LAPaL
THE LONG-ACTING THERAPEUTICS PATENTS AND LICENCES DATABASE

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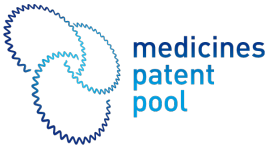
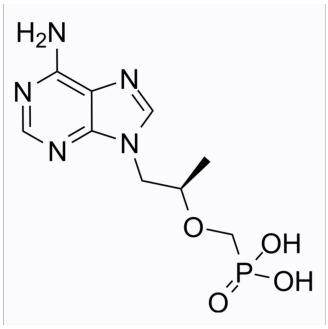




Tenofovir-Lamivudine-Dolutegravir (TLD) - long-acting injectable (LAI) (TLD LAI)

Developer(s)

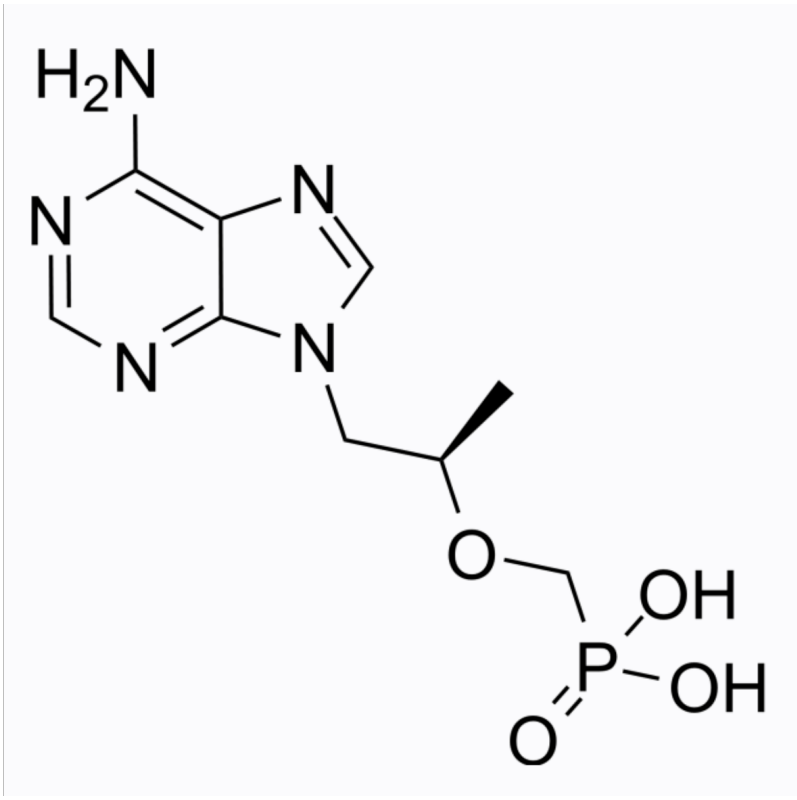
University of Washington

https://www.washington.edu/

United States

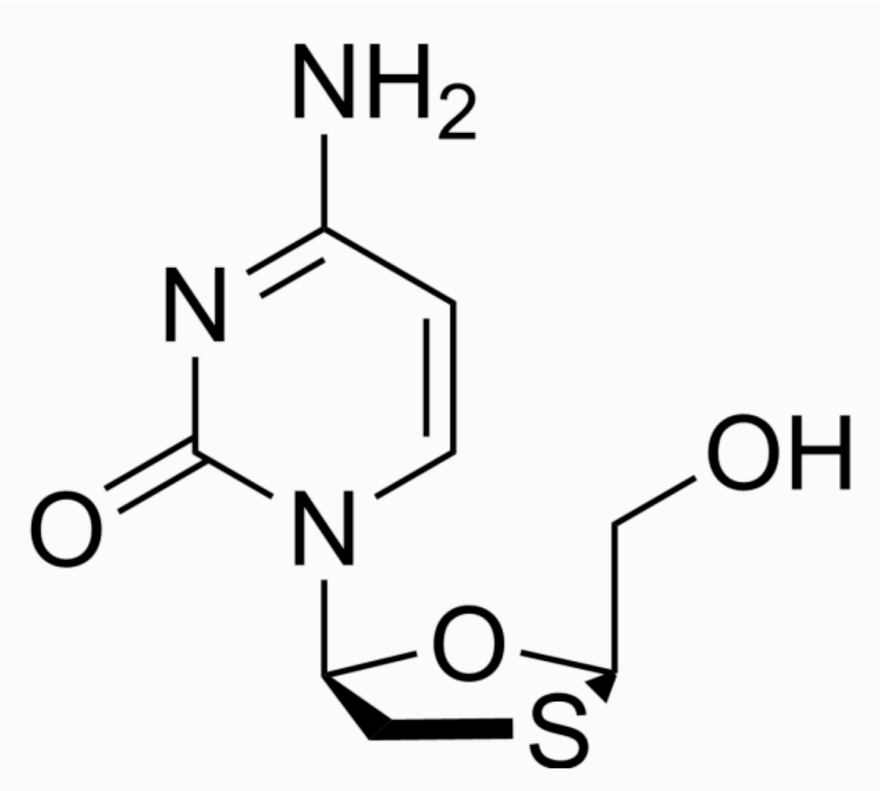
The University of Washington is a public research university based in Seattle, Washington, USA. Originally founded in 1861, the institution has an extraordinary track record of scientific inventions & discoveries. Its Targeted Long-acting Combination Antiretroviral Therapy (TLC-ART) program aims to develop safe, stable, scalable and tolerable long-acting ART combinations for the treatment of HIV.

