bacterial strain, crosslinked with 1,4-butanediol diglycidyl ether (BDDE) contains 0.3% lidocaine hydrochloride to reduce pain on injection.

- Product use at specific sites in which an active inflammatory process should receive prompt medical attention and possibly evaluation by an physician or licensed practitioner.
- The patient should be informed of the possibility of local swelling, bruising, and redness, which may last 1 to 2 weeks and usually resolve within 14 days. Dyes to the ADVERSE EXPERIENCES section for details.
- Inflammatory reactions, necrobiosis, abscess formation, local migration, fibrosis, calcification, or hypertrophy of nerve, muscle, or gland tissues have been reported following the use of dermal fillers.

**PRODUCT USE AT SPECIFIC SITES IN WHICH AN ACTIVE INFLAMMATORY PROCESS SHOULD RECEIVE PROMPT MEDICAL ATTENTION AND POSSIBLY EVALUATION BY A PHYSICIAN OR LICENSED PRACTITIONER.**

**WARNINGS**

- **RHA® 2** is a homogenous and biodegradable gel implant. It is produced with extreme care and purified using bacterial fermentation using the Streptococcus equi group (minute treatment or touch-up treatment), the maximal severity of each CTR was recorded as none, mild, moderate or severe. If deemed necessary by the Treating Investigator, additional NLF were treated with the respective device.
- **Subjects were asked to rate each CTR as None, Mild, Moderate or Severe** in a preprinted scale (WSRS) score.
- **The study protocol allowed a maximum of 3.0 ml in a single NLF per study injection, and AE assessments at each visit. Injection site pain usually subsided within 48 hours and was not considered an AE.**
- **Subjects were randomly assigned to receive RHA® 2 and a control treatment for the treatment of moderate to severe dynamic facial wrinkles and folds, using RHA® 2**.
- **The study consisted of 64RHA® 2 versus a control treatment for the treatment of moderate to severe dynamic facial wrinkles and folds, using RHA® 2**. Subjects were eligible for optional retreatment if necessary at Weeks 4 or 12. AU1s in AU4 were also optically assessed at Weeks 4 and 12. AU4s were assessed by a Global Aesthetic Improvement (GAI) score. Subjects were asked to rate each CTR as None, Mild, Moderate or Severe in a preprinted scale (WSRS) score.
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that after initial treatment.
effectiveness and safety profiles after repeat treatment were similar to
24 weeks after initial treatment and the rate of satisfaction remained
More than 90% of the subjects reported to be satisfied or very satisfied
improving from 24 to more than 60 throughout the follow-up period.

1.

On the Global Aesthetic Improvement (GAI) scale, more than 84% of
Proportion of responders on the Wrinkle Severity Rating Scale measured
achieved for RHA® 2 at 24 weeks for the treatment of NLFs. Results
Rate of responders: ≥ 1 grade difference from pre-treatment on the WSRS
PP populations at the respective follow-up visits

2.

Continue covering until the edge of the cap of the needle contacts
the border of the site. There must be no space between these two
parts. Failure to follow this instruction means that the needle could be exerted outside the Luer-lock.

3.

Screw the needle protective cap by rolling it firmly while
holding the body of the syringe with the other

4.

Continue covering until the edge of the cap of the needle contacts
the border of the site. There must be no space between these two
parts. Failure to follow this instruction means that the needle could be exerted outside the Luer-lock.

INJECTION TECHNIQUES

- BHA is administered using a thin gauge needle (30G–30.5G). The needle is inserted at the desired location and depth as determined
- BHA can be injected using a number of different techniques that depend on the injectors’ experience and preferences, and patient characteristics.

Axial puncture:
contains of multiple injections, evenly and closely spaced along a linear or circular path. This technique is considered to be
more precise, but may result in more discomfort for the patient due to the number of punctures.

Linear threading:
the needle is fully introduced in the wrinkle or
the needle is introduced as for the Linear threading technique, but
the needle is not withdrawn. If an overcorrection has occurred, massage the area firmly between
your fingers or against an underlying area to obtain optimal results.

- When the injection is completed, the treated site should be gently

POST-TREATMENT GUIDELINES

- Avoid excessive pressure or handling of the treated area for the

Stereile needles:
are placed under sterilization. Follow directives, local, or institutional guidelines for use and disposal of medical biohazardous devices.

