



## Horizon Therapeutics plc to Acquire Viela Bio, Inc. to Significantly Expand Development Pipeline and Grow Rare Disease Medicine Portfolio

February 1, 2021

- Conference Call Today at 8 a.m. EST to Discuss Transaction -

- Provides TEPEZZA® (teprotumumab-trbw) Supply Update; Submitted Prior Approval Supplement to FDA to Support Increased Scale Production of TEPEZZA -

DUBLIN & GAITHERSBURG, Md.--(BUSINESS WIRE)--Feb. 1, 2021-- Horizon Therapeutics plc (Nasdaq: HZNP) and Viela Bio, Inc. (Nasdaq: VIE) today announced the companies have entered into a definitive agreement under which Horizon will acquire all of the issued and outstanding shares of Viela Bio, Inc. common stock for \$53.00 per share in cash, which represents a fully diluted equity value of approximately \$3.05 billion, or approximately \$2.67 billion net of Viela's cash and cash equivalents. As previously announced, Horizon had \$2.08 billion in cash and cash equivalents at December 31, 2020. The transaction is expected to close by the end of the first quarter of 2021.

"This acquisition represents a significant step forward in advancing our strategy – to expand our pipeline in order to accelerate our growth over the long term," said Tim Walbert, chairman, president and chief executive officer, Horizon. "Adding Viela's research and clinical development capabilities along with its deep, mid-stage biologics pipeline to our seasoned R&D and commercial teams, advances our transformation to an innovation-driven biotech company where we will build on the success of TEPEZZA and KRYSTEXXA to bolster our long-term growth trajectory. We intend to maximize the full potential of Viela's pipeline, including the pursuit of additional future indications."

### Strategic Rationale

- Adds to commercial rare disease medicine portfolio with UPLIZNA® (inebilizumab-cdon)
  - UPLIZNA is the first and only FDA-approved B-cell-depleting humanized monoclonal antibody for the treatment of neuromyelitis optica spectrum disorder (NMOSD), a rare, severe, autoimmune disease that attacks the optic nerve, spinal cord and brain stem, which leads to loss of vision and paralysis, in adults who are anti-aquaporin-4 (AQP4) antibody positive.
- Strengthens current R&D capability by adding a team with early-stage research, translational and clinical development capabilities along with deep scientific knowledge in autoimmune and severe inflammatory diseases.
- Adds deep, mid-stage biologics pipeline focused primarily on autoimmune and severe inflammatory diseases.
  - The current Viela pipeline includes four therapeutic candidates currently in nine development programs.
    - **UPLIZNA**
      - Phase 3 trials in myasthenia gravis, a chronic, rare autoimmune neuromuscular disease and in IgG4-related disease, a group of disorders marked by tumor-like swelling and fibrosis of affected organs.
      - Phase 2 trial for kidney transplant desensitization (paused due to COVID-19).
    - **VIB4920**
      - Investigational fusion protein designed to block a key co-stimulatory pathway involved in many autoimmune and inflammatory diseases.
      - Phase 2b trial in Sjögren's syndrome and Phase 2 trials for kidney transplant rejection and rheumatoid arthritis.
    - **VIB7734**
      - Investigational human monoclonal antibody designed to deplete plasmacytoid dendritic cells (pDCs), a cell type believed to be critical to the pathogenesis of multiple autoimmune diseases.
      - Phase 2 trial for systemic lupus erythematosus (SLE) expected to begin in the first half of 2021.
      - Phase 1 study for the treatment of COVID-19-related acute lung injury.
    - **VIB1116**
      - Monoclonal antibody for autoimmune diseases expected to begin Phase 1 first-in-human trial in mid-2021.

"We are pleased that Horizon recognizes the value of our robust R&D pipeline, our commercial medicine UPLIZNA, which is an important treatment option for patients with NMOSD, and our talented team," said Bing Yao, Ph.D., chairman and chief executive officer, Viela Bio, Inc. "We believe that the combined pipeline, including the pursuit of additional potential indications, has the potential to yield innovative new medicines to treat autoimmune and severe inflammatory diseases. Our collective R&D expertise coupled with Horizon's commercial capabilities, has the potential to provide benefit to more patients with high unmet treatment needs."

## Financial Impact

Horizon anticipates the transaction will reduce its adjusted EBITDA by approximately \$140 million in 2021, nearly all of which is attributable to increased R&D investment.