Drug structure



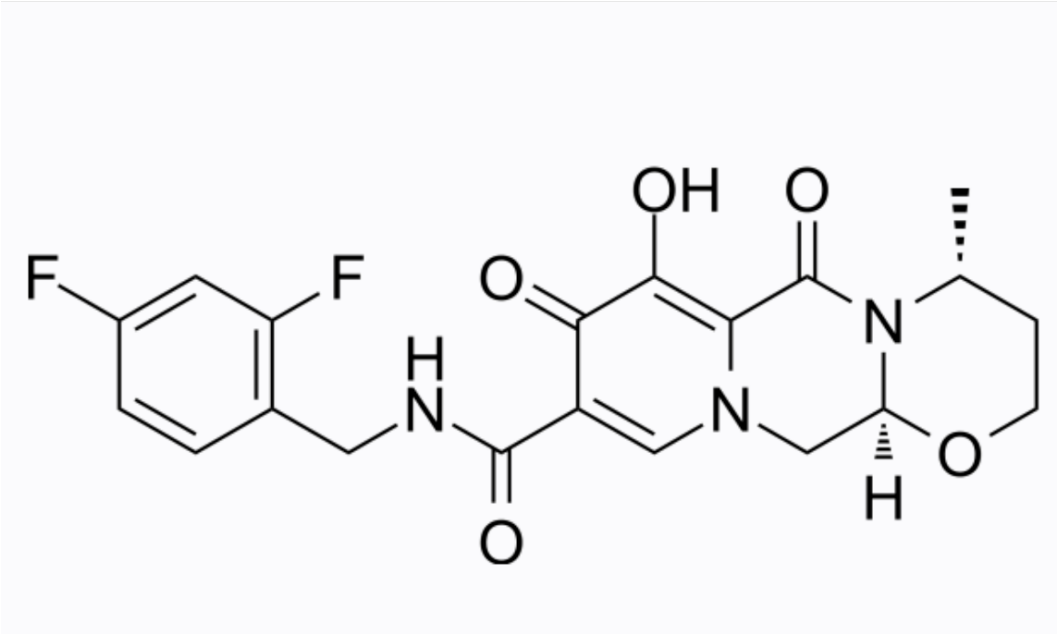
tenofovir (aka GS 1278 aka PMPA)

MedChemExpress



lamivudine (aka BCH-189)

MedChemExpress



dolutegravir (aka S/GSK1349572)

Drug information

Associated long-acting platforms

Aqueous drug particle suspension, Based on other organic particles

Administration route

Subcutaneous

Therapeutic area(s)

HIV
HBV

Use case(s)

Treatment

Use of drug

Ease of administration

Administered by a community health worker
Administered by a nurse
Administered by a specialty health worker
Self-administered
To be determined

User acceptance

Not provided

Drug information

Drug's link(s)

Not provided

Generic name

Not yet developed

Brand name

Not yet assigned

Compound type

Small molecule

Summary

Tenofovir disoproxil fumarate/Lamivudine/Dolutegravir (TLD; TDF/3TC/DTG) is a fixed-dose antiretroviral drug combination used for the treatment of HIV. It consists of two NNRTIs (TDF/3TC) and an InSTI (DTG). Since 2018, WHO HIV treatment guidelines have recommended daily oral TLD as the preferred first-line regimen for initiating antiretroviral therapy (ART) among adults and adolescents living with HIV. In most PEPFAR-supported countries, more than 80% of people receiving HIV-ART were prescribed oral TLD as of March 2022. Researchers at the University of Washington are currently developing a long-acting injectable version of tenofovir+lamivudine+dolutegravir via drug-combination-nanoparticle (DcNP) technology platform which would enable effective TLD concentrations for up to 4 weeks.

Approval status

Still in clinical development

Regulatory authorities

Still in clinical development

Delivery device(s)

No delivery device

Scale-up and manufacturing prospects

Scale-up prospects

A novel long-acting TLD drug-combination nano-particulate (DcNP) formulation for subcutaneous injection was prepared with biocompatible lipid excipients. The highly-scalable DcNP technology enables drugs with disparate physiochemical properties to be formulated into products that remain stable in aqueous suspension. First, TLD was dissolved with lipid-excipients in hydrated-alcohol, followed by a controlled solvent-removal process to create the TLD-DcNP powder. Next, the TLD-DcNP particle-size was reduced (60-80 nm) resulting in a stable-injectable TLD product suitable for subcutaneous dosing.

Tentative equipment list for manufacturing

Rotary evaporator (rotavap). High pressure homogeniser (e.g. Emulsiflex-c5; Avestin Inc., Canada). Spray-dryer (e.g. 4M8Trix Unit; ProCepT, Belgium).

Manufacturing

TLD-in-DcNP injectable suspension was prepared by dissolving 40.27 mmol DSPC, 5.97mmol HCl, 5.66 mmol DTG and 4.49mmol mPEG2000-DSPE in 472 ml ethanol at 70°C. Following dissolution, 28 ml of 200 mM $NaHCO_3$ buffer containing 5.85 mmol TFV and 5.85 mmol 3TC was added. The solution was then spray-dried under controlled-solvent-removal process to generate the TLD-in-DcNP powder. The powder in 0.45% w/v NaCl–20 mM $NaHCO_3$ buffer suspension was held at 75°C and homogenised to achieve stable particles (50–70 nm). The suspension was cooled to 25°C and stored at 4°C.

Specific analytical instrument required for characterization of formulation

Particle size determined by photon correlation spectroscopy using a NICOMP 380 ZLS (Particle Sizing Systems, Santa Barbara, CA). Osmolality (Vapro 5520 osmometer; Wescor, Logan, UT) and pH (Hydrion paper). Drug quantification via LC-MS/MS using acetonitrile precipitation.

Clinical trials

Not provided

Excipients

Proprietary excipients used

Lipid excipients: DSPC and DSPE-mPEG2000

Novel excipients or existing excipients at a concentration above Inactive Ingredients Database (IID) for the specified route of administration

Not provided

Residual solvents used

Not provided

Patent info

Compound patent families

Patent informations

Patent description	Representative patent	Categories	Patent holder	Licence with MPP	Patent source
Glecaprevir/Pibrentasvir use in HCV (without IFN or RBV) - treatment regimen Expiry date: 2038-02-09 The present invention features interferon-free therapies for the treatment of HCV. Preferably, the treatment is over a shorter duration of treatment, such as no more than 12 weeks. In one aspect, the treatment comprises administering at least two direct acting antiviral agents to a subject with HCV infection, wherein the treatment lasts for 12 weeks and does not include administration of either interferon or ribavirin, and said at least two direct acting antiviral agents comprise (a) Compound 1 or a pharmaceutically acceptable salt thereof and (b) Compound 2 or a pharmaceutically acceptable salt thereof.	CA2994496	Use	Abbvie Inc	Yes	

Patent status

Patent status/countries	Low, Low- middle and upper-middle	High income

Granted		United States of America
Filed		Canada
Not in force	China, Brazil, Mexico, Türkiye, North Macedonia, Albania, Bosnia and Herzegovina, Montenegro, Serbia, Moldova, Republic of, Morocco, Tunisia	Australia, Japan, United States of America, Belgium, Germany, France, Luxembourg, Netherlands, Switzerland, United Kingdom, Sweden, Italy, Austria, Liechtenstein, Greece, Spain, Denmark, Monaco, Portugal, Ireland, Finland, Cyprus, Bulgaria, Czechia, Estonia, Slovakia, Hungary, Poland, Iceland, Malta, Norway, San Marino, Croatia, Romania, Latvia, Lithuania, Slovenia

MPP Licence(s)

