Sandoz International
Sandoz Global Communications
Industriestr. 25
83607 Holzkirchen
Germany

http://www.sandoz.com

MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG

Sandoz presents real-world data showing effectiveness of Erelzi® (etanercept-szzs) in rheumatic disease treatment

- *Interim results from COMPACT, a multi-country, real-world study of Erelzi for approved rheumatic diseases presented at 2019 ACR/ARP Annual Meeting*
- *US analysis of long-term financial impact when switching to biosimilar etanercept also presented, modeling significant cost savings for health systems*
- *Sandoz is the pioneer and a global leader in biosimilars, with eight approved biosimilars worldwide and more than 10 in the pipeline*

Holzkirchen, November 12, 2019 – Sandoz, a Novartis division and a global leader in biosimilars, presented an interim analysis (abstract number 553) from the COMPACT study on real-world treatment of rheumatic disease patients wit

h biosimilar Erelzi® (etanercept-szzs) at the 2019 American College of Rheumatology and Association of Rheumatology Professionals (ACR/ARP) Annual Meeting in Atlanta, Georgia. US analysis of long-term financial impact when switching to biosimilar etanercept modeling significant cost savings for health systems was also presented.

Patients with rheumatoid arthritis (RA), active and progressive psoriatic arthritis (PsA) and ankylosing spondylitis (AS) were included in the COMPACT analysis that showed initial results of effectiveness and safety. For RA patients, improvements in effectiveness and functional disability were shown. No new safety signals were observed compared to previously published data on etanercept.[1]

COMPACT is an ongoing observational study of treatment of RA, PsA and AS patients with Erelzi. In total, 430 patients were recruited in Germany, United Kingdom, Spain, Poland, and Canada. The interim analysis reports out initial effectiveness data for the RA patient subgroup, as well as safety data for all enrolled patients at Week 12.

“If untreated, rheumatoid arthritis can have a devastating impact on patients, with at least 50 percent of people in developed countries[2] unable to hold down a full-time job within ten years of onset,” said Florian Bieber, Global Head of Development, Sandoz Biopharmaceuticals. “Interim data from the COMPACT study, along with long-term US cost savings modeling analysis, help build confidence in the value of biosimilars, which may enable more patients to access advanced biologic medicines earlier and offer significant savings for overburdened health systems.”

“The interim analysis from the COMPACT study adds evidence to a growing body of research that confirms the safety and efficacy of biosimilar etanercept,” said COMPACT study investigator Dr. Marc Schmalzing, Deputy Head and Senior Physician of the Department of Rheumatology/Clinical Immunology, University of Wurzburg. “In addition to the existing clinical research on Erelzi, we now can see how this biosimilar is performing in a real-world patient population setting with comorbidities and concomitant medications.”

In addition to the COMPACT analysis, results from a US economic model (abstract number 251) were presented by Sandoz. Investigators evaluated the economic impact of switching patients from a reference etanercept to a biosimilar in patients with rheumatic diseases in the US, taking into consideration the upfront costs when implementing a formulary change. Results demonstrated that despite the early, administrative costs associated with managing the formulary process, substantial cost savings can be realized by integrated delivery networks (IDNs) when transitioning patients to the biosimilar. For IDNs with low administrative costs, the total potential pharmacy cost savings were shown to be $62.4 million over five years, assuming that up to 1,331 patients per year are treated with etanercept across all three indications.[3]

“This model shows that substantial pharmacy cost savings, about $10,000 per switched patient per year, far outweighed the relatively minor incremental administrative and labor costs associated with implementation of a formulary change,” said Edward Li, Author and Associate Director, Health Economics and Outcomes Research (HEOR)

By actively investing in the future of biosimilars, Sandoz expects to continue to lead the marketplace and deliver on its promise to help millions of patients in immunology, oncology, endocrinology and other underserved therapy areas access biologic medicines sustainably and affordably.

