

TRIAL RESULTS – 17th November 2021

Neoadjuvant Opdivo + Chemo Significantly Improves EFS in Patients with Resectable NSCLC in Ph 3 CheckMate -816 Trial

“While the intent of surgery is curative in resectable non-small cell lung cancer, between 30% to 55% of patients experience recurrence after surgery and ultimately succumb to the disease, presenting a strong need for additional options that can disrupt this cycle,” said Nicolas Girard, M.D., Ph.D., professor of respiratory medicine at Paris Saclay University and head of the Thorax Institute Curie Montsouris in Paris. “The positive event-free survival data seen with neoadjuvant nivolumab plus chemotherapy is groundbreaking and can have important implications for how we treat resectable non-small cell lung cancer.”

Ph 2b Study of Sacituzumab Govitecan Conducted in China of Patients With mTNBC Meets Primary ORR Endpoint

“These topline results confirm that sacituzumab govitecan has the potential to help change the treatment outlook for people in China living with mTNBC,” said Yang Shi, Chief Medical Officer for Oncology at Everest Medicines. “These data, along with the benefit seen in the global ASCENT study, support its potential as a novel treatment for patients who currently have extremely limited options.”

SITC 2021: Positive preliminary results announced from Ph 2b study of BO-112 + anti-PD1 in confirmed anti-PD1 progressor melanoma

“These are potentially game-changing results showing that BO-112 can rescue melanoma patients who have failed first-line immune-therapy with anti-PD1,” said Dr Carlos Paya, Executive Chairman of Highlight Therapeutics. “Anti-PD1 based immunotherapy has revolutionized oncology treatments, but only a fraction of patients initially respond and many of these patients progress thereafter. These initial Phase 2 results show that BO-112 combined with a leading PD1 inhibitor rescue around 65% of anti-PD1 failing patients, making many of them respond to the combined treatment. These much-anticipated outcomes demonstrate BO-112’s potential as a best-in-class therapy for melanoma patients whose disease has progressed on prior anti-PD1 treatment, and we now look forward to further clinical studies, not only in melanoma but in other major tumor types in which anti-PD1 resistance is also an issue.”

SITC 2021: Clinical and Research Updates on NC318 and NC410 Candidates Provided

“We are pleased to share promising data from our NC318 and NC410 programs at this year’s SITC annual meeting,” said Han Myint, MD, NextCure’s chief medical officer. “Results from our ongoing Phase 1 and Phase 2 trials suggest that NC318 may have a clinical benefit in patients. Retrospective analysis of patient biopsies from the Phase 1 and Phase 2 trials showed better outcomes in S15+ patients compared to S15- patients receiving NC318. Selecting for patients with S15+ expression coupled with a higher and more frequent dosing regimen that increases overall drug exposure is anticipated to impact clinical outcomes. Additionally, data from our NC410 program show that NC410 is safe and well-tolerated in patients and demonstrates early

indications of immune modulation. We look forward to continuing the advancement of both programs to improve the treatment landscape for cancer patients.”

SITC2021: INT230-6 +/- Ipilimumab Shows Evidence of Direct Tumor Necrosis and Promising OS Results in Adult Subjects with Metastatic Sarcomas

“Patients with metastatic and refractory cancers continue to have poor survival. Response rates remain low in most tumor types even with the use of immunotherapies such as checkpoint inhibitors,” said Jacob S. Thomas, M.D., Assistant Professor of Clinical Medicine, Keck School of Medicine at the University of Southern California (USC) and oncologist at USC’s Norris Comprehensive Cancer Center, part of Keck Medicine of USC. “INT230-6 demonstrates direct tumor killing in injected lesions. In addition, analysis shows increases of immune cells in tumors and the shrinkage of uninjected tumors or abscopal results. These data suggest dosing INT230-6 may activate a T-cell mediated immune response. Results presented at SITC indicate that use of intratumoral INT230-6 appears to be a viable approach in treating metastatic disease alone or in combination with immunotherapies.”

SITC 2021: Positive Preliminary Data from Ph 1b Trial Evaluating Batiraxcept (AVB-500) + Cabozantinib for Treatment of ccRCC Announced

“We are encouraged by batiraxcept’s early profile in patients with clear cell renal cell carcinoma,” said Gail McIntyre, Ph.D., DABT, Chief Executive Officer of Aravive. “The current response rate of batiraxcept in combination with cabozantinib is encouraging. Cabozantinib alone produces response rates between 17-28% in a similar population. In heavily pretreated patients, batiraxcept demonstrates clinical activity across the 15 mg/kg and 20 mg/kg doses with a tolerable safety profile. These results reinforce our confidence in the potential of batiraxcept to improve outcomes across multiple types of cancer by targeting the GAS6/AXL signaling pathway. We look forward to initiating the Phase 2 trial in the fourth quarter of 2021 and building on these promising data.”

SITC 2021: Clinical Data for Lifileucel in Combination with Pembrolizumab in Advanced Cancers Announced

David M. O'Malley, M.D., Professor, Department of Obstetrics and Gynecology, The Ohio State University College of Medicine, Director of the Division of Gynecologic Oncology, The Ohio State University Comprehensive Cancer Center (OSUCCC – James) and investigator in the C-145-04 study, stated, “Immune checkpoint inhibitors are standard-of-care in the treatment of several types of advanced cancer, including cervical cancer, melanoma, and head and neck cancer. Unmet needs remain to help more patients respond and to enhance the depth and durability of responses. I was impressed by the increase in overall response rate for lifileucel in combination with pembrolizumab in cervical cancer patients, which was consistent with higher response rates in head and neck cancer and melanoma patients. Taken together the clinical data show great promise for TIL in combination with pembrolizumab across multiple solid tumors.”