MPP licence on Glecaprevir/Pibrentasvir (G/P)

https://medicinespatentpool.org/licence-post/glecaprevir-pibrentasvir-g-p/

Patent and know-how licence on long-acting formulations using Tandem Nano's emulsion-templated freeze-drying technology (ETFD)

https://medicinespatentpool.org/licence-post/long-acting-technologies-for-hcv-tb-and-malaria-treatment

Patent informations

Patent description	Representative patent	Categories	Patent holder	Licence with MPP	Patent source
Solid composition comprising dispersed atovaquone nanoparticles Expiry date: 2037-06-15 A solid composition comprising nanoparticles of atovaquone dispersed within one or more carrier materials, wherein the atovaquone is present in an amount of at least 10 wt%. Also described is an intramuscularly- or subcutaneously-injectable formulation of nanoparticles of atovaquone	WO2017216564	Composition	The Johns Hopkins University, The University of Liverpool	Yes	

Patent status

Patent status/countries	Low, Low- middle and upper-middle	High income
Granted	China, India, Sierra Leone, Eswatini, Liberia, Namibia, Sao Tome and Principe, Mozambique, Zambia, Zimbabwe, Tanzania, United Republic of, Malawi, Ghana, Rwanda, Sudan, Botswana, Lesotho, Kenya, Gambia (the)	Australia, Canada
Filed	Brazil, Albania, Serbia, Türkiye, North Macedonia, South Africa	Liechtenstein, Italy, Norway, Malta, Denmark, Belgium, United Kingdom, Greece, Netherlands, Hungary, Croatia, Switzerland, Spain, San Marino, Slovenia, Austria, Romania, Iceland, Cyprus, Finland, France, Bulgaria, Slovakia, Poland, Latvia, Ireland, Estonia, Germany, Luxembourg, Portugal, Czechia, Lithuania, Monaco, Sweden, Japan, United States of America

Patent status/countries	Low, Low- middle and upper-middle	High income
Not in force	World Intellectual Property Organization (WIPO), Brazil, Morocco, Bosnia and Herzegovina, Montenegro, Moldova, Republic of, Uganda	World Intellectual Property Organization (WIPO), Chile, United States of America

MPP Licence(s)

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Patent informations

Patent description	Representative patent	Categories	Patent holder	Licence with MPP	Patent source
Glecaprevir/Pibrentasvir solid compositions II Expiry date: 2036-07-18 The present invention features solid pharmaceutical compositions comprising Compound 1 and Compound 2. In one embodiment, the solid pharmaceutical composition includes (1) a first layer which comprises 100 mg Compound 1, as well as a pharmaceutically acceptable hydrophilic polymer and a pharmaceutically acceptable surfactant, all of which are formulated in amorphous solid dispersion; and (2) a second layer which comprises 40 mg Compound 2, as well as a pharmaceutically acceptable hydrophilic polymer and a pharmaceutically acceptable surfactant, all of which are formulated in amorphous solid dispersion.	WO2017015211	Composition	Abbvie Inc	Yes	

Patent status

Patent status/countries	Low, Low- middle and upper-middle	High income
Granted	South Africa	Australia, Canada, Japan, Israel, New Zealand, Panama

Patent status/countries	Low, Low- middle and upper-middle	High income
Filed	Costa Rica, Turkmenistan, Belarus, Tajikistan, Kazakhstan, Egypt, Viet Nam, Türkiye, North Macedonia, Albania, Bosnia and Herzegovina, Montenegro, Serbia, Ecuador, Guatemala, Mongolia, Thailand	Korea, Republic of, Russian Federation, Belgium, Germany, France, Luxembourg, Netherlands, Switzerland, United Kingdom, Sweden, Italy, Austria, Liechtenstein, Greece, Spain, Denmark, Monaco, Portugal, Ireland, Finland, Cyprus, Bulgaria, Czechia, Estonia, Slovakia, Hungary, Poland, Iceland, Malta, Norway, San Marino, Croatia, Romania, Latvia, Lithuania, Slovenia, New Zealand, Singapore, Hong Kong
Not in force	World Intellectual Property Organization (WIPO), Brazil, China, Colombia, Philippines, Peru, Dominican Republic, Indonesia, India, Mexico, Moldova, Republic of, Malaysia, Ukraine	Korea, Republic of, United States of America, World Intellectual Property Organization (WIPO), Chile, Russian Federation

MPP Licence(s)

MPP licence on Glecaprevir/Pibrentasvir (G/P)

https://medicinespatentpool.org/licence-post/glecaprevir-pibrentasvir-g-p/

Patent and know-how licence on long-acting formulations using Tandem Nano's emulsion-templated freeze-drying technology (ETFD)

https://medicinespatentpool.org/licence-post/long-acting-technologies-for-hcv-tb-and-malaria-treatment

Patent informations

Patent description	Representative patent	Categories	Patent holder	Licence with MPP	Patent source
Glecaprevir/Pibrentasvir solid compositions I Expiry date: 2036-06-24 The present invention features solid pharmaceutical compositions comprising Compound 1 and Compound 2. In one embodiment, the solid pharmaceutical composition includes (1) a first layer which comprises 100 mg Compound 1, as well as a pharmaceutically acceptable hydrophilic polymer and a pharmaceutically acceptable surfactant, all of which are formulated in amorphous solid dispersion; and (2) a second layer which comprises 40 mg Compound 2, as well as a pharmaceutically acceptable hydrophilic polymer and a pharmaceutically acceptable surfactant, all of which are formulated in amorphous solid dispersion.	WO2016210273	Composition	Abbvie Inc	Yes	

Patent status

Patent status/countries	Low, Low- middle and upper-middle	High income
Granted	Mexico, Indonesia, South Africa, Mongolia, Malaysia, Colombia	Australia, Israel, Japan, Korea, Republic of, United States of America, Panama

Patent status/countries	Low, Low- middle and upper-middle	High income
Filed	Brazil, Costa Rica, Turkmenistan, Belarus, Tajikistan, Kazakhstan, Azerbaijan, Kyrgyzstan, Armenia, Türkiye, Egypt, India, Ecuador, Guatemala, Thailand, Albania, North Macedonia, Serbia, Bosnia and Herzegovina, Montenegro	Canada, Belgium, Russian Federation, Germany, France, Luxembourg, Netherlands, Switzerland, United Kingdom, Sweden, Italy, Austria, Liechtenstein, Greece, Spain, Denmark, Monaco, Portugal, Ireland, Finland, Cyprus, Bulgaria, Czechia, Estonia, Slovakia, Hungary, New Zealand, Singapore, Hong Kong, Iceland, Norway, Poland, Romania, San Marino, Croatia, Latvia, Lithuania, Malta, Slovenia
Not in force	World Intellectual Property Organization (WIPO), Philippines, China, Dominican Republic, Peru, Viet Nam, Ukraine	Japan, United States of America, World Intellectual Property Organization (WIPO), Chile, Russian Federation

