

# DISCOVER BIMZELX®

A first-of-its-kind treatment for adults with active psoriatic arthritis (*PsA*), active non-radiographic axial spondyloarthritis (*nr-axSpA*) with objective signs of inflammation, and active ankylosing spondylitis (*AS*)\*

SEE ALL THE BENEFITS AND SAFETY INFORMATION AT **BIMZELX.com** 

\*BIMZELX is the only FDA-approved biologic that selectively inhibits the two immune system proteins IL-17A & IL-17F (interleukins), key drivers of inflammation.

#### USE

BIMZELX® is a prescription medicine used to treat adults with active psoriatic arthritis, active non-radiographic axial spondyloarthritis with objective signs of inflammation, and active ankylosing spondylitis.

#### **IMPORTANT SAFETY INFORMATION**

BIMZELX® is a medicine that affects your immune system and may increase your risk of serious side effects, including suicidal thoughts and behavior, serious infections including tuberculosis, liver problems, and inflammatory bowel disease.



# BIMZELX<sup>®</sup> (bimekizumab-bkzx) TREATS *PsA* AT THE SOURCE

BIMZELX is the only FDA-approved biologic that selectively targets IL-17A and IL-17F, two of the key proteins that trigger the symptoms associated with *PsA*, to calm inflammation.

### IN COMBINED CLINICAL TRIALS FOR PsA:\*

### MORE THAN 4 IN 10 PEOPLE SAW 50% OR GREATER IMPROVEMENT IN THEIR JOINT PAIN, SWELLING, AND STIFFNESS

44% of people taking BIMZELX saw at least 50% improvement in *PsA* symptoms at 16 weeks vs 9% of people taking placebo.



### MOST PEOPLE SAW 90% CLEARER SKIN, MANY SAW 100% CLEAR SKIN

Of those with *PsA* and psoriasis in these studies, 65% of people taking BIMZELX saw 90% clearer skin at 16 weeks vs 4% of people taking placebo. 52% of people taking BIMZELX saw 100% clear skin at 16 weeks vs 3% of people taking placebo.

# MOST PEOPLE FELT

52% of people taking BIMZELX felt an improvement in fatigue at 16 weeks vs 36% of people taking placebo, as reported using a tool called the Functional Assessment of Chronic Illness Therapy-Fatigue, or FACIT-Fatigue.

### PEOPLE EXPERIENCED IMPROVEMENT IN **QUALITY OF LIFE** AT 16 WEEKS

People taking BIMZELX reported greater improvements in their ability to perform everyday activities like climbing stairs and carrying groceries vs people taking placebo.

\*Results are from a 160 mg dose of BIMZELX, given as an injection under the skin every 4 weeks. Results may vary. Every person responds to treatment differently.

#### USE

BIMZELX® is a prescription medicine used to treat adults with active psoriatic arthritis, active non-radiographic axial spondyloarthritis with objective signs of inflammation, and active ankylosing spondylitis.

#### IMPORTANT SAFETY INFORMATION

Suicidal thoughts and behavior have happened in some people treated with BIMZELX. Get medical help right away or call the National Suicide and Crisis Lifeline at 988 if you, your caregiver, or your family member notice in you any symptoms.

## BIMZELX® TREATS **nr-axSpA** AND AS FROM WITHIN

BIMZELX is the only FDA-approved biologic that selectively targets IL-17A and IL-17F, two of the key proteins that trigger the inflammation associated with *nr-axSpA* and *AS*.

# $\langle \rangle$

### FOR PEOPLE WITH *nr-axSpA* OR *AS*, **40% OR GREATER IN BACK PAIN, STIFFNESS, AND SPINAL INFLAMMATION IS POSSIBLE**

In 2 separate clinical studies, at least 40% symptom improvement was achieved by 48% of people with *nr-axSpA* taking BIMZELX vs 21% of people taking placebo, and 45% of people with *AS* taking BIMZELX vs 23% of people taking placebo.