References:

1. Schmalzing M, Askari A, Walsh D. Etanercept Biosimilar GP2015 (Erelzi®) in Rheumatic Diseases: Interim Analysis of Real-World data from COMPACT: A multicentric, prospective, observational cohort study. Presented at the 2019 ACR/ARP Annual Meeting. November 10, 2019.
2. Data on file.
3. Mezzio D, Li E, Balu S. Long-Term Financial Impact of Switching From Reference to Biosimilar Etanercept When Considering Short-Term Formulary Management Costs in the US. Presented at the 2019 ACR/ARP Annual Meeting. November 10, 2019.

About Erelzi®

Erelzi is the Sandoz biosimilar of the reference medicine, Enbrel®. Erelzi has been studied in a global development program, which included a comprehensive comparison of Erelzi and Enbrel® at the analytical, preclinical, and clinical levels.

Erelzi® IMPORTANT SAFETY INFORMATION

What is the most important information I should know about ERELZI?
ERELZI may cause serious side effects, including:
1. Risk of Infection
2. Risk of Cancer

1. Risk of Infection

ERELZI can lower the ability of your immune system to fight infections. Some people have serious infections while taking etanercept products. These infections include tuberculosis (TB), and infections caused by viruses, fungi, or bacteria that
spread throughout their body. Some people have died from these infections.
• Your healthcare provider should test you for TB before starting ERELZI.
• Your healthcare provider should monitor you closely for symptoms of TB during treatment with ERELZI even if you tested negative for TB.
• Your healthcare provider should check you for symptoms of any type of infection before, during, and after your treatment with ERELZI.
You should not start taking ERELZI if you have any kind of infection unless your healthcare provider says it is okay.

2. Risk of Cancer

• There have been cases of unusual cancers, some resulting in death, in children and teenage patients who started using TNF-blocking agents at less than 18 years of age.
• For children, teenagers, and adults taking TNF-blocker medicines, including etanercept products, the chances of getting lymphoma or other cancers may increase.
• People with rheumatoid arthritis, especially those with very active disease, may be more likely to get lymphoma.

Before starting ERELZI, be sure to talk to your healthcare provider:
ERELZI may not be right for you. Before starting ERELZI, tell your healthcare provider about all of your medical conditions, including:
Infections. Tell your healthcare provider if you:
• have an infection. See "What is the most important information I should know about ERELZI?"
• are being treated for an infection.
• think you have an infection.
• have symptoms of an infection such as fever, sweats or chills, cough or flu-like symptoms, shortness of breath, blood in your phlegm, weight loss, muscle aches, warm, red or painful areas on your skin, sores on your body, diarrhea or stomach pain, burning when you urinate or urinating more often than normal, and feel very tired.
• have any open cuts on your body.
• get a lot of infections or have infections that keep coming back.
• have diabetes, HIV, or a weak immune system. People with these conditions have a higher chance for infections.
• have TB, or have been in close contact with someone with TB.
• were born in, lived in, or traveled to countries where there is a risk for getting TB. Ask your healthcare provider if you
are not sure.
• live, have lived in, or traveled to certain parts of the country (such as the Ohio and Mississippi River valleys, or the Southwest) where there is a greater risk for getting certain kinds of fungal infections (histoplasmosis, coccidioidomycosis, blastomycosis). These infections may happen or become more severe if you use ERELZI. Ask your healthcare provider if you do not know if you live or have lived in an area where these infections are common.
• have or have had hepatitis B.
Also, before starting ERELZI, tell your healthcare provider:
• About all the medicines you take including prescription and over-the-counter medicines, vitamins and herbal supplements including:
    o **Orencia (abatacept) or Kineret (anakinra).** You have a higher chance for serious infections when taking ERELZI with Orencia or Kineret.
    o **Cyclophosphamide (Cytoxan).** You may have a higher chance for getting certain cancers when taking ERELZI with cyclophosphamide.
    o **Anti-diabetic medicines**. If you have diabetes and are taking medication to control your diabetes, your healthcare provider may decide you need less anti-diabetic medicine while taking ERELZI.

