The first and only virus-like particle (VLP) vaccine recommended by the ACIP for chikungunya[1-3]

Designed to protect travelers ages 12 and over from chikungunya.[2]

ACIP=Advisory Committee on Immunization Practices.

Vimkunya®
(Chikungunya Vaccine, Recombinant)
Injection

Indications and Usage

VIMKUNYA is a vaccine indicated for the prevention of disease caused by chikungunya virus in individuals 12 years of age and older.

The indication is approved under accelerated approval based on anti-chikungunya virus neutralizing antibody levels. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

Important Safety Information

Contraindications

Do not administer VIMKUNYA to individuals with a history of a severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine.

Please see Important Safety Information for VIMKUNYA on slide 3 and full Prescribing Information available at this presentation.

CHIKUNGUNYA: A debilitating viral disease spread by mosquitoes[4]

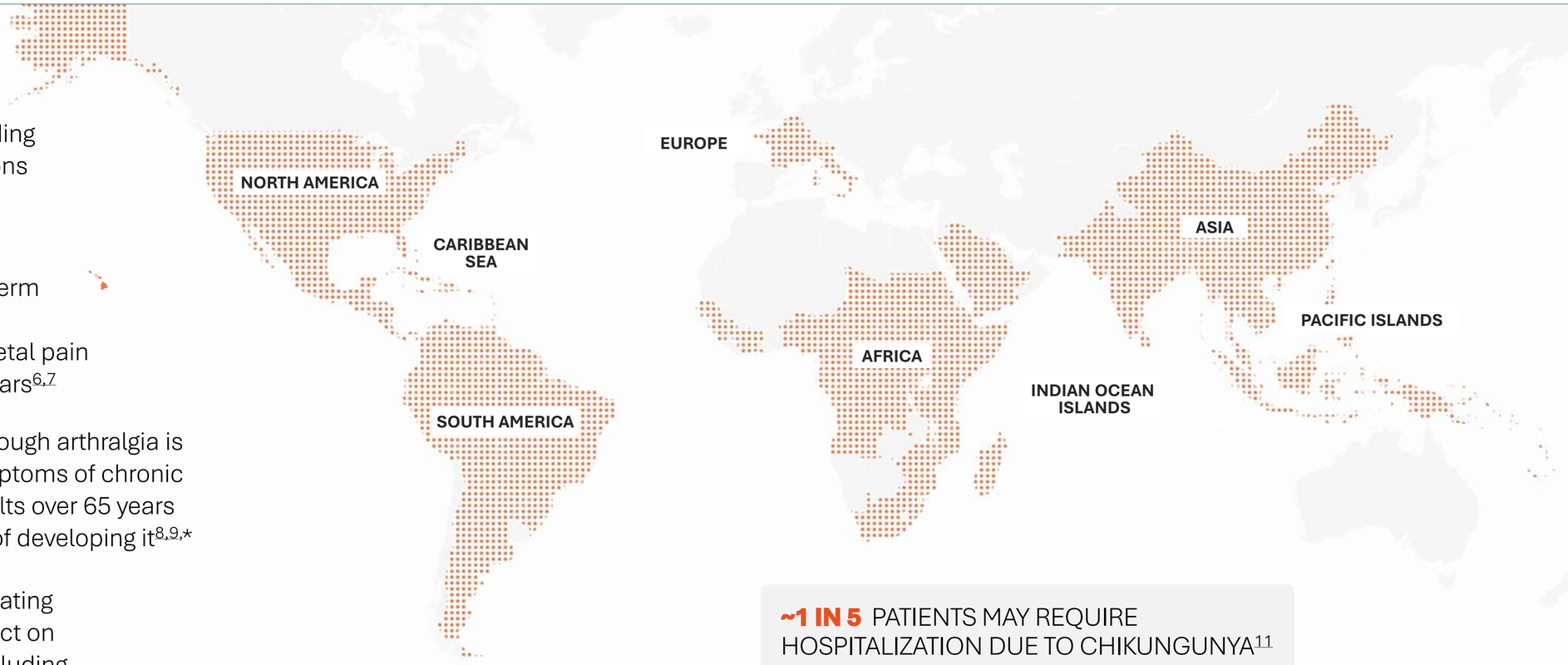
119

Found in 119 countries, including many popular travel destinations in Latin America, Africa, and Southeast Asia[5]