## Transaction Terms and Approvals

The acquisition is structured as a two-step cash tender offer for all the issued and outstanding shares of Viela Bio, Inc. common stock at a price of \$53.00 per share. Following successful completion of the tender offer, Horizon will acquire all remaining shares not tendered in the offer through a second step merger at the same price per share as in the tender offer. The transaction has been unanimously approved by Horizon's and Viela's boards of directors and is subject to the satisfaction of customary closing conditions, including the expiration or termination of the waiting period under the Hart-Scott Rodino Antitrust Improvements Act of 1976. Stockholders holding approximately 54% of the outstanding shares of common stock of Viela, including AstraZeneca UK Limited, have agreed to tender their shares in the offer pursuant to support agreements.

## Financing

Horizon intends to finance the transaction through \$1.3 billion of external debt along with cash on hand. Horizon has put in place fully committed financing with Citigroup Global Markets Inc. and Morgan Stanley Senior Funding, Inc.

## Advisors

Morgan Stanley & Co. LLC is the sole financial advisor to Horizon in the transaction. Horizon's legal advisor is Cooley LLP.

Goldman Sachs & Co. LLC is the sole financial advisor to Viela in the transaction. Viela's legal advisor is Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.

## TEPEZZA Supply Update

Last week, Horizon submitted a prior approval supplement to the U.S. Food and Drug Administration (FDA) to support increased scale production of TEPEZZA drug product for the treatment of Thyroid Eye Disease (TED). The submission includes data to support more product output with each manufacturing slot than is currently approved by the FDA. Horizon will continue to discuss potential additional data requirements and approval timeline with the FDA. Horizon continues to anticipate the disruption could last through the first quarter of 2021.

As previously announced on December 17, 2020, this increased production scale is necessary due to government-mandated COVID-19 vaccine production orders pursuant to the Defense Production Act of 1950 (DPA) related to manufacturing that dramatically reduced the number of drug product production slots available to Horizon at the drug product contract manufacturer of TEPEZZA.

## Conference Call Today at 8 a.m. EST

At 8 a.m. EST/1 p.m. IST today, Horizon will host a live webcast to review this acquisition. The live webcast and a replay may be accessed at <http://ir.horizontherapeutics.com>. Please connect to Horizon's website at least 15 minutes prior to the live webcast to ensure adequate time for any software download that may be needed to access the webcast. A replay of the webcast will be available approximately two hours after the live webcast.

## About Neuromyelitis Optica Spectrum Disorders (NMOSD)

NMOSD is a unifying term for neuromyelitis optica (NMO) and related syndromes. NMOSD is a rare, severe, relapsing, neuroinflammatory autoimmune disease that attacks the optic nerve, spinal cord and brain stem. Approximately 80% of all patients with NMOSD test positive for anti-AQP4 antibodies.

These AQP4 autoantibodies are produced by CD19+ B cells and bind primarily to astrocytes in the central nervous system. Binding of AQP4 antibodies to central and peripheral nervous system cells is believed to trigger attacks, which can damage the optic nerve, spinal cord and brain. Loss of vision, paralysis, loss of sensation, bladder and bowel dysfunction, nerve pain and respiratory failure can all be manifestations of the disease. Each NMOSD attack can lead to further damage and disability. NMOSD occurs more commonly in women and may be more common in individuals of African and Asian descent.

## About TEPEZZA

### INDICATION

TEPEZZA is indicated for the treatment of Thyroid Eye Disease.

### IMPORTANT SAFETY INFORMATION

#### Warnings and Precautions

**Infusion Reactions:** TEPEZZA may cause infusion reactions. Infusion reactions have been reported in approximately 4% of patients treated with TEPEZZA. Reported infusion reactions have usually been mild or moderate in severity. Signs and symptoms may include transient increases in blood pressure, feeling hot, tachycardia, dyspnea, headache and muscular pain. Infusion reactions may occur during an infusion or within 1.5 hours after an infusion. In patients who experience an infusion reaction, consideration should be given to premedicating with an antihistamine, antipyretic or corticosteroid and/or administering all subsequent infusions at a slower infusion rate.

**Preexisting Inflammatory Bowel Disease:** TEPEZZA may cause an exacerbation of preexisting inflammatory bowel disease (IBD). Monitor patients with IBD for flare of disease. If IBD exacerbation is suspected, consider discontinuation of TEPEZZA.

**Hyperglycemia:** Increased blood glucose or hyperglycemia may occur in patients treated with TEPEZZA. In clinical trials, 10% of patients (two-thirds of whom had preexisting diabetes or impaired glucose tolerance) experienced hyperglycemia. Hyperglycemic events should be managed with medications for glycemic control, if necessary. Monitor patients for elevated blood glucose and symptoms of hyperglycemia while on treatment with

TEPEZZA. Patients with preexisting diabetes should be under appropriate glycemic control before receiving TEPEZZA.

