PRESS RELEASE DETAILS

VIELA BIO ANNOUNCES U.S. FDA ACCEPTS FOR REVIEW INEBILIZUMAB BIOLOGICS LICENSE APPLICATION FOR NEUROMYELITIS OPTICA SPECTRUM DISORDER

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U.S. FDA accepts for review Viela Bio's first BLA filing

Gaithersburg, MD—August 27, 2019 –Viela Bio today announced that the U.S. Food and Drug Administration (FDA) has accepted for review its Biologics License Application (BLA) for inebilizumab, an investigational anti-CD19 monoclonal antibody, for the treatment of patients with neuromyelitis optica spectrum disorder (NMOSD) — a rare autoimmune disease characterized by unpredictable attacks that often lead to severe, irreparable disability including blindness and paralysis.

"The acceptance of our first BLA filing for review represents a huge milestone for inebilizumab and another important step in delivering this novel therapy to patients in need," said Jorn Drappa, M.D., Ph.D., Chief Medical Officer and Head of Research & Development at Viela Bio. "We believe that inebilizumab can play a critical role in reducing the risk of developing an NMOSD attack, thereby contributing to the health of patients with this devastating and debilitating disease. We look forward to working closely with the FDA to move this therapy toward approval."

The safety and efficacy results provided in the application are from the pivotal N-MOmentum trial, the largest global, placebo-controlled study in NMOSD. The study, which enrolled 231 patients with and without the AQP4-IgG antibody—a key biomarker for the disease—met its primary and a majority of the secondary endpoints. Results demonstrated that inebilizumab reduced the risk of developing an NMOSD attack by 77% when compared to placebo in AQP4-IgG seropositive patients after 28 weeks of treatment. In addition, inebilizumab impacted measurements of worsening disability, hospitalizations and new central nervous system MRI lesions.

These **study results** were presented at the plenary session of the recent American Academy of Neurology (AAN) annual meeting.

About Neuromyelitis Optica Spectrum Disorders (NMOSD)

NMOSD is a recently proposed unifying term for neuromyelitis optica (NMO) — also known as Devic's disease — and related syndromes. NMOSD is a rare, severe, relapsing, neuroinflammatory autoimmune disease that can be fatal. In NMOSD, about 80% of patients have autoantibodies to a water channel protein called aquaporin-4 (AQP4). These AQP4-IgG autoantibodies are produced by plasmablasts and plasma cells and bind primarily to astrocytes in the central nervous system. Binding of

AQP4-IgG antibodies to central 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 leads to further damage and disability. NMOSD occurs more commonly in women and may be more common in individuals of African and Asian descent. There is currently no cure for NMOSD.

About Inebilizumab

Inebilizumab is a humanized monoclonal antibody that binds with high affinity to CD19, a protein expressed on a broad range of B cells, including antibody-secreting plasmablasts and plasma cells. After binding to CD19, these cells are rapidly depleted from circulation. Inebilizumab is an investigational new drug for which there is no marketing authorization.

About N-MOmentum

The N-MOmentum study enrolled 231 NMOSD patients, including patients with and without AQP4-IgG antibodies. Patients were randomized to receive two intravenous doses of inebilizumab monotherapy or placebo and followed for 6.5 months. Patients were subsequently given the option to enter into an open-label extension in which all patients receive inebilizumab every 6 months. The primary endpoint was time from treatment initiation to occurrence of an NMOSD attack, which was reviewed by an independent, blinded external Adjudication Committee. NMOSD attack diagnosis was standardized using 18 clinically meaningful criteria that were developed for the study. The open-label extension portion of the study is ongoing. More information can be found on **clinicaltrials.gov (Study NCT02200770)**

About Viela Bio

Viela Bio, headquartered in Gaithersburg, Maryland, is a clinical-stage biotechnology company pioneering and advancing treatments for severe inflammation and autoimmune diseases by selectively targeting shared critical pathways that are the root cause of disease.

For more information, please visit **www.vielabio.com**

Forward-Looking Statements

This press release contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this press release, including statements regarding our strategy, product candidates, future operations, prospects, plans, objectives of management, the timing and progress of clinical development of our product candidates, and the benefits of inebilizumab to patients with NMOSD are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue" or the negative of these terms or other comparable terminology, which are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

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