



September 21, 2016

## **Eleven Biotherapeutics Acquires Viventia Bio to Create Targeted Protein Therapeutics Oncology Company**

*-Viventia's Lead Product Candidate, Vicinium<sup>TM</sup>, being developed for high-grade non-muscle invasive bladder cancer, with topline Phase 3 data expected in 1H 2018-*

*-Proxinium<sup>TM</sup> being developed for late-stage squamous cell carcinoma of the head and neck with Phase 2 initiation planned for early 2017-*

*-Stephen Hurly to Serve as President and Chief Executive Officer of Combined Company-*

*-Company to Host Conference Call and Webcast Today September 21, 2016 at 8:30 AM ET-*

CAMBRIDGE, Mass. & TORONTO--(BUSINESS WIRE)-- Eleven Biotherapeutics, Inc. (NASDAQ: EBIO) and Viventia Bio Inc., today announced that the two companies and the shareholders of Viventia entered into a definitive share purchase agreement under which Eleven Biotherapeutics agreed to, and simultaneously completed, the acquisition of Viventia. Under the agreement, Eleven purchased all of the outstanding capital stock of Viventia in exchange for the issuance of 4,013,431 newly issued shares of Eleven common stock, which represented approximately 19.9% of the voting power of Eleven as of immediately prior to the issuance of such shares, and the agreement by Eleven to pay to the selling shareholders certain post-closing contingent cash payments upon the achievement of specified milestones and based upon net sales related to Viventia's lead product candidate, Vicinium.

The acquisition creates a NASDAQ-listed company focused on the development of novel therapies based upon antibody fragments genetically fused to cytotoxic proteins, or targeted protein therapeutics (TPTs), as new treatments in areas of oncology with significant unmet need. The combined company will continue to be named Eleven Biotherapeutics, and Stephen Hurly, formerly Viventia's chief executive officer, was appointed President and Chief Executive Officer of Eleven in connection with the acquisition. Abbie C. Celniker, Eleven's former President and Chief Executive Officer, will remain a director of Eleven Biotherapeutics.

Eleven's pipeline now includes Viventia's lead product candidates Vicinium and Proxinium. Vicinium is in a Phase 3 clinical trial for high grade non-muscle invasive bladder cancer (NMIBC), with topline data expected in the first half of 2018. To date, Vicinium has been evaluated in more than 100 patients. In a Phase 2 clinical trial, Vicinium demonstrated a complete response rate of 40% at three months with no drug-related serious adverse events observed in the trial.

Proxinium is expected to enter Phase 2 development in early 2017 for the treatment of late-stage squamous cell carcinoma of the head and neck. In previous clinical trials, Proxinium was generally safe and well-tolerated and showed signs of anti-tumor activity. Proxinium has received Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA), and Fast Track designation from the FDA. Both product candidates are anti-EpCAM (epithelial cell adhesion molecule) fusion proteins that have been optimized for local tumor administration.

Eleven's pipeline now also includes Viventia's earlier stage pipeline of next generation TPT candidates that are designed and optimized for systemic administration for the potential treatment of a broader spectrum of cancer types.

"We are excited to join with Eleven to create a company with extensive experience in engineering and developing novel protein therapeutics for local delivery that we believe may maximize efficacy and reduce toxicity. Our TPTs combine specific tumor targeting with a protein based tumor killing payload, and will be developed to serve cancer patients in areas of high unmet need. Together we have a strong Board of Directors, management team, product pipeline and technology platform, and the capital needed to support the Company's development plans into 2018," said Stephen Hurly, Chief Executive Officer of Eleven Biotherapeutics.

"As previously announced, Eleven performed an extensive review of our strategic alternatives, and our Board of Directors believes that the acquisition of Viventia offers Eleven shareholders a compelling opportunity for enhancing long-term value," said Abbie Celniker, Ph.D., former President and Chief Executive Officer of Eleven Biotherapeutics and current member of Eleven's Board of Directors. "Our combined company will continue to support Roche as they develop EBI-031, and will benefit from the capital contributed by this partnership, which provides the necessary funding to enable further development of Vicinium and Proxinium."

## **About Targeted Protein Therapeutics (TPTs)**

Viventia's drug development is currently focused on locally administered targeted protein therapeutics (TPTs) for the treatment of cancer. Viventia's TPTs are expressed as a single fusion protein with a differentiated payload mechanism, eliminating the need for payload conjugation and multi-step manufacturing. We believe TPTs have a dual action of both directly killing the cancer cell and enhancing the local immune response.

## **License Agreement with Roche**

On August 16, 2016, Eleven announced the effectiveness of its exclusive license agreement with F. Hoffman-La Roche Ltd. and Hoffman-La Roche Inc. (Roche) for Eleven's IL-6 antagonist antibody technology, including EBI-031. Eleven granted Roche an exclusive, worldwide license to develop and commercialize EBI-031 and all other IL-6 antagonist antibody technology owned by Eleven. Eleven has received \$30 million in payments from Roche, including a \$7.5 million upfront payment in connection with the effectiveness of the license agreement, and a \$22.5 million milestone payment based on the Investigational New Drug (IND) application for EBI-031 becoming effective. Under the terms of the agreement, Eleven could receive up to an additional \$240 million upon the achievement of certain future regulatory, development and commercialization milestones. In addition, Eleven could be entitled to receive royalties based on net sales of potential future products containing EBI-031 or any other potential future products containing other Eleven IL-6 compounds.

## **Viventia Acquisition Details**

Under the share purchase agreement, Eleven purchased all of the outstanding capital stock of Viventia in exchange for the issuance of 4,031,431 newly issued shares of Eleven common stock, which represented approximately 19.9% of the voting power of Eleven as of immediately prior to the issuance of such shares, and the agreement by Eleven to pay to the selling shareholders certain post-closing contingent cash payments upon the achievement of specified milestones and based upon net sales related to Viventia's lead product candidate, Vicinium.