MPP Licence(s)

MPP licence on Glecaprevir/Pibrentasvir (G/P)

https://medicinespatentpool.org/licence-post/glecaprevir-pibrentasvir-g-p/

Patent and know-how licence on long-acting formulations using Tandem Nano's emulsion-templated freeze-drying technology (ETFD)

https://medicinespatentpool.org/licence-post/long-acting-technologies-for-hcv-tb-and-malaria-treatment

Patent informations

Patent description	Representative patent	Categories	Patent holder	Licence with MPP	Patent source
Glecaprevir crystal forms Expiry date: 2035-06-05 The present invention features crystalline forms of Compound I. In one embodiment, a crystalline form of Compound I has characteristic peaks in the PXRD pattern as shown in any one of Figures 1-4.	WO2015188045	Polymorphs	Abbvie Inc	Yes	

Patent status

Patent status/countries	Low, Low- middle and upper-middle	High income
Granted	Mexico	United States of America, Australia
Filed	Türkiye, North Macedonia, Albania, Serbia, China	Canada, Japan, Belgium, Germany, France, Luxembourg, Netherlands, Switzerland, United Kingdom, Sweden, Italy, Austria, Liechtenstein, Greece, Spain, Denmark, Monaco, Portugal, Ireland, Finland, Cyprus, Bulgaria, Czechia, Estonia, Slovakia, Hungary, Poland, Iceland, Malta, Norway, San Marino, Croatia, Romania, Latvia, Lithuania, Slovenia
Not in force	World Intellectual Property Organization (WIPO), Türkiye, North Macedonia, Albania, Bosnia and Herzegovina, Montenegro, Serbia, Morocco	Australia, Japan, World Intellectual Property Organization (WIPO), Belgium, Germany, France, Luxembourg, Netherlands, Switzerland, United Kingdom, Sweden, Italy, Austria, Liechtenstein, Greece, Spain, Denmark, Monaco, Portugal, Ireland, Finland, Cyprus, Bulgaria, Czechia, Estonia, Slovakia, Hungary, Poland, Iceland, Malta, Norway, San Marino, Croatia, Romania, Latvia, Lithuania, Slovenia

MPP Licence(s)

MPP licence on Glecaprevir/Pibrentasvir (G/P)

https://medicinespatentpool.org/licence-post/glecaprevir-pibrentasvir-g-p/

Patent and know-how licence on long-acting formulations using Tandem Nano's emulsion-templated freeze-drying technology (ETFD)

https://medicinespatentpool.org/licence-post/long-acting-technologies-for-hcv-tb-and-malaria-treatment

Patent informations

Patent description	Representative patent	Categories	Patent holder	Licence with MPP	Patent source
Pibrentasvir crystal forms Expiry date: 2035-05-08 The present invention features crystalline forms of Compound I. In one embodiment, a crystalline form of Compound I has characteristic peaks in the PXRD pattern as shown in one of Figures 1-10.	WO2015171993	Polymorphs	Abbvie Inc	Yes	

Patent status

Patent status/countries	Low, Low- middle and upper-middle	High income
Granted	Mexico	Australia, Japan, United States of America
Filed	China, Albania, Serbia, Türkiye, North Macedonia	Canada, Liechtenstein, Italy, Norway, Malta, Denmark, Belgium, United Kingdom, Greece, Netherlands, Hungary, Croatia, Switzerland, Spain, San Marino, Slovenia, Austria, Romania, Iceland, Cyprus, Finland, France, Bulgaria, Slovakia, Poland, Latvia, Ireland, Estonia, Germany, Luxembourg, Portugal, Czechia, Lithuania, Monaco, Sweden, United States of America
Not in force	World Intellectual Property Organization (WIPO), China, Morocco, Albania, Serbia, Bosnia and Herzegovina, Montenegro, Türkiye, North Macedonia, Mexico	World Intellectual Property Organization (WIPO), Australia, Liechtenstein, Italy, Norway, Malta, Denmark, Belgium, United Kingdom, Greece, Netherlands, Hungary, Croatia, Switzerland, Spain, San Marino, Slovenia, Austria, Romania, Iceland, Cyprus, Finland, France, Bulgaria, Slovakia, Poland, Latvia, Ireland, Estonia, Germany, Luxembourg, Portugal, Czechia, Lithuania, Monaco, Sweden, Japan

MPP Licence(s)

MPP licence on Glecaprevir/Pibrentasvir (G/P)

https://medicinespatentpool.org/licence-post/glecaprevir-pibrentasvir-g-p/

Patent and know-how licence on long-acting formulations using Tandem Nano's emulsion-templated freeze-drying technology (ETFD)

https://medicinespatentpool.org/licence-post/long-acting-technologies-for-hcv-tb-and-malaria-treatment

Patent informations

Patent description	Representative patent	Categories	Patent holder	Licence with MPP	Patent source
Glecaprevir/Pibrentasvir use in HCV (without IFN or RBV) II Expiry date: 2035-04-01 The present invention features interferon-free therapies for the treatment of HCV. Preferably, the treatment is over a shorter duration of treatment, such as no more than 12 weeks. In one aspect, the treatment comprises administering at least two direct acting antiviral agents to a subject with HCV infection, wherein the treatment lasts for 12 weeks and does not include administration of either interferon or ribavirin, and said at least two direct acting antiviral agents comprise (a) Compound 1 or a pharmaceutically acceptable salt thereof and (b) Compound 2 or a pharmaceutically acceptable salt thereof.	WO2015153793	Use	Abbvie Inc	Yes	

Patent status

Patent status/countries	Low, Low- middle and upper-middle	High income
Granted	Mexico	Australia, Japan, United States of America
Filed	China, Albania, North Macedonia, Serbia, Türkiye	Canada, Belgium, Germany, France, Luxembourg, Netherlands, Switzerland, United Kingdom, Sweden, Italy, Austria, Liechtenstein, Greece, Finland, Hungary, Iceland, Ireland, Norway, Poland, Portugal, Romania, San Marino, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Latvia, Lithuania, Malta, Monaco, Slovakia, Slovenia, Spain

Patent status/countries	Low, Low- middle and upper-middle	High income
Not in force	World Intellectual Property Organization (WIPO), China, Bosnia and Herzegovina, Montenegro, Brazil	Australia, Japan, United States of America, World Intellectual Property Organization (WIPO)

MPP Licence(s)

MPP licence on Glecaprevir/Pibrentasvir (G/P)

https://medicinespatentpool.org/licence-post/glecaprevir-pibrentasvir-g-p/

Patent and know-how licence on long-acting formulations using Tandem Nano's emulsion-templated freeze-drying technology (ETFD)

https://medicinespatentpool.org/licence-post/long-acting-technologies-for-hcv-tb-and-malaria-treatment

