REGULATORY NEWS – 30th MARCH 2022

Complete Response Letter for Sintilimab + Pemetrexed and Platinum Chemotherapy for the First-Line Treatment of People with Nonsquamous NSCLC

- FDA issued a complete response letter (CRL) for the Biologics License Application (BLA) for the investigational medicine sintilimab injection in combination with pemetrexed and platinum chemotherapy for the first-line treatment of people with nonsquamous NSCLC.
- The letter indicates that the review cycle is complete but the FDA is unable to approve the application in its current form, consistent with the outcome of the Oncologic Drugs Advisory Committee Meeting in February.
- The CRL includes a recommendation for an additional clinical study, specifically a multiregional clinical trial comparing standard of care therapy for first line metastatic NSCLC to sintilimab with chemotherapy utilizing a non-inferiority design with an overall survival endpoint.
- Along with Innovent, Lilly is assessing next steps for the sintilimab program in the U.S.

Pivotal Ph 3 Trial Design for Gedatolisib in the Treatment of Advanced Breast Cancer announced

"We are excited to finalize the trial design for our pivotal Phase 3 study following productive meetings with the FDA," said Brian Sullivan, CEO and co-founder of Celcuity. "This design, we believe, provides us with an opportunity to generate data that could support the future submission to the FDA of a New Drug Application for gedatolisib to treat a broad patient population."

Positive CHMP opinion for Kymriah® CAR-T cell therapy for adult patients with relapsed or refractory follicular lymphoma in Europe

“Follicular lymphoma patients will often relapse, many having shorter responses to treatment with each subsequent line of therapy,” said Catherine Thieblemont, MD, PhD, Professor of Hematology in the Paris VII- University, France and Head of the Hemato-Oncology Unit of St-Louis Hospital in Paris. “If approved, Kymriah may offer an effective new option with potentially definitive results for these patients with a highly favorable safety profile.”

Regulatory Update Provided on Zandelisib Following Meeting with the FDA

“The FDA’s current position on the assessment of benefit and risk of PI3K inhibitors solely based on single arm studies appears to have evolved, as evidenced by the position the FDA communicated at the recent meeting on zandelisib, and the upcoming ODAC meeting scheduled for April 21, 2022 to discuss whether randomized data should be required for the

class of PI3K inhibitors to demonstrate appropriate evidence of efficacy and safety," said Daniel P. Gold, Ph.D., president and chief executive officer of MEI Pharma. "Clearly, the outcome of our recent FDA meeting is a disappointing development. Nonetheless we will continue to focus on the ongoing Phase 3 COASTAL study as we consider options that provide the most expeditious approval pathway utilizing randomized data, and which we believe will demonstrate the potential of zandelisib to help patients. Today's announcement in no way diminishes our conviction to the development of zandelisib and the promise of its emerging clinical profile. Based on current projections, MEI believes we have sufficient cash for operations to complete the COASTAL study enrollment in 2024."

Positive CHMP Opinion Recommending CARVYKTI® (Ciltacabtagene Autoleucel) for the Treatment of Patients with Relapsed and Refractory Multiple Myeloma

"Although significant advances have been made in the treatment of multiple myeloma, it remains a heterogenous disease that is challenging to treat," said Edmond Chan MBChB M.D. (Res), EMEA Therapeutic Area Lead Haematology, Janssen-Cilag Limited. "Therapeutic innovations with novel mechanisms of action are urgently needed. Our focus is on bringing transformative treatments to the medical community, like cilta-cel, for patients with multiple myeloma in need of new options."

CHMP recommends EU approval of Polivy combination for people with previously untreated diffuse large B-cell lymphoma

"A significant proportion of people newly diagnosed with diffuse large B-cell lymphoma, an aggressive form of blood cancer, do not respond adequately to existing therapies," said Levi Garraway, M.D., Ph.D., Roche's Chief Medical Officer and Head of Global Product Development. "Therefore, more treatment options are needed that could increase a person's chance of cure, and we look forward to bringing this new Polivy combination to people with DLBCL as soon as possible."

Positive EU CHMP Opinion for KEYTRUDA® for Patients With MSI-H or dMMR Tumors in Five Different Types of Cancer

"We are committed to advancing the use of biomarkers to identify patients most likely to respond to KEYTRUDA," said Dr. Scot Ebbinghaus, vice president, global clinical development, Merck Research Laboratories. "This positive CHMP opinion reinforces the predictive value of MSI-H/dMMR across many different cancer types and the importance of biomarker testing. KEYTRUDA has already become an important first-line treatment option for certain patients in Europe with MSI-H or dMMR colorectal cancer, and we are pleased the CHMP has recommended KEYTRUDA as a monotherapy for additional patients with MSI-H or dMMR tumors."

Positive EU CHMP Opinion for KEYTRUDA® Plus Chemotherapy, With or Without Bevacizumab, as Treatment for Patients With Persistent, Recurrent or Metastatic Cervical Cancer Whose Tumors Express PD-L1 (CPS ≥1)

“The CHMP’s positive recommendation brings us closer to providing patients with an immunotherapy regimen that has the potential to extend the lives of certain people living with persistent, recurrent or metastatic cervical cancer compared to current standard of care treatment,” said Dr. Gursel Aktan, vice president, global clinical development, Merck Research Laboratories. “We look forward to the European Commission’s decision, which could mark the first time an anti-PD-1/L1 regimen is approved in the EU for these patients.”