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Lumosa to Initiate Phase 2 Human Clinical Trial for LT3001 to treat Acute Ischemic Stroke

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Enrolment process to accelerate in the US and Taiwan for Safety, tolerability and pharmacokinetic exploration ofthe novel drug

Lumosa Therapeutics, on 13 June 2019, announced that the company is ready to commence the Phase 2 proof of concept (PoC) study for its LT3001, a novel drug for the treatment of acute ischemic stroke (AIS) that showed good safety, tolerability and pharmacokinetic profiles in its Phase 1 study, as the US FDA has no objections during the 30-day reviewing period on the company's Investigational New Drug (IND) application. Lumosa is also actively seeking global partners for co-development for this project.

LT3001 is a novel small molecule for the treatment of acute ischemic stroke. Animal studies have demonstrated LT3001's multiple functions in restoring cerebral blood flow and reducing ischemic/reperfusion injury. Lumosa has established the safety, tolerability and pharmacokinetic exploration of LT3001 through the completion of the Phase 1 trial involving 16 healthy volunteers.

Results of the single-dose escalation of LT3001 administered through intravenous injection to the healthy subjects showed that LT3001 was well tolerated without any adverse events. However, the mild headache was observed in one subject in the high-dose group but the symptom was relieved in a short time.

In terms of pharmacokinetic analysis, the blood concentration of LT3001 in low-dose subjects is higher than that of the effective dose calculated using animal models. Dose selection of LT3001's Phase 2 PoC study will be based on the above results.

After reviewing these promising data, Lumosa decided to submit the Phase 2 IND to the US FDA on 9 May 2019. The regulation states that after accepting the application, the agency has 30 days to review the documents. As the FDA made no requests for clarifications or indicated that the study is placed on clinical hold during the reviewing period, the application became effective automatically. Lumosa plans to conduct the Phase 2 study following the approved protocol.

To accelerate subject enrollment, Lumosa will recruit patients in Taiwan and the US. An IND application containing the protocols that were sent to the US FDA will be submitted soon to Taiwan FDA for approval.

Should the development proceed as planned, Lumosa will initiate the clinical trial in the US by Q3 or Q4 of 2019; for Taiwan, patient enrolment will start in 2020. Subject recruitment is expected to take two years to complete; however, the definite time of completion will depend on the actual outcome.

The current treatment for acute ischemic stroke (AIS) is a thrombolytic agent named rt-PA. Unfortunately, the benefit of rt-PA is limited due to its high risks involving haemorrhage and short treatment time window, and only 3%~5% AIS patients are treated with thrombolytics. Lumosa will actively seek co-development partners for LT3001 in the world to share development risks, and soon materialize LT3001's intellectual value.