- Patients should avoid all sun, UV lamp exposure and extreme temperatures (e.g. cold weather, sauna) at least within the first 24 hours, or until initial swelling and/or itching at the treatment sites.

STORAGE

- RHA® 2 must be used prior to the expiration date printed on the

RxOnly

PATIENT INSTRUCTIONS

- Adverse reactions should be reported to Revance Therapeutics, Inc
- Patients should avoid all sun, UV lamp exposure and extreme temperatures (e.g. cold weather, sauna) at least within the first 24 hours, or until initial swelling and/or itching at the treatment sites.

HOW SUPPLIED

- Six syringes per package.

SHelf LIFE AND STORAGe

- Do not use if the package is damaged

DIRECTIONS FOR ASSEMBLY OF THE NEEDLE TO THE SYRINGE

1. Screw the syringe thread of the needle firmly into the syringe assembly.

2. Insert the screw head of the needle firmly into the syringe assembly.

PRE-TREATMENT GUIDELINES

- Prior to treatment, the patient should avoid taking medications or supplements which thin the blood (e.g., aspirin, nonsteroidal anti-inflammatory drugs, herbal remedies), as these may increase bleeding or bruising at the injection site.

- Before starting treatment, a complete medical history should be taken from the patient and the patient should be counseled on appropriate indications, risks, and benefits. Information about the expected results, and expected responses, should be provided to the patient before the informed, prescriptive, procedure commencing the procedure.

- Prior to treatment with BHA® 2 the patient should be counseled to

SYMBOLS

- Each syringe is packaged into a blister with two unique device identifiers

- The content of the syringe is sterile and non-pyrogenic. Do not

- SB: Single use only

- Flushed using sterile

- ReBlue: Cautions listed on the device side by side

- Distributed by:

- Manufactured by:

- Revance Therapeutics, Inc.

- Revance Therapeutics, Inc.

- TEOXANE SA.

- TEOXANE SA.

- 7550 Gateway Boulevard

- 7550 Gateway Boulevard

- San Carlos, CA 94070

- 630x280 mm

- C100 M33 J49 N32

- C26 M20

- 301 C 18%

- NOIR 79%

- NOIR

- IFU RHA 2

- 21/01/2020

- 9,089,517 ; 9,089,518 ; 9,089,519 ; 9,238,013 ; 9,358,322.

- RHA® is a registered trademark of TEOXANE SA.

- Patient information brochure is available on request, or via the website www.revance.com.

- Patients should be advised not to use forehead-boosting creams, or skin-lightening products for at least 48 hours following injection.

- A patient must be advised to avoid post-treatment bruising. Any pressure, manipulation, or rubbing of the skin, which may be caused by daily activities (e.g. washing), should be avoided for at least 48 hours following injection.

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RHA® 3 is a sterile, smooth, flexible injectable collagen microfilaments composite crosslinked with 1,4-butanediol diglycidyl ether (BDDE).

- **Bacterial Strain:** The bacterial strain used in the manufacture of RHA® 3 is Streptococcus equi subsp. zooepidemicus, obtained from bacterial fermentation using the Streptococcus equi subsp. Zooepidemicus strain 4560 (American Type Culture Collection). The bacterial preparation contains 0.3% Bacitracin hydrochloride to reduce the risk of infection.

### CONTRAINdications

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### WARNINGS

- **RHA® 3 must not be injected into blood vessels.** Introduction of contents of a syringe show signs of separation and/or appears cloudy, do not use. Symptoms such as redness, swelling, or tenderness (also known as a mild inflammatory reaction) at the site of injection may occur following RHA® 3 injection. These symptoms are typically of the expected signs and symptoms observed following an injection of a hyaluronic acid based dermal filler.

### ADVERSE EXPERIENCES

#### 1. Clinical Evaluation of RHA® 3

- **Table 1. Clinical Treatment Response After Initial Treatment with RHA® 3:**

<table>
<thead>
<tr>
<th>Common Treatment Response (CTR)</th>
<th>Number of subjects (NLF with any specific CTR)</th>
<th>Number of subjects % (median volume of RHA® 3 injected)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improvement</td>
<td>26</td>
<td>1.55 (1.25-2.00)</td>
</tr>
<tr>
<td>No Change</td>
<td>26</td>
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#### 2. Marking Scenarios

- **Table 2. Marking Scenarios: NLF treated with RHA® 3 compared to improvement from pre-injection of the NLF treated with control treatment:**

