



Preclinical & Clinical Development Landscape for Mpox & Poxviruses

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- 2 antivirals approved by Stringent Regulatory Authority (U.S., EU) and 1 by Other National Authority (Russia) for the treatment of human smallpox disease.
- For the treatment of Mpox disease, 1 antiviral is approved by a Stringent Regulatory Authority (EU) and permitted for emergency use to treat Mpox in the U.S.

Assembly/Release

Tecovirimat (oral; IV)

- Adults and pediatric
- Oral tablet, twice daily for 14 days
- Approved for Smallpox (U.S., EU)
- Approved for Mpox (EU)
- Expanded Access-Investigational New Drug (EA-IND) protocol for Mpox (U.S.)

NIOCH-14 (oral; Russia only)

Replication

Brincidofovir

- Adults and pediatric
- Oral tablet, oral suspension, once weekly for two doses
- Approved for Smallpox (U.S., Canada)
- FDA-authorized single-patient emergency use IND (e-IND) for Mpox (U.S.)

- ▶ Relatively small number of established oral [antiviral] treatment options for Mpox disease
- ▶ Potential need for additional classes of oral drugs with complementary MOA
- ▶ Vaccination is only available option for prophylaxis; pre- and post-exposure prophylaxis (PrEP & PEP)
- ▶ Preparedness must consider manufacturing time and stability; stockpiling is common and may vary between countries

Compound/Indications for Poxviridae* by Stage of Development

Compound	Developer/Sponsor	Developer Country	Poxviridae Indication(s)	Mechanism of Action	Category
Approved Antiviral					
NIOH-14	Vector Center	Russia	Smallpox/Other Poxviruses	Assembly/Release	Approved – O.N.A.
Tecovirimat (oral)	Siga Technologies	United States	Smallpox/Other Poxviruses	Assembly/Release	Approved – S.A.
Tecovirimat (oral; IV)	Siga Technologies	United States	Mpox	Assembly/Release	Approved – S.A.
Brincidofovir	Chimerix	United States	Smallpox/Other Poxviruses	Replication	Approved – S.A.
Phase 1					
ASC10	Asclepis Pharma	China	Mpox	Replication	Watch & Wait
Preclinical					
Cidofovir	Chimerix, Emergen BioSolutions	United States	Mpox	Replication	Approved Antiviral-Indication Expansion
Cidofovir	Chimerix, Emergen BioSolutions	United States	Smallpox/Other Poxviruses	Replication	Approved Antiviral-Indication Expansion
Simeprevir	Johnson & Johnson Innovative Medicine	United States	Mpox	Assembly/Release	Archived – in silico data only
NV-387-T	NanoViricides	United States	Mpox	Entry	Investigational Antiviral-Indication Expansion
Ribavirin	Bausch Health, Roche	Canada, Switzerland	Mpox	IMPDH	Ribavirin-Indication Expansion
CP-COV03 (Niclosamide)	University of California Berkeley, Hyundai Bioscience	United States, South Korea	Mpox	Anthelmintic	Anthelmintic
Nitroxoline	Goethe University Frankfurt	Germany	Mpox	Antibiotic	Antibiotic
Brilacidin	Innovation Pharmaceuticals	United States	Mpox	Antibiotic	Antibiotic
Sabizabulin	Veru	United States	Smallpox/Other Poxviruses	Host Target	Host Target
Naldemedine	Shionogi	Japan	Mpox	Host Target	Host Target
Lixivaptan	Centessa Pharmaceuticals	United Kingdom	Mpox	Host Target	Host Target
Fosdagrocorat	Pfizer	United States	Mpox	Host Target	Host Target

*As of July 12, 2024



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We welcome all feedback through [our online portal](#). As with previous listings, developers are invited to submit non-confidential information on their compound candidates. All reports are updated quarterly.

For more information, contact nina@intrepidalliance.org.

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