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Rakuten to begin Ph 3 clinical trial for treatment of recurrent head and neck cancer in India

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Rakuten Medicalâ??s therapies based on Alluminox platform are investigational outside of Japan, and not approved in India for commercial use

US-headquartered Rakuten Medical, Inc. has been granted permission from the Central Drugs Standard Control Organisation (CDSCO) to conduct its global, pivotal Phase 3 clinical trial evaluating Alluminox treatment (photoimmunotherapy) using ASP-1929 in patients with locoregional, recurrent head and neck squamous cell carcinomas (HNSCC) in India, and the registration of clinical trial information with the Clinical Trial Registry of India (CTRI) has been completed.

The study sites will include several leading medical institutions in India such as the Tata Memorial Centre and Narayana Health, and the treatment will be administered to enrolled patients once ready. This ASP-1929-301 study is currently underway in several countries such as the US and Taiwan, and will enroll 275 patients globally including Indian patients.

In India, more than 200,000 new cases of head and neck cancer are diagnosed each year, which accounts for approximately 25% of all new head and neck cancer cases worldwide.

ASP-1929 is a conjugation of an antibody cetuximab and IRDye 700DX, a light activatable dye, and is Rakuten Medical's first pipeline drug developed on its Alluminox platform.

The US Food and Drug Administration (FDA) has granted Fast Track designation for the drug in January 2018. In Japan, in September 2020, ASP-1929 received marketing approval from the Ministry of Health, Labour and Welfare for unresectable locally advanced or recurrent head and neck cancer as brand name Akalux, together with BioBlade Laser System, the medical device used in combination with the drug under the Conditional Early Approval System. Outside of Japan, ASP-1929 and the laser device system have not yet been approved by any regulatory authority.