## IN SEPARATE **nr-axSpA OR AS CLINICAL TRIALS**\*

# PEOPLE FELT

People taking BIMZELX reported a greater reduction in fatigue compared to people taking placebo at 16 weeks, as reported using a tool called the Bath Ankylosing Spondylitis Disease Activity Index, or BASDAI.



People taking BIMZELX reported greater improvements in their ability to perform everyday activities like climbing stairs and carrying groceries vs people taking placebo.

\*Results are from a 160 mg dose of BIMZELX, given as an injection under the skin every 4 weeks. Results may vary. Every person responds to treatment differently.

#### USE

BIMZELX® is a prescription medicine used to treat adults with active psoriatic arthritis, active non-radiographic axial spondyloarthritis with objective signs of inflammation, and active ankylosing spondylitis.

#### IMPORTANT SAFETY INFORMATION

BIMZELX affects the immune system. It may increase your risk of infections, which can be serious. Do not use BIMZELX if you have any symptoms of infection without talking to your doctor. If you have any symptoms of infection after starting BIMZELX, call your doctor right away.



### THE FIRST AND ONLY FDA-APPROVED TREATMENT THAT TARGETS AND BLOCKS IL-17A & IL-17F

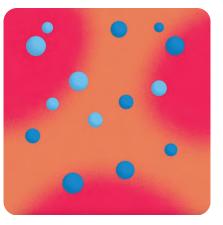
How does BIMZELX<sup>®</sup> (bimekizumab-bkzx) work differently?

With *PsA*, *nr-axSpA*, and *AS*, the immune system overproduces proteins, like IL-17A and IL-17F, that cause inflammation. Most biologic treatments target just one of those proteins.

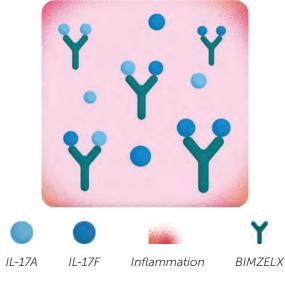
BIMZELX is the first and only FDA-approved treatment that targets and blocks IL-17A and IL-17F from causing inflammation by binding to them, calming inflammation in the body, and helping reduce the symptoms of *PsA*, *nr-axSpA*, and *AS*.



#### **INFLAMMATION IN THE BODY**



#### BIMZELX TARGETING AND BLOCKING IL-17A & IL-17F



For illustrative purposes only.

#### USE

BIMZELX® is a prescription medicine used to treat adults with active psoriatic arthritis, active non-radiographic axial spondyloarthritis with objective signs of inflammation, and active ankylosing spondylitis.

#### **IMPORTANT SAFETY INFORMATION**

Your doctor should check you for tuberculosis (TB) before you start BIMZELX and watch you closely for signs of TB during treatment with BIMZELX. If you have TB, or had it in the past, your doctor may treat you for it before you start BIMZELX.

# 1 DOSE EVERY 4 WEEKS<sup>\*</sup>

If you and your healthcare provider decide BIMZELX is right for you, here's what you need to know about dosing.

## HOW BIMZELX DOSING WORKS FOR PEOPLE WITH *PsA*, *nr-axSpA*, AND *AS*:

### Handle

>>>> BIMZELX AUTOINJECTOR

Needle Guard

Even if your symptoms improve and you begin to feel better, do not skip a dose. Always take BIMZELX as prescribed and do not discontinue treatment without speaking to your rheumatologist.

### **1 DOSE**

• EVERY 4 WEEKS ᡗ

- All doses are 160 mg.
- For people with both *PsA* and moderate-to-severe plaque psoriasis: start with 1 dose every 4 weeks for 5 doses. Then continue with 1 dose every 8 weeks. All doses are 320 mg, given as 2 separate, 160-mg injections under the skin.

\*Patients weighing  $\geq$ 120 kg (265 lb) may be prescribed a dose every 4 weeks after week 16.

### **GETTING COMFORTABLE WITH SELF-INJECTION**

You or your caregiver (if required) can administer BIMZELX at home using the BIMZELX autoinjector.