Keep a list of all your medications with you to show your healthcare provider and pharmacist each time you get a new medicine. Ask your healthcare provider if you are not sure if your medicine is one listed above.
Other important medical information you should tell your healthcare provider before starting ERELZI, includes if you:
• have or had a nervous system problem such as multiple sclerosis or Guillain-Barré syndrome.
• have or had heart failure.
• are scheduled to have surgery.
• have recently received or are scheduled to receive a vaccine.
    o All vaccines should be brought up-to-date before starting ERELZI.
    o People taking ERELZI should not receive live vaccines.
    o Ask your healthcare provider if you are not sure if you received a live vaccine.
• are allergic to rubber or latex.

  - o The internal needle cover within the cap of the Sensoready Pen and the needle cap of the prefilled syringe contains latex.

• have been around someone with varicella zoster (chicken pox).
• are pregnant or plan to become pregnant. It is not known if ERELZI will harm your unborn baby. If you took ERELZI during pregnancy, talk to your healthcare provider prior to the administration of live vaccines to your infant.
• are breastfeeding or plan to breastfeed. ERELZI can pass into breast milk. Talk to your healthcare provider about the best way to feed your baby while taking ERELZI.

What are the possible side effects of ERELZI?
ERELZI can cause serious side effects including:
Infections. ERELZI can make you more likely to get infections or make any infection that you have worse. Call your healthcare provider right away if you have any symptoms of an infection. See “Before starting ERELZI, be sure to talk to your healthcare provider” for a list of symptoms of infection.
• **Previous Hepatitis B infection**. If you have been previously infected with the hepatitis B virus (a virus that affects the liver), the virus can become active while you use ERELZI. Your doctor may do a blood test before you start treatment with ERELZI and while you use ERELZI.
• **Nervous system problems.** Rarely, people who use TNF-blocker medicines have developed nervous system problems such as multiple sclerosis, seizures, or inflammation of the nerves of the eyes. Tell your healthcare provider right away if you get any of these symptoms: numbness or tingling in any part of your body, vision changes, weakness in your arms and legs, and dizziness.
• **Blood problems.** Low blood counts have been seen with other TNF-blocker medicines. Your body may not make enough of the blood cells that help fight infections or help stop bleeding. Symptoms include fever, bruising or bleeding very easily, or looking pale.
• **Heart failure** including new heart failure or worsening of heart failure you already have. New or worse heart failure can happen in people who use TNF-blocker medicines like ERELZI. If you have heart failure your condition should be watched closely while you take ERELZI. Call your healthcare provider right away if you get new or worsening symptoms of heart failure while taking ERELZI, such as shortness of breath or swelling of your lower legs or feet.
• **Psoriasis.** Some people using etanercept products developed new psoriasis or worsening of psoriasis they already had. Tell your healthcare provider if you develop red scaly patches or raised bumps that may be filled with pus. Your healthcare provider may decide to stop your treatment with ERELZI.
• **Allergic reactions**. Allergic reactions can happen to people who use TNF-blocker medicines. Call your healthcare provider right away if you have any symptoms of an allergic reaction. Symptoms of an allergic reaction include a severe rash, a swollen face, or trouble breathing.
• **Autoimmune reactions, including:**
  - o Lupus-like syndrome. Symptoms include a rash on your face and arms that gets worse in the sun. Tell your healthcare provider if you have this symptom. Symptoms may go away when you stop using ERELZI.
  - o Autoimmune hepatitis. Liver problems can happen in people who use TNF-blocker medicines, including ERELZI. These problems can lead to liver failure and death. Call your healthcare provider right away if you have any of these symptoms: feel very tired, skin or eyes look yellow, poor appetite or vomiting, pain on the right side of your stomach (abdomen).

Common side effects of ERELZI include:
• **Injection site reactions** such as redness, swelling, itching, or pain. These symptoms usually go away within 3 to 5 days. If you have pain, redness, or swelling around the injection site that does not go away or gets worse, call your healthcare provider.
• **Upper respiratory infections** (sinus infections).

These are not all the side effects with ERELZI. Tell your healthcare provider about any side effect that bothers you or does not go away.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

INDICATIONS

Rheumatoid Arthritis: ERELZI is indicated for reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active rheumatoid arthritis (RA). ERELZI can be initiated in combination with methotrexate (MTX) or used alone.

Polyarticular Juvenile Idiopathic Arthritis: ERELZI is indicated for reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis (JIA) in patients ages 2 and older.

