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FINAL RESULTS OF BIOAVAILABILITY STUDY OF PHEBRA'S ORAL ARSENIC CAPSULE FOR ACUTE PROMYELOCYTIC LEUKAEMIA (APL) CONFIRM BIOEQUIVALENCE OF ORAL AND IV FORMULATIONS

Australian pharmaceutical group Phebra ('**Company**') congratulates the Australasian Leukaemia and Lymphoma Group (ALLG) on the release of their abstract EP433 at the virtual European Hematology Association (EHA) 2021 Conference.

The abstract builds on the initial bioequivalence data from the first phase of the trial, published at EHA in June 2019 and reveals the final results from the ALLG APML5 bioavailability study undertaken by the ALLG at hospitals across Australia in 31 patients with previously untreated APL.

The aim of the APML5 study, was to characterise the bioavailability of Phebra's oral arsenic trioxide (ATO) capsules and intravenous ATO in patients undergoing standard-of-care consolidation therapy by comparing the total arsenic $AUC_{0\text{-}24}$ and C_{max} in whole blood and plasma. Estimates of the geometric mean or oral /IV ratios for all pK parameters closely approximate unity confirming bioequivalence of the oral and IV formulations.

Phebra's extensive knowledge of arsenic formulations and long-standing relationships with Australian healthcare providers led to a collaboration with the ALLG. Phebra provided funding and supplied the oral ATO capsules and IV ATO injection for the ALLG trial.

With its decade-long ongoing manufacture and supply of Phenasen® (arsenic trioxide) Injection, from its multi-purpose sterile injectables facility in Sydney, Australia, Phebra was the first pharmaceutical company to pursue and achieve registration of arsenic trioxide injection for the treatment of newly-diagnosed APL patients. APL is a rare subtype of Acute Myeloid Leukaemia (AML), which accounts for only 10% of all AML diagnoses. AML is rare disease diagnosed at a rate of 3.7 per 100,000 of population.[1.]

Phebra Chief Executive Officer (CEO) Andre Vlok, said: "We're excited that the study's final pK results confirm the bioequivalence of the oral and IV formulations. It demonstrates that Phebra's novel oral ATO formulation has the real potential to be a viable, new treatment option for blood cancer patients."

Phebra Executive Director of Research, Dr Mal Eutick, added: "This innovative oral arsenic capsule will provide a beneficial treatment option for patients with APL, importantly, reducing the time they need to spend at hospitals undergoing infusions. We congratulate the ALLG and the team of researchers for their collaboration with Phebra on this breakthrough treatment."

The Chief Executive Officer of the ALLG, Delaine Smith, said: "Clinical trials are essential to understand the biology of the disease and to improve the survival and care of patients. The ALLG member network of haematologists collaborate to conduct high quality trials and research projects that create Better Treatments and Better Lives. The oral capsule formulation of ATO can provide a more convenient treatment option and improve the lives of those with APL."

About Phebra:

Phebra is an Australian based specialty pharmaceutical group which develops, manufactures and markets critical medicines in Australia and across the world.

At Phebra, we create critical medicines that save and improve lives.

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About the ALLG:

The ALLG is a not-for-profit clinical trial organisation that sponsors local investigator initiated clinical trials. Membership of the ALLG is approximately 450 clinicians, made up of the Haematologists treating Leukaemia and Lymphoma across Australia and New Zealand. The ALLG plans, designs, conducts, monitors and publishes investigator initiated clinical trials.

www.allg.org.au

[1]Leukaemia Foundation https://www.leukaemia.org.au/disease-information/leukaemias/acute-promyelocytic-leukaemia/ Accessed May 2021