Patent informations

Patent description	Representative patent	Categories	Patent holder	Licence with MPP	Patent source
Glecaprevir/Pibrentasvir and RBV use in HCV (without IFN) II Expiry date: 2035-04-01 The present invention features interferon-free therapies for the treatment of HCV. Preferably, the treatment is over a shorter duration of treatment, such as no more than 12 weeks. In one aspect, the treatment comprises administering at least two direct acting antiviral agents and ribavirin to a subject with HCV infection, wherein the treatment lasts for 12 weeks and does not include administration of interferon, and said at least two direct acting antiviral agents comprise (a) Compound 1 or a pharmaceutically acceptable salt thereof and (b) Compound 2 or a pharmaceutically acceptable salt thereof.	WO2015153792	Use	Abbvie Inc	Yes	

Patent status

Patent status/countries	Low, Low- middle and upper-middle	High income
Granted		
Filed		Taiwan, Province of China

Patent status/countries	Low, Low- middle and upper-middle	High income
Not in force	World Intellectual Property Organization (WIPO), China, Mexico, Albania, North Macedonia, Serbia, Türkiye, Bosnia and Herzegovina, Montenegro	Australia, Canada, Japan, United States of America, World Intellectual Property Organization (WIPO), Belgium, Germany, France, Finland, Greece, Hungary, Iceland, Ireland, Italy, Netherlands, Norway, Poland, Portugal, Romania, San Marino, Austria, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Monaco, Slovakia, Slovenia, Spain, Sweden, Switzerland, United Kingdom

MPP Licence(s)

MPP licence on Glecaprevir/Pibrentasvir (G/P)

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Patent and know-how licence on long-acting formulations using Tandem Nano's emulsion-templated freeze-drying technology (ETFD)

https://medicinespatentpool.org/licence-post/long-acting-technologies-for-hcv-tb-and-malaria-treatment

Patent informations

Patent description	Representative patent	Categories	Patent holder	Licence with MPP	Patent source
Glecaprevir/Pibrentasvir use in HCV (without IFN or RBV) Expiry date: 2034-03-14 The present invention features interferon- and ribavirin-free therapies for the treatment of HCV. Preferably, the treatment is over a shorter duration of treatment, such as no more than 12 weeks. In one aspect, the treatment comprises administering at least two direct acting antiviral agents without interferon and ribavirin to a subject with HCV infection, wherein the treatment lasts for 12 weeks, and said at least two direct acting antiviral agents comprise (a) Compound 1 or a pharmaceutically acceptable salt thereof and (b) Compound 2 or a pharmaceutically acceptable salt thereof.	WO2014152514	Use	Abbvie Inc	Yes	

Patent status

Patent status/countries	Low, Low- middle and upper-middle	High income
Granted	Brazil, Mexico, Serbia, South Africa, Turkmenistan, Belarus, Tajikistan, Kazakhstan, Azerbaijan, Kyrgyzstan, Armenia, Türkiye, North Macedonia, Albania	Canada, Australia, Cyprus, Denmark, Spain, Israel, Japan, Korea, Republic of, New Zealand, Poland, Portugal, Slovenia, Belgium, Germany, France, Luxembourg, Netherlands, Switzerland, Russian Federation, United Kingdom, Sweden, Italy, Austria, Liechtenstein, Greece, Monaco, Ireland, Finland, Bulgaria, Czechia, Estonia, Slovakia, Hungary, Iceland, Malta, Norway, San Marino, Croatia, Romania, Latvia, Lithuania

Patent status/countries	Low, Low- middle and upper-middle	High income
Filed	Serbia, Türkiye, North Macedonia, Albania	Cyprus, Denmark, Spain, Hong Kong, Korea, Republic of, Poland, Portugal, Singapore, Slovenia, Belgium, Germany, France, Luxembourg, Netherlands, Switzerland, United Kingdom, Sweden, Italy, Austria, Liechtenstein, Greece, Monaco, Ireland, Finland, Bulgaria, Czechia, Estonia, Slovakia, Hungary, Iceland, Malta, Norway, San Marino, Croatia, Romania, Latvia, Lithuania
Not in force	World Intellectual Property Organization (WIPO), China, Mexico, Serbia, Turkmenistan, Belarus, Tajikistan, Kazakhstan, Azerbaijan, Kyrgyzstan, Armenia, Türkiye, North Macedonia, Albania, Bosnia and Herzegovina, Montenegro	Cyprus, Denmark, Spain, Japan, Poland, Portugal, Slovenia, Taiwan, Province of China, United States of America, World Intellectual Property Organization (WIPO), Belgium, Germany, France, Luxembourg, Netherlands, Switzerland, Russian Federation, United Kingdom, Sweden, Italy, Austria, Liechtenstein, Greece, Monaco, Ireland, Finland, Bulgaria, Czechia, Estonia, Slovakia, Hungary, Iceland, Malta, Norway, San Marino, Croatia, Romania, Latvia, Lithuania

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https://medicinespatentpool.org/licence-post/glecaprevir-pibrentasvir-g-p/

Patent and know-how licence on long-acting formulations using Tandem Nano's emulsion-templated freeze-drying technology (ETFD)

https://medicinespatentpool.org/licence-post/long-acting-technologies-for-hcv-tb-and-malaria-treatment

Patent informations

Patent description	Representative patent	Categories	Patent holder	Licence with MPP	Patent source
Glecaprevir/Pibrentasvir and RBV use in HCV (without IFN) Expiry date: 2034-03-14 The present invention features interferon -free therapies for the treatment of HCV. Preferably, the treatment is over a shorter duration of treatment, such as no more than 12 weeks. In one aspect, the treatment comprises administering at least two direct acting antiviral agents and ribavirin to a subject with HCV infection, wherein the treatment lasts for 12 weeks and does not include administration of interferon, and said at least two direct acting antiviral agents comprise (a) Compound 1 and (b) Compound 2 or a pharmaceutically acceptable salt thereof as disclosed in the description.	WO2014152635	Use	Abbvie Inc	Yes	

Patent status

Patent status/countries	Low, Low- middle and upper-middle	High income
Granted	Serbia, South Africa	Israel, Korea, Republic of
Filed		Canada, Denmark, Spain, Hong Kong, Croatia, Israel, Poland, Portugal, Singapore, Slovenia, Taiwan, Province of China, Norway, Cyprus