SITC 2021: Clinical Activity of AGEN1181 Demonstrated Across Nine Treatment-Resistant Cancers

"AGEN1181 as monotherapy and in combination with balstilimab has shown durable responses in heavily pre-treated, poorly immunogenic 'cold' cancers, as well as those who have failed to respond to prior PD-1 inhibition," said Steven O'Day, MD, Chief Medical Officer of Agenus. "This regimen is well tolerated, with no hypophysitis, pneumonitis, or high-grade hepatitis observed to date. The clinical performance of AGEN1181 is consistent with its Fc-enhanced design, safely expanding the benefit of immunotherapy to a broader patient population."

SITC 2021: Immune Analysis from Ph 2 TNBC Trial Demonstrates Trilaciclib Enhanced Patients' T Cell Immune Function When Administered Prior to Chemotherapy

"The Phase 2 immunologic data analysis suggests that administering trilaciclib prior to chemotherapy may enhance antitumor efficacy by modulating the composition and response of immune cell subsets," said John Yi, PhD, Director of Translational Medicine at G1 Therapeutics.

SITC 2021: Preliminary Results from Ph 1/2 Dose Escalation Study of COM701 with Opdivo® and BMS-986207 Presented

"The preliminary data reported from this Phase 1/2 triple combination dose escalation study demonstrate that triple blockade of PVRIG, TIGIT and PD-1 is well tolerated, with a favorable safety and toxicity profile and a maximum tolerated dose was not reached." said principal investigator and presenting author Ecaterina Elena Dumbrava, M.D., Assistant Professor of Investigational Cancer Therapeutics, at the University of Texas MD Anderson Cancer Center. "The totality of the data is encouraging and I look forward to enrolling patients to the expansion cohorts in select tumor types to potentially address the unmet need of patients who do not respond to existing immune checkpoint inhibitors."

SITC 2021: Preliminary Results from Ph 1 Dose Escalation Monotherapy Study of COM902 Presented

"The primary objective of this Phase 1 dose escalation study of COM902 monotherapy was to evaluate safety and tolerability and we were pleased to see that COM902 was well tolerated with a favorable safety profile. A maximum tolerated dose of COM902 was not reached." said principal investigator and presenting author, Ecaterina Elena Dumbrava, M.D., Assistant Professor of Investigational Cancer Therapeutics at the University of Texas MD Anderson Cancer Center. "It is encouraging to achieve a disease control rate of 50% in these heavily pretreated patients who typically do not respond to PD- (L)1 inhibitors. I look forward to enrolling patients in the combination study with COM701 to continue exploring new therapeutic options for patients in need."

SITC 2021: Clinical Responses across Multiple Solid Tumor Types in Ongoing ACTengine® IMA203 Ph 1a Trial Targeting PRAME Reported

"We observed multiple clinical responses early-on during dose escalation and saw anti-tumor activity at much lower doses than would have been expected in the field of TCR-T. IMA203 T cells will now be tested at the target dose level and have the potential to provide meaningful

benefits to patients with advanced stages of cancer,” commented Martin Wermke, MD, Coordinating Investigator of Immatics’ ACTengine® trials in Germany and Head of the Early Clinical Trial Unit of the National Center for Tumor Diseases at the University Hospital Carl Gustav Carus in Dresden, Germany. “I am looking forward to presenting this exciting data set to the scientific and medical community at SITC and to supporting the further development of IMA203.”

SITC 2021: Updated Data announced from ASPEN-01 trial of Evorpaccept Showing Emerging Clinical Benefit in Survival-Based Endpoints in Patients with Advanced Solid Tumors

“These updated data provide growing support that evorpaccept in combination with the standard regimens studied may translate into a meaningful survival benefit in patients with advanced HNSCC and GC who historically have poor outcomes,” said Keun-Wook Lee, M.D., Ph.D., Professor of Seoul National University College of Medicine and Director of Clinical Trials Center, Seoul National University Bundang Hospital, Seoul, Korea.

SITC 2021: Improved and Statistically Significant Survival Benefit Reported for Three Key Patient Groups in Final Ph IIb AIPAC Study Results in Metastatic Breast Cancer

Immutep CEO, Marc Voigt commented: “These very pleasing final results give us additional confidence that efti can ultimately deliver a meaningful clinical improvement for diverse sets of cancer patients. The results from our AIPAC trial are especially pleasing because metastatic breast cancer patients in the chemotherapy setting are a difficult to treat and large patient population where immunotherapies often fail to provide an additional benefit. These supportive results are also timely as we solidify the trial design for our planned Phase III study in metastatic breast cancer, subject to regulatory body interactions.”

SITC 2021: Promising Updated Patient Response Data reported from the Ph I/IIa EVICTION Trial with ICT01

“These latest data from the EVICTION trial support our confidence that ICT01 has significant potential to provide meaningful therapeutic effects, particularly in patients with advanced, metastatic solid tumors that did not respond to prior checkpoint inhibitor therapy,” commented Paul Frohna, MD, PhD, Chief Medical Officer at ImCheck Therapeutics. “Although the brain metastasis response needs replication in more patients, this provides a highly valuable, clinical development opportunity in a group of patients with high unmet medical need that we intend to explore further.”