2 in 5 patients can have long-term symptoms like polyarthralgia/ polyarthritis and musculoskeletal pain that last for months or even years[6,7]

Risk of chronic arthralgia: Although arthralgia is one of the most common symptoms of chronic chikungunya, women and adults over 65 years of age may be at a higher risk of developing it[8,9,*]

Severe polyarthralgia: A debilitating long-term symptom with impact on many activities of daily life, including at work and at home, walking, and personal hygiene[10]



~1 IN 5 PATIENTS MAY REQUIRE HOSPITALIZATION DUE TO CHIKUNGUNYA[11]

Regions that have reported chikungunya cases according to the World Health Organization, 2020.[12]

*Based on a cohort of Brazilian chikungunya patients. Of 153 patients, 65 reported chronic arthralgia lasting >3 months. Female sex (RR 1.79, 95% CI 1.20-2.69) and age (RR 1.02 for each 1-year increase, 95% CI: 1.01-1.03) were independent risk factors for chronic arthralgia.[8]

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Indications and Usage

VIMKUNYA is a vaccine indicated for the prevention of disease caused by chikungunya virus in individuals 12 years of age and older.

The indication is approved under accelerated approval based on anti-chikungunya virus neutralizing antibody levels. Continued approval for this indication may be contingent upon verification of clinical benefit in a confirmatory trial.

Important Safety Information

Contraindications
Do not administer VIMKUNYA to individuals with a history of a severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine.

Warnings and Precautions

- Appropriate medical treatment must be immediately available to manage potential anaphylactic reactions.
- Immunocompromised individuals, including individuals receiving immunosuppressive therapy, may have a diminished immune response to VIMKUNYA.
- Syncope (fainting) may occur in association with administration of injectable vaccines including VIMKUNYA. Procedures should be in place to avoid injury from fainting.

Adverse Reactions
In clinical studies, the most common solicited adverse reactions (>10%) in individuals 12 through 64 years of age were pain at the injection site (23.7%), fatigue (19.9%), headache (18%), and myalgia (17.6%). The most commonly reported solicited adverse reactions (>5%) in individuals 65 years of age and older were injection site pain (5.4%), myalgia (6.3%), and fatigue (6.3%).

Use in Specific Populations
There are no clinical studies of VIMKUNYA in pregnant individuals.

To report SUSPECTED ADVERSE REACTIONS, contact Bavarian Nordic Inc. at 1-833-365-9596 or drug.safety@bavarian-nordic.com or VAERS at 1-800-822-7967 or www.vaers.hhs.gov.

Please see full Prescribing Information available at this presentation.

Vimkunya®
(Chikungunya Vaccine, Recombinant)
Injection

The first and only VLP vaccine for chikungunya available in the US[1,2]

VIMKUNYA contains proteins that assemble into virus-like particles (VLPs) that mimic the chikungunya virus but cannot cause disease.[2,13,14]

Discover the science behind
the VLP technology of VIMKUNYA.
Watch the video on the next slide.

1 **MIMICS LIVE VIRUS[2,13,14]**
VIMKUNYA uses VLP technology to mimic live chikungunya virus.

2 **CANNOT INFECT CELLS[13]**
VLP vaccines do not include viral genetic material and cannot infect cells or replicate.

3 **PROVEN IMMUNE RESPONSE[2,13]**
VIMKUNYA aims to elicit a durable immune response. Its immunogenicity and tolerability were assessed in two phase 3 trials.

4 **CLINICALLY ASSESSED SAFETY[2,14-16]**
Assessed in more than 3000 people in 5 clinical studies: three phase 2 studies and two phase 3 studies.

5 **ACIP RECOMMENDED[3]**
The latest ACIP recommendation is clear—chikungunya vaccination matters.

