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Asieris Completes Enrolment for US APL-1202 Phase Ib Clinical Trial

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Study to evaluate the safety, tolerability, and PK characteristics of APL-1202 when dosed in combination with intravesical BCG

Asieris, a China-based biotech company specializing in the development and commercialization of new drugs for the treatment of genitourinary tumours and related diseases, on 24 June 2019, announced the completion of enrolment for its APL-1202 Phase Ib trial in the US. This new drug is being developed for the treatment of non-muscle invasive bladder cancer (NMIBC). APL-1202 is the first oral and reversible methionine aminopeptidase II type (MetAP2) inhibitor under clinical development in the world. It has novel mechanisms of action of inhibiting both tumour cell growth and angiogenesis. APL-1202 is currently in registration clinical trial in China.

The primary objective of this Phase Ib clinical trial in the US is to evaluate the safety, tolerability, and PK characteristics of APL-1202 when dosed in combination with intravesical BCG. Enrolled subjects are NMIBC patients who have received at least one induction course of intravesical BCG. This trial is expected to complete all patient follow-up in September.

Asieris is currently planning to launch a Phase II global clinical trial to evaluate the efficacy and safety of a combination of APL-1202 with BCG in NMIBC patients.

"We are very excited to have participated in the Phase I trial combining APL-1202 with BCG in patients with non-muscle invasive bladder cancer previously treated and who are resistant to BCG. This trial has the potential to significantly improve the care of patients with non-muscle invasive bladder cancer. This is a very exciting therapeutic option for our patients given its oral route of delivery," commented John P. Sfakianos, MD, Assistant Professor of Icahn School of Medicine at Mount Sinai and a leading investigator of this trial. "I am enthusiastic about the future studies involving this treatment".

"The completion of enrollment for our APL-1202 Phase Ib clinical trial in the US represents a remarkable milestone for APL-1202's global clinical development. In a Phase II trial in China, APL-1202 as a single agent demonstrated encouraging clinical efficacy and safety. Its combination with intravesical chemotherapy is in a pivotal clinical trial in China. Intravesical BCG is the first-line therapy for NMIBC globally, and through the clinical trials of APL-1202 in combination with

intravesical BCG, we hope to provide better treatment for NMIBC patients in the world," Kevin Pan, co-founder, chairman and CEO of Asieris said.

Bladder Cancer is one of the most common malignant tumours. According to Globalcan, the incidence of bladder cancer in 2018 was 549,343, while mortality was 199,922. The majority of patients are male, and most of them reside in developed countries. Currently, the common treatment of NMIBC is Trans-Urethral Resection of Bladder Tumour (TURBT). Because of the high tumour recurrence rate after TURBT, intravesical chemo- or immune-therapies are required after the procedure. At present, the choice of second-line treatment for relapsed patients is very limited. For high-risk NMIBC patients who have failed intravesical therapies, radical cystectomy is the standard treatment. No oral drugs have been approved for NMIBC to date.