Patent status/countries	Low, Low- middle and upper-middle	High income
Not in force	World Intellectual Property Organization (WIPO), Brazil, China, Mexico, Serbia, Turkmenistan, Belarus, Tajikistan, Kazakhstan, Azerbaijan, Kyrgyzstan, Armenia, Türkiye, North Macedonia, Albania, Bosnia and Herzegovina, Montenegro	Australia, Denmark, Spain, Hong Kong, Croatia, Japan, New Zealand, Poland, Portugal, Slovenia, Taiwan, Province of China, United States of America, World Intellectual Property Organization (WIPO), Russian Federation, Norway, Cyprus, Belgium, Germany, France, Luxembourg, Netherlands, Switzerland, United Kingdom, Sweden, Italy, Austria, Liechtenstein, Greece, Monaco, Ireland, Finland, Bulgaria, Czechia, Estonia, Slovakia, Hungary, Iceland, Malta, San Marino, Romania, Latvia, Lithuania

MPP Licence(s)

MPP licence on Glecaprevir/Pibrentasvir (G/P)

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https://medicinespatentpool.org/licence-post/long-acting-technologies-for-hcv-tb-and-malaria-treatment

Patent informations

Patent description	Representative patent	Categories	Patent holder	Licence with MPP	Patent source
Pibrentasvir use in HCV Expiry date: 2033-09-17 Pan-genotypic HCV inhibitors are described. This invention also relates to methods of using these inhibitors to treat HCV infection.	WO2014047039	Use	Abbvie Inc	Yes	

Patent status

Patent status/countries	Low, Low- middle and upper-middle	High income
Granted	Brazil, Mexico, South Africa, Türkiye, North Macedonia, Albania, Bosnia and Herzegovina, Montenegro, Serbia	Australia, Japan, New Zealand, Belgium, Germany, France, Luxembourg, Netherlands, Switzerland, United Kingdom, Sweden, Italy, Austria, Liechtenstein, Greece, Spain, Denmark, Monaco, Portugal, Ireland, Finland, Cyprus, Bulgaria, Czechia, Estonia, Slovakia, Hungary, Poland, Iceland, Malta, Norway, San Marino, Croatia, Romania, Latvia, Lithuania, Slovenia
Filed	Mexico, Türkiye, North Macedonia, Albania, Serbia	Canada, Hong Kong, Singapore, Taiwan, Province of China, Belgium, Germany, France, Luxembourg, Netherlands, Switzerland, United Kingdom, Sweden, Italy, Austria, Liechtenstein, Greece, Spain, Denmark, Monaco, Portugal, Ireland, Finland, Cyprus, Bulgaria, Czechia, Estonia, Slovakia, Hungary, Poland, Iceland, Malta, Norway, San Marino, Croatia, Romania, Latvia, Lithuania, Slovenia
Not in force	World Intellectual Property Organization (WIPO), China, Bosnia and Herzegovina, Montenegro	Japan, United States of America, World Intellectual Property Organization (WIPO), Russian Federation

MPP Licence(s)

MPP licence on Glecaprevir/Pibrentasvir (G/P)

https://medicinespatentpool.org/licence-post/glecaprevir-pibrentasvir-g-p/

Patent and know-how licence on long-acting formulations using Tandem Nano's emulsion-templated freeze-drying technology (ETFD)

https://medicinespatentpool.org/licence-post/long-acting-technologies-for-hcv-tb-and-malaria-treatment

Patent informations

Patent description	Representative patent	Categories	Patent holder	Licence with MPP	Patent source
Carrier liquids and methods of producing such liquids Expiry date: 2032-08-20 The invention provides a method for the preparation of a carrier liquid which comprises the steps of: (I) preparing a single phase solution comprising: (a) a solvent or a mixture of miscible solvents, (b) a liquid carrier material, which is soluble in solvent (a), and (c) a dopant material which is also soluble in solvent (a); (II) cooling (preferably freezing) the single phase solution produced in step (I) to a temperature at which at least both the solvent (a) and carrier material (b) become solid; and (III) removing solid solvent (a) from the cooled (frozen) single phase solution in vapour form, such that the remaining cooled (frozen) carrier material (b) and dopant material (c) are returned to ambient temperature thus providing a product of liquid carrier material (b) having dopant material (c) dispersed therein.	WO2013030535	Process	IOTA NANOSOLUTIONS LIMITED	Yes	

Patent status

Patent status/countries	Low, Low- middle and upper-middle	High income
Granted	India	United Kingdom, Hungary, France, Ireland, Germany, United States of America
Filed		

Patent status/countries	Low, Low- middle and upper-middle	High income
Not in force	World Intellectual Property Organization (WIPO), Albania, Serbia, Bosnia and Herzegovina, Montenegro, Türkiye, North Macedonia	World Intellectual Property Organization (WIPO), Liechtenstein, Italy, Norway, Malta, Denmark, Belgium, United Kingdom, Greece, Netherlands, Croatia, Switzerland, Spain, San Marino, Slovenia, Austria, Romania, Iceland, Cyprus, Finland, Bulgaria, Slovakia, Poland, Latvia, Estonia, Luxembourg, Portugal, Czechia, Lithuania, Monaco, Sweden

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Patent informations

Patent description	Representative patent	Categories	Patent holder	Licence with MPP	Patent source
Pibrentasvir compound II Expiry date: 2032-02-24 Compounds effective in inhibiting replication of Hepatitis C virus ("HCV") are described. This invention also relates to processes of making such compounds, compositions comprising such compounds, and methods of using such compounds to treat HCV infection.	WO2012116257	Compound	Abbvie Inc	Yes	

Patent status

Patent status/countries	Low, Low- middle and upper-middle	High income
Granted	China, Mexico	Taiwan, Province of China, Spain, Germany, France, United Kingdom, Italy
Filed		Spain
Not in force	World Intellectual Property Organization (WIPO), Türkiye, North Macedonia, Albania, Bosnia and Herzegovina, Montenegro, Serbia	Canada, Japan, United States of America, World Intellectual Property Organization (WIPO), Belgium, Luxembourg, Netherlands, Switzerland, Sweden, Austria, Liechtenstein, Greece, Denmark, Monaco, Portugal, Ireland, Finland, Cyprus, Bulgaria, Czechia, Estonia, Slovakia, Hungary, Poland, Iceland, Malta, Norway, San Marino, Croatia, Romania, Latvia, Lithuania, Slovenia

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Patent informations

Patent description	Representative patent	Categories	Patent holder	Licence with MPP	Patent source
Pibrentasvir compound Expiry date: 2031-10-12 Compounds effective in inhibiting replication of Hepatitis C virus (HCV) are described. This invention also relates to processes of making such compounds, compositions comprising such compounds, and methods of using such compounds to treat HCV infection.	WO2012051361	Compound	Abbott Laboratories	Yes	