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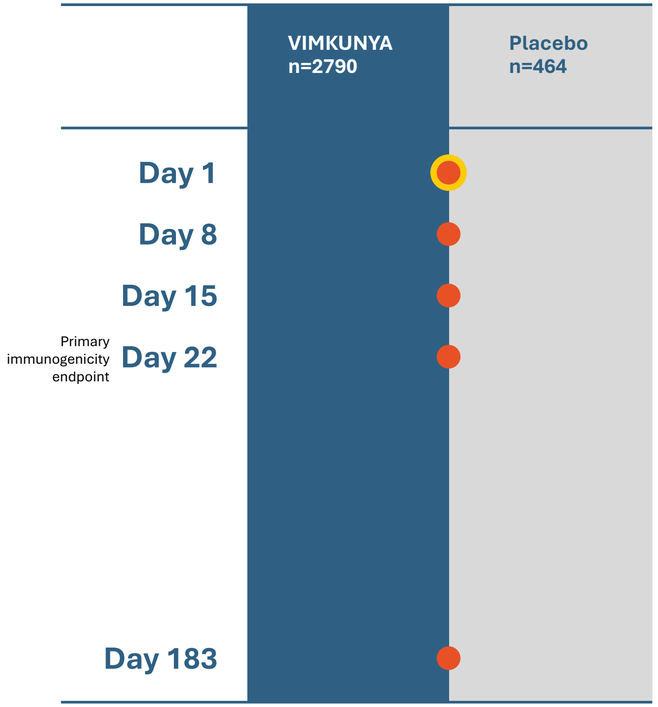
Vimkunya® (Chikungunya Vaccine, Recombinant) Injection

VIMKUNYA immunogenicity and tolerability were assessed in two phase 3 trials[2,17-20]

EBSI-CV-317-004

Adolescents and adults: 12 to <65 years of age



Multicenter, randomized, double-blind, placebo-controlled study.

Co-primary endpoints:

- Safety of VIMKUNYA
- Difference in seroresponse rate at Day 22
- SNA GMT at Day 22
- Lot consistency of SNA GMT at Day 22 (18–45 years of age)

Key secondary endpoints:

- Seroresponse rate at Days 15, 183, and 8
- GMT at Days 15, 183, and 8

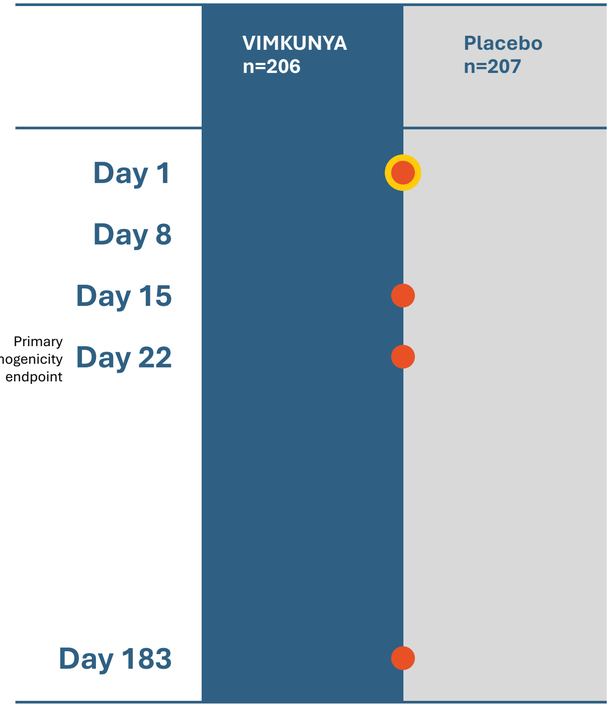
Vaccination with VIMKUNYA or placebo

Blood draw

Safety assessments: Solicited AEs (Day 1–8); Unsolicited AEs (Day 1–29); Serious AEs/AEs of special interest/medically-attended AEs (Day 1–183)

EBSI-CV-317-005

Older adults: ≥65 years of age



Multicenter, randomized, double-blind, placebo-controlled study.