Please visit BIMZELX.com/injection to watch the BIMZELX autoinjector video and familiarize yourself with proper injection procedure.

Some patients may use prefilled syringes to administer BIMZELX.



#### INJECTION QUESTIONS? THE BIMZELX Navigate® TEAM CAN HELP.

**Viewing Window** 

Learn more about patient support and more on page 17.

#### USE

BIMZELX® is a prescription medicine used to treat adults with active psoriatic arthritis, active non-radiographic axial spondyloarthritis with objective signs of inflammation, and active ankylosing spondylitis.

#### **IMPORTANT SAFETY INFORMATION**

New cases of inflammatory bowel disease or "flare-ups" have happened with BIMZELX. If you have inflammatory bowel disease (ulcerative colitis or Crohn's disease), tell your healthcare provider if you have worsening disease symptoms during treatment with BIMZELX or develop new symptoms of stomach pain or diarrhea.

# SAFETY & SIDE EFFECTS

Important things to know before starting your treatment.



## TELL YOUR HEALTHCARE PROVIDER ABOUT ALL YOUR MEDICAL CONDITIONS, INCLUDING IF YOU:

- Have a history of depression, or suicidal thoughts or behavior
- Are being treated for an infection, have an infection that does not go away or keeps coming back, or have symptoms of an infection
- Have tuberculosis (TB) or have been in close contact with someone with TB
- Have liver problems
- Have inflammatory bowel disease (Crohn's disease or ulcerative colitis)
- Have recently received or are scheduled to receive an immunization (vaccine). You should avoid receiving live vaccines during treatment with BIMZELX.
- Are pregnant or plan to become pregnant. It is not known if BIMZELX can harm your unborn baby.
  - If you become pregnant while taking BIMZELX, you are encouraged to enroll in the Pregnancy Registry, which is used to collect information about the health of you and your baby. Talk to your healthcare provider or call 1-877-311-8972 to enroll in this registry or visit http://mothertobaby.org/pregnancy-studies/.
- Are breastfeeding or plan to breastfeed. It is not known if BIMZELX passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby during treatment with BIMZELX.

**Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements.



#### THE MOST COMMON SIDE EFFECTS OF BIMZELX:

**For PsA include:** upper respiratory tract infections, headache, urinary tract infections, oral thrush or infections in the mouth, and diarrhea.

For *nr-axSpA* include: upper respiratory tract infections, headache, cough, joint pain, tonsillitis, urinary tract infections, oral thrush or infections in the mouth, diarrhea, feeling tired, muscle aches, and an increase in liver enzyme levels.

**For AS include:** upper respiratory tract infections, headache, pain at injection site, vaginal yeast infections, oral thrush or infections in the mouth, diarrhea, and rash.

These are not all of the possible side effects of BIMZELX. Call your doctor for medical advice about side effects.



TALK TO YOUR HEALTHCARE PROVIDER IF YOU HAVE QUESTIONS About the safety and side EFFECTS of BIMZELX.

#### USE

BIMZELX® is a prescription medicine used to treat adults with active psoriatic arthritis, active non-radiographic axial spondyloarthritis with objective signs of inflammation, and active ankylosing spondylitis.

#### **IMPORTANT SAFETY INFORMATION**

Elevated liver enzyme levels have happened with BIMZELX. Your doctor will do blood tests to check your liver enzyme levels before starting treatment and during treatment, and may tell you to stop taking BIMZELX if you develop liver problems. Call your doctor right away if you develop any signs or symptoms of liver problems like pain on the right side of your stomach, feeling very tired, loss of appetite, nausea or vomiting, itching, dark urine, light-colored stool, or yellowing of your skin or the whites of your eyes.

# **Psa** Can Impact you In Unseen Ways

While its exact cause is unknown, PsA is thought to be caused by an overactive immune system. This overactivity can lead to inflammation that causes joint pain, swelling, and even skin plagues for some.