### **Adverse Reactions**

The most common adverse reactions (incidence  $\geq 5\%$  and greater than placebo) are muscle spasm, nausea, alopecia, diarrhea, fatigue, hyperglycemia, hearing impairment, dysgeusia, headache and dry skin.

For additional information on TEPEZZA, please see [Full Prescribing Information](#) at [TEPEZZAhcp.com](http://TEPEZZAhcp.com).

### **About KRYSTEXXA**

#### **INDICATIONS AND USAGE**

KRYSTEXXA® (pegloticase injection) is a PEGylated uric acid specific enzyme indicated for the treatment of chronic gout in adult patients refractory to conventional therapy.

Gout refractory to conventional therapy occurs in patients who have failed to normalize serum uric acid and whose signs and symptoms are inadequately controlled with xanthine oxidase inhibitors at the maximum medically appropriate dose or for whom these drugs are contraindicated.

**Important Limitations of Use: KRYSTEXXA is not recommended for the treatment of asymptomatic hyperuricemia.**

#### **IMPORTANT SAFETY INFORMATION**

##### **WARNING: ANAPHYLAXIS AND INFUSION REACTIONS**

**Anaphylaxis and infusion reactions have been reported to occur during and after administration of KRYSTEXXA. Anaphylaxis may occur with any infusion, including a first infusion, and generally manifests within 2 hours of the infusion. However, delayed-type hypersensitivity reactions have also been reported. KRYSTEXXA should be administered in healthcare settings and by healthcare providers prepared to manage anaphylaxis and infusion reactions. Patients should be premedicated with antihistamines and corticosteroids. Patients should be closely monitored for an appropriate period of time for anaphylaxis after administration of KRYSTEXXA. Serum uric acid levels should be monitored prior to infusions, and healthcare providers should consider discontinuing treatment if levels increase to above 6 mg/dL, particularly when 2 consecutive levels above 6 mg/dL are observed.**

The risk of anaphylaxis and infusion reactions is higher in patients who have lost therapeutic response.

Concomitant use of KRYSTEXXA and oral urate-lowering agents may blunt the rise of sUA levels. Patients should discontinue oral urate-lowering agents and not institute therapy with oral urate-lowering agents while taking KRYSTEXXA.

In the event of anaphylaxis or infusion reaction, the infusion should be slowed, or stopped and restarted at a slower rate.

Patients should be informed of the symptoms and signs of anaphylaxis and instructed to seek immediate medical care should anaphylaxis occur after discharge from the healthcare setting.

##### **CONTRAINDICATIONS: G6PD DEFICIENCY ASSOCIATED HEMOLYSIS AND METHEMOGLOBINEMIA**

Patients should be screened for G6PD deficiency prior to starting KRYSTEXXA. Hemolysis and methemoglobinemia have been reported with KRYSTEXXA in patients with G6PD deficiency. KRYSTEXXA should not be administered to these patients.

##### **GOUT FLARES**

An increase in gout flares is frequently observed upon initiation of anti-hyperuricemic therapy, including treatment with KRYSTEXXA. If a gout flare occurs during treatment, KRYSTEXXA need not be discontinued. Gout flare prophylaxis with a non-steroidal anti-inflammatory drug (NSAID) or colchicine is recommended starting at least 1 week before initiation of KRYSTEXXA therapy and lasting at least 6 months, unless medically contraindicated or not tolerated.

##### **CONGESTIVE HEART FAILURE**

KRYSTEXXA has not been studied in patients with congestive heart failure, but some patients in the clinical trials experienced exacerbation. Caution should be exercised when using KRYSTEXXA in patients who have congestive heart failure, and patients should be monitored closely following infusion.

##### **ADVERSE REACTIONS**

The most commonly reported adverse reactions in clinical trials with KRYSTEXXA were gout flares, infusion reactions, nausea, contusion or ecchymosis, nasopharyngitis, constipation, chest pain, anaphylaxis and vomiting.

Please see [Full Prescribing Information](#) and [Medication Guide](#) for more information.

### **About UPLIZNA**

#### **INDICATION**

UPLIZNA is indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive.

#### **IMPORTANT SAFETY INFORMATION**

UPLIZNA is contraindicated in patients with:

- A history of life-threatening infusion reaction to *UPLIZNA*
- Active hepatitis B infection
- Active or untreated latent tuberculosis

## WARNINGS AND PRECAUTIONS

**Infusion Reactions:** UPLIZNA can cause infusion reactions, which can include headache, nausea, somnolence, dyspnea, fever, myalgia, rash or other symptoms. Infusion reactions were most common with the first infusion but were also observed during subsequent infusions. Administer pre-medication with a corticosteroid, an antihistamine and an anti-pyretic.

