NEWS RELEASE

Merz Aesthetics Continues to Fuel Confidence by Expanding Belotero Balance® (+) Filler Treatment Areas

9/28/2023

FDA Approval Received for New Under-Eye Indication

RALEIGH, N.C.--(BUSINESS WIRE)-- Merz Aesthetics, the world's largest dedicated medical aesthetics business, announced today the U.S. Food and Drug Administration (FDA) approved Belotero Balance® (+) for volume augmentation for the improvement of the infraorbital hollow (IOH) in adults over the age of 21, further expanding the usage and capability of Belotero Balance® (+), and addressing consumer under-eye concerns.

Merz Aesthetics Continues to Fuel Confidence by Expanding Belotero Balance® (+) Filler Treatment Areas (Photo: Business Wire)

"We're so excited to be able to offer this new Belotero Balance® (+) indication to healthcare professionals and consumers and are thrilled with the promising results that we've seen to date through our studies," said Patrick Urban, President, North America, Merz Aesthetics. "At Merz Aesthetics, we hold ourselves to the standard of always continuing to innovate and offer the best possible treatments for our customers to bring to their patients. This innovation is an impressive addition to our dermal filler portfolio here in the U.S., and one we're very proud of."

This approval stems from positive pivotal study results demonstrating the efficacy and safety of Belotero Balance® (+) for the treatment of infraorbital hollows in June of 2023. This pivotal study enrolled 150 adults with moderate to severe infraorbital hollows. Subjects were randomized to a Belotero Balance (+) treatment group or a delayed treatment/control group. At Week 8 (the primary endpoint), the estimated average responder rate for the treatment group was 80.6%, while the estimated average responder rate in the control/delayed-treatment group

was 1.9%. The difference between the estimated response rates was 78.7%, showing superiority of Belotero Balance (+) treatment over control. Response was defined as ≥ 1-point improvement in both infraorbital hollows compared to baseline at Week 8 on the Merz Infraorbital Hollow Assessment Scale (MIHAS) – a 5-grade, scientifically validated scale. Additionally, at Week 8, 98.9% of subjects in the treatment group showed improvement on the Global Aesthetics Improvement Scale as determined by the treating investigator.

“This latest indication for Belotero Balance® (+) is an exciting step in our U.S. brand portfolio, allowing us to provide our HCP partners with a way to help their patients correct under-eye volume loss,” said Dr. Samantha Kerr, Chief Scientific Officer, Merz Aesthetics.

Overall, Belotero Balance (+) was well tolerated in the study, and the safety profile was consistent with previously reported studies, with the most common treatment-related adverse event being injection-site swelling (6.3% of subjects).

Until now, Belotero Balance® (+) was indicated for injection into the mid-to-deep dermis for correction of moderate-severe facial wrinkles and folds, such as nasolabial folds and perioral lines. This FDA approval adds the indication for injection into the infraorbital hollows. Infraorbital hollowing refers to the U-shaped depression under the eyes that extends from the nasal bone to the outer corner of the eye. Infraorbital hollows occur in the area directly under the eye when subcutaneous fat and soft tissue volume diminishes.

Unique technology makes Belotero Balance® different from other hyaluronic acid (HA) fillers. It is manufactured using the advanced Dynamic Cross-Linking Technology (DCLT), leading to tailored Cohesive Polydensified Matrix (CPM®) consisting of a monophasic gel, providing the ideal rheology for seamless, natural tissue integration in the under-eye hollows.

“Infraorbital hollowing that often occurs naturally in younger people or with aging can impact a person’s confidence, which is why patients seek medical aesthetics treatment to improve the appearance of this area of the face,” said Brian S. Biesman, M.D. F.A.C.S.

“I have countless patients coming to me with concerns about under-eye volume loss,” adds Dr. Daniel Campos, DNP, APRN Board-Certified specializing in non-surgical aesthetic and anti-aging treatments in Miami, Florida. “To be able to offer a safe and effective treatment from the Merz Aesthetics portfolio is an exciting advancement, and one I’m very much looking forward to bringing to my practice.”

First approved in 2011, Belotero Balance® is a hyaluronic acid (HA) filler that provides a smooth, all-around refinement for filler patients. Belotero Balance® (+) offers the same benefits plus the advantages of a lidocaine formulation.

Belotero Balance® (+) is an injectable filler known for blending evenly with skin tissue for a seamless feel with minimal tissue disruption. The HA in Belotero Balance® (+) is specially formulated in a proprietary process to create a uniquely smooth and cohesive gel that blends into the structure of the skin, while creating a smooth, natural look and feel.