The acquisition was approved by the boards of directors of both companies.

Stifel, Nicolaus & Company, Incorporated acted as financial advisor and Wilmer Cutler Pickering Hale and Dorr LLP is acting as legal advisor to Eleven. Hogan Lovells US LLP acted as legal counsel to Viventia.

## **Management and Organization**

In connection with the acquisition, Eleven's Board of Directors elected Stephen Hurly and Leslie L. Dan, Viventia's former Executive Chairman and largest beneficial owner prior to the acquisition, to serve as members of Eleven's Board of Directors, and Cary G. Pfeffer, M.D., resigned from the Eleven's Board of Directors. Stephen Hurly will serve as President and Chief Executive Officer of Eleven. Also in connection with the acquisition, Arthur P. DeCillis, M.D., Viventia's Chief Medical Officer, was appointed as Chief Medical Officer of Eleven, and Karen L. Turbidy, Eleven's Chief Development Officer, resigned from Eleven. In addition, Gregory Adams Ph.D., Chief Development Officer and Glen MacDonald, Ph.D., Chief Scientific Officer, will join Eleven's management team from Viventia. John McCabe, will continue to serve as Chief Financial Officer of Eleven. Abbie C. Celniker, former President and Chief Executive Officer of Eleven, will remain a member of Eleven's Board of Directors. Following the acquisition, an entity affiliated with Leslie L. Dan became the second largest shareholder of Eleven.

## **Conference Call and Webcast**

Eleven Biotherapeutics and Viventia will host a conference call and audio webcast today at 8:30 a.m. ET to discuss the acquisition. To access the conference call, please dial (844) 831-3025 (domestic) or (315) 625-6887 (international) at least five minutes prior to the start time and refer to conference ID 85062695.

An audio webcast of the call will also be available on the Investors & Media section of the Company's website, [www.elevenbio.com](http://www.elevenbio.com). An archived webcast will be available on the Company's website approximately two hours after the event and will be available for 30 days.

## **About Eleven Biotherapeutics**

Eleven Biotherapeutics, Inc. is a late clinical-stage company advancing a broad pipeline of novel anti-cancer agents based on the Company's targeted protein therapeutics (TPTs) platform. The Company's TPTs genetically combine antibody-based fragments with protein immunotoxin payloads to create a single protein molecule through the Company's proprietary one-step manufacturing process. The Company believes its TPTs can potentially offer significant advantages in treating cancer

versus existing antibody drug conjugate technologies. The Company's approach to drug design creates TPTs that it believes facilitate effective tumor targeting with cancer cell-killing properties unique to protein payloads versus small molecules. The ability of TPTs cancer cell-killing properties to promote an anti-tumor immune response suggest that TPTs will potentially combine well with immune oncology drugs. TPTs fusion protein construction provides enhanced linker stability and an efficient and cost effective manufacturing process. For more information please refer to the Company's website [www.elevenbio.com](http://www.elevenbio.com).

### **About Non-Muscle Invasive Bladder Cancer (NMIBC)**

In the U.S., NMIBC is the second most common malignancy of the genitourinary system, accounting for 70% to 80% of all bladder cancers, and is the sixth most common cancer diagnosed worldwide. The American Cancer Society estimated that approximately 74,000 new cases of bladder cancer were diagnosed in 2015 and that this cancer caused approximately 16,000 deaths in the US in 2015. NMIBC is highly recurrent and requires ongoing, invasive monitoring.

The standard immunotherapy drug for bladder cancer is the Bacillus Calmette-Guérin (BCG) vaccine which was approved by the U.S. Food and Drug Administration (FDA) to treat NMIBC carcinoma in situ in 1990. As a front-line therapy, BCG, with or without transurethral resection of the bladder tumor (TURBT) is associated with high failure rates: 50% of patients experience disease recurrence within one year and 90% relapse within five years.

For more information please visit [www.mybladdercancer.com](http://www.mybladdercancer.com).

### **About Squamous Cell Carcinoma of the Head and Neck (SCCHN)**

Squamous cell carcinoma is the most frequent malignant tumor of the head and neck region. Head and neck cancer is the seventh most common cancer in the world. Head and neck cancers are strongly associated with certain environmental and lifestyle risk factors.

Existing treatment options for squamous cell carcinoma of the head and neck include surgery, drug agents, radiation or combination therapy. There is no treatment option for patients who progress after receiving these treatments.

### **Cautionary Note on Forward-Looking Statements**

Any statements in this press release about future expectations, plans and prospects for the Company, including statements about benefits of the Acquisition, future management of the Company, Viventia's business, the Company's strategy, future operations, advancement or maturation of its product candidates and product pipeline, clinical development of the Company's product candidates, including expectations regarding timing of regulatory submissions and initiation of clinical trials, regulatory requirements for initiation of clinical trials and registration of product candidates, the sufficiency of its cash resources and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the uncertainties inherent in the initiation and conduct of clinical trials, availability and timing of data from clinical trials, whether results of early clinical trials or preclinical studies will be indicative of the results of future trials, the adequacy of any clinical models, uncertainties associated with regulatory review of clinical trials and applications for marketing approvals and other factors discussed in the "Risk Factors" section of the Company's report on Form 10-Q for the quarter ended June 30, 2016 as filed with the Securities and Exchange Commission, the "Risk Factors of Viventia's Business" filed as Exhibit 99.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on September 21, 2016 and other reports on file with the Securities and Exchange Commission. In addition, the forward-looking statements included in this press release represent the Company's views as of the date hereof. The Company anticipates that subsequent events and developments will cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date hereof.

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