REGULATORY NEWS – 17th November 2021

LUMYKRAS® (sotorasib) Receives Positive Opinion From EMA CHMP For Patients With KRAS G12C-Mutated Advanced NSCLC

"After 40 years of cancer research to target the KRAS mutation, many in the scientific community believed that KRAS was 'undruggable' leaving patients with this mutation with limited treatment options," said David M. Reese, M.D., executive vice president of Research and Development at Amgen. "The LUMYKRAS development program was designed to bring this targeted therapy to patients with KRAS G12C-mutated non-small cell lung cancer as quickly as possible. The EMA CHMP positive opinion brings patients in the EU closer to this transformative therapy and highlights our commitment to improving patient outcomes in difficult-to-treat cancers."

Update Provided on Pre-BLA Meeting With FDA for Omidubicel

“Despite the delay in timing to bring omidubicel to patients after a potential FDA approval, we are encouraged by the FDA’s reaction to our Phase 3 data as the pivotal trial of omidubicel. We have gained further clarity with the FDA on the requirements for demonstrating comparability for our commercial manufacturing facility,” said Julian Adams, Ph.D., Chief Executive Officer of Gamida Cell. “With the FDA’s feedback in hand, we believe that we are one step closer for omidubicel to be made available to patients in need.”

Clinical Update Provided on Upcoming Ph 3 Clinical Trial, FLAMINGO-01

CEO Snehal Patel commented, “Our objective is to make GLSI-100 available to as many patients as possible as soon as possible. This will include opening FLAMINGO-01 in many clinical sites that are geographically situated to maximize access for patients. We continue to hear from patients interested in participating in our GLSI-100 trial and expect to be able to refer them to participating sites as appropriate. We recommend that patients or their physicians contact a participating clinical trial site near them once these sites have been opened and we communicate the participating sites to the public. We have been pleasantly surprised by the level of interest in our trial by major teaching hospitals led by breast cancer KOLs. While these sites may lead to strong enrollment, they may also lead to additional collaboration designed to optimize treatment with GLSI-100 in subsequent trials. We will be meeting with these KOLs at the upcoming in-person San Antonio Breast Cancer Symposium in December 2021 and look forward to opening the first sites and the trial soon thereafter.”

Breakthrough Therapy Designation Application Submitted to FDA for Leronlimab as a Treatment for mTNBC

Nader Pourhassan, Ph.D., CytoDyn’s President and Chief Executive Officer, commented, “In our view, these findings provide strong support for our decision to submit an application for Breakthrough Therapy designation for leronlimab as a treatment for mTNBC. Patients with this horrific disease currently have few, if any, treatment options, and we hope that leronlimab can provide a therapeutic choice for substantially improved clinically relevant endpoints, quality of life, tolerability and safety over currently available SOC. We hope to receive a response from the

FDA before the end of the year. We are grateful to have already received Fast Track designation for leronlimab for this indication (mTNBC) and congratulate Dr. Nitya Ray and his team for preparing the data analysis needed to file this BTD application so quickly."