



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: Ustekinumab

Ref: TFORD/MB/016 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 Ustekinumab

Information About the Candidate for Approved Indication(s)	
Common Name of Drug	Ustekinumab
Brand Name	Stelara
Category/ Type	Monoclonal antibody
Drug Bank ID/Link	DB05679 <a href="https://www.drugbank.ca/drugs/DB05679">https://www.drugbank.ca/drugs/DB05679</a>
Mode of Action	Ustekinumab is a human immunoglobulin (Ig) G1 kappa monoclonal antibody directed against interleukin (IL)-12 and IL-23, which are cytokines that are involved in immune and inflammatory responses.
Therapeutic Target	IL-12 and IL-23 p40 subunit
Is action Host or Virus directed?	Host
Currently Approved for which Indication(s)	1. Moderate to severe plaque psoriasis 2. Active psoriatic arthritis 3. Moderately to severely active Crohn's Disease 4. Moderately to severely active Ulcerative Colitis
Approved Dose	Subcutaneous: 45 mg/0.5 mL or 90 mg/mL in a single-dose prefilled syringe Intravenous: 130 mg/26 mL (5 mg/mL) solution in a single-dose vial
Route of Administration	Subcutaneous or Intravenous injection
Safety Profile of drug (dose range in which it has been tested to be safe in humans)	Signs of dose-limiting toxicity were not observed with intravenous administration of single doses up to 6 mg/kg in clinical trials. Information on overdose of ustekinumab is limited
Adverse events/Side effects reported at the current approved dose	Nasopharyngitis, Upper Respiratory Tract Infection, Headache, Fatigue, Vomiting, Nasopharyngitis, Injection site Erythema, Vulvovaginal candidiasis/mycotic infection, Bronchitis, Pruritus, Urinary Tract Infection, and Sinusitis
Reported Drug-Drug Interactions	Contraindicated (13) Serious - Use Alternative (47) Monitor Closely (65) (Clinicians need to note relevant drug-drug interactions depending on nature of use)
Link to Datasheet	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/7610">https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/7610</a>

	<a href="#">44lbl.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?	Yes	
Indian Manufacturer(s)	Possibly Serum Institute	
International Manufacturer(s)	Janssen Biotech	
Price of the Drug in India	Rs. 1.4 Lakh/45mg (1 dose)	
<b>Information about the candidate for COVID19</b>		
Repurposing Claim	Data not available	
Rationale for Repurposing for COVID19/MoA?	<p>No literature evidence. A recent Lancet correspondence says “Cytokine blockers, such as Infliximab, Adalimumab (anti-tumor necrosis factor [TNF]), and Ustekinumab (anti-interleukin [IL]-12/IL-23 [p40 subunit]), used for the treatment of psoriasis, rheumatoid arthritis, and inflammatory bowel diseases, are used with success for inducing and maintaining remission. Unfortunately, however, the use of these therapies enhances the risk of bacterial and viral infections, and of viral reactivation in cases with previous viral infection.”</p> <p><a href="https://www.thelancet.com/journals/lanrhe/article/PIIS2665-9913(20)30092-8/fulltext">https://www.thelancet.com/journals/lanrhe/article/PIIS2665-9913(20)30092-8/fulltext</a></p>	
Proposed use as Primary or Adjuvant?	Data not available	
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 (Phase I not completed)	
IP Status	<b>Status/ Molecule</b>	<b>Ustekinumab (Stelara)</b>
	Pending application	Not available
	Approved and active applications	<p><a href="#">IN236195</a>  Title: An Isolated Mammalian Anti 1L-12 Antibody And A Composition Comprising The Same  Assignee: Centor Inc  Priority date: 07/08/2000  Grant Date: 14/10/2009  Expected expiry date: 07/08/2021</p> <p><a href="#">IN309445</a>  Title: Antibodies To IL-6 And Use Thereof  Assignee: Alder Biopharmaceuticals, Inc.  Priority date: 25/11/2008  Grant date: 19/03/2019  Expected Expiry date: 24/11/2029</p>
	Expired or lapsed or status not known applications	<p><a href="#">4138/DELNP/2010</a>  Title: Protein Formulations And Methods Of Making Same  Assignee: Abbvie Biotechnology Ltd.  Priority date: 30/11/2007  Publication date: 12/11/2010</p> <p><a href="#">9182/DELNP/2012</a>  Title: Antibodies with enhanced or suppressed effector function  Assignee: Zymeworks Inc.  Priority date: 29/03/2010  Publication date: 04/07/2014  Status: Abandoned section 21(1)</p> <p><a href="#">7217/DELNP/2012</a>  Title: Pyrazole Derivatives As JAK inhibitors  Assignee: Almirall S.A.</p>

	<p>Priority date:18/02/2010                  Publication date: 18/12/2015                  Status: Abandoned section 21(1)  <a href="#">1385/KOLNP/2012</a>                  Title: Antibodies To Il-6 And Use Thereof                  Assignee: Alderbio Holdings Llc.                  Priority date:24/11/2009                  Publication date: 01/03/2013                  Status: Abandoned section 21(1)  <a href="#">11100/DELNP/2012</a>                  Title: Heteroaryl imidazolone derivatives as JAK inhibitors                  Assignee: Almirall S.A.                  Priority date: 15/06/2010                  Publication date: 05/02/2016                  Status: No updates on Indian patent site  <a href="#">4688/DELNP/2012</a>                  Title: Imidazopyridine Derivatives As JAK inhibitors                  Assignee: Almirall S.A.                  Priority date: 24/12/2009                  Publication date: 04/12/2015                  Status: Abandoned section 21(1)</p>
Other Key References	<p><a href="#">Implications of COVID-19 for patients with pre-existing digestive diseases</a></p>

## 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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