Psoriatic Arthritis: ERELZI is indicated for reducing signs and symptoms, inhibiting the progression of structural damage of active arthritis, and improving physical function in patients with psoriatic arthritis (PsA). ERELZI can be used with or without methotrexate.

Ankylosing Spondylitis: ERELZI is indicated for reducing signs and symptoms in patients with active ankylosing spondylitis (AS).

Plaque Psoriasis: ERELZI is indicated for the treatment of adult patients (18 years or older) with chronic moderate to severe plaque psoriasis (PsO) who are candidates for systemic therapy or phototherapy.

See more at: **https://www.ERELZI.com**

Click here for full **prescribing information**.

Disclaimer
This press release contains forward-looking statements within the meaning of the United States Private Securities Litigation Reform Act of 1995. Forward-looking statements can generally be identified by words such as “potential,” “can,” “will,” “plan,” “expect,” “anticipate,” “look forward,” “believe,” “committed,” “investigational,” “pipeline,” “launch,” or similar terms, or by express or implied discussions regarding potential marketing approvals, new indications or labeling for the investigational or approved products described in this press release, or regarding potential future revenues from such products. You should not place undue reliance on these statements. Such forward-looking statements are based on our current beliefs and expectations regarding future events, and are subject to significant known and unknown risks and uncertainties. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those set forth in the forward-looking statements. There can be no guarantee that the investigational or approved products described in this press release will be submitted or approved for sale or for any additional indications or labeling in any market, or at any particular time. Neither can there be any guarantee that, if approved, such biosimilar products will be approved for all indications included in the reference product’s label. Nor can there be any guarantee that such products will be commercially successful in the future. In particular, our expectations

regarding such products could be affected by, among other things, the uncertainties inherent in research and development, including clinical trial results and additional analysis of existing clinical data; regulatory actions or delays or government regulation generally; the particular prescribing preferences of physicians and patients; competition in general, including potential approval of additional generic or biosimilar versions of such products; global trends toward health care cost containment, including government, payor and general public pricing and reimbursement pressures and requirements for increased pricing transparency; litigation outcomes, including intellectual property disputes or other legal efforts to prevent or limit Sandoz from selling its products; general political and economic conditions; safety, quality or manufacturing issues; potential or actual data security and data privacy breaches, or disruptions of our information technology systems, and other risks and factors referred to in Novartis AG's current Form 20-F on file with the US Securities and Exchange Commission. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

About Sandoz
Sandoz, a Novartis division, is a global leader in generic pharmaceuticals and biosimilars. Our purpose is to pioneer access for patients by developing and commercializing novel, affordable approaches that address unmet medical need. Our ambition is to be the world's leading and most valued generics company. Our broad portfolio of high-quality medicines, covering all major therapeutic areas, accounted for 2018 sales of USD 9.9 billion. Sandoz is headquartered in Holzkirchen, in Germany's Greater Munich area.

Sandoz is on Twitter. Sign up to follow @Sandoz global at http://twitter.com/Sandoz_Global

# # #

Novartis Media Relations
E-mail: media.relations@novartis.com

Eric Althoff
Novartis Global Media Relations
+41 61 324 7999 (direct)
+41 79 593 4202 (mobile)
eric.althoff@novartis.com

Antonio Ligi
Novartis Global Media Relations
+ 41 61 324 1374 (direct)
+ 41 79 723 3681 (mobile)
antonio.ligi@novartis.com

Michelle Bauman
Sandoz Global Communications
+1 973 714 8043 (mobile)
michelle.bauman@sandoz.com

Chris Lewis
Sandoz Global Communications
+49 174 244 9501 (mobile)
chris.lewis@sandoz.com

Novartis Investor Relations

Central investor relations line: +41 61 324 7944
Email: investor.relations@novartis.com

Central		**North America**	
Samir Shah	+41 61 324 7944	Sloan Simpson	+1 862 778 3275
Pierre-Michel Bringer	+41 61 324 1065	Cory Twining	+1 212 830 2407
Thomas Hungerbuehler	+41 61 324 8425		
Isabella Zinck	+41 61 324 7188		