**Infections:** The most common infections reported by UPLIZNA-treated patients in the randomized and open-label periods included urinary tract infection (20%), nasopharyngitis (13%), upper respiratory tract infection (8%) and influenza (7%). Delay UPLIZNA administration in patients with an active infection until the infection is resolved.

Increased immunosuppressive effects are possible if combining UPLIZNA with another immunosuppressive therapy.

The risk of hepatitis B virus (HBV) reactivation has been observed with other B-cell-depleting antibodies. Perform HBV screening in all patients before initiation of treatment with UPLIZNA. Do not administer to patients with active hepatitis.

Although no confirmed cases of Progressive Multifocal Leukoencephalopathy (PML) were identified in UPLIZNA clinical trials, JC virus infection resulting in PML has been observed in patients treated with other B-cell-depleting antibodies and other therapies that affect immune competence. At the first sign or symptom suggestive of PML, withhold *UPLIZNA* and perform an appropriate diagnostic evaluation.

Patients should be evaluated for tuberculosis risk factors and tested for latent infection prior to initiating UPLIZNA.

Vaccination with live-attenuated or live vaccines is not recommended during treatment and after discontinuation, until B-cell repletion.

**Reduction in Immunoglobulins:** There may be a progressive and prolonged hypogammaglobulinemia or decline in the levels of total and individual immunoglobulins such as immunoglobulins G and M (IgG and IgM) with continued UPLIZNA treatment. Monitor the level of immunoglobulins at the beginning, during, and after discontinuation of treatment with UPLIZNA until B-cell repletion especially in patients with opportunistic or recurrent infections.

**Fetal Risk:** May cause fetal harm based on animal data. Advise females of reproductive potential of the potential risk to a fetus and to use an effective method of contraception during treatment and for 6 months after stopping UPLIZNA.

**Adverse Reactions:** The most common adverse reactions (at least 10% of patients treated with UPLIZNA and greater than placebo) were urinary tract infection and arthralgia.

For additional information on UPLIZNA, please see Prescribing Information at [www.UPLIZNA.com](http://www.UPLIZNA.com).

## About Horizon

Horizon is focused on researching, developing and commercializing medicines that address critical needs for people impacted by rare and rheumatic diseases. Our pipeline is purposeful: we apply scientific expertise and courage to bring clinically meaningful therapies to patients. We believe science and compassion must work together to transform lives. For more information on how we go to incredible lengths to impact lives, please visit [www.horizontherapeutics.com](http://www.horizontherapeutics.com) and follow us on [Twitter](#), [LinkedIn](#), [Instagram](#) and [Facebook](#).

## About Viela Bio, Inc.

Viela Bio, Inc., headquartered in Gaithersburg, Maryland, is a biotechnology company dedicated to the discovery, development and commercialization of novel treatments for autoimmune and severe inflammatory diseases. For more information, please visit [www.vielabio.com](http://www.vielabio.com).

## Forward-Looking Statements

This press release contains forward-looking statements. Forward-looking statements are generally identified by the words “expects”, “anticipates”, “believes”, “intends”, “estimates”, “plans”, “will be” and similar expressions. These forward-looking statements include, without limitation, statements related to the anticipated consummation of the acquisition of Viela Bio, Inc. (“Viela”) and the timing and benefits thereof, Horizon Therapeutics plc’s (“Horizon”) strategy, plans, objectives, expectations (financial or otherwise) and intentions, future financial results and growth potential, anticipated product portfolio, development programs, the timing of the initiation of clinical trials, the potential benefits and applications of inebilizumab, patent terms and other statements that are not historical facts. These forward-looking statements are based on Horizon’s and Viela’s current expectations and inherently involve significant risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, risks related to Horizon Therapeutics USA, Inc.’s ability to complete the transaction on the proposed terms and schedule; whether the tender offer conditions will be satisfied; whether sufficient stockholders of Viela tender their shares in the transaction; the final terms and conditions of Horizon’s financing for the transaction; the outcome of legal proceedings that may be instituted against Viela and/or others relating to the transaction; the failure (or delay) to receive the required regulatory approvals relating to the transaction; the possibility that competing offers will be made; risks associated with acquisitions, such as the risk that the businesses will not be integrated successfully, that such integration may be more difficult, time-consuming or costly than expected or that the expected benefits of the transaction will not occur; risks related to future opportunities and plans for Viela and its products, including uncertainty of the expected financial performance of Viela and its products; risks related to the uncertainty of the research, development and regulatory approval process for product candidates; disruption from the proposed transaction, making it more difficult to conduct business as usual or maintain relationships with customers, employees or suppliers; the occurrence of any event, change or other circumstance that could give rise to the termination of the acquisition agreement, and the possibility that if Viela does not achieve the perceived benefits of the proposed transaction as rapidly or to the extent anticipated by financial analysts or investors, the market price of Horizon’s shares could decline, the risk that further TEPEZZA manufacturing run cancellations, whether as a result of additional government orders or other issues at Horizon’s third party manufacturers, or failed manufacturing runs could exacerbate and prolong TEPEZZA supply disruptions; whether the FDA approves Horizon’s prior approval supplement for

