Press release 04 April 2018

Silurian Pharmaceuticals, Inc. Announces that the Food and Drug Administration (FDA) Granted Brevenal Orphan Drug Designation for the Treatment of Cystic Fibrosis

07.30.00 PT Silurian Pharmaceuticals, Inc, received approval for its Orphan Drug Designation application in the USA for BREVENAL for the treatment of Cystic Fibrosis. The approval granted by the FDA for BREVENAL covers all Cystic Fibrosis (CF) patients with no limitations to any specific mutation subgroups.

BREVENAL is a disease modifying drug that significantly improves inhibited mucociliary clearance and reverses bronchoconstriction, commonly experienced by CF patients. Brevenal's effect is independent of the cystic fibrosis transmembrane conductance regulator (CFTR), the defective cause of CF disease. Brevenal's activity is seen across CFTR mutations including nonsense (X) mutations. BREVENAL is also additive to existing CFTR modulators.

Treatment with BREVENAL is expected to prevent and reduce the number and severity of pulmonary exacerbations in CF patients. Pulmonary exacerbations are directly correlated with reduced lung function and mortality in CF patients. Brevenal treatment, in turn, will contribute to the quality of life of patients whilst improving their life expectancy.

CF is a rare genetic disease found in about 30,000 people in the U.S. and approximately 80,000 world-wide. Currently, there are no medical therapies to cure CF. In order to stimulate the pharmaceutical industry to develop and market medicines for a small number of patients, the US-FDA offers a range of incentives to encourage the development of these 'orphan' medicines for rare diseases in the USA. These incentives include protocol assistance, i.e. scientific advice specific for designated orphan medicines, and 5 to 7 years of market exclusivity once the medicine is approved for marketing. In addition, the company expects to get additional exclusivity for the treatment of children with CF. Orphan designated medicinal products also benefit from regulatory fee reductions and access to the centralized procedure for marketing authorization. Receiving orphan drug designation will accelerate Brevenal's development and provide extended marketing exclusivity following marketing approval. "We are excited to see that the FDA recognizes the potential of BREVENAL as a new treatment for CF-patients in the USA," said Dr. Isaac Cohen, Silurian's CEO.

We hope to launch Phase 1 clinical studies in CF patients next year, following the conclusion of all pre-clinical safety toxicology studies," said Dr. Cohen, CEO of Silurian Pharmaceuticals. "There is a real need for novel disease modifying compounds to directly address the mucociliary dysfunction characteristic of CF, and the profile of BREVENAL, if confirmed in clinical studies, would be ideal for clinicians to have as a therapeutic option" said Dr Carlos Milla Pediatric Pulmonologist who heads up the CF programme at Stanford's Lucille Packard Children's hospital

Silurian Pharmaceuticals, Inc., Emeryville, CA, designs and develops novel therapies for pulmonary disorders such as CF, COPD and idiopathic pulmonary fibrosis (IPF). Silurian's lead product is BREVENAL, a small molecule being developed as an inhaled product.

Investors:

Dr Richard Stokvis MD
Chief Commercial Officer
+31 6 39841368

Media:

Dr Isaac Cohen, OMD PhD
Chief Executive Officer
+1 510 409 2894

Forward-looking statements This release may contain forward-looking statements, including statements regarding the anticipated timing of (pre-) clinical studies with BREVENAL and the progression and results of such studies, and the status and outcome of interactions with regulators. Silurian cautions the reader that forward-looking statements are not guarantees of future performance. Forward-looking statements involve known and unknown risks, uncertainties and other factors which might cause the actual results, financial condition and liquidity, performance or achievements of Silurian, or industry results, to be materially different from any historic or future results, financial conditions and liquidity, performance or achievements expressed or implied by such forward-looking statements. In addition, even if Silurian' results, performance, financial condition and liquidity, and the development of the industry in which it operates are consistent with such forward-looking statements, they may not be predictive of results or developments in future periods. Among the factors that may result in differences are the inherent uncertainties associated with competitive developments, clinical trial and product development activities and regulatory approval requirements (including that data from the ongoing clinical trial with BREVENAL may not support registration or further development of BREVENAL due to safety, efficacy or other reasons), estimating the commercial potential of Silurian' product candidates.