Co-primary endpoints:

- Safety of VIMKUNYA
- Difference in seroresponse rate at Day 22
- SNA GMT at Day 22

Key secondary endpoints:

- Seroresponse rates at Days 15 and 183
- GMT at Days 15 and 183

Vaccination with VIMKUNYA or placebo

Blood draw

Safety assessments: Solicited AEs (Day 1–8); Unsolicited AEs (Day 1–29); Serious AEs/AEs of special interest/medically-attended AEs (Day 1–183)

AEs=adverse events; CHIKV=chikungunya virus; GMT=geometric mean titer; SNA=serum neutralizing antibody.

Please see Important Safety Information for VIMKUNYA on slide 3 and full Prescribing Information available at this presentation.

Vimkunya® (Chikungunya Vaccine, Recombinant) Injection

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(Chikungunya Vaccine, Recombinant)
Injection

Adverse reactions in patients 12 through 64 years of age[2]

Percentages of participants with solicited local and systemic adverse reactions through 7 days after vaccination (12–64 years of age)

ADVERSE REACTION	VIMKUNYA % (N=2790)	Placebo % (N=464)
Solicited Local (Injection Site) Adverse Reactions[a]		
Pain (any)[b]	23.7	10.7
Pain (severe)	0.1	0
Redness/Erythema (≥25 mm)	0.5	0
Redness/Erythema (>100 mm)	<0.1	0
Swelling (≥25 mm)	0.4	0
Solicited Systemic Adverse Reactions[a]		
Fatigue (any)[c]	19.9	17.0
Fatigue (severe)	0.7	0.2
Headache (any)[b]	18.0	16.6
Headache (severe)	0.3	0.4
Myalgia/Muscle Pain (any)[c]	17.6	9.6
Myalgia/Muscle Pain (severe)	0.4	0.4
Chills (any)[c]	8.6	3.3
Chills (severe)	0.1	0
Arthralgia/Joint Pain (any)[c]	7.7	7.2
Arthralgia/Joint Pain (severe)	0.3	0.2
Nausea (any)[d]	7.5	6.6
Nausea (severe)	0.4	0
Fever (≥38.0°C or ≥100.4°F)	0.9	0.2
Fever (≥39.0°C or ≥102.1°F)	0.2	0

Adverse reactions were mostly mild to moderate in patients 12 through 64 years of age

The most common solicited local adverse reaction (>10%) was injection site pain (23.7%). The most common solicited systemic adverse reactions (>10%) were fatigue (19.9%), headache (18.0%), and myalgia (17.6%).

Note: Solicited adverse reactions were collected from the vaccination day through 7 days post-vaccination (an 8-day period). Percentages are based on the number of participants in the Study 1 safety population with at least one diary observation for a given symptom for a given day. Denominators for solicited adverse reactions varied from 2760–2765 for VIMKUNYA and 457–458 for placebo.

[a] Severity=mild, moderate, severe intensity. Absence of rows for severe reactions indicates that no reactions of this severity were reported in either group.

[b] Defined as mild (no interference with activity), moderate (repeated use of non-narcotic pain reliever >24 hours or interference with activity), severe (any use of narcotic pain reliever or prevents daily activity).

[c] Defined as mild (no interference with activity), moderate (some interference with activity), severe (prevents daily activity).

[d] Defined as mild (no interference with activity or 1–2 episodes/24 hours), moderate (some interference with activity or >2 episodes/24 hours), severe (prevents daily activity, requires outpatient intravenous hydration).

Please see Important Safety Information for VIMKUNYA on slide 3 and full Prescribing Information available at this presentation.

Vimkunya®
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Injection

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Injection

Adverse reactions in patients 65 years of age and older[2]

Percentages of participants with solicited local and systemic adverse reactions through 7 days after vaccination (≥65 years of age)

ADVERSE REACTION	VIMKUNYA % (N=205)	Placebo % (N=200)
Solicited Local (Injection Site) Adverse Reactions[a]		
Pain (any)[b]	5.4	1.5
Redness/Erythema (≥25 mm)	0	0.5
Swelling (≥25 mm)	0	0
Solicited Systemic Adverse Reactions[a]		
Myalgia/Muscle Pain (any)[c]	6.3	6.5
Fatigue (any)[c]	6.3	6.0
Fatigue (severe)	0.5	0
Headache (any)[b]	4.4	7.5
Headache (severe)	0.5	0
Arthralgia/Joint Pain (any)[c]	2.9	4.0
Chills (any)[c]	2.9	3.0
Nausea (any)[d]	2.9	1.5
Fever (≥38.0°C or ≥100.4°F)	0	1.0

Adverse reactions were mostly mild to moderate in patients 65 years of age and older

The most common solicited local adverse reaction (>5%) was injection site pain (5.4%). The most common solicited systemic adverse reactions (>5%) were myalgia (6.3%) and fatigue (6.3%).