TEPEZZA and the timing for any approval, as well as other risks related to Horizon's and Viela's businesses detailed from time-to-time under the caption "Risk Factors" and elsewhere in Horizon's and Viela's respective Securities and Exchange Commission ("SEC") filings and reports, including their respective Annual Reports on Form 10-K for the year ended December 31, 2019 and subsequent quarterly and current reports filed with the SEC. The risks and uncertainties may be amplified by the COVID-19 pandemic, which has caused significant economic uncertainty. The extent to which the COVID-19 pandemic impacts Horizon's and Viela's businesses, operations, and financial results, including the duration and magnitude of such effects, will depend on numerous factors, which are unpredictable, including, but not limited to, the duration and spread of the outbreak, its severity, the actions to contain the virus or treat its impact, and how quickly and to what extent normal economic and operating conditions can resume. Horizon and Viela undertake no duty or obligation to update any forward-looking statements contained in this press release as a result of new information, future events or changes in their expectations, except as required by law.

#### **Additional Information and Where to Find It**

The tender offer described in this press release (the "Offer") has not yet commenced, and this press release is neither a recommendation, nor an offer to purchase nor a solicitation of an offer to sell any shares of the common stock of Viela or any other securities. On the commencement date of the Offer, a tender offer statement on Schedule TO, including an offer to purchase, a letter of transmittal and related documents, will be filed with the SEC by Horizon, Horizon Therapeutics USA, Inc. and Teiripic Merger Sub, Inc., and a Solicitation/Recommendation Statement on Schedule 14D-9 will be filed with the SEC by Viela. The offer to purchase shares of Viela common stock will only be made pursuant to the offer to purchase, the letter of transmittal and related documents filed as a part of the Schedule TO. INVESTORS AND SECURITY HOLDERS ARE URGED TO READ BOTH THE TENDER OFFER STATEMENT AND THE SOLICITATION/RECOMMENDATION STATEMENT REGARDING THE OFFER, AS THEY MAY BE AMENDED OR SUPPLEMENTED FROM TIME TO TIME, WHEN THEY BECOME AVAILABLE BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION THAT INVESTORS AND SECURITY HOLDERS SHOULD CONSIDER BEFORE MAKING ANY DECISION REGARDING TENDERING THEIR COMMON STOCK, INCLUDING THE TERMS AND CONDITIONS OF THE TENDER OFFER. Investors and security holders may obtain a free copy of these statements (when available) and other documents filed with the SEC at the website maintained by the SEC at [www.sec.gov](http://www.sec.gov) or by directing such requests to the Information Agent for the Offer, which will be named in the tender offer statement. Investors may also obtain, at no charge, the documents filed or furnished to the SEC by Viela under the "Investors/Media" section of Viela's website at [www.vielabio.com](http://www.vielabio.com).

View source version on [businesswire.com](https://www.businesswire.com/news/home/20210201005296/en/): <https://www.businesswire.com/news/home/20210201005296/en/>

#### **Horizon contacts:**

Tina Ventura

Senior Vice President, Investor Relations

[investor-relations@horizontherapeutics.com](mailto:investor-relations@horizontherapeutics.com)

Ruth Venning

Executive Director, Investor Relations

[investor-relations@horizontherapeutics.com](mailto:investor-relations@horizontherapeutics.com)

#### **U.S. Media Contacts:**

Geoff Curtis

Executive Vice President, Corporate Affairs & Chief Communications Officer

[media@horizontherapeutics.com](mailto:media@horizontherapeutics.com)

#### **Ireland Media Contact:**

Gordon MRM

Ray Gordon

[ray@gordonmrm.ie](mailto:ray@gordonmrm.ie)

#### **Viela Bio contacts:**

##### **Investors:**

Solebury Trout

Chad Rubin

646-378-2947

[crubin@soleburytrout.com](mailto:crubin@soleburytrout.com)

##### **Media:**

Solebury Trout

Amy Bonanno

914-450-0349

[abonanno@soleburytrout.com](mailto:abonanno@soleburytrout.com)

Source: Horizon Therapeutics plc