About Merz Aesthetics

Merz Aesthetics is a medical aesthetics business with a long history of empowering health care professionals, patients and employees to live every day with confidence. We aim to help people around the world look, feel and live like the best versions of themselves — however they define it. Clinically proven, its product portfolio includes injectables, devices and skin care treatments designed to meet each patient's needs with high standards of safety and efficacy. Being family owned for more than 110 years, Merz Aesthetics is known for building unique connections with customers who feel like family. Merz Aesthetics' global headquarters is in Raleigh, N.C., USA, with a commercial presence in 52 countries worldwide. It is also a part of Merz Group, which was founded in 1908 and is based in Frankfurt, Germany. Learn more at US.MerzAesthetics.com.

To earn exclusive rewards, bonuses, and discounts on Merz Aesthetics' portfolio of treatments, join the Xperience+ Rewards Program. To learn more about Xperience+, visit **www.xperiencemerz.com**.

BELOTERO BALANCE (+) Important Consumer Safety Information

What is BELOTERO BALANCE® (+)?

BELOTERO BALANCE is a prescription injection that is approved to temporarily smooth out and fill in moderate to-severe nasolabial folds (the folds or wrinkles that go from the side of the nose to the corner of the mouth) and improve the appearance of under-eye hollows in adults over the age of 21.

Who should not use BELOTERO BALANCE?

BELOTERO BALANCE should not be used in patients with a history of or presence of multiple or severe allergies, including those with a history of anaphylaxis. BELOTERO BALANCE should not be used in patients with allergies to gram-positive bacterial proteins.

What is the most important information I should know about BELOTERO BALANCE?

Introduction of BELOTERO BALANCE into the vasculature may lead to embolization, occlusion of the vessels, ischemia, or infarction. Take extra care when injecting soft tissue fillers, for example inject the product slowly and

apply the least amount of pressure necessary. Rare but serious adverse events associated with the intravascular injection of soft tissue fillers in the face have been reported and include temporary or permanent vision impairment, blindness, cerebral ischemia or cerebral hemorrhage, leading to stroke, skin necrosis, and damage to underlying facial structures. Immediately stop the injection if patient exhibits any of the following symptoms, including changes in vision, signs of a stroke, blanching of the skin, or unusual pain during or shortly after the procedure. Patients should receive prompt medical attention and possibly evaluation by an appropriate health care practitioner specialist should an intravascular injection occur.

As with all events that involve an injection through the skin, there is a risk of infection. Laser treatments or chemical peels or any other treatments that affect the skin can increase the risk of infection. Do not use BELOTERO BALANCE if you have a skin inflammation or a skin infection. Do not use until the infection is healed.

Patients getting BELOTERO BALANCE may have an injection site reaction. These reactions can include inflammation and usually last less than seven days.

For approximately 24 hours after treatment, avoid:

- strenuous activity
- extensive sun or heat exposure
- aspirin or non-steroidal anti-inflammatory drugs
- alcoholic beverages

Exposure to any of the above can cause temporary redness, swelling, and/or itching at the injection site.

It is not known how BELOTERO BALANCE will work in areas of the face other than the smile lines. It is not known how BELOTERO BALANCE will work in women who are pregnant or breastfeeding or people who are less than 21 years of age.

What should I tell my doctor before injections with BELOTERO BALANCE?

Tell your doctor if you are taking medicines that affect blood clotting, like aspirin, an NSAID or warfarin. These medicines may put you at an increased risk of bruising or bleeding at the treatment site. Tell your doctor if you have a skin reaction like cold sores, cysts, pimples, rashes, hives, or an infection. Treatment with BELOTERO BALANCE should be delayed until the reaction goes away. Tell your doctor if you are taking medicines that affect your immune system.

What are the most common adverse events seen with BELOTERO BALANCE?

The most common adverse events seen in clinical studies with BELOTERO BALANCE were swelling, bruising, redness, hardening of the skin, pain, altered color, or itching. Other side effects that have occurred in clinical studies of BELOTERO BALANCE include headache, swelling of the side of the nose, moderate cold sore, lip numbness, and lip dryness. Side effects were often mild to moderate and often resolved within 7 days.

Delayed-onset inflammation near the site of injection is one of the known adverse events associated with dermal fillers. Cases of delayed-onset inflammation have been reported to occur at the treatment site following viral or bacterial illnesses or infections, vaccinations, or dental procedures. Typically, the reported inflammation was responsive to treatment or resolved on its own.

Information on adverse events from post-market surveillance of BELOTORO BALANCE are included in the Package Insert (PI) and Patient Information Guide (PIG) based on an assessment of seriousness and potential causal relationship to BELOTERO BALANCE.

Please see the PI and PIG available on **www.belotero.com** for a complete list of these events.

Important: For full safety information, please visit **www.belotero.com** or call MyMerz Solutions at 1-844-469-6379 or by email **AxUS-adverse.events@merz.com**.

Rx only

Dan Strickford
Director, U.S. Brand Communications, Merz Aesthetics
(919) 582-8239
Dan.Strickford@merz.com

Amanda Karpen
DeVries Global
AKarpen@devriesglobal.com

Source: Merz Aesthetics