Patent status

Patent status/countries	Low, Low- middle and upper-middle	High income
Granted	Colombia, Argentina, China, Dominican Republic, Turkmenistan, Belarus, Tajikistan, Kazakhstan, Azerbaijan, Kyrgyzstan, Armenia, Moldova, Republic of, Ecuador, Türkiye, North Macedonia, Albania, Bosnia and Herzegovina, Montenegro, Serbia, Mexico, Peru, Ukraine, Bolivia (Plurinational State of), Indonesia, Malaysia, Philippines, Viet Nam, South Africa, Brazil	United States of America, Australia, Chile, Japan, Korea, Republic of, New Zealand, Singapore, Taiwan, Province of China, Uruguay, Denmark, Spain, Portugal, Slovenia, Canada, Israel, Hong Kong, Russian Federation, Belgium, Germany, France, Luxembourg, Netherlands, Switzerland, United Kingdom, Sweden, Italy, Austria, Liechtenstein, Greece, Monaco, Ireland, Finland, Cyprus, Bulgaria, Czechia, Estonia, Slovakia, Hungary, Poland, Iceland, Malta, Norway, Croatia, Romania, Latvia, Lithuania, Panama

Patent status/countries	Low, Low- middle and upper-middle	High income
Filed	Costa Rica, Ecuador, Türkiye, North Macedonia, Albania, Bosnia and Herzegovina, Montenegro, Serbia, India, Bolivia (Plurinational State of), Mongolia, Pakistan, Paraguay, Thailand, Venezuela (Bolivarian Republic of), Guatemala	Denmark, Spain, Portugal, Slovenia, Belgium, Germany, France, Luxembourg, Netherlands, Switzerland, United Kingdom, Sweden, Italy, Austria, Liechtenstein, Greece, Monaco, Ireland, Finland, Cyprus, Bulgaria, Czechia, Estonia, Slovakia, Hungary, Poland, Iceland, Malta, Norway, San Marino, Croatia, Romania, Latvia, Lithuania, Bahrain, Kuwait, Qatar, Saudi Arabia, Oman, United Arab Emirates
Not in force	World Intellectual Property Organization (WIPO), Costa Rica, Argentina, China, Turkmenistan, Belarus, Tajikistan, Kazakhstan, Azerbaijan, Kyrgyzstan, Armenia, Moldova, Republic of, Türkiye, North Macedonia, Albania, Bosnia and Herzegovina, Montenegro, Serbia, Mexico, Peru, Egypt, Viet Nam	United States of America, World Intellectual Property Organization (WIPO), Chile, New Zealand, Uruguay, Denmark, Spain, Portugal, Slovenia, Canada, Russian Federation, Belgium, Germany, France, Luxembourg, Netherlands, Switzerland, United Kingdom, Sweden, Italy, Austria, Liechtenstein, Greece, Monaco, Ireland, Finland, Cyprus, Bulgaria, Czechia, Estonia, Slovakia, Hungary, Poland, Iceland, Malta, Norway, San Marino, Croatia, Romania, Latvia, Lithuania

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Patent informations

Patent description	Representative patent	Categories	Patent holder	Licence with MPP	Patent source
Glecaprevir compound Expiry date: 2031-09-20 The present invention discloses compounds of Formula (I) or pharmaceutically acceptable salts, esters, or prodrugs thereof: Formula (I) which inhibit serine protease activity, particularly the activity of hepatitis C virus (HCV) NS3-NS4A protease. Consequently, the compounds of the present invention interfere with the life cycle of the hepatitis C virus and are also useful as antiviral agents. The present invention further relates to pharmaceutical compositions comprising the aforementioned compounds for administration to a subject suffering from HCV infection. The invention also relates to methods of treating an HCV infection in a subject by administering a pharmaceutical composition comprising the compounds of the present invention.	WO2012040167	Compound	Enanta Pharmaceuticals, Inc	Yes	

Patent status

Patent status/countries	Low, Low- middle and upper-middle	High income

Granted	Argentina, Brazil, China, Colombia, Costa Rica, Dominican Republic, Turkmenistan, Belarus, Tajikistan, Kazakhstan, Azerbaijan, Kyrgyzstan, Armenia, Moldova, Republic of, Ecuador, Türkiye, North Macedonia, Albania, Bosnia and Herzegovina, Montenegro, Serbia, Guatemala, Mexico, Peru, South Africa, India, Bolivia (Plurinational State of), Mongolia, Philippines, Malaysia, Pakistan, Indonesia, Ukraine	Canada, Australia, Cyprus, Denmark, Spain, Hong Kong, Croatia, Israel, Japan, Korea, Republic of, New Zealand, Portugal, Singapore, Slovenia, San Marino, United States of America, Chile, Russian Federation, Belgium, Germany, France, Luxembourg, Netherlands, Switzerland, United Kingdom, Sweden, Italy, Austria, Liechtenstein, Greece, Monaco, Ireland, Finland, Bulgaria, Czechia, Estonia, Slovakia, Hungary, Poland, Iceland, Malta, Norway, Romania, Latvia, Lithuania, Uruguay, Panama, Bahrain, Kuwait, Qatar, Saudi Arabia, Oman, United Arab Emirates, Macao
Filed	Argentina, India, Paraguay, Viet Nam, Venezuela (Bolivarian Republic of), Thailand	Cyprus, Denmark, Spain, Croatia, Portugal, Slovenia, San Marino, Taiwan, Province of China, Luxembourg, Netherlands, Hungary, Poland, Norway, Lithuania, Bahrain, Kuwait, Qatar, Saudi Arabia, Oman, United Arab Emirates
Not in force	World Intellectual Property Organization (WIPO), Colombia, Costa Rica, Dominican Republic, Ecuador, Türkiye, North Macedonia, Albania, Bosnia and Herzegovina, Montenegro, Serbia, Guatemala, Egypt, Malaysia, Indonesia	Australia, Cyprus, Denmark, Spain, Croatia, Japan, Korea, Republic of, Portugal, Slovenia, San Marino, United States of America, World Intellectual Property Organization (WIPO), Belgium, Germany, France, Luxembourg, Netherlands, Switzerland, United Kingdom, Sweden, Italy, Austria, Liechtenstein, Greece, Monaco, Ireland, Finland, Bulgaria, Czechia, Estonia, Slovakia, Hungary, Poland, Iceland, Malta, Norway, Romania, Latvia, Lithuania, Uruguay, Bahrain, Kuwait, Qatar, Saudi Arabia, Oman, United Arab Emirates