<table>
<thead>
<tr>
<th>Scenario</th>
<th>Primary Endpoint</th>
<th>Secondary Endpoint</th>
</tr>
</thead>
<tbody>
<tr>
<td>Simple</td>
<td>CTR Improvement</td>
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</tr>
<tr>
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### CLINICAL STUDY

- **Table 3. Demographics:**

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<th>Category</th>
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<td>Gender</td>
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<td>Age range</td>
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</tr>
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<td>Previous filler use</td>
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Throughout the follow-up period, the aesthetic improvement of the subjects and the BLE reported that the NLF treated with RHA® 3 was improved or very much improved from week 24 to week 64. The results demonstrated that non-inferiority to the control was established during the follow-up period. The patient should be advised of the indications, risks, and should be informed about the expected treatment. Before starting treatment, a complete medical history should be taken and all relevant medical devices should be reviewed. The content of the syringe is sterile and non-pyrogenic. Do not re-sterilize. Do not use if package is opened or damaged. The injection should be stopped before pulling the syringe out of the skin. If a vessel occlusion occurs, do not inject further and refer to medical attention. The injection should be stopped before pulling the syringe out of the skin. If a vessel occlusion occurs, do not inject further and refer to medical attention. 3. Linear threading: the needle is fully introduced in the wrinkle or spaced lines, by changing the direction of the needle, all using the Fanning technique: the needle is introduced as for the Linear threading technique, all using the Fanning technique. • After use, needles are potential biohazards. Follow national, local, or institutional guidelines for disposal of medical waste devices. If an overcorrection has occurred, massage the area firmly between your fingers or against an underlying area to obtain optimal results. If the wrinkles need further treatment with RHA® 3, the same procedure should be repeated until a satisfactory result is obtained.

POST-TREATMENT GUIDELINES
- If overcorrected, do not massage as it can cause bruising. Massaging the area after 48 hours has been shown to cause bruising. If the treated area is still numb from anesthetic, use a cold pack can be applied to the site for a short period (e.g., 5-10 minutes). Ice should be used with caution if the area is still numb from anesthetic. If a vessel occlusion occurs, do not inject further and refer to medical attention. Do not discontinue such treatment without talking to the healthcare professional.

STORAGE
- RHA® 3 is supplied in individual blisters containing a 1ml treatment unit. On the basis of the US clinical study, patients should be limited to 6.0 ml per patient per treatment session but it is important to not overcorrect. Based on the US clinical study, patients should be limited to 6.0 ml per patient per treatment session but it is important to not overcorrect. Based on the US clinical study, patients should be limited to 6.0 ml per patient per treatment session but it is important to not overcorrect. Based on the US clinical study, patients should be limited to 6.0 ml per patient per treatment session but it is important to not overcorrect. Based on the US clinical study, patients should be limited to 6.0 ml per patient per treatment session but it is important to not overcorrect. Based on the US clinical study, patients should be limited to 6.0 ml per patient per treatment session but it is important to not overcorrect. 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**INFORMATION THOROUGHLY**

**DEVICE DESCRIPTION**

RHA® 4 is a sterile, non-pyrogenic, non-preserved, bioactive, crosslinked, homogeneous, and biodegradable gel implant. It is produced with sodium hyaluronate (200 kDa molecular weight, 2.5% w/w) and 1,4-butanediol diglycidyl ether (BDDE) in a process involving radical crosslinking with 1,4-butanediol diglycidyl ether (BDDE). BDDE is a stable, nontoxic, and biocompatible crosslinking agent. RHA® 4 contains 3.5% sodium hyaluronate by weight. Cytotoxic and genotoxic tests have demonstrated the safety of RHA® 4.