# MANY THINGS CAN TRIGGER *PsA*, INCLUDING THE ENVIRONMENT AND GENES

Understanding what can cause inflammation can help you gain control over it. Injury, physical stress, and infections can activate a response from your immune system, which can lead to symptoms in the joints of:

• Fingers

Knees

- Toes
- Wrists

- Shoulders
- Lower back

The red areas below show where joint inflammation may commonly occur in your body with *PsA*.



#### PLAQUE PSORIASIS (PSO) IS ALSO PART OF THE STORY

Nearly 90% of people suffering from *PsA* also struggle with *PSO*, with symptoms including red, itchy, and painful plaques on their skin and changes in the nails called nail psoriasis.

#### USE

BIMZELX<sup>®</sup> is a prescription medicine used to treat adults with active psoriatic arthritis, active non-radiographic axial spondyloarthritis with objective signs of inflammation, and active ankylosing spondylitis.

#### **IMPORTANT SAFETY INFORMATION**

Tell your doctor if you have recently received or are scheduled to receive a vaccine. You should avoid receiving live vaccines during treatment with BIMZELX.

Please see full **Important Safety Information** on pages 18-19 and the accompanying full **Prescribing Information**, including **Medication Guide**.

Not an actual BIMZELX patient.

# DON'T LET *nr-axSpA* and *AS* GO UNMANAGED

*nr-axSpA* and *AS* are both chronic inflammatory diseases caused by an overactive immune system.

In *nr-axSpA*, the inflammation causes pain in the pelvis and lower spine. Because the joint inflammation associated with *nr-axSpA* can't be seen in an X-ray, this can lead to a long delay in diagnosis times. For some patients, diagnosis has taken up to 10 years.

Most people experience symptoms in the:

- Sacroiliac joints: joints where the spine and pelvis meet
- Spine
- · Peripheral joints: joints in the arms and legs
- Entheses: where tendons and ligaments meet bone



*AS*, which can progress from *nr-axSpA*, can be associated with skeletal damage. The chronic inflammation associated with *AS* can lead to irreversible structural changes that result in spinal fusion and reduced spinal mobility.

AS can be seen in X-rays, and symptoms are most felt in the:

- Sacroiliac joints: joints where the spine and pelvis meet
- Spine
- Peripheral joints: joints in the arms and legs
- Entheses: where tendons and ligaments meet bone



#### USE

BIMZELX<sup>®</sup> is a prescription medicine used to treat adults with active psoriatic arthritis, active non-radiographic axial spondyloarthritis with objective signs of inflammation, and active ankylosing spondylitis.

#### **IMPORTANT SAFETY INFORMATION**

The most common side effects of BIMZELX in plaque psoriasis include upper respiratory infections, fungal infections (oral thrush or infections in the mouth, throat, skin, nails, feet, or genitals), headache, pain, redness or swelling at injection site, Herpes Simplex infections (cold sores in or around the mouth), stomach flu (gastroenteritis), small red bumps on your skin, acne, or feeling tired.

The most common side effects of BIMZELX in psoriatic arthritis include upper respiratory tract infections, headache, urinary tract infections, oral thrush or infections in the mouth, and diarrhea.

The most common side effects of BIMZELX in non-radiographic axial spondyloarthritis include upper respiratory tract infections, headache, cough, joint pain, tonsillitis, urinary tract infections, oral thrush or infections in the mouth, diarrhea, feeling tired, muscle aches, and an increase in liver enzyme levels.

The most common side effects of BIMZELX in ankylosing spondylitis include upper respiratory tract infections, headache, pain at injection site, vaginal yeast infections, oral thrush or infections in the mouth, diarrhea, and rash.



### PATIENT SUPPORT AS UNIQUE AS YOU ARE

BIMZELX Navigate<sup>®</sup> provides personalized resources to support you during your treatment journey.



YOUR SINGLE, COMPASSIONATE POINT OF connection

When you enroll, you'll be paired with a dedicated Nurse Navigator—one person you can rely on to connect you to everything BIMZELX Navigate® has to offer. Contact Nurse Navigators at: 833-931-6877, 8am-8pm ET M-F

<sup>1</sup>Nurse Navigators do not provide medical advice and will refer you to your healthcare professional for any treatment-related questions.