Note: Solicited adverse reactions were collected from the vaccination day through 7 days post-vaccination (an 8-day period). N=Number of participants in the Study 2 safety population with at least one diary observation for a given symptom for a given day.

[a] Severity=mild, moderate, severe intensity. Absence of rows for severe reactions indicates that no reactions of this severity were reported in either group.

[b] Defined as mild (no interference with activity), moderate (repeated use of non-narcotic pain reliever >24 hours or interference with activity), severe (any use of narcotic pain reliever or prevents daily activity).

[c] Defined as mild (no interference with activity), moderate (some interference with activity), severe (prevents daily activity).

[d] Defined as mild (no interference with activity or 1–2 episodes/24 hours), moderate (some interference with activity or >2 episodes/24 hours), severe (prevents daily activity, requires outpatient intravenous hydration).

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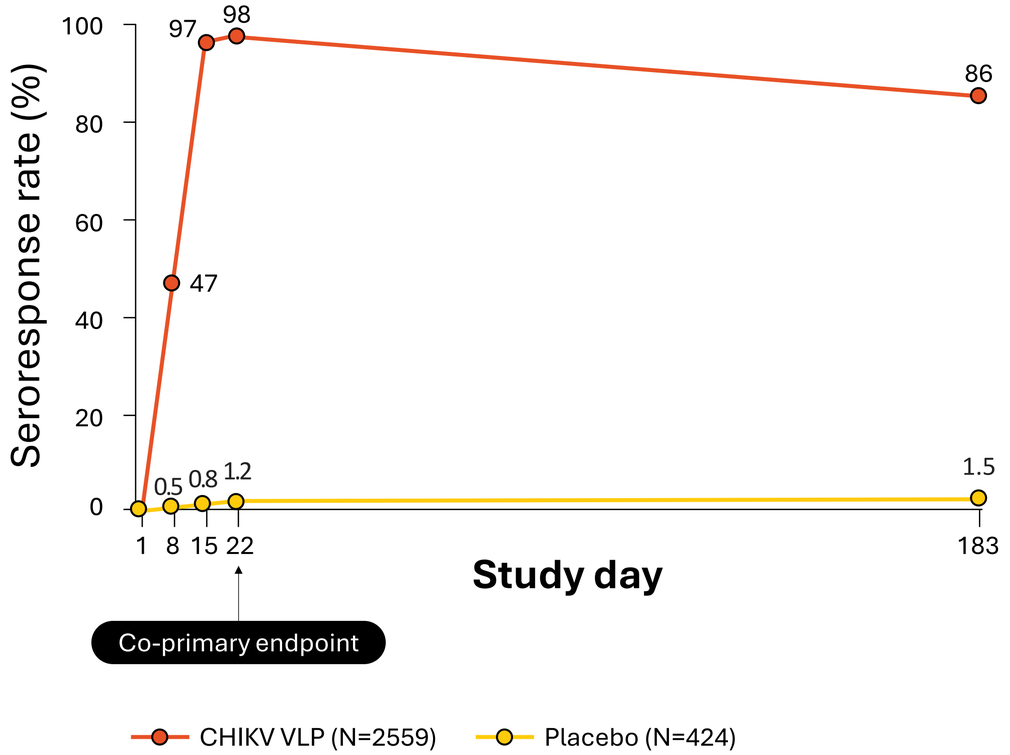
With VIMKUNYA, almost all patients achieved a durable seroresponse at 3 weeks[2,17]

Anti-chikungunya SNA response rate

In adult (≥18 to <65 years of age) and adolescent (12 to <18 years of age) patients[2,17]*



*Seroresponse rate (considered the presumptive seroprotection rate) was defined as the percentage of subjects who achieved an anti-chikungunya SNA NT_{80} titer ≥100.[17]

NT_{80}=80% neutralization titer; SNA=serum neutralizing antibody.

