

# HHS LICENSE-BASED VACCINES & THERAPEUTICS

Presented by: NIH Office of Technology Transfer

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### Vimkunya

Vimkunya® (chikungunya vaccine, recombinant): The first single-dose, VLP chikungunya vaccine for ages 12+. Mimics the virus without risk of infection.

**Licensee:** Bavarian Nordic  
**FDA Approval:** 2/14/2025  
**Agency:** NIH

### Spikevax

Spikevax® (COVID-19 vaccine, mRNA) An mRNA vaccine for active immunization against COVID-19 in adults 18+.

**Licensee:** ModernaTX Inc.  
**FDA Approval:** 1/31/2022  
**Agency:** NIH

### Tecartus

Tecartus® (brexucabtagene autoleucl) A CD19-directed immunotherapy for mantle cell lymphoma (MCL) and B-cell precursor acute lymphoblastic leukemia (ALL).

**Licensee:** Kite Pharma  
**FDA Approval:** 7/24/2020  
**Agency:** NIH

### Ella

Ella® A progesterone agonist/antagonist used as emergency contraception.

**Licensee:** Laboratoire HRA Pharma  
**FDA Approval:** 3/10/2015  
**Agency:** NIH

### Amtagvi

Amtagvi® (lifileucel): The first and only one-time, individualized T cell therapy for unresectable/metastatic melanoma.

**Licensee:** Iovance Biotherapeutics Inc  
**FDA Approval:** 2/16/2024  
**Agency:** NIH

### Comirnaty

Comirnaty® (COVID-19 vaccine, mRNA) An mRNA vaccine for active immunization against COVID-19 in individuals 16+.

**Licensee:** BioNTech/Pfizer  
**FDA Approval:** 8/23/2021  
**Agency:** NIH

### Descovy

Descovy® (tenofovir alafenamide plus emtricitabine) Used for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection, excluding receptive vaginal sex.

**Licensee:** Gilead Sciences  
**FDA Approval:** 10/3/2019  
**Agency:** CDC

### Myalept

Myalept® (metreleptin) Adjunct therapy for generalized lipodystrophy, replacing deficient leptin and managing metabolic complications.

**Licensee:** Aegerion Pharmaceuticals Inc.  
**FDA Approval:** 2/25/2014  
**Agency:** NIH

### Roctavian

Roctavian® (valoctocogene roxaparvovec-rvoo) is an adeno-associated virus vector-based gene therapy for the treatment of adults with severe hemophilia A.

**Licensee:** BioMarin Pharmaceutical  
**FDA Approval:** 6/28/2023  
**Agency:** NIH

### Emtricitabine and Tenofovir Disoproxil Fumarate

Emtricitabine and tenofovir disoproxil fumarate (generic) is used for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection

**Licensee:** CIPLA  
**FDA Approval:** 4/2/2021      **Agency:** CDC

### Emtricitabine and Tenofovir Disoproxil Fumarate

Emtricitabine and tenofovir disoproxil fumarate (generic) is used for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection

**Licensee:** Larus Labs  
**FDA Approval:** 7/26/2019      **Agency:** CDC

### Truvada

Truvada® (emtricitabine and tenofovir disoproxil fumarate) is used for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection. First FDA approved therapeutic for HIV prevention.

**Licensee:** Gilead Sciences  
**FDA Approval:** 7/16/2012  
**Agency:** CDC

### Abrysvo

Abrysvo® (respiratory syncytial virus vaccine) Protects infants and adults from RSV-related lower respiratory tract disease. First of its kind for infants.

**Licensee:** Pfizer  
**FDA Approval:** 5/31/2022  
**Agency:** NIH

### Abecma

Abecma® (idecabtagene viclecel) CAR T-cell therapy for relapsed/refractory multiple myeloma in adults after at least four prior therapies.

**Licensee:** Bluebird Bio  
**FDA Approval:** 3/26/2021  
**Agency:** NIH

### Dengvaxia

Dengvaxia® (Dengue Tetravalent Vaccine, Live) Vaccine to prevent all four dengue virus serotypes, for 9-16 year olds with prior dengue infection in endemic regions.

**Licensee:** Sanofi Pasteur  
**FDA Approval:** 5/1/2019  
**Agency:** NIH

### Velcade

Velcade® A proteasome inhibitor for multiple myeloma, approved for patients who have failed prior therapies.

**Licensee:** Millennium Pharmaceuticals  
**FDA Approval:** 5/13/2003  
**Agency:** NIH

### Arexvy

Arexvy® (respiratory syncytial virus vaccine, adjuvanted) First RSV vaccine for adults 60+. Uses recombinant RSV F glycoprotein to prevent lower respiratory tract disease.

**Licensee:** GlaxoSmithKline  
**FDA Approval:** 5/3/2023  
**Agency:** NIH

### Ebanga

Ebanga™ (ansuvimab-zykl) A monoclonal antibody to treat Zaire ebolavirus infection in adults and children by blocking viral entry.

**Licensee:** Ridgeback Biotherapeutics  
**FDA Approval:** 12/21/2020  
**Agency:** NIH

### Spravato

Spravato® (esketamine) A nasal spray used with an oral antidepressant to treat treatment-resistant depression in adults.

**Licensee:** Janssen Therapeutics  
**FDA Approval:** 3/6/2019  
**Agency:** NIH

### Hemgenix

Hemgenix® (etranacogene dezaparvovec-drlb) is a one-time gene therapy for the treatment of adults 18 years of age and older living with hemophilia B.

**Licensee:** uniQure/CSL  
**FDA Approval:** 11/22/2022  
**Agency:** NIH

### Zokinvy

Zokinvy® (lonafarnib) Farnesyltransferase inhibitor for Hutchinson-Gilford Progeria Syndrome (HGPS) and Progeroid Laminopathies (PL), preventing defective protein buildup linked to premature aging.

**Licensee:** Progeria Research Foundation/Elger Biopharmaceuticals  
**FDA Approval:** 11/20/2020  
**Agency:** NIH

### Yescarta

Yescarta® CAR T-cell immunotherapy to treat adult patients with relapsed or refractory large B-cell lymphoma.

**Licensee:** Kite Pharma  
**FDA Approval:** 10/18/2017  
**Agency:** NIH

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