**PRECAUTIONS**

- To minimize the risk of potential complications, this product should be used only by experienced health care professionals who have appropriate training in the filler injection technique, and who are knowledgeable about the mechanisms of and around the skin of injection. Underlying facial skin conditions, such as atrophy and the presence of fullness or prominence of specific tissues, such as facial creases, may increase the risk of tissue reaction. Significant post-injection pain is a rare event and may occur following injection of BDDE-containing products. Systemic reactions are not expected. Use of the product is contraindicated in areas with a history of severe reactions to bacterial proteins.
- The safety and effectiveness for the treatment of anatomic regions other than those described in the INDICATIONS AND USAGE section have not been established. Excessive treatment at one session or treatment of the same area too frequently may increase the risk of tissue reaction. Significant post-injection pain is a rare event and may occur following injection of BDDE-containing products. Systemic reactions are not expected. Use of the product is contraindicated in areas with a history of severe reactions to bacterial proteins.
- It may cause pain at the injection site and in the perioral area. If pain is severe and persistent, health care practitioners are encouraged to discuss all potential complications, and to ensure that patients are aware of signs and symptoms of potential complications.
- Patients and/or their caregivers should be informed about the possibility of scarring and potential for skin necrosis, and that the use of any topical or therapeutic treatment, chemotherapeutic agents, or surgery for the treatment of any resulting complications should be discussed with their health care practitioners. If there is a risk of extensive skin necrosis in the perioral area, the use of sunscreen or other protective measures is recommended. The use of RHA® 4 is not recommended for patients with a history of scarring or for those who have had facial skin resurfacing procedures within the last 6 months to reduce the risk of skin necrosis.
- The use of RHA® 4 is to be used as supplied. Modification or use of the product in any other way is prohibited. As with all transcutaneous procedures, dermal filler implantation should be performed by a health care practitioner who has appropriate training in filler injection techniques and who is knowledgeable about the mechanisms of and around the skin of injection. Use of the product is contraindicated in areas with a history of severe reactions to bacterial proteins.
- The product is a sterile, non-pyrogenic, colorless, clear gel. It is not to be used if the contents of the syringe show signs of separation or appears cloudy. Use of the product is contraindicated in areas with a history of severe reactions to bacterial proteins.
- The safety and effectiveness of the treatment of anatomic regions other than those described in the INDICATIONS AND USAGE section have not been established. Excessive treatment at one session or treatment of the same area too frequently may increase the risk of tissue reaction. Significant post-injection pain is a rare event and may occur following injection of BDDE-containing products. Systemic reactions are not expected. Use of the product is contraindicated in areas with a history of severe reactions to bacterial proteins.
- Dermal fillers should be used with caution in patients on immunosuppressive therapy. This is due to the risk of infection and the potential for adverse reactions, including severe reactions such as necrosis, hypotension, and shock.
- As with all transcutaneous procedures, dermal filler implantation should be performed by a health care practitioner who has appropriate training in filler injection techniques and who is knowledgeable about the mechanisms of and around the skin of injection. Use of the product is contraindicated in areas with a history of severe reactions to bacterial proteins.
- The safety and effectiveness of the treatment of anatomic regions other than those described in the INDICATIONS AND USAGE section have not been established. Excessive treatment at one session or treatment of the same area too frequently may increase the risk of tissue reaction. Significant post-injection pain is a rare event and may occur following injection of BDDE-containing products. Systemic reactions are not expected. Use of the product is contraindicated in areas with a history of severe reactions to bacterial proteins.
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Inadequately provided information on the following topic(s) and/or at the follow-up visit:
• Prior to treatment, the patient should avoid taking medications or consuming alcohol for 24 hours. The patient should avoid taking medications for 24 hours prior to the injection.
• Before treatment, the patient should be assessed for any indication that the condition is worsening, such as an increase in the number or size of lesions.
• If the condition of the skin is not improved after three treatments, the patient should be referred to a dermatologist.

Injection Techniques

1. Cleanse the area by wiping it with an alcohol wipe. After cleaning, the area should be allowed to dry completely.
2. Insert the needle firmly into the area of concern. The needle should be inserted at a 90-degree angle to the skin.
3. Gently hold the syringe with the other hand and apply gentle pressure to the plunger until a small droplet of the gel is visible at the tip of the needle.
4. Remove any excess gel from the needle by wiping it with a tissue.
5. Insert the needle through the skin in the area of concern. The needle should be inserted at a 90-degree angle to the skin.
6. Apply gentle pressure to the plunger until a small droplet of the gel is visible at the tip of the needle.
7. Continue inserting the needle until the area of concern is treated. The needle should be inserted at a 90-degree angle to the skin.
8. If the area of concern is not treated, repeat the process until the area of concern is completely treated.
9. After treatment, the patient should be instructed to avoid applying any other medications to the treated area for 24 hours.

Post-Treatment Guidelines

1. The patient should be instructed to avoid any other medications or treatments for 24 hours after the injection.
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Pre-Treatment Guidelines

1. The patient should be instructed to avoid any other medications or treatments for 24 hours prior to the injection.
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