



Document prepared by Nerve Center of TFORD, Venture Center, Pune  
**Task Force on Repurposing of Drugs (TFORD) for COVID19**  
 S&T Core Group on COVID19 constituted by PSA to Gol

## Molecule Brief: Camostat mesylate

Ref: TFORD/MB/012 Date: 12 April 2020

**About this document:** This document summarizes information available on drug candidates for COVID19. One Molecule Brief document covers one candidate at a time.

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### 1. Summary Information on Camostat mesylate

Information About the Candidate for Approved Indication(s)	
Common Name of Drug	Camostat mesylate
Brand Name	Foipan
Category/ Type	Serine protease inhibitor
Drug Bank ID/Link	DB13729 <a href="https://www.drugbank.ca/drugs/DB13729">https://www.drugbank.ca/drugs/DB13729</a>
Mode of Action	Not well understood. For pancreatitis, studies show that Camostat inhibits monocytes and pancreatic stellate cells activity.
Therapeutic Target	Serine Protease Inhibitor Transmembrane Protease Serine 2 (TMPRSS2) enzyme inhibitor Inhibits trypsin, prostatic, matriptase and plasma kallikrein activity
Is action Host or Virus directed?	Virus
Currently Approved for which Indication(s)	Camostat has been approved in Japan for treatment of chronic pancreatitis and postoperative reflux esophagitis.
Approved Dose	600 mg of Camostat mesylate daily divided in three doses.
Route of Administration	Oral
Safety Profile of drug (dose range in which it has been tested to be safe in humans)	A US Phase I study has been initiated to test the safety profile <a href="https://www.clinicaltrials.gov/ct2/show/study/NCT02693093">NCT02693093</a> : A Phase 1, Single Dose PK and Safety Study With Camostat Mesylate followed by a Phase 2, Randomized, Double-Blind, Parallel-Group Dose-Ranging Study to Evaluate the Safety and Efficacy of camostat mesylate when Compared to Placebo in Subjects With Chronic Pancreatitis in the USA: Completion date March 2021
Adverse events/Side effects reported at the current approved dose	Itch, rash, nausea, abdominal discomfort, abdominal distension and diarrhea
Reported Drug-Drug Interactions	Data not available
Link to Datasheet	<a href="http://www.shijiebiaopin.net/upload/product/201272318373223.PDF">http://www.shijiebiaopin.net/upload/product/201272318373223.PDF</a>
Current TRL level of the Drug	TRL-9 (Approved Drug)
Has the drug been repurposed for any other indication before?	No
Is the Drug being sold in India?	No

Indian Manufacturer(s)	No
International Manufacturer(s)	Ono Pharmaceutical
Price of the drug in India	Data not available
<b>Information About the Candidate for COVID-19</b>	
Repurposing Claim	New Indication (COVID-19) + New Dose (not confirmed)
Rationale for Repurposing for COVID19/MoA?	<ol style="list-style-type: none"> <li>Pre-clinical evidence shows TMPRSS2 to be a key protease that facilitates binding of SARS-CoV-2 to the ACE2 receptor and enable viral replication. TMPRSS2 is showing to prime the Spike protein on the virus to enable its binding to ACE2 receptor. <ul style="list-style-type: none"> <li><a href="https://www.ncbi.nlm.nih.gov/pmc/articles/pmid/32142651/">https://www.ncbi.nlm.nih.gov/pmc/articles/pmid/32142651/</a></li> <li><a href="#">Enhanced isolation of SARS-CoV-2 by TMPRSS2-expressing cells</a></li> <li><a href="#">SARS-CoV-2 receptor ACE2 and TMPRSS2 are predominantly expressed in a transient secretory cell type in sub segmental bronchial branches</a></li> </ul> </li> <li>Other in-vitro and in-vivo evidence exists to show that SARS and MERs viruses also require TMPRSS2 for human receptor binding. <a href="#">TMPRSS2 Contributes to Virus Spread and Immunopathology in the Airways of Murine Models after Coronavirus Infection</a></li> <li>Pre-clinical evidence shows Camostat can inhibit SARS-CoV-2 –ACE2 binding (details below)</li> </ol>
Proposed use as Primary or Adjuvant?	Primary
Pre-Clinical Data available for COVID-19	<a href="#">1. SARS-CoV-2 Cell Entry Depends on ACE2 and TMPRSS2 and Is Blocked by a Clinically Proven Protease Inhibitor</a> Results: Camostat partially blocks entry of the SARS-CoV-2 into lung cells in-vitro by inhibiting TMPRSS2.
Status of Clinical Trials	1 Ongoing
Trial Details	See details below

Trial ID/Link	Type of Trial	Number of patients	Drug Combination/ Dose/Stage of Disease	Primary and Secondary Measures	Has data from the trial been published (Yes/No)
<a href="#">NCT04321096</a>	Randomized	180	No combination  Dose: 2x100 mg pills 3 times daily for 5 days:  Stage: Data not available	Primary: Days to clinical improvement from study enrolment Secondary: Safety evaluation, Clinical status as assessed by the 7-point ordinal scale, Mortality, admission to ICU, duration of supplemental oxygen, days of self reported recovery	No

Key Data from Clinical Trials	Data not available	
TRL Level for COVID19	<b>TRL 6 (Phase I)</b>	
IP Status	<b>Status/ Molecule</b>	<b>Camostat mesylate</b>
	Pending applications	Not
	Approved and Active applications	NCE patent was filed in Japan. India was designated.
	Expired or Lapsed application or status not known	<a href="#">7162/DELNP/2007</a> Title: Organic Compounds Assignee: Novartis AG Priority Date: 14/04/2005 Publication date: 05/10/2007 Status: Not updated on patent site <a href="#">1148/DELNP/2015</a>

	<p>Title: Compositions Comprising An Antibody And Camostat Mesylate (CM)                  Assignee: Glaxo Group Limited                  Priority date: 21/08/2012                  Publication date: 31/08/2016                  Status: Not updated on patent site  <a href="#">1147/DELNP/2015</a></p> <p>Title: Compositions Comprising A Single Variable Domain And Camostat Mesylate (CM)                  Assignee: Glaxo Group Limited                  Priority Date: 28/08/2012                  Publication date: 26/06/2015                  Status: Not updated on patent site</p>
<p>Other Key References</p>	<ol style="list-style-type: none"> <li>1. <a href="https://www.sciencemag.org/news/2020/04/these-drugs-don-t-target-coronavirus-they-target-us">https://www.sciencemag.org/news/2020/04/these-drugs-don-t-target-coronavirus-they-target-us</a></li> <li>2. <a href="https://www.contagionlive.com/news/could-a-japanese-encephalitis-drug-prevent-covid19">https://www.contagionlive.com/news/could-a-japanese-encephalitis-drug-prevent-covid19</a></li> </ol>

## 2. Background information

### **About TFORD-COVID19**

*The Principal Scientific Advisor to the GoI, Dr K VijayRaghavan, has constituted a S&T Core Group on COVID19. Under the aegis of the S&T Core Group on COVID19, a Task Force has been constituted focused on Repurposing of Drugs for COVID19 (in short "TFORD-COVID19"). The Task Force is being coordinated by Dr V Premnath, Head, NCL Innovations at CSIR-NCL and Director, Venture Center and Dr Anurag Agarwal, Director, CSIR-IGIB. The Nerve Center for the Coordination is located at Venture Center, Pune (located in the campus of CSIR-NCL).*

### **Credits**

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