BIMZELX NAVIGATE SAVINGS FROM YOUR FIRST DOSE, YOU MAY PAY \$15 per loye

Our simplified approach to financial support helps make getting on treatment faster and easier.

- From your first dose, you may pay only \$15 per dose.\*
- Once your insurance approves coverage of BIMZELX, eligible patients may start receiving treatment for as little as \$5 per dose.<sup>†</sup>
- Your Nurse Navigator is committed to you, ready to answer questions about your prescription status, insurance coverage, and your treatment goals.<sup>‡</sup>
- Your Nurse Navigator can help you enroll into the BIMZELX Navigate Savings Program.

\*For eligible, commercially insured patients only. Eligible patients whose insurance coverage is delayed or denied may receive BIMZELX for \$15 per dose for up to 2 years or until the patient's coverage is approved, whichever comes first. View complete eligibility requirements and terms at BIMZELX.com/Patient-Support/Navigate-Benefits.

'Eligible, commercially insured patients with approved coverage pay as little as \$5 per dose. View complete eligibility requirements and terms at BIMZELX.com/Patient-Support/Navigate-Benefits.



BIMZELX MYNAVIGATE ONLINE veyouvcey

### Stay focused on treatment goals with tools and resources, at NavigateStartsHere.com

- Request a free sharps container
- Connect with your Nurse Navigator\*\*
- Injection Support

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• Access educational resources

\*\*Nurse Navigators do not provide medical advice and will refer you to your healthcare professional for any treatment-related questions.



Scan with your phone or visit NavigateStartsHere.com.

Create your account online. You'll gain immediate access to most materials, but some personalized information may take up to 3 hours to load.



#### **IMPORTANT SAFETY INFORMATION**

### What is the most important information I should know about BIMZELX<sup>®</sup> (bimekizumab-bkzx)?

BIMZELX is a medicine that affects your immune system. BIMZELX may increase your risk of having serious side effects, including:

- Suicidal thoughts and behavior have happened in some people treated with BIMZELX. Get medical help right away or call the National Suicide and Crisis Lifeline at 988 if you, your caregiver, or your family member notice in you any of the following symptoms:
  - new or worsening depression or anxiety
  - o thoughts of suicide, dying, or hurting yourself
  - changes in behavior or mood
  - acting on dangerous impulses
  - attempt to commit suicide
- Infections. BIMZELX is a medicine that may lower the ability of your immune system to fight infections and may increase your risk of infections.
  - Your healthcare provider should check you for infections and tuberculosis (TB) before starting treatment with BIMZELX.
  - If your healthcare provider feels you are at risk for TB, you may be treated with medicine for TB before you begin treatment with BIMZELX and during your treatment.
  - Your doctor should watch you closely for signs and symptoms of TB during and after treatment with BIMZELX. Do not take BIMZELX if you have an active TB infection.

#### Before starting BIMZELX, tell your healthcare provider if you:

- are being treated for an infection
- have an infection that does not go away or that keeps coming back
- have TB or have been in close contact with someone with TB
- think you have an infection or have symptoms of an infection such as:
  - fever, sweats, or chills
     weight loss
  - muscle aches

blood in your phleam

- cough
- shortness of breath
- from your psoriasis o diarrhea or stomach pain

• warm, red, or painful skin or

sores on your body different

 burning when you urinate or urinating more often than normal

After starting BIMZELX, call your healthcare provider right away if you have any of the signs of infection listed above. Do not use BIMZELX if you have any signs of infection unless you are instructed to by your healthcare provider. See "What are the possible side effects of BIMZELX?" for more information about side effects.

#### What is **BIMZELX**?

BIMZELX is a prescription medicine used to treat:

- adults with moderate-to-severe plaque psoriasis who may benefit from taking injections or pills (systemic therapy) or treatment using ultraviolet light alone or with pills (phototherapy).
- adults with active psoriatic arthritis.
- adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation.
- adults with active ankylosing spondylitis.
- It is not known if BIMZELX is safe and effective in children.