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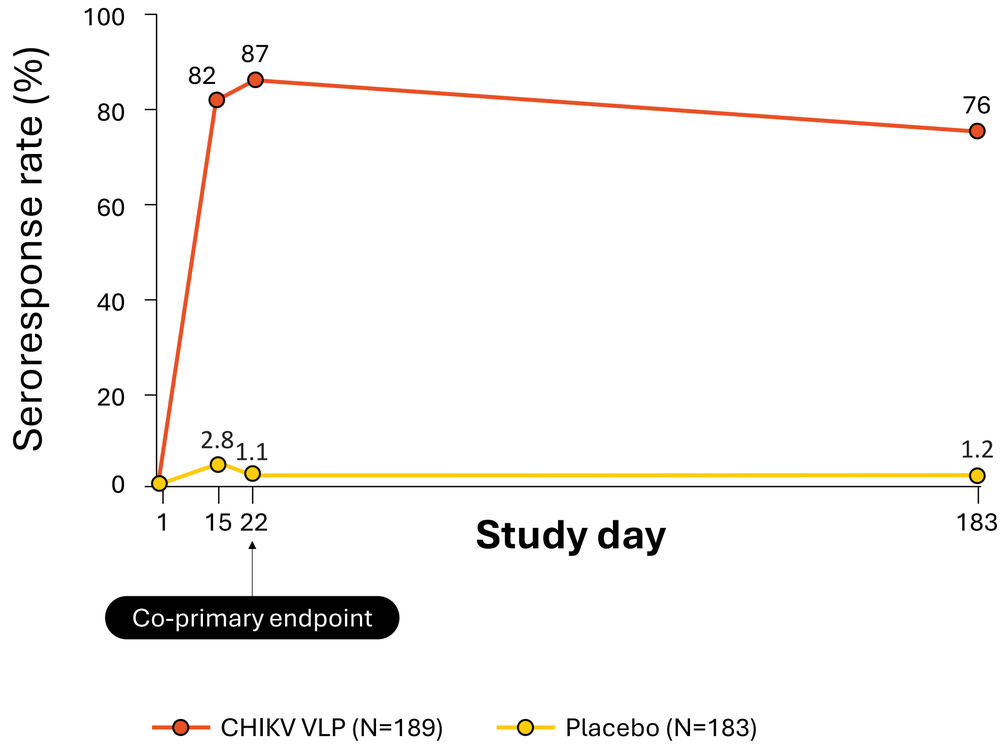
In older adults, VIMKUNYA also achieved a durable seroresponse at 3 weeks[2,19]

82% of older adults demonstrated a seroresponse in 2 weeks.[2,19]

Anti-chikungunya SNA response rate

In older adult (≥65 years of age) patients[2,19,*]



*Seroresponse rate (considered the presumptive seroprotection rate) was defined as the percentage of subjects who achieved an anti-chikungunya SNA NT_{80} titer ≥100.[19]

NT_{80}=80% neutralization titer; SNA=serum neutralizing antibody.

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Injection

Vimkunya®
(Chikungunya Vaccine, Recombinant)
Injection

VIMKUNYA helps protect your patients from chikungunya with a single-dose pre-filled syringe[2]

ADMINISTRATION

VIMKUNYA is administered as a single 0.8 mL intramuscular dose from a pre-filled syringe.

NO RECONSTITUTION

There's no need to reconstitute VIMKUNYA before use. Once opened, simply shake, attach a needle, and inject. See full Prescribing Information for complete administration instructions.

CONTRAINDICATIONS

Do not administer VIMKUNYA to individuals with a history of a severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine.

VIMKUNYA is the only chikungunya vaccine available in a pre-filled syringe[2,21]

Please see Important Safety Information for VIMKUNYA on slide 3 and full Prescribing Information available at this presentation.

Vimkunya®
(Chikungunya Vaccine, Recombinant)
Injection

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