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ASIA EDITION

Asieris announces approval for Ph 1 trial of bladder cancer drug in Australia

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APL-1202 is being developed as a new drug of Asieris for the treatment of non-muscle invasive bladder cancer (NMIBC)

Asieris Pharmaceuticals, a China-based biotech company specializing in the development and commercialization of new drugs for the treatment of genitourinary tumors and related diseases, has announced that Australian regulatory authorities have approved its Phase I clinical trial of APL-1501. The objective of this Phase I study is to evaluate the safety, tolerability, and pharmacokinetic (PK) characteristics of APL-1501.

APL-1501, which is independently developed by the Prodrug Accurate Drug Delivery (PADD) platform of Asieris, is an oral sustained-release product based on APL-1202 and will be the second generation product of APL-1202 to support new clinical development globally. APL-1501 inherits the unique oral administration of APL-1202 and the druggability of APL-1501 is improved by the design of prodrug molecules.

APL-1202 is being developed as a new drug of Asieris for the treatment of non-muscle invasive bladder cancer (NMIBC). It is the first oral and reversible methionine aminopeptidase II type (MetAP2) inhibitor currently under Phase III clinical development in the world. APL-1202 finished patient enrollment in a pivotal registration trial in China in 2019.

APL-1202 also completed the Phase I clinical trial in the US. Currently, the standard treatment of NMIBC is a Trans-Urethral Resection of Bladder Tumor (TURBT). Because of a high tumor recurrence rate after TURBT, intravesical chemo- or immune-therapies are required after the procedure. At present, choice of second-line treatment for relapsed patients is very limited. A radical cystectomy is the standard treatment for recurring high-risk NMIBC patients. No oral drugs have been approved for NMIBC to date.