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FOR IMMEDIATE RELEASE

SASPiPhi Ltd. Receives MHRA Clinical Trial Authorisation For The First-in-Human Clinical Trial Of SASPject PT3.9.

Cambridge, UK – 17th September 2026

SASPiPhi is delighted to announce that it has received **Clinical Trial Authorisation** from the UK Medicines and Healthcare products Regulatory Agency (**MHRA**) to initiate a Phase 1b/2a clinical trial of **SASPject PT3.9**. This authorisation is subject to clinical trial funding and insurance being in place, and final HRA Authorisation.

The clinical trial, **STEPS-CF**, is a First-in-Human trial assessing safety and early efficacy of the engineered phage therapeutic, SASPject PT3.9, in people living with cystic fibrosis with lung infections due to *Pseudomonas aeruginosa*. The study is registered on the UK's Clinical Study Registry with study registration number ISRCTN57413769.

The study, which is expected to enrol between 44 and 64 participants, will be led by Chief Investigator **Dr Freddy Frost (Liverpool Heart and Chest Hospital)**, and **NIHR Liverpool Clinical Research Facility**, and will involve up to 10 other sites around the UK.

Richard Nagle, Director and Chief Commercial Officer of SASPiPhi Ltd., said:

“This is an important milestone for SASPiPhi, representing the result of significant work by our team and collaborators. We are now preparing to take SASPject PT3.9 into the clinic for the first time, a critical step in evaluating its potential as a treatment for people living with cystic fibrosis.”

Dr Anne Barnard, Director and Chief Technology Officer of SASPiPhi Ltd., added:

“We are delighted to have received authorisation for the first-in-human trial of SASPject PT3.9. This allows us to continue the SASPject PT3.9 programme initiated by our late co-founder, Dr Heather Fairhead, and developed by our many colleagues and collaborators, past and present. The data generated by the STEPS-CF trial will help to assess the therapeutic potential of SASPject PT3.9 and inform further development of the wider SASPject platform.”



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The Company will provide further updates on the clinical programme as and when appropriate.

About SASPiPhi Ltd.

SASPiPhi Ltd. is the UK-based developer of the patented SASPject platform, which utilises innovative, engineered phage-based therapeutics to treat bacterial infections, particularly those caused by antibiotic-resistant bacteria. SASPiPhi's lead product, SASPject PT3.9, is designed to treat *Pseudomonas aeruginosa* infections. Other products in development target *Staphylococcus aureus* and *Acinetobacter baumannii*.

Enquiries

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