb. “With the impact of COVID-19, we are committed to supporting patients with cancer and overcoming challenges that patients, physicians and the research community may face during this time. We look forward to coming together virtually to share important data that continues to advance innovation for patients.”

**Summary of Presentations:**

**Selected Bristol Myers Squibb studies at the 2020 ASCO Virtual Annual Meeting include:**

**Gastrointestinal Malignancies**

- Nivolumab (NIVO) + low-dose ipilimumab (IPI) as first-line (1L) therapy in microsatellite instability-high/mismatch repair-deficient (MSI-H/dMMR) metastatic colorectal cancer (mCRC): Two-year clinical update
  Author: Heinz-Josef Lenz
  Abstract: #4040
  Poster Session: Gastrointestinal Cancer—Colorectal and Anal (Poster: #32)

- Phase 3 APACT trial of adjuvant nab-paclitaxel plus gemcitabine (nab-P + gem) vs. gem alone for patients with resected pancreatic cancer (PC): outcomes by geographic
  Author: Reni
  Abstract: #4515
  Poster Session: Gastrointestinal Cancer—Gastroesophageal, Pancreatic, and Hepatobiliary (Poster: #123)

**Genitourinary Malignancies**

- Biomarker analyses from the Phase 3 CheckMate -214 trial of Opdivo plus Yervoy or sunitinib in aRCC
  Author: Motzer
  Abstract: #5009
  Clinical Science Symposium: Updates on Immunotherapy Biomarkers Development in Kidney and Bladder Cancers

- Evaluation of predictive biomarkers for Opdivo in patients with mccRCC from the CheckMate -025 (CM -025) trial
  Author: Ficial
  Abstract: #5023
  Poster Session: Genitourinary Cancer—Kidney and Bladder (Poster: #92)

- FRACTION-RCC: Innovative, high-throughput assessment of Opdivo plus Yervoy for treatment refractory aRCC
  Author: Choueiri
  Abstract: #5007
  Oral Session: Genitourinary Cancer—Kidney and Bladder

- Immunogenomic characterization of advanced clear cell RCC treated with PD-1 blockade
  Author: Braun
  Abstract: #5010
  Clinical Science Symposium: Updates on Immunotherapy Biomarkers Development in Kidney and Bladder Cancers

**Leukemia**

- CC-486 is safe and well-tolerated as maintenance therapy in elderly patients (≥75 years) with acute myeloid leukemia (AML) in first remission following induction chemotherapy: Results from the phase III QUAZAR AML-001 trial
  Author: Ravandi
  Abstract: #7530
  Poster Session: Hematologic Malignancies—Leukemia, Myelodysplastic Syndromes, and Allotransplant (Poster: #303)

- Enasidenib plus azacitidine significantly improves complete remission and OR vs azacitidine alone in patients with newly diagnosed AML with isocitrate dehydrogenase 2 (IDH2) mutations: Results of a randomized Phase 2 study
  Author: Dinardo
  Abstract: #7501
  Oral Session: Hematologic Malignancies—Leukemia, Myelodysplastic Syndromes, and Allotransplant

- Escalated dosing schedules of CC-486 for patients experiencing first acute myeloid leukemia (AML) relapse: Results from the phase III QUAZAR AML-001 maintenance trial
  Author: Doehner
  Abstract: #7513
  Poster Session: Hematologic Malignancies—Leukemia, Myelodysplastic Syndromes, and Allotransplant (Poster: #286)
• Health-related quality of life (HRQoL) in the Phase III QUAZAR-AML-001 trial of CC-486 maintenance therapy for patients with acute myeloid leukemia (AML) in first remission following induction chemotherapy (IC)
  Author: Roboz
  Abstract: #7533
  Poster Session: Hematologic Malignancies—Leukemia, Myelodysplastic Syndromes, and Allotransplant (Poster: #306)

• Longer-term RBC transfusion reduction in the Phase 3 MEDALIST study of luspatercept in patients with lower-risk MDS with ring sideroblasts (RS)
  Author: Komrokji
  Abstract: #7518
  Poster Session: Hematologic Malignancies—Leukemia, Myelodysplastic Syndromes, and Allotransplant (Poster: #291)

Lymphoma

• Burden of cytokine release syndrome (CRS) and neurologic events (NE) in patients (Pts) with relapsed/refractory non-Hodgkin lymphoma (NHL) receiving lisoctagatene maraleucel (Liso-cell; jCAR017) in TRANSCEND NHL 001
  Author: Abramson
  Abstract: #6637
  Poster Session: Health Services Research, Clinical Informatics, and Quality of Care (Poster: #328)

• Lisocabtagene maraleucel (liso-cell) for treatment of second-line (2L) transplant noneligible (TNE) relapsed/refractory (R/R) aggressive large B-cell non-Hodgkin lymphoma (NHL): updated results from the PILOT study
  Author: Sehgal
  Abstract: #8040
  Poster Session: Hematologic Malignancies—Lymphoma and Chronic Lymphocytic Leukemia (Poster: #373)

• Opdivo plus brentuximab vedotin for R/R classical Hodgkin lymphoma (cHL) in children, adolescents, and young adults (CAYA)
  Author: Cole
  Abstract: #8013
  Poster Session: Hematologic Malignancies—Lymphoma and Chronic Lymphocytic Leukemia (Poster: #346)