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Patent informations

Patent description	Representative patent	Categories	Patent holder	Licence with MPP	Patent source
Nanodispersions of anti-viral drugs Expiry date: 2031-04-08 The invention provides a composition and an antiviral drug preparation, each comprising at least one water-insoluble antiviral drug and at least one water-soluble carrier material, wherein the water-insoluble antiviral drug is dispersed through the water-soluble carrier material in nano-disperse form. The present invention further provides processes for preparing the compositions and drug preparations, and also aqueous nano-dispersions obtained by combining water and the compositions.	WO2011128623	Composition, Process	Duncalf, David John, Foster, Alison Jayne, Iota Nanosolutions Limited, Long, James, Rannard, Steven Paul, Wang, Dong	Yes	

Patent status

Patent status/countries	Low, Low- middle and upper-middle	High income
Granted	India	Liechtenstein, Belgium, United Kingdom, Switzerland, Cyprus, France, Ireland, Germany, Luxembourg, Monaco, Israel, United States of America
Filed		
Not in force	World Intellectual Property Organization (WIPO), China, Albania, Serbia, Bosnia and Herzegovina, Montenegro, Türkiye, North Macedonia	World Intellectual Property Organization (WIPO), Canada, Italy, Norway, Malta, Denmark, United Kingdom, Greece, Netherlands, Hungary, Croatia, Spain, San Marino, Slovenia, Austria, Romania, Iceland, Finland, Bulgaria, Slovakia, Poland, Latvia, Estonia, Portugal, Czechia, Lithuania, Sweden, Japan

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Patent informations

Patent description	Representative patent	Categories	Patent holder	Licence with MPP	Patent source
Anti-parasitic nano-dispersed compositions Expiry date: 2027-06-29 The present invention relates to nanodisperse antiparasitcs and provides a composition comprising at least one water insoluble anti-parasitic drug and a water-soluble carrier material, wherein the water-insoluble anti-parasitic drug (preferably an Artemisinin-type drug or a quinine type drug) is dispersed through the carrier material in nano-disperse form having a peak diameter of the nano-disperse form below 1000nm	WO2008006713	Composition	Duncalf, David, John, Essa, Asha, Hassan, Foster, Alison, Jayne, Long, James, Rannard, Steven, Paul, Unilever N.V, Unilever Plc, Wang, Dong	Yes	

Patent status

Patent status/countries	Low, Low- middle and upper-middle	High income
Granted	South Africa, Congo, Mauritania, Guinea-Bissau, Niger, Senegal, Cameroon, Mali, Togo, Burkina Faso, Benin, Côte d'Ivoire, Central African Republic, Guinea, Gabon, Equatorial Guinea, Chad	Canada, Liechtenstein, Italy, Belgium, United Kingdom, Netherlands, Hungary, Croatia, Switzerland, Spain, Austria, France, Ireland, Germany, Sweden, United States of America
Filed		

Patent status/countries	Low, Low- middle and upper-middle	High income
Not in force	World Intellectual Property Organization (WIPO), Argentina, Brazil, China, Albania, Serbia, Bosnia and Herzegovina, Türkiye, North Macedonia, Mexico, South Africa, India, Sierra Leone, Eswatini, Namibia, Mozambique, Uganda, Zambia, Zimbabwe, Tanzania, United Republic of, Malawi, Ghana, Sudan, Botswana, Lesotho, Kenya, Gambia (the), Indonesia	World Intellectual Property Organization (WIPO), Australia, Canada, Chile, Liechtenstein, Italy, Malta, Denmark, Belgium, United Kingdom, Greece, Netherlands, Hungary, Croatia, Switzerland, Spain, Slovenia, Austria, Romania, Iceland, Cyprus, Finland, France, Bulgaria, Slovakia, Poland, Latvia, Ireland, Estonia, Germany, Luxembourg, Portugal, Czechia, Lithuania, Monaco, Sweden, Japan, United States of America, Israel

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Supporting material

Publications

Perazzolo S, Stephen ZR, Eguchi M, Xu X, Delle Fratte R, Collier AC, Melvin AJ, Ho RJY. A novel formulation enabled transformation of 3-HIV drugs tenofovir-lamivudine-dolutegravir from short-acting to long-acting all-in-one injectable. AIDS. 2023 Nov 15;37(14):2131-2136. DOI: 10.1097/QAD.0000000000003706. Epub 2023 Aug 24. PMID: 37650755; PMCID: PMC10959254.

Objective: To develop an injectable dosage form of the daily oral HIV drugs, tenofovir (T), lamivudine (L), and dolutegravir (D), creating a single, complete, all-in-one TLD 3-drug-combination that demonstrates long-acting pharmacokinetics.

Design: Using drug-combination-nanoparticle (DcNP) technology to stabilize multiple HIV drugs, the 3-HIV drugs TLD, with disparate physical-chemical properties, are stabilized and assembled with lipid-excipients to form TLD-in-DcNP . TLD-in-DcNP is verified to be stable and suitable for subcutaneous administration. To characterize the plasma time-courses and PBMC concentrations for all 3 drugs, single subcutaneous injections of TLD-in-DcNP were given to nonhuman primates (NHP, M. nemestrina).

Results: Following single-dose TLD-in-DcNP , all drugs exhibited long-acting profiles in NHP plasma with levels that persisted for 4 weeks above predicted viral-effective concentrations for TLD in combination. Times-to-peak were within 24 hr in all NHP for all drugs. Compared to a free-soluble TLD, TLD-in-DcNP provided exposure enhancement and extended duration 7.0-, 2.1-, and 20-fold as AUC boost and 10-, 8.3-, and 5.9-fold as half-life extension. Additionally, DcNP may provide more drug exposure in cells than plasma with PBMC-to-plasma drug ratios exceeding one, suggesting cell-targeted drug-combination delivery.

Conclusions: This study confirms that TLD with disparate properties can be made stable by DcNP to enable TLD concentrations of 4 weeks in NHP. Study results highlighted the potential of TLD-in-DcNP as a convenient all-in-one, complete HIV long-acting product for clinical development.

Additional documents

- Transformation of 3 current short-acting HIV drugs, tenofovir, lamivudine and dolutegravir (TLD)

Useful links

- Targeted Long-Acting Combination Antiretroviral Therapy (TLC-ART) Program Updates Pipeline Report

Access principles

Collaborate for development

Consider on a case by case basis, collaborating on developing long acting products with potential significant public health impact, especially for low- and middle-income countries (LMICs), utilising the referred to long-acting technology

Not provided

Share technical information for match-making assessment

Provide necessary technical information to a potential partner, under confidentiality agreement, to enable preliminary assessment of whether specific medicines of public health importance in LMICs might be compatible with the referred to long-acting technology to achieve a public health benefit

Not provided

Work with MPP to expand access in LMICs

In the event that a product using the referred to long-acting technology is successfully developed, the technology IP holder(s) will work with the Medicines Patent Pool towards putting in place the most appropriate strategy for timely and affordable access in low and middle-income countries, including through licensing

Not provided

Comment & Information

Not provided