### Before using BIMZELX, tell your healthcare provider about all of your medical conditions, including if you:

- have any of the conditions or symptoms listed in the section "What is the most important information I should know about BIMZELX?"
- · have a history of depression, or suicidal thoughts or behavior
- have liver problems
- have inflammatory bowel disease (Crohn's disease or ulcerative colitis)

- have recently received or are scheduled to receive an immunization (vaccine). You should avoid receiving live vaccines during treatment with BIMZELX.
- are pregnant or plan to become pregnant. It is not known if BIMZELX can harm your unborn baby.
  - If you become pregnant while taking BIMZELX, you are encouraged to enroll in the Pregnancy Registry, which is used to collect information about the health of you and your baby. Talk to your healthcare provider or call 1-877-311-8972 to enroll in this registry or visit http://mothertobaby.org/pregnancy-studies/.
- are breastfeeding or plan to breastfeed. It is not known if BIMZELX passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby during treatment with BIMZELX.

#### Tell your healthcare provider about all the medicines you take,

including prescription and over-the-counter medicines, vitamins, and herbal supplements.

#### What are the possible side effects of BIMZELX?

BIMZELX may cause serious side effects. See "What is the most important information I should know about BIMZELX?"

- Elevated liver enzyme levels. Your healthcare provider will do blood tests to check your liver enzyme levels before starting treatment and during treatment with BIMZELX. Your healthcare provider may temporarily stop or permanently stop your treatment with BIMZELX if you develop liver problems. Call your healthcare provider right away if you develop any signs or symptoms of liver problems, including:
  - pain on the right side of your stomach-area
- itchingdark urine

whites of your eyes

- light-colored stool
  yellowing of your skin or the
- feeling very tiredloss of appetite
- nausea and vomiting
- Inflammatory bowel disease. New cases of inflammatory bowel disease or "flare-ups" have happened with BIMZELX. If you have inflammatory bowel disease (Crohn's disease or ulcerative colitis), tell your healthcare provider if you have worsening disease symptoms during treatment with BIMZELX or develop new or worsening signs of Crohn's disease or ulcerative colitis.

The most common side effects of BIMZELX in people treated for psoriasis include: upper respiratory tract infections, headache, Herpes Simplex

infections (cold sores in or around the mouth), small red bumps on your skin, feeling tired, fungal infections (oral thrush or infection in the mouth, throat, skin, nails, feet, or genitals), pain, redness or swelling at injection site, stomach flu (gastroenteritis), and acne.

The most common side effects of BIMZELX in people treated for **psoriatic arthritis include:** upper respiratory tract infections, headache, urinary tract infections, oral thrush or infections in the mouth, and diarrhea.

The most common side effects of BIMZELX in people treated for non-radiographic axial spondyloarthritis include: upper respiratory tract infections, headache, cough, joint pain, tonsillitis, urinary tract infections, oral thrush or infections in the mouth, diarrhea, feeling tired, muscle aches, and an increase in liver enzyme levels.

The most common side effects of BIMZELX in people treated for ankylosing **spondylitis include:** upper respiratory tract infections, headache, pain at injection site, vaginal yeast infections, oral thrush or infections in the mouth, diarrhea, and rash.

These are not all of the possible side effects of BIMZELX. Call your doctor for medical advice about side effects.

Use BIMZELX exactly as your doctor tells you to use it.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit <u>www.fda.gov/medwatch</u>, or call 1-800-FDA-1088.

Please see the accompanying full **Prescribing Information**, including **Medication Guide**.





### UNIQUELY PERSONAL TREATMENT SUPPORT

#### BIMZELX patients can enroll today.





Scan with your phone or visit NavigateStartsHere.com.



Create your account online. You'll gain immediate access to most materials, but some personalized information may take up to 3 hours to load.



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Inspired by patients. Driven by science.

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