• Outpatient treatment with lisocabtagene maraleucel (liso-cell) across a variety of clinical sites from 3 ongoing clinical studies in relapsed/refractory (R/R) large B-cell lymphoma (LBCL)
  Author: Bachier
  Abstract: #8037
  Poster Session: Hematologic Malignancies—Lymphoma and Chronic Lymphocytic Leukemia (Poster: #370)

Melanoma

• Estimating treatment-free survival (TFS) over extended follow-up in patients (pts) with advanced melanoma (MEL) treated with immune-checkpoint inhibitors (ICIs): Five-year follow-up of CheckMate 067
  Author: Regan
  Abstract: #10043
  Poster Session: Melanoma/Skin Cancers (Poster: #392)

• Integrative tumor and immune cell multi-omic analyses predict melanoma response to immune checkpoint blockade
  Author: Anagnostou
  Abstract: #10009
  Clinical Science Symposium: Systems Biology Approaches to Immunotherapy Response and Toxicity

Multiple Myeloma

• First-in-human phase I study of the novel CELMoD agent CC-92480 combined with dexamethasone (DEX) in patients (pts) with relapsed/refractory multiple myeloma (RRMM)
  Author: Richardson
  Abstract: #8500
  Oral Session: Hematologic Malignancies—Plasma Cell Dyscrasia

• Idecabtagene vicleucel (ide-cel; bb2121), a BCMA-targeted CAR T-cell therapy, in patients with relapsed and refractory multiple myeloma (RRMM): Initial KarMMa results
  Author: Munshi
  Abstract: #8503
  Oral Session: Hematologic Malignancies—Plasma Cell Dyscrasia

• Orvacaktagene autoleucel (orva-cel), a B-cell maturation antigen (BCMA)-directed CAR T cell therapy for patients (pts) with relapsed/refractory multiple myeloma (RRMM): update of the phase 1/2 EVOLVE study (NCT03430011)
  Author: Mailankody
  Abstract: #8504
  Oral Session: Hematologic Malignancies—Plasma Cell Dyscrasia

• KarMMa-RW: a study of real world treatment patterns in heavily pretreated patients with relapsed and refractory multiple myeloma (RRMM) and comparison of outcomes to KarMMa
  Author: Jagannath
  Abstract: #8525
  Poster Session: Hematologic Malignancies—Plasma Cell Dyscrasia (Poster: #425)

Non-Small Cell Lung Cancer
Bristol Myers Squibb: Advancing Cancer Research

At Bristol Myers Squibb, patients are at the center of everything we do. The goal of our cancer research is to increase patients’ quality of life, long-term survival and make cure a possibility. We harness our deep scientific experience, cutting-edge technologies and discovery platforms to discover, develop and deliver novel treatments for patients.

Building upon our transformative work and legacy in hematology and Immuno-Oncology that has changed survival expectations for many cancers, our researchers are advancing a deep and diverse pipeline across multiple modalities. In the field of immune cell therapy, this includes registrational chimeric antigen receptor (CAR) T-cell agents for numerous diseases, and a growing early-stage pipeline that expands cell and gene therapy targets, and technologies. We are developing cancer treatments directed at key biological pathways using our protein homeostasis platform, a research capability that has been the basis of our approved therapies for multiple myeloma and several promising compounds in early to mid-stage development. Our scientists are targeting different immune system pathways to address interactions between tumors, the microenvironment and the immune system to further expand upon the progress we have made and help more patients respond to treatment. Combining these approaches is key to delivering new options for the treatment of cancer and addressing the growing issue of resistance to immunotherapy. We source innovation internally, and in collaboration with academia, government, advocacy groups and biotechnology companies, to help make the promise of transformational medicines a reality for patients.

About Bristol Myers Squibb

Bristol Myers Squibb is a global biopharmaceutical company whose mission is to discover, develop and deliver innovative medicines that help patients prevail over serious diseases. For more information about Bristol Myers Squibb, visit us at BMS.com or follow us on LinkedIn, Twitter, YouTube, Facebook and Instagram.

Celgene and Juno Therapeutics are wholly owned subsidiaries of Bristol-Myers Squibb Company. In certain countries outside the U.S., due to local laws, Celgene and Juno Therapeutics are referred to as, Celgene, a Bristol-Myers Squibb Company and Juno Therapeutics, a Bristol-Myers Squibb Company.

Cautionary Statement Regarding Forward-Looking Statements

This press release contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995 regarding, among other things, the research, development and commercialization of pharmaceutical products. All statements that are not statements of historical facts are, or may be deemed to be, forward-looking statements. Such forward-looking statements are based on historical performance and current expectations and projections about our future financial results, goals, plans and objectives and involve inherent risks, assumptions and uncertainties, including internal or external factors that could delay, divert or change any of them in the next several years, that are difficult to predict, may be beyond our control and could cause our future financial results, goals, plans and objectives to differ materially from those expressed in, or implied by, the statements. No forward-looking statement can be guaranteed. Forward-looking statements in this press release should be evaluated together with the many risks and uncertainties that affect Bristol Myers Squibb’s business and market, particularly those identified in the cautionary statement and risk factors discussion in Bristol Myers Squibb’s Annual Report on Form 10-K for the year ended December 31, 2019, as updated by our subsequent Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and other filings with the Securities and Exchange Commission. The forward-looking statements included in this document are made only as of the date of this document and except as otherwise required by applicable law, Bristol Myers Squibb undertakes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events, changed circumstances or otherwise.

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$BMY presents data from 50+ company-sponsored studies and presentations spanning solid tumors, cell therapy and hematology at #ASCO20