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ASIA EDITION

Hexvix obtained CDE approval for the inclusion in the clinical real-world evidence pilot study

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Hexvix became the ninth drug to take part in the clinical real-world evidence pilot study

Asieris Pharmaceuticals, a global innovative biopharma company specializing in discovering and developing innovative drugs for the treatment of genitourinary tumors and other major diseases, announced that the Hainan Provincial Medical Products Administration, in accordance with advice from the National Medical Products Administration Center for Drug Evaluation (CDE), has approved the inclusion of Asieris' drug Hexvix, a drug for the diagnosis of bladder cancer, in the clinical real-world evidence pilot study. Hexvix became the ninth drug to take part in the clinical real-world evidence pilot study.

Studies showed that the combined use of Hexvix and BLC significantly increased the detection rate of papillary carcinoma by 24.9%, compared with white light cystoscopy. Specifically, it increased the detection rate of primary carcinoma by 20.7% and that of relapsed carcinoma by 27.7%. In addition, because the bladder carcinoma in situ (CIS) is flat and difficult to observe directly with white light cystoscopy, the use of Hexvix combined with BLC increased the detection rate of CIS by 26.7%, specifically by 28.0% in patients with primary carcinoma and by 25.0% in patients with relapsed carcinomaThe results also showed that patients treated with Hexvix and BLC had a 16% reduction in recurrence compared to those treated with white cystoscopy.[3]

Hexvix has been approved in the United States and many European countries. The combined use of Hexvix and blue light cystoscopy (BLC) for the management of non-muscle invasive bladder cancer (NMIBC) has been included in the global expert consensus guidelines and Chinese Urological Association Guideline.