



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: Galidesivir

Ref: TFORD/MB/009 **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 Galidesivir

Information About the Candidate for Approved Indication(s)	
Common Name of Drug	Galidesivir (Synonyms- Immucillin A, Galidesivirum, BCX4430)
Brand Name	Not yet approved
Category/ Type	Antiviral
Drug Bank ID/Link	DB11676 https://www.drugbank.ca/drugs/DB11676
Mode of Action	It is an adenosine analogue that inhibits viral RNA polymerase function by terminating non obligate RNA chain and inhibits viral replication
Therapeutic Target	RdRp
Is action Host or Virus directed?	Virus directed
Currently Approved for which Indication(s)	Investigational Phase 1 for yellow fever (NCT03891420) Phase 1 for Marburg virus (NCT03800173)
Approved Dose	Data not available
Route of Administration	Given Intravenous and intramuscular during Phase I studies http://ir.biocryst.com/node/19921/pdf
Safety Profile of drug (dose range in which it has been tested to be safe in humans)	Data not available
Adverse events/Side effects reported at the current approved dose	Data not available
Reported Drug-Drug Interactions	Data not available
Link to Datasheet	Data not available
Current TRL level of the Drug	TRL-6 (Phase I completed)
Has the drug been repurposed for any other indication before?	Development for use in humans was then being fast-tracked due to concerns about the lack of treatment options for the 2013-2016 Ebola virus epidemic in West Africa
Is the Drug being sold in India?	No
Indian Manufacturer(s)	No

International Manufacturer(s)	Being developed by BioCryst Pharmaceuticals						
Price of the Drug in India	Data not available						
Information about the candidate for COVID19							
Repurposing Claim	New Indication (COVID-19) + New Dose (not confirmed)						
Rationale for Repurposing for COVID19/MoA?	<ol style="list-style-type: none"> 1. In-vitro evidence of broad spectrum activity against more than 20 RNA viruses in nine different families, including filoviruses, togaviruses, bunyaviruses, arenaviruses, paramyxoviruses, coronaviruses and flaviviruses. Data not published. https://www.clinicaltrialsarena.com/analysis/coronavirus-mers-cov-drugs/ 2. In-vitro Antiviral activity of BCX4430 (Galidesivir): assessed by conducting additional high-content image (HCI)-based and neutral-red uptake antiviral assays. BCX4430 exhibited antiviral activity against Coronaviridae families. SAR-CoV: EC₅₀ – 57.7µM, EC₉₀ >95µM and CC₅₀ >296 https://www.nature.com/articles/nature13027 3. In-vivo evidence - In animal studies, Galidesivir was effective in increasing the survival rates from infections caused by various pathogens, including Ebola, Marburg, Yellow Fever and Zika viruses. 25 mg/kg Galidesivir administered twice daily (BID) IM beginning immediately following viral challenge protected 100% (6 of 6) of animals. 4. Manufacturer also claims that a Phase 1 clinical safety and pharmacokinetics study in healthy subjects has been completed. Data from this study is not available. (This data has not been published. It is from the manufacturer's website - https://www.biocryst.com/our-program/galidesivir/) 						
Proposed use as Primary or Adjuvant?	Primary						
Pre-Clinical Data available for COVID-19	Data not available						
Status of Clinical Trials	No ongoing trials						
Trial Details	Data not available						
Key Data from Clinical Trials	Data not available						
TRL Level for COVID19	TRL < 5 (Not completed Phase I)						
IP Status	<table border="0"> <tr> <td>Status/ Molecule</td> <td>Galidesivir (BCX4430 (in clinical trials))</td> </tr> <tr> <td>Pending applications</td> <td>1438/KOLNP/2013 Title: Methods And Compositions For Inhibition Of Polymerase Assignee: Biocryst Pharmaceuticals Inc. Priority date: 15/10/2010 Publication date: 27/09/2013 Status: Reply submitted on 24/10/2018. 201717001958 Title: Substituted Nucleosides Nucleotides And Analogs Thereof Assignee: Alios Biopharma Inc Priority date: 24/06/2014 Publication date: 26/05/2017 Status: Withdrawn by the applicant u/s 11 (B) 201838039907 (Divisional to 1438/KOLNP/2013) Title: Compositions For Inhibition Of Polymerase Assignee: Biocryst Pharmaceuticals, Inc. Priority date: 15/10/2010 Publication date: 16/11/2018 Status: Awaiting Examination</td> </tr> <tr> <td>Approved and Active applications</td> <td>IN308689 Title: Compositions And Methods For Inhibiting Viral Polymerase</td> </tr> </table>	Status/ Molecule	Galidesivir (BCX4430 (in clinical trials))	Pending applications	1438/KOLNP/2013 Title: Methods And Compositions For Inhibition Of Polymerase Assignee: Biocryst Pharmaceuticals Inc. Priority date: 15/10/2010 Publication date: 27/09/2013 Status: Reply submitted on 24/10/2018. 201717001958 Title: Substituted Nucleosides Nucleotides And Analogs Thereof Assignee: Alios Biopharma Inc Priority date: 24/06/2014 Publication date: 26/05/2017 Status: Withdrawn by the applicant u/s 11 (B) 201838039907 (Divisional to 1438/KOLNP/2013) Title: Compositions For Inhibition Of Polymerase Assignee: Biocryst Pharmaceuticals, Inc. Priority date: 15/10/2010 Publication date: 16/11/2018 Status: Awaiting Examination	Approved and Active applications	IN308689 Title: Compositions And Methods For Inhibiting Viral Polymerase
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	<p>Expired or Lapsed application</p> <p>IN231852 (No .pdf available on WIPO site) Title: Process For Preparing Nucleoside Analogs Acting As Inhibitors Of Nucleoside Phosphorylases And Nucleosidases. Assignee: Albert Einstein College Of Medicine & Industrial Research Limited Priority date: 04/02/2003 Grant date: 12/03/2009 Expected expiry: 30/01/2024 Status: Ceased: 30/01/2017</p>
<p>Other Key References</p>	<ol style="list-style-type: none"> 1. https://file.medchemexpress.com/batch_PDF/HY-18649A/Galidesivir-DataSheet-MedChemExpress.pdf 2. https://www.nature.com/articles/nature13027.pdf 3. http://ir.biocryst.com/node/19921/pdf 4. https://clinicaltrials.gov/ct2/show/NCT